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AGARD

ADVISORY GROUP FOR AEROSPACE RESEARCH & DEVELOPMENT
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Aeromedical Support Issues in Contingency Operations

(le Soutien aéromédical lors des opérations non programmées)

Papers presented at the AMP Symposium, held in Rotterdam, The Netherlands, 29 September - 1 October 1997.

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- Continuously stimulating advances in the aerospace sciences relevant to strengthening the common defence posture;
- Improving the co-operation among member nations in aerospace research and development;
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Aeromedical Support Issues in Contingency Operations

(AGARD CP-599)

Executive Summary

The Aerospace Medical Panel (AMP) of the former NATO Advisory Group for Aerospace Research and Development (AGARD) held a Symposium on "Aeromedical Support Issues in Contingency Operations" in Rotterdam, The Netherlands, 29 September - 1 October 1997.

Contingency Operations constitute a diverse array of military missions that include peacekeeping, humanitarian aid, peacemaking/enforcement, full scale offensive actions, and relief operations other than war such as aid to civil powers in counterterrorism and in natural disasters. The increasing prevalence of Contingency Operations in NATO missions presents some significant and unique challenges to aircrew health, safety and performance. This Symposium was held to review and discuss different technological solutions for facilitating aeromedical support in Contingency Operations. Aeromedical support issues were addressed in four important areas: (1) Sustained and Continuous Operations, (2) Medical Management in Remote Locations, (3) Medical Information, and (4) Adaptation to Operational Conditions.

Benefits to the military, particularly to the operations elements, resulting from this Symposium include:

- new understandings in the use of sleep management tools to counter sleep loss and fatigue in extended operations;
- better insights into the properties and use of drugs such as melatonin and modafinil for maintaining sustained alertness in critical operations;
- the sense that effective crew formations may have to be judiciously selected to handle different flight regimes in extended operations;
- knowledge of the important advances in technology being developed and tested for conducting critical care medicine in far forward areas and during evacuation;
- realization that severe trauma management requires extensive validation in different simulated contingency situations;
- awareness of promising developments in blood substitutes and resuscitative surgery for severe trauma management in the field;
- new strategies for the prevention and management of infectious diseases including HIV infection;
- recognition that new advances in deployment telemedicine will enable cost-effective patient care in remote locations;
- further confirmation of the importance of computer resources for rapidly accessing critical medical information sources; and
- reasons for concern that the psychiatric effects of combat may be permanent if coping strategies are not implemented and stress-related care is not given at the appropriate time.

A recurring theme in this Symposium has been the importance of "lessons learned" from past Contingency Operations. The recommendation is made that the new Human Factors and Medicine Panel of the RTO* use its various assets to develop and maintain a computerized data entry and recording system to register the collective post-operational NATO medical and medical support experiences from each Contingency Operation. The information from this data base could be analyzed and used by the NATO countries and their allies to enhance medical care in future operations.

* NATO's Research and Technology Organization, formed by a merger of AGARD and the DRG of NATO.

Le soutien aéromédical lors des opérations non programmées

(AGARD CP-599)

Synthèse

Le Panel de médecine aérospatiale (AMP) de l'ancien AGARD de l'OTAN a organisé un symposium sur "Le soutien aéromédical lors des opérations non programmées" à Rotterdam, au Pays-Bas, du 29 septembre au 1 octobre 1997.

Les opérations d'urgence constituent un éventail de missions militaires allant du maintien de la paix aux opérations offensives de grande envergure en passant par l'aide humanitaire et le rétablissement/interposition pour la paix. Elles incluent également les opérations d'assistance autres que les opérations de guerre, telles que programmes d'aide aux autorités civiles en cas de catastrophe naturelle ou d'actes de terrorisme. La fréquence de plus en plus élevé des opérations d'urgence au sein de l'OTAN présente des défis spécifiques non-négligeables pour la santé, la sécurité et les performances des équipages. Ce symposium a eu pour objectif d'examiner les différentes solutions technologiques, en vue de faciliter le soutien aéromédical lors des opérations d'urgence. Les discussions ont porté sur les quatre principaux domaines suivants : 1) Les opérations prolongées et permanentes, 2) La gestion médicale sur des sites éloignés, 3) L'information médicale, et 4) L'adaptation aux conditions opérationnelles.

Pour les militaires ce symposium a représenté un grand intérêt en raison des sujets suivants :

- nouvelle perception de l'utilisation des outils de gestion du sommeil destinés à lutter contre la privation de sommeil et la fatigue lors des opérations prolongées;
- meilleur aperçu des caractéristiques et de l'emploi de médicaments tels que la mélatonine et le modafinil pour maintenir l'état d'éveil lors d'opérations décisives;
- notion du choix judicieux des membres des équipages à effectuer en fonction des différents plans de vol lors d'opérations prolongées;
- informations sur les avancées technologiques importantes en cours de développement et d'essais qui pourraient permettre de dispenser des soins médicaux dans des zones très avancées et lors des opérations d'évacuation;
- constatation du fait que la gestion des traumatismes graves doit s'appuyer sur une validation préalable par simulation des différentes situations d'urgence;
- prise en compte des développements prometteurs dans le domaine des succédanés du sang et de la chirurgie de réanimation pour la gestion des traumatismes graves sur le champ de bataille;
- nouvelles stratégies pour la prévention et la gestion des maladies contagieuses y compris l'infection HIV;
- reconnaissance du fait que les nouvelles avancées de la télémédecine sur le champ de bataille permettront de disperser des soins médicaux de façon économique sur des sites éloignés;
- nouvelle confirmation de l'importance des moyens informatiques pour l'accès rapide aux sources d'informations médicales essentielles et
- justication des préoccupations concernant les retombées psychiatriques au combat, qui peuvent être permanentes si les mécanismes d'adaptation appropriés ne sont pas appliqués et si les soins anti-stress ne sont pas dispensés au moment opportun.

L'un des thèmes répétitifs de ce symposium a été l'importance des "enseignements tirés" des opérations d'urgence réalisées dans le passé. Il a été recommandé au nouveau Panel Facteurs humains et médecine de la RTO*, en fonction des moyens dont il dispose, de développer et de tenir à jour un système informatisé de saisie et d'enregistrement de données, pour suivre les expériences acquises lors de chaque opération d'urgence pour les corps médicaux comme pour le soutien médical. Les informations contenues dans cette base de données pourraient alors être analysées et utilisées par les pays membres de l'OTAN et leurs alliés pour améliorer à l'avenir le niveau des soins médicaux dispensés sur le champ de bataille.

* La RTO résulte de la fusion de l'AGARD et du GRD de l'OTAN.

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† Paper not available at time of printing

Preface

Contingency Operations constitute military missions such as peacekeeping, humanitarian aid, peacemaking/enforcement, full scale offensive operations and relief operations other than war such as aid to civil powers in counterterrorism and in natural disasters. Increasingly, these operations will involve greater NATO participation in the post "Post-Cold-War" era. Significantly, NATO nations are turning to the application of science and technology, particularly computer resources, to address the unique problems associated with Contingency Operations. From a medical standpoint, there are many logistic, support and environmental factors which impede effective health and critical care medicine in Contingency Operations. This Symposium considered both the aeromedical problems encountered and the role of technological solutions as aids to resolving the issues in terms of:

- Sustained and Continous Operations
  - Sleep loss and fatigue on performance
  - Pharmacological and non-pharmacological management
- Medical Management in Remote Locations
  - Logistics and evacuation
  - Technological aids and solutions
  - Managing trauma in the field
  - Controlling infectious diseases
- Medical Information
  - Information management
  - Use of deployment telemedicine
- Adaptation to Operational Conditions
  - Leadership and management issues including the handling of stress

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1. INTRODUCTION

The Aerospace Medical Panel (AMP) of the NATO Research & Technology Organization (RTO - merger of the former NATO Advisory Group for Aerospace Research and Development (AGARD) and the NATO Defence Research Group (DRG)) held a Symposium on "Aeromedical Support Issues in Contingency Operations" at the Golden Tulip Hotel in Rotterdam, The Netherlands, 29 September - 3 October 1997. Fifty-five papers, including two keynote addresses, were given from seven NATO countries, Argentina, Australia, The Czech Republic, and Switzerland. These are included in this Conference Proceedings, as is an abstract by an author who was not able to attend the presentations, plus each edited, transcribed Discussion that followed the ten Sessions that form this Symposium. There were 154 registrants for the Meeting.

2. THEME

Contingency Operations constitute a diverse array of operations ranging from peacekeeping (e.g., Cyprus), to humanitarian aid (Bosnia-Herzegovina before Dayton Accord), to peace making/enforcement (Somalia, Bosnia-Herzegovina after Dayton Accord), to full scale offensive operations (Persian Gulf War). Military operations other than war (MOOTW) such as relief from the effects of natural disasters and terrorism also constitute Contingency Operations. These operations usually involve the cooperation of multinational Forces, and/or other government and non-government organizations. They may be conducted in hostile environments; often, far from national support bases, in regions as disparate as the mountainous terrain of Bosnia-Herzegovina and the deserts of Somalia and Kuwait. A lack of host nation infrastructures and the uncertain capabilities for interoperability with non-NATO allies pose additional logistical problems. The resolution of these problems will facilitate the effective and rapid NATO response requirements of Contingency Operations.

The increasing prevalence of Contingency Operations in NATO presents significant and unique challenges to aircrew health, safety and performance as well as to those responsible for promoting aeromedical support. Central to these issues is the fact that greater emphasis must be placed on the application of science and technology to enhance aeromedical support. Rapid response times require, not only the efforts of traditional research and development, but, also, real-time initiatives for addressing the novel operational realities of Contingency Operations. Papers were solicited that addressed both traditional and novel technological solutions that meet the needs of aeromedical support in Contingency Operations.

3. PURPOSE AND SCOPE

The purpose of this Symposium was to review the novel and emerging technological aids that will provide timely and effective medical and human factors solutions for protecting and sustaining combat troops and support personnel in Contingency Operations.

The scope was broad covering several dimensions requiring unique technological solutions in:

- sustained and continuous operations (e.g., long duration flights),
- medical management in remote locations (e.g., casualty care),
- medical information technologies in remote environments (e.g., telemedicine), and
- adapting personnel to challenging environments (e.g., coping with stress).

4. SYMPOSIUM PROGRAM

A Keynote Address by General John de Chastelain (Ret. CF) opened the programme. He spoke to the challenges imposed by the post 'Post-Cold-War' in preparing for Contingency Operations.

The remaining papers were arranged as four Topics in ten Sessions as follows:

A. Topic: Sustained and Continuous Operations
Moderator: Air Cdre A.N. Nicholson, UK
Commandant, RAF SAM, Farnborough, UK

a. Session I - Extended Operations: Effects of Sleep Loss and Fatigue on Performance
Chairman: Med en Chef D. Lagarde, FR

Four papers addressed the issue.

b. Session II - Extended Operations: Non-Pharmacological Management
Chairman: Med en Chef D. Lagarde, FR

Two papers addressed the issue.

c. Session IIIA - Extended Operations: Pharmacological Management
Chairman: Med en Chef D. Lagarde, FR

Five papers discussed the use of stimulants for enhancing performance; another on the effects of anti-emetics for evaluating crew performance.

d. Session IIIB - Extended Operations: Pharmacological Management (Including Use of Melatonin)
Chairman: LCol C. Alonso-Rodriguez, SP

Five papers further discussed the use of drugs, including four on melatonin, for enhancing crew performance.

B. Topic: Medical Management in Remote Locations

a. Session IV - Aeromedical Support Issues: Logistics and Evacuation
Moderator: Air Cdre T.M. Gibson, UK
Director, Medical Personnel, Policy and Plans, RAF Innsworth, UK
Chairman: Maj H. O'Neill, CA

Six papers addressed the issue.

b. Session V - Aeromedical Support Issues: Technological Aids and Solutions
Moderator: Col R. Kilpatrick, US
US European Command Surgeon, Stuttgart,GE
Chairman: Col T.J. Lyons, US

Nine papers in this session addressed a number of technological aids and solutions for use in contingency situations.

c. Session VI - Contingency Operations: The Management of Operational Medical Problems
Moderator: Col R. Kilpatrick, US
Chairman: Maj H. O'Neill, CA

Three papers addressed the issue, with the major focus being on trauma management.

d. Session VII - Contingency Operations: Control of Communicable Diseases

Moderator: Magg Gen CSA Prof R. D'Amelio
Direttore Generale della Sanita' Militaire, Roma, IT
Chairman: LCol C. Alonso-Rodriguez, SP

Five papers addressed the issue.

C. Topic: Medical Information
Moderator: None

a. Session VIII - Contingency Operations: Information Management Including Deployment Telemedicine
Chairman: Dr J.P. Landolt, CA

Seven papers discussed the issue, six of which addressed developments in deployment telemedicine.

D. Topic: Adaptation to Operational Conditions
Moderator: Dr D.R. Jones, US
Former Editor: Aviation, Space and Environmental Medicine

a. Session IX - Contingency Operations: Leadership and Management Issues
Chairman: LCol C. Alonso-Rodriguez, SP

Seven papers discussed the issue.

Each Moderator was requested to give a short overview of the topic under discussion including current research areas, problems requiring research, problems requiring resolution and how the Session would help in providing answers.

During the Symposium, four relevant demonstrations and a display were presented, as follows:

- Vital Signs Monitor (**VITSEM**) - A. Nichols, CME Telemetrics, Waterloo, ON, CA - see Paper #31,
- Life Support for Trauma and Transport (LSTAT) Test and Evaluation Unit - Dr F.J. Pearce, Walter Reed Army Institute of Research, Washington, DC, US - see Paper #30,
- Canadian Aeromedical Evacuation Course - Maj. J.M. Robertson, 1 Canadian Air Division, Winnipeg, MB, CA,
- Live telemedical transmission of traumatic radiographic images from Bosnia-Herzegovina to The Netherlands - Capt(N) H.J. Prins, Central Military Hospital, Utrecht, NE - see Paper #54, and
- High-Level Biosafety Containment Facility - LCol G.W. Christopher and the Aeromedical Isolation Team, US Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD, US - see Paper #46.

An informative technical tour of facilities and presentations took place with visits to Central Military Hospital, Utrecht, and the Netherlands Aerospace Medical Centre and TNO Human Factors Research Institute; the latter two both located at Soesterberg.

5. TECHNICAL EVALUATION

5.1 Keynote Address

General de Chastelain, in Keynote Address #1, gave a global overview of the issues facing NATO in its preparation for Contingency Operations in the post 'Post-Cold-War' era. He characterized this era as the period beginning with the recent decision to enlarge NATO with the inclusion of Poland, Hungary, The Czech Republic, and possibly other countries. This era will herald the cooperation of NATO states with non-aligned countries in maintaining peace and stability in Europe and elsewhere.

General de Chastelain believes that, because NATO is a military organization, it is uniquely placed to respond to Contingency Operations and is responding to these challenges today. He cited the main challenge that NATO faces in preparing for Contingency Operations is "... the willingness of member and non-member states to maintain military Forces trained to the professional level required for war." He argued persuasively that the diverse demands of today's Contingency Operations can only be met effectively by "... Forces prepared to the professional standards

required to fight." a battle. Other important challenges cited for participating nations to consider related to:

- the requirements for specialized training to accommodate the multiplicity of roles entailed in Contingency Operations;
- an unencumbered rapid reaction capability at high readiness;
- cooperation amongst organizations and the need for standardization in regard to medical support, where practicable, including the provision of an effective capability for aeromedical evacuation;
- enhanced logistics capabilities; and
- the need to interact effectively with non-government organizations including the media.

5.2 Sustained and Continuous Operations

In the post Post-Cold-War era, sustained and continuous operations will take on a more strategic dimension in NATO operations than they did during the Cold War. Air operations will be conducted in all weather, day and night conditions. Mission effectiveness may be encumbered through the stresses of very long duration flights, by technological advances such as operating with night-vision devices, from operator information overload, because of hazardous flight paths such as nap-of-the-earth night flying, and from general workload fatigue. All of these factors will have an effect on maintaining peak performance. Some of the papers on the topic discussed the significance of sleep loss and fatigue on performance; others explored a number of alertness strategies, including pharmacological countermeasures, to minimize performance degradation.

5.2.1 Extended operations: Effects of sleep loss and fatigue on performance

Extended air operations may entail multiple time zone changes, irregular work schedules and stresses related to workload. Such factors will result in circadian rhythm disruption, sleep loss and fatigue. Sleep debt and fatigue are known to be contributory factors to operational errors, and to illness if they are allowed to persist.

Stone and Nicholson (Paper #1) opened the session by defining the issues involved in coping with irregularity of rest during round-the-clock operations. They contended that the ability of aircrew to maintain performance with prolonged duty overnight depended greatly on obtaining sufficient sleep during critical rest periods. Even with good sleep, sustaining alertness may be difficult if the duty periods are prolonged and the rest periods are irregular. Short evening sleeps preceding a period of overnight duty, naps during the duty period, breaks in duty and the use of stimulants are some of the ways recommended for maintaining vigilance overnight.

Whitmore, French and Armstrong (#2) assessed the effects of fatigue on aircrew performance during repeated or sustained, simulated bomber missions lasting 36 hours or more. There were strong circadian patterns associated with the speech, cognitive, physiological and subjective fatigue measurements taken. Consistently, aircrew were able to perform their missions successfully, in part, due to the fact they were exceptionally well rested. However, there were indications that, if adequate sleep and strategic napping are not obtained in a real mission, then fatigue levels could be high, and loss of vigilance and inadvertent daytime sleeping may become a problem. The authors recommended ergonomic design changes that are specific to long duration flights (e.g., improved noise abatement in head sets and adequate seat padding for ejection seats) for ameliorating the effects of fatigue on performance.

Mollard and colleagues (#6) also looked at the factors subserving vigilance in long duration flights. In one study, electrophysiological recordings were taken from aircrew during round trips between Africa and France, flying overnight with a twelve-hour stopover before returning to home base. There was a two-day rest period and then the process was repeated. From the data, the authors determined that the main factors

contributing to lack of alertness in these aircrew were sleep deprivation, jet lag and boredom. As expected, fatigue and drowsiness increased as the flight progressed. However, in some pilots, fatigue further increased while drowsiness decreased by the end of the flight. These pilots felt more tired and believed that they endured a heavier workload than they had experienced during the first flight. They did not recover sufficiently during the stopover. This suggested to the authors that fatigue and recovery are variable from pilot to pilot. From these experiments, they hope to develop strategies for regulating flight and rest times, and identify effective crew formations for different flight durations.

Chelette and colleagues (#3) compared the performance in trained male and female pilots conducting air combat maneuvers up to +9Gz in a human centrifuge under two conditions: the rested state and twenty-four hours of sleep deprivation. All subjects wore full coverage, anti-G suits and employed positive pressure breathing. Based on the objective measures taken, sleep deprived subjects' ability to perform offensive maneuvers remained unchanged after twenty-four hours without sleep, even though subjective sensations indicated fatigue and a feeling of decreased performance. The authors cautioned, however, that under such sleep loss and fatigue, survival could be compromised in situations requiring more uncertain and spatially demanding defensive maneuvers.

5.2.2 Extended operations: Non-pharmacological management

Researchers at the Netherlands Aerospace Medical Centre addressed the issues of strategic napping and early starts on performance and flight safety of aircrew during irregular work schedules.

Valk and Simons (#4) concluded that, by introducing forty-minute rest periods during long duration operations, the level of alertness and performance in pilots was improved over those who did not sleep. They recommended that cockpit measures need to be instituted to enhance sleep in the resting pilot (e.g., by employing a head rest, eye shades and reclining seat), and improve alertness in the other pilot flying the aircraft during this rest period (e.g., by increasing the level of cockpit illumination). Additionally, for safety purposes, the level of alertness should be assessed in the latter pilot before the rest period commences. In the ensuing discussions that followed the session, indications were given that 'controlled cockpit napping' to relieve fatigue and sleepiness is being considered by some commercial airlines (see Discussion #2 in these Proceedings).

Simon and Valk (#5) contended that work starting times before 0600 hours should be avoided as pilots on such schedules suffered from a shortage of sleep that affected performance. If early starts cannot be avoided, then a compensatory sleep recovery phase should be instituted in order to prevent a cumulative sleep debt from occurring.

5.2.3 Extended operations: Pharmocological management

Non-pharmacological sleep management for enhancing alertness in flight crew may prove to be ineffective or inappropriate. For example, in operations such as night-time, intensive air operations, or long duration flights requiring sustained alertness, non-pharmacological measures are not likely to be practical. Additionally, because of individual differences in aircrew, such methods may not always be reliable. Pharmacological measures, which have quick onset times without significant side effects, hold the promise for maintaining aircrew operational efficiency throughout the flight in situations requiring sustained vigilance.

Paper #7 by Jouvet was to have discussed the neurological basis of the pharmacological management of the sleep - wake cycle. The author was not able to make the presentation; however, he requested that his Abstract to the Technical Programme Committee be included in the Conference Proceedings.

As Jouvet has noted, wakefulness and sleep are regulated by two distinct systems. Thus, there are two different pharmacological methods of controlling the state of wakefulness. One may stimulate the wakeful system with drugs such as dextroamphetamine and caffeine, or one may inhibit the sleep-inducing mechanisms with drugs such as modafinil.

In a previous communication to the AMP, Caldwell reported on the effects of dextroamphetamine in sustaining helicopter pilot alertness in sustained operations under laboratory conditions. That study demonstrated the efficacy of using dextroamphetamine as a viable countermeasure for sustaining operator performance during periods that prevented restorative sleep (see Paper #38 in AGARD-CP-579). In the present study, Caldwell (#8) explored the efficacy of dextroamphetamine (10-mg dose) for short-term sustainment of performance during sustained operations - the final 23 hours in a 40-hour period of wakefulness - in the actual flight of a UH-60 (Black Hawk) helicopter. Results indicated a better performance in most flight maneuvers when comparing dextroamphetamine with a placebo. This comparison showed that there were marked reductions in the subjective feelings of fatigue, confusion and depression, as well as an increased vigour when using dextroamphetamine. No significant side effects were detected. However, in his Abstract to the Technical Programme Committee, mild asymptomatic increases in heart rate and heart pressure were indicated. This is not unexpected given the fact that dextroamphetamine, like other amphetamines, acts on the peripheral nervous system producing deleterious cardiovascular effects when given in sufficiently large doses. Caldwell concluded by supporting the use of dextroamphetamine for short-term operations requiring up to 40 hours of continuous wakefulness. In the discussions that followed the session papers, concerns were raised regarding the compromising of higher-level function through the administration of high doses of dextroamphetamine (see Discussion #3 in these Proceedings).

Lagarde (#9) provided an overview of the current interest in modafinil as a sleep management drug. He stated that it induces good quality sleep in narcoleptic and hypersomnolent patients. Its likely site of action is the anterior hypothalamus. Large doses (600 mg) of modafinil have shown a neuroprotective effect in animals against lesions occurring in the hippocampus from toxic organophosphate compounds. Although limited experiments have been conducted in healthy subjects, all studies have demonstrated the potential of modafinil in sustaining performance during extended operations where there is progressive sleep loss. In particular, the combination of strategic naps and modafinil produces very good levels of vigilance and performance during prolonged sleep deprivation. This combination also seems to enhance post-nap recovery.

Raphel et al. (#10) assessed the dose-related effects of modafinil on spatial cognition during sixty hours of sleep deprivation. Results showed that a dose of 300 mg given over 24 hours is required to maintain effective cognitive performance in most of the spatial abilities investigated. This was the usual case in cognitive tasks requiring visual attention (effective for 60 hours of sleep deprivation) and mental imagery (effective for no more than 42 hours). In their Abstract to the Technical Programme Committee, the authors contended that lower doses are more beneficial for cognitive situations requiring visual - vestibular interactions. No physiological side effects have been associated with the ingestion of modafinil. However, in response to a question from the audience, Raphel indicated that recent experiments have shown an 'overconfidence' factor in sleep deprived subjects taking modafinil. There was no euphoria associated with this effect; nevertheless, there is concern that it may have a deleterious effect on cognitive decision making (also, see J. Sleep Res., 6: 84, 1997).

Slow release caffeine, in capsule form, has been developed by NESTEC in Lausanne, Switzerland to counteract the transitory and deleterious side effects of aqueous caffeine and

dextroamphetamine that contraindicate their use as effective sleep deprivation countermeasures. Papers by Sicard et al. (#11) and Doireau et al. (#12) studied the efficacy of slow release caffeine in sleep deprived, male and female subjects during experimental extended operations. The pharmacokinetic parameters assessed were larger in females. This was associated with greater susceptibility to sleep deprivation and less body weight than that of males, and the use of oral contraceptives. Both sexes tolerated the drug well, and alertness and psychomotor performance improved in both in a dose-related manner. One study showed that good cognitive performance can be maintained with 300 mg caffeine (the recommended dosage) for up to 45 hours of sleep deprivation. With this dose, performance is not degraded during sleep recovery.

Jones (Appendix A, Keynote Address #2) cautioned that drugs for extending alertness in deployment missions "... should not be used unless the estimated risk of **not** using them exceeds the risk of using them." Therefore, it would be informative to compare some of the risks in using dextroamphetamine, caffeine and modafinil as sleep management aids. Dextroamphetamine induces serious side effects including cardiovascular and psychiatric disturbances, sleep interference and addiction. Aqueous caffeine causes irritability, diuresis and tremors. Slow release caffeine appears to alleviate the harmful effects of aqueous caffeine, and does not impair recovery sleep. Modafinil does not appear to be addictive nor does it induce drug tolerance. It does not affect recovery sleep and appears to have few physiological and psychological side effects, although the "overconfidence" effect in sleep deprived subjects should be investigated more thoroughly. (See Aviat. Space Environ. Med., 62: 432, 1991 for more details on these drugs.)

French and colleagues (#13) have developed and tested a rapid and reliable technique for assessing aircrew performance when taking drugs on military duty. Its efficacy was demonstrated by testing two anti-emetic drugs, granisetron (2 mg) and ondansetron (8 mg), both of which were rendered safe to use as protective countermeasures in aircrew in danger of radiation exposure. The method uses a battery of cognitive, physiological and operational measures and metrics to evaluate performance. In the context of this Symposium, this method has significant merit in that it screens for assessing potential drug interactions with circadian rhythms and with the efforts for ameliorating sleep deprivation.

5.2.4 Extended operations: Pharmacological management (including use of melatonin)

The role of melatonin in controlling circadian rhythms was discussed by Brown and Vos (#14), and Steffen and Suhner (#15). Melatonin is secreted by the pineal gland during darkness and cues the sleep - wake cycle, promoting sleep and thermoregulation. It may be administered orally, intravenously, by nasal spray or by absorption through the buccal cavity. It is claimed that melatonin administered orally or through the application of environmental lighting has had beneficial effects in treating delayed-phase sleep disorders from jet lag, shift work and other biological regulation maladjustments, in both normal and clinical volunteers, during the light - dark cycle. Tryptophan, an amino acid precursor of melatonin that is converted to melatonin in the gut, is also effective in treating jet lag. Melatonin (or tryptophan) treatment produces effects nearly identical to those of light. More clinical studies are required on the proper regimen, dosage and pharmacokinetics of melatonin, how it acts on the brain (phase shift adjuster, sleep inducer or both), and its effect on the hormonal and immune systems in both males and females. It would probably be prudent not to use melatonin indiscriminately until these issues were positively resolved. Moreover, very few controlled studies have been done that evaluated performance changes from melatonin administration in aircrew conducting tasks across several time zones.

The differences in circadian rhythm behaviour of aircrew during and after eastward and westward flights that cross multiple transmeridian time

zones are an area of concern to fatigue management strategists. Tresguerres and colleagues (#16) investigated urinary melatonin excretion in pilots flying transmeridian flights from Madrid to Mexico and return, and from Madrid to Tokyo and return. In westward flights (to Mexico), melatonin excretion began to resynchronize with the new situation on the second day. In eastward flights (to Tokyo), there was a complete desynchronization of melatonin excretion. Brown and Vos cited contradictory, converse results in subjective evaluations of jet lag in aircrew in transmeridian flights between Auckland, New Zealand and London, UK. That is, in these transatlantic flights, the eastward direction was associated with the more severe jet lag, while in the Tresguerres study, it is the westward direction that was more bothersome. In pilots older than 50 years, Tresguerres noted that melatonin excretion was lower and the excretory rhythm fixed to the place of departure. This may signify an age-related decreased capacity for adaptation to multiple time zone changes. These important results impact on aircrew rest schedules and workloads. In preparation for transmeridian flights, planners of long duration missions may have to take into account flight direction, flight path and pilot age in administering their fatigue management strategies.

Paper #17 was to have assessed the effects of melatonin-induced daytime sleep on alertness and performance during sustained operations. However, the authors were unable to present their paper.

Operational necessities may require aircrew travelling across multiple time zones to commence work immediately on arrival. One option would be to employ melatonin at appropriate times during the flight to try to shift the circadian rhythm to reduce or eliminate the 'grounding' time on arrival before effective work can begin. Comperatore and colleagues (#18) performed studies to provide some answers to this problem. Using females as subjects, they studied the adverse side effects following sleep of a 10-mg dose of melatonin given at two different times prior to the daily sleep cycle. In one study, where melatonin administration and bedtime took place at 2300 hours, participants exhibited significant increases in errors throughout the day during testing on a vigilance test battery. In the second study, where melatonin dosing took place at 1300 hours and bedtime commenced at 1630 hours, there were no significant decrements in performance on the test battery after eight hours of sleep had occurred. For several hours following this period of sleep, however, melatonin concentrations had achieved endogenous levels. In other instances though, in both studies, melatonin concentrations remained well above physiological levels. Consistent with previous findings by other researchers, cognitive performance during such high levels of melatonin degraded significantly. The authors suggested that aviator's grounding time after melatonin administration must take into account not only drug half-life, but also the time of testing and the requirement for normal sleep. Moreover, for long range deployments across several time zones, melatonin administered during the afternoon may not require a grounding time beyond the time travelled to the destination.

Sicard (#19) described a study by the French that evaluated the hypnotic drug, zolpidem, for its potential in optimizing rest periods during daytime wakefulness in sustained operations. Subjects belonging to ground air force personnel and navy fighter pilots received the drug (10 mg) at 2200 hours and 0100 hours, respectively. The subjective quality of sleep was better with zolpidem when compared to that of a placebo in all subjects. Moreover, there were no residual side effects observed, leading the author to believe that zolpidem can be used operationally. (Although only an abstract is included in these Proceedings, more details on this study are provided in Aviat. Space Environ. Med., 64: 371, 1993.) A comment from the audience referring to an independent analogous study supported these conclusions.

5.3 Medical Management in Remote Locations

The emphasis in treating the sick and injured in Contingency Operations will be on stabilizing

and removing them as quickly as possible while providing medical care en route to rear echelon combat areas or to assigned areas in the case of local disasters in MOOTW. More likely than not, the aeromedical mode using helicopters or short-take-off-and-landing aircraft will be best suited for in-theatre types of evacuation in most Contingency Operations. Papers on this topic addressed the issues from the point of view of aeromedical logistics and evacuation, and the use of technology in trauma and communicable-disease control management in austere locations. In particular, Major General P. K. Carlton, Jr. and his team from Wilford Hall Medical Center, Lackland AFB, Texas made major contributions to this topic (11 papers), promoting a number of different strategies for enhancing casualty care in such contingency situations.

5.3.1 Aeromedical support issues: Logistics and evacuation

Typical of the kinds of experiences and deficiencies that one might expect in Contingency Operations are those reported by Dines (#20) following her recent posting as a medical officer to the United Nations Special Commission (UNSCOM) to Iraq. She commented on the challenges of harsh climate, the physiological and logistic difficulties in providing NBC protection, the poor local medical infrastructure, and the lengthy evacuation and supply chains. The relative importance of each of these challenges will change over time and remedial measures will evolve accordingly. (This underscored the importance of documenting the 'lessons learned' in each Contingency Operation.) Managing sanitation and heat exposure were the key to minimizing morbidity. Routine medical briefings were given to minimize the occurrence of preventable diseases. Rotary- and fixed-wing aircraft employed for evacuation were often delayed by administrative problems or for political reasons. In these types of environment, the coordination of effective aeromedical evacuation is essential for saving lives and boosting morale. Medical logistics rely extensively on the effective use of information technology. For example, the inappropriate substitution of medical items by suppliers was resolved by using a CD-ROM catalogue and e-mail to obtain the exact items from the suppliers. As in all contingencies, planning and flexibility are the key to the success of the operation.

Aeromedical evacuation was the subject of a recent AGARD/AMP Symposium. The focus was on interoperability, coordination, and standardization of procedures, command and control, and training in planning for evacuating casualties in multinational operations (AGARD-CP-554). In this Symposium, Gibson (#21) has expounded on some of the factors influencing operational medical planning up to, and beyond, aeromedical evacuation. The components that must be addressed include:

- the development of operational concepts according to:
  - a government's willingness to commit forces to MOOTW,
  - the requirement for novel force structures,
  - casualty estimates,
  - interoperability with allies willing to take lead-nation tasking, and
  - a pervasive, inquiring media that fuels public expectations of quick success and low casualty rates;
- the judicious use of new technologies including:
  - weapons with greater wounding capability,
  - enhanced personal protective clothing and equipment, and
  - enhanced medical treatment capability;
- the application of operational medical doctrine according to the:
  - availability and location of surgical/medical support,
  - requirements for and development of casualty treatment regimes,
  - decisions regarding stabilization and surgery before or after evacuation; and
  - lessons learned and changes made as a result of previous Contingency Operations.

Gibson regarded medical staff involvement in operational planning from the beginning to the final stages of the mission as the most important aspect of medical participation in Contingency Operations. Without such involvement, there is a great danger that non-medical planners may make inappropriate or wrong decisions that could seriously affect the outcome of medical support operations.

Hersack, Carlton and Farmer (#22) discussed some impediments in meeting medical readiness in future Contingency Operations. Of significance were:

- the political realities of a decreased defense budget and a reduced military force, and
- the operational constraints imposed by a limited lift capability and time-distance problems in moving field hospitals and medical supplies to forward areas.

These restrictions have necessitated changes in US casualty care policies and practices (further discussed also by Hersack et al. (#23) and Miller (#24)). For instance, this results in a smaller medical presence in the forward battlefield area with a greater emphasis placed on casualty prevention. Also, there has been a change in US military policy from 'treat and return to duty' to 'evacuate and replace'. This necessitates frequent aeromedical evacuations from the forward area to free critically-needed bed space. Moreover, it entails movement of stabilized patients who continue to be seriously ill. (Current practices dictate that only stable patients undergoing convalescence should be moved to definitive care centers.) This implies that far-forward resuscitative surgery will become an essential requirement of casualty care. Additionally, continuous en-route patient care from point of first contact to point of placement in a definitive care center will be part of this new medical strategy.

Both Hersack et al. (#23) and Miller (#24) described a mobile aeromedical staging facility that incorporated a critical care aeromedical transport team (CCATT) which augments, but does not replace, aeromedical evacuation aircrew in providing continuity of care during high casualty patient movement. (The CCATT consists of a physician specializing in intensive care, a critical care nurse and a cardiopulmonary technician. It uses medical equipment commonly used in the intensive care units in medical centers. Between missions, the CCATT works out of a regional central medical facility.) To overcome the limited lift capability, Hersack, Carlton and Farmer recommended that modular medical units and man-portable elements be used for providing essential medical care in a timely manner in the forward area. Trauma and critical care training for both aircrew and health care workers should be given to resolve problems arising from the stresses of flight during evacuation.

Paper #25 was to have described the logistics involved in deploying an air mobile, advanced surgical center to The Former Republic of Yugoslavia. However, the authors were not able to give this paper.

Carlton and Pilcher (#26) described the concept of a Mobile Field Surgical Team (MFST), a five person unit, that brings surgical care directly into the evacuation system. Advanced man-portable, surgical equipment is used to perform surgery for combat casualties. Major trauma can be treated under very austere conditions. The team can move quickly and set up wherever it is needed; i.e., en route, in forward areas, the area of greatest need, before other units arrive, etc. The team carries no more than 600 pounds (270 kg) of surgical equipment for treating trauma in remote locations. The MFST and CCATT concepts were successfully tested in the resuscitative surgery and critical care of injured civilians following a cargo aircraft crash into Manta, Ecuador in 1996.

5.3.2 Aeromedical support issues: Technological aids and solutions

Contingency commitments in austere regions rely increasingly on novel technological aids and solutions to enhance medical support and medical logistics. New developments in modular components, miniaturization, information and display technologies including signal acquisition

and processing, microcomputerization, power sources, sensors and materials have all contributed to the development of a series of practical medical devices and facilities for providing intensive care medicine in austere field locations or during aeromedical evacuation. Many of these are commercial-off-the-shelf (COTS) procurements that are modified for field use.

Papers #27, #28 and #29 discussed device developments that have enabled far-forward and en-route intensive care medicine to be applied that is comparable to that of a hospital intensive care unit. These devices include capable mechanical ventilators, cardiac and respiratory monitors, and precision infusion pumps/syringes. Patients have been safely cared for and moved with severe respiratory failure, with arterial lines in place, those that are hemodynamically unstable, and some that require continuous drug and substance infusions. Point-of-care (POC) laboratory testing; i.e., testing at the patient 'bedside', is being investigated as a means of rapid and accurate diagnosis of blood products to enable quick and effective treatment of critically ill patients in the field and during extended air evacuations. Instruments that can analyze arterial and venous blood gases and conduct electrolyte, glucose, hemoglobin and thrombosis/hemostasis determinations are commercially available. The technical requirements for a POC device is that it must be less than ten pounds, use small quantities of blood, use battery power sources having minimal life times of four to six hours, and be easy to calibrate. Current POC devices can be expensive, and problems with extremes in temperature and (potentially) barometric pressure, and the requirement for continuous accuracy may limit their usefulness in the field. Experiences were described using POC devices during transmeridian transportation of critically ill patients in Operation JOINT ENDEAVOR and the Korean Airline crash in Guam in 1997.

An inability to adequately monitor vital signs or provide therapeutic needs during ground or air transport to a definitive care treatment facility is a major impediment to moving marginally stable or unstable post-surgical patients. Pearce and colleagues (#30) described a transportable, stretcher-based, mini-intensive care unit that incorporates resuscitative and life sustaining capabilities into a universally adaptive platform for trauma management and patient life support under such conditions. The system, called the Life Support for Trauma and Transport (LSTAT), is comprised of a lightweight, composite base unit, a NATO standardized stretcher and a canopy that covers the patient. The system base contains a pressure compensated ventilator, oxygen source, suction capability, three-channel infusion pump, blood chemistry analyzer, environmental controls providing patient thermoregulation and protection from biological and chemical agents, onboard computer, power converters, batteries and a physiological monitoring system. Medical parameters, system performance data, and user interaction information are continuously monitored and logged by an on-board computer. Physiological data can be displayed on local displays or on remote, wireless hand held or head mounted displays. Provision is made for storage of up to 72 hours of physiological and systems data that can be up-loaded to a local or remote host computer. These data can also be communicated to the receiving hospital during evacuation for review by physicians to aid in their medical preparations for subsequent treatment. The system is applicable to both military and civilian operations. In discussions following this paper, concerns were raised regarding the weight of the LSTAT, and how this could be resolved.

Dyck and Nichols (#31) described a vital signs monitor (**VITSEM**), that is based on microprocessor technology, which monitors heart rate, body temperature and blood oximetry continuously, and blood pressure as required during critical care treatment in the field. The device is inexpensive to manufacture, robust, hand held, and operates on batteries for 12 hours of continuous use. The current version measures 14.7 cm x 9.3 cm x 5.4 cm and weighs 390 g. Information is displayed on a digital, backlit display. The device has performed well in two demanding conditions: in the noisy environment

of a helicopter used for aeromedical evacuation, and in conjunction with a casualty bag in an NBC environment. Notwithstanding this good performance, care needs to be taken when reading blood pressures with the current **VITSEM** in vibration environments. The device is available commercially from CME Telemetrix, Waterloo, Ontario, Canada, and is currently being evaluated by the Canadian Forces.

Mason (#32) discussed the conceptual development at Brooks Air Force Base of an advanced system for transporting patients having unstable spinal cord injuries, and extremity and cervical traction requirements during aeromedical evacuations. The system envisioned will provide traction and kinetic therapy through incremental side-to-side rotation comparable to that available in permanent medical facilities. The system is expected to be versatile and robust enough to be used also for patient treatment of multiple trauma, burns, chest wounds, pulmonary complications and postoperative conditions.

Mason and Elsass (#33) reported on developments of an advanced hybrid oxygen system that will ensure the availability of medical grade oxygen wherever required. The oxygen system is a two component unit: a molecular sieve for generating gaseous oxygen and a cryogenic unit for liquefying the oxygen. The system will produce and liquefy 99% pure oxygen at 33 l/minute. A total of 20 l of liquid oxygen will be stored. The fielded system will weigh less than 400 pounds (180 kg), occupy less than 20 cubic feet (0.55 m^3) of space and require electrical power less than 220 volts AC at 400 Hz. The current laboratory version does not meet these specifications yet. The fielded system will be located at the mobile aeromedical staging facility (see Papers #23 & #24), on-board aeromedical evacuation aircraft and at other remote facilities.

Advances in miniaturization and computer technology have led to the development of commercially-available smaller and more versatile mechanical ventilators. In particular, some of these ventilators incorporate modes of ventilation that improve patient tolerance to mechanical ventilation. Grissom and colleagues (#34) tested the performance of the Univent Model 750 and Univent Eagle Model 754 ventilators on a test lung at altitudes from 600 to 16,000 feet (180 to 4900 m). Although both models performed well, the autocalibration feature of the Model 754 made it more suitable for aeromedical evacuation. Unless recalibration of the Model 750 is conducted with each change of altitude, tidal volumes greater than predicted will be delivered which might be detrimental to patients with poor lung capacity. The Model 754 portable ventilator weighs less than 13 pounds (6 kg) (Aviat. Space Environ. Med. 68:285, 1997).

Ultrasound has become a very important diagnostic tool in medicine. Advances in technology have enabled hand held systems to be developed, which have good imaging qualities, and are suitable for field use in remote locations. Van Dalen (#35) described field experiences of The Netherlands Armed Forces in the ultrasound examination of blunt traumas and the detection of foreign objects in injured patients during peacekeeping operations in the Former Republic of Yugoslavia. He predicted that small, portable ultrasound imagers will soon become part of the armamentaria of diagnostic equipment used by field trauma units.

5.3.3 Contingency Operations: The management of operational medical problems

The quick stabilization and treatment of the traumatized patient in the combat area has always been the main goal of the military physician given that some eighty percent of deaths occur within sixty minutes - the so-called golden hour - of receiving a severe injury. In Contingency Operations the goal is to move skilled, critical care workers rapidly into the combat or disaster areas. These people must have the tools, preparedness and flexibility required to conduct trauma procedures quickly and as simply as possible. Papers in this session addressed some specific ways of managing trauma in such operations.

To accommodate the political realities and operational constraints of today's Contingency Operations on medical readiness, the US Air Force has introduced the concept of MFST, a five-person surgical unit that provides on-the-spot trauma surgery in very austere conditions (see comments to Paper #26). In Paper #36, Carlton and colleagues described some simulation procedures that they conducted to facilitate resuscitative surgery by the MFST. Evaluations undertaken were field disinfection techniques, trauma surgery using only equipment and supplies from an MFST backpack, surgery on anesthetized traumatized swine using night vision goggles in a near-dark environment, and an assessment of the use of thermal imaging in medical care. Important lessons were learned; e.g., that resuscitative surgery without the benefit of infrared illumination in a light-limited environment is impractical. Additional simulation and testing of MFST equipment and concepts will be conducted before field implementation occurs. Such validation procedures are necessary steps for evaluating team capability and competency in different kinds of contingency situations.

Paper #37 was to have considered the field management of severe thoracic injuries. However, the authors were not able to give this paper.

Major vascular injuries to the extremities present a significant challenge to the military surgeon in the field. Without prompt restoration of blood flow to an ischemic limb (6 hours or less), amputation is almost assured. Reconstructive surgery of the arteries is technically demanding, time consuming and resource intensive. The use of temporary arterial shunts is an alternative to surgical reconstruction. Dawson and colleagues (#38) used anesthetized pigs to test patency and flow rates through silastic shunts placed after division of the common iliac artery. Patency was maintained for 24 hours using a non-heparin-bonded shunt. Results showed that limb blood flow on the shunted side was maintained at 40 - 70% of that of the control side. Oxygen extraction in the shunted limb increased to compensate for the moderate decrement in blood flow, thereby, preventing any major ischemic damage. The authors recommended using 4 mm x 5 mm tapered, reinforced shunts for most peripheral human arteries; 3.5 mm x 4.5 mm shunts for upper extremity and other smaller arteries. The efficacy of the method still needs to be demonstrated in humans in trauma conditions.

Blood products must be refrigerated and they have a shelf life of only thirty days. This becomes a serious problem in remote regions where refrigeration is difficult to maintain, and where facilities for blood grouping and blood typing are unavailable. In an attempt to circumvent such problems, several organizations are working towards a blood substitute that they expect to be basically non-toxic, universally compatible, that essentially free from risk of disease transmission, bind and release oxygen like normal blood, and have a long shelf life, particularly at ambient temperatures.

Magnin and Carmichael (#39) described their product **Hemolink™** - a highly purified, stroma-free human haemoglobin - as having the potential of an effective blood substitute in remote regions, during difficult air evacuations and other military situations where emergency and trauma care are required. Pre-clinical trials in dogs and rats have established that **Hemolink™** is an effective oxygen carrier and volume replacement fluid. No renal or other end organ toxicity was demonstrated at the dosage used. In experimentally-induced haemorrhagic shock, **Hemolink™** restored vital sign parameters to normal values in these animals. Phase I clinical trials in human volunteers have demonstrated that **Hemolink™**, up to a dose of 42 g of haemoglobin, is a safe blood substitute. Side effects were few and not serious, with the main one being a 15% increase in arterial blood pressure which may be beneficial in trauma situations where hypotension is a problem. Phase II surgical trials, where blood loss in individuals is a factor, have commenced; future trials will assess trauma and other intensive care issues.

Papers #40 and #41 were to have discussed new lung protective and treatment strategies to

reduce Acute Respiratory Distress Syndrome (ARDS), a common cause of morbidity and death. However, the author was not able to give these papers.

5.3.4 Contingency Operations: Control of communicable diseases

Infectious diseases are a leading cause of death worldwide. The military represents a population at special risk. Deployment to remote regions during Contingency Operations may expose NATO troops to infectious diseases that are uncommon in many of their respective countries and to which they will have little natural immunity. This is particularly the case in tropical regions where the terrain and weather conditions support a multitude of endemic disease pathogens such as those causing malaria, dysentery and Ebola virus infection. The rapid deployment of troops into regional areas where there are such serious disease pathogens may compromise the operation if there is not sufficient time to employ effective countermeasures to prevent contacting the infectious diseases. Good field hygiene and proper sanitation practices are essential in containing diseases but these may be dependent on geographical locale and operational demands. Many examples can be cited where local health care, sanitation and safe water are not available. Deployed troops are also at an increased risk of getting human immunodeficiency virus (HIV) infection and the acquired immune deficiency syndrome (AIDS) in these remote regions, both in the field from contaminated blood and from social situations, that will have to be addressed. Additionally, there is always the threat of rogue nations introducing intentional disease pathogens into the theatre of operations for which there are no adequate antidotes, and this must be considered in contingency commitments.

The persistent and mutable nature of re-emerging infectious diseases, such as the tuberculosis bacterium, and/or the vectors spreading them, such as the anopheline mosquito spreading the malarial parasite, are a continuous problem to those controlling infectious diseases. Developing new drugs to combat these pathogens is expensive and drug companies are reluctant to invest the large funds required to conduct the research and clinical trials in an uncertain world economy and where there are likely to be poor monetary returns. Because of these factors, the military has taken the initiative in fighting infectious diseases in some countries. For example, new antimalarial compounds were mostly discovered in US military laboratories in response to the need for protecting US service personnel operating in tropical regions.

The above two paragraphs are a background to the thrusts described by authors in this Session for the prevention and containment of infectious diseases in Contingency Operations.

The World Health Organization (WHO) is responsible for the worldwide monitoring and control of infectious diseases; this includes surveillance of both military and civilian populations. D'Amelio and Heymann (#42) described a cooperative venture between the WHO and the military for the creation of a network of watches for monitoring infectious diseases in the military that is complementary to its existing civilian counterpart. Seventy-six countries replied positively to an initial questionnaire requesting an indication of the presence of a diagnostic laboratory and/or a notification system for infectious diseases in their military populations. This was followed up with a second questionnaire to the countries responding that requested more detailed information on:

- the diagnostic capabilities of the laboratories,
- the characteristics of the notification system,
- whether a diagnostic schedule for infectious diseases is mandated on recruitment, and
- any compulsory vaccination schedules.

Forty-seven countries replied to the second questionnaire.

Some interesting results were obtained from the surveys of D'Amelio and Heymann. Of countries replying to the first survey, at least 70% have a diagnostic capability and just over 80% have a notification system. Over 75% of

respondents to the second survey have a diagnostic capability in at least four of the areas of bacteriology, virology, parasitology, immunology and molecular biology. Regarding a notification system for infectious diseases, just over 50% of countries responding have a computerized surveillance network. On recruitment, more than 80% of countries screen for tuberculosis and/or syphilis, while 55% screen for HIV infection accompanied sometimes by screening for other viral diseases such as hepatitis A, B and C viruses. Forty percent of nations screen for parasitic diseases on recruitment. The compulsory vaccination schedule for the military is mixed: a few countries have no basic immunization schedule; others focus mainly on immunization against tetanus and diphtheria toxoids, and typhoid fever. In NATO countries, Canada leads the way in the immunization requirements of its military personnel (9 vaccination types), followed by Italy and The Netherlands (7 each), and the United States (6). The results of these surveys represent an important first step in a global network for the monitoring, detection, containment and treatment of both endemic and intentional infectious disease outbreaks in both civilian and military populations.

Armed Forces are at an increased risk of acquiring HIV infection and sexually-transmitted diseases (STD) during deployment. The HIV risks are primarily related to sexual activity and drug injection; however, the safety of field blood supplies may also be a concern. Kingma (#43) recommended some measures for decreasing the risk of these infections in deployed troops. These include:

- civil - military collaboration in prevention and care;
- training medical care workers in prevention education;
- repetitively briefing troops on preventive measures;
- emphasizing the avoidance of high risk STD and HIV areas;
- promoting an STD health-care-seeking attitude;
- providing accessible STD counselling, testing, and other essential services;
- teaching universal precautions and blood safety procedures;
- creating a non-stigmatizing atmosphere for troops that are HIV positive; and
- providing continuous care and support to troops that are HIV positive or have AIDS.

Kingma also discussed the pros and cons of mandatory and voluntary testing and screening for HIV infection in the military. He did not support excluding HIV positive individuals from occupations on the basis of HIV infection alone. He recommended that, in those instances where neurocognitive performance impairment has implications for safety, whether occurring from HIV infection or not, appropriate periodic skills assessments relevant to the individual's occupation should be conducted. For example, this would be the case for pilots flying high performance aircraft in which some neurocognitive impairment may compromise critical decision making. He recommended using tests based on neurocognitive evaluations from computerized simulators such as **CogScreen** which mimics real-life conditions and detects subtle changes in cognitive functioning. (The application of **CogScreen** in assessing return to flying in head injured aviators was the subject of Paper #13 in a previous symposium - see AGARD-CP-579.).

Steffen (#44) noted the wide differences in immunization practices of countries participating in peacekeeping operations. He felt that this was due primarily to a lack of knowledge of the requirements for immunization in the peacekeeping regions, a lack of coordination amongst health care managers, and the lack of sufficient financial support to adequately address the issue. He has proposed that priorities in immunization must be based on the estimated incidence rate of various vaccine preventable diseases; consideration of the actual severity of symptomatic infection and other factors usually should play a secondary role. In support of this recommendation, he noted the following:

- Impaired hygienic conditions are the rule

rather than the exception in these missions.

- In such conditions for personnel not immunized, the risk is greatest for hepatitis A, hepatitis B, typhoid fever and measles with the annual incidence possibly exceeding 1 (or even 10) per 1000 individuals.
- The risk of yellow fever, poliomyelitis, Japanese encephalitis, and plague may be rare in some places but substantial in others.
- Cholera, diphtheria, tetanus, tuberculosis and rabies are a lesser, though worldwide, risk.
- In some missions, immunization against influenza may be required.
- In the near future, emerging gastrointestinal infections such as enterotoxigenic *Escherichia coli*, rotavirus and others causing traveler's diarrhea (the most frequent infection at monthly incidence rates of 10 to 80%) may require vaccination programs.

Williams (#45) assessed the degree of compliance with anti-malarial preventive measures (chemoprophylaxis and personal protection) in deployed USAF troops during Operation ASSURED RESPONSE, the mission to evacuate foreign nationals following the breakdown of civil order in Liberia. Before departing, all troops received a medical threat briefing, doxycycline for chemoprophylaxis, and, as protective measures, **DEET** insect repellent and permethrin spray as a clothing insect repellent. In spite of extensive attempts emphasizing the importance of complying with these anti-malarial measures, only 88% of personnel took their doxycycline regularly, and only 24% used all preventive measures. An even lower rate of doxycycline compliance (79%) was recorded in US Army personnel deployed for the same Operation. Moreover, no USAF personnel, but four US Army individuals contracted *Plasmodium falciparum* malaria, a major disease pathogen associated with significant morbidity and mortality in this region. Differences in compliance between the two groups was partially associated with differences in attendance at the pre-deployment medical threat briefing (attendance USAF: US Army = 2:1). Williams discussed strategies for improving compliance, and ways of reducing exposure to malarial mosquitoes (e.g., keeping personnel in well-screened areas at night whenever possible). As is the case for AIDS and STD prevention, this study showed that military commanders and health care personnel must be trained appropriately, and be proactive and apply behavioural change strategies throughout all phases of troop deployment to ensure that good preventive compliance measures are maintained.

The rapid identification and characterization of highly lethal and communicable disease agents, whether indigenous or introduced, is essential for implementing proper preventive measures and providing for optimal patient care. The US Army Medical Research Institute of Infectious Diseases (USAMRIID) has developed a high-level pathogen containment facility that accompanies an Aeromedical Isolation Team (AIT) to remote regions to evacuate patients suspected of having highly contagious infections (Christopher and Eitzen (#46)). This portable containment facility enables a rapid diagnostic assay of a number of pathogens to be done *in situ*; as well, it provides standard clinical laboratory support during air evacuation. Containment of pathogens from the point of patient retrieval to arrival back at USAMRIID is controlled by maintaining the sealed facility under negative air pressure. Patient care monitoring and substance infusion can also be conducted during transport. The AIT is a rapid response team consisting of a physician, a registered nurse and four to six medics, trained in minimizing the risk of disease transmission. AIT deployment will occur in instances requiring basic research and clinical investigation of unidentified pathogens, and where patient isolation is mandated to prevent further disease transmission. The USAMRIID can deploy two AIT teams simultaneously. Each team can take care of one patient.

5.4 Medical Information

Critical to the success of Contingency Operations is the issue of keeping the number of casualties as low as possible. In part, the public in the NATO countries demands this as a condition

to entering hostilities. As always, the military surgeon is expected to stabilize the casualty quickly, and diagnose and treat the injury or infection as soon as possible. There is also the aspect that medical personnel from some NATO countries must support very long deployment missions such as that in Bosnia-Herzegovina, while still treating casualties as if they had occurred in a local, major industrial center where critical care facilities and resources are readily available. There are several information technologies under development that lend themselves to aiding battlefield trauma and disease management more effectively, starting as far forward as possible in the combat zone and continuing during aeromedical evacuation. Of these technologies, telemedical applications, portable diagnostic imaging, and computer-based, medical information management tools are the most prominent.

5.4.1 Contingency Operations: Information management including use of deployment telemedicine

Medical information management in the NATO context should commence with the all-Service, seamless tracking of all ill or injured personnel during treatment and evacuation using advanced data processing and decision support systems in each Contingency Operation. Hughes (#47) addressed the issue from the perspective of the US Department of Defense Medical Global Command and Control System (MGCCS). Seamlessness and interoperability are conducted across all levels of command and medical care, contingency or other commitment, data acquisition platform, and systems integration. The MGCCS is part of a larger, all-Service, global, command and control system that collects, processes and tracks information from the point of entry through all stages of deployment. The MGCCS employs the US Transportation Command (TRANSCOM) Regulating and Command and Control Evacuation System (**TRAC^{2}ES**), an interactive graphics and map-oriented user interface having algorithms employing artificial intelligence techniques to plan, monitor, coordinate and remove impediments for improved patient care and evacuation. A **TRAC^{2}ES** World Wide Web site enables in-transit patient treatment information. (See Paper #11 in AGARD-CP-554 for further details on **TRAC^{2}ES**.) The ensuing discussions following the session focused on;

- the need for a NATO Standard for medical information exchange on an electronic format; and
- the requirements for, and security of, medical information stored on a Smart Card, the latter of which contains personal information and forms part of the MGCSS concept (see Discussion #9 in these Proceedings).

Deployment telemedicine uses real-time voice, video and data communication links to diagnose and treat patients remotely using resources *in situ* for patient care. New advances in telecommunications and computer technologies have lowered the cost and driven the military to using telemedical technology in remote locations for enhancing health care delivery. Specifically, some of the crucial components of modern telemedicine systems include: high-speed analog-to-digital data conversion, compression and transmission capabilities; satellite and microwave communication links; high resolution, hand-held video cameras; miniaturized microphones; portable imaging devices; and powerful personal computers that are used for various clinical consultations. Physiological data such as echocardiograms, electrocardiographic and electroencephalograhic recordings, and X-ray and ultrasound images can be stored and then forwarded with high resolution between field stations and major medical centers where they are replayed for interpretive purposes. Of course, much of telemedical consultation also will involve real time, interactive video consultation between health care workers (Farmer et al. (#51)). In that regard, portable video teleconferencing units that enable personnel in forward-area medical facilities, such as those in Bosnia-Herzegovina, or intermediate-staging field hospital to communicate with specialists in major medical centers are being assessed for feasibility. The practicality of doing minimally-invasive surgery

remotely by telemedical techniques is being seriously explored.

The cost of telemedicine - including capital equipment - in treating patients on-site in military operations must be balanced against the cost in air lifting patients to hospitals far from the region of conflict or disaster; e.g., air flights from Bosnia-Herzegovina to the United States or Canada. Telemedical consultations also abrogate the inherent risks to both patient and evacuation crew from travelling over difficult terrain, in bad weather and through land mines. Of course, telemedical applications are being considered for patient care in the air in long-range (greater than 10-12 hour) aeromedical evacuations where health care workers may not include a physician (Farmer et al. (#51)). In that regard, there are some major impediments to realizing air-to-ground telemedicine as an effective means of augmenting critical care. Particularly noteworthy are problems of equipment interference with aircraft navigational systems, and the need for standardization of clinical treatments and equipment interfaces. Using COTS technology, making equipment highly portable, being 'user friendly' and easy to maintain, and incorporating emerging advances in computer hardware and software will do much to enhance telemedicine as a viable means of patient care in Contingency Operations (Morris and colleagues (#50)). One must also factor into the equation of cost-effectiveness the speed with which telemedical consultations between physicians can provide relief to both physician and patient in the diagnosis and treatment of suspected infectious diseases, poisonous snake or insect bites, and other traumatic possibilities.

Some indications of the effect of telemedicine on the cost and quality of medicine delivered has been given by Walters (Milit. Med. 161:531-536, 1996). This retrospective analysis from deployed military medical units in Somalia, Haiti, Croatia and the Former Yugoslav Republic of Macedonia demonstrated that telemedical consultations positively affected diagnosis in 30%, treatment in 32% and the overall patient status in 70% of cases. This study also emphasized the importance "of a formal organizational infrastructure that ensures proper training, develops standard operating procedures, and enables efficient equipment maintenance." Evans and colleagues (#48) in this Symposium spoke to the evolution of such an infrastructure noting that for the development of a global military and civilian telemedicine network, test beds, demonstrations and symposia will be required to establish proof of concept.

Paper #49 was to have discussed the use of telemedicine as a cost-effective emergency medical service linking several hospitals in the Baltic countries. However, this paper was not presented.

Macedonia and colleagues (#52) described a portable telemedicine system, **MUSTPAC**, that is designed largely from COTS components for remote field hospital use. The system is built around a three-dimensional ultrasound imager that permits immediate visualization of internal bleeding, damage to solid organs and penetrating injuries. Scanning the volumetric data set obtained by the imager with a 'virtual probe' enables a conventional two-dimensional diagnostic interpretation to be made. The system requires very little training and can be used by inexperienced operators. It operates in a store-and-forward fashion over low bandwidth, communication links. Expanded versions will include video teleconferencing capabilities. The unit can operate for short periods on batteries. Production models weighing 27 kg are envisaged. The current **MUSTPAC** was tested in Bosnia-Herzegovina.

Wilford Hall Medical Center in San Antonio, Texas has conceptualized the development of a modular, portable, diagnostic imaging system, ***StatRad***, for use in remote locations, that would be integrated digitally with major medical centers (Freckleton and colleagues (#53)). As envisaged, ***StatRad*** would consist of a multi-mode system employing ultrasound with Doppler capability, X-ray technology, fluoroscopy, and axial computerized tomography. Digital images would

be stored locally and/or transmitted elsewhere for radiographic interpretation. Using Internet and CD ROM computerized resources, ***StatRad*** could be used for medical teleconsultation with physicians in remote medical centers, and enable reference medical information to be accessed by forward deployed, health care workers. The realization of ***StatRad*** as a portable imaging unit will require significant additional development.

Prins (#54) described some basic concerns with deployment telemedicine as experienced by The Netherlands Armed Forces that are applicable to other countries relying on this form of casualty care management in austere locations. These were identified as follows:

- Telemedicine will never be a substitute for medical or surgical experience in the field.
- Telemedicine should be used very sparingly; e.g., for consultation only, during acute situations, where there are large numbers of casualties.
- Telemedicine was not readily accepted by the field surgeons due to:
  - psychological reasons,
  - the low level grade of injuries that can be diagnosed radiologically with current systems,
  - the inexperience in diagnosing from a monitor screen,
  - the unsatisfactory quality of the video prints,
  - too low a bandwidth to transmit real-time video images, and
  - difficulty in maintaining communication connections between the field hospital and the central hospital in The Netherlands.

The first two concerns are self evident; the last one will be largely addressed through proper training, greater experience and improved technological developments.

5.5 Adaptation to Operational Conditions

Frequently, Contingency Operations involve the deployment of troops to remote regions in unfamiliar surroundings for extended periods of duty. Sometimes, this takes place in operational environments where there has been no previous experience, such as those where the military is helping civilian agencies in humanitarian relief activities or where the rules of combat are not clear as in Somalia where different warring factions imposed their own territorial claims. Also, a lack of host nation infrastructures may mean that, initially at least, troops will have to be self-sustaining and rely on their own initiatives. Of course, there is also the lack of familiarity of terrain and weather, and the constant threat of infection and injury that are an ongoing concern to deployed troops. All of these are stressful conditions requiring adaptation to operational conditions if the mission is not to be compromised. There are also the stresses associated with being away from home and loved ones for extended periods of time, and the eroding morale problems that occur over time in all conflicts or natural disasters. All of these factors require exceptional medical leadership entailing the use of a diversity of acquired skills for dealing with the stresses imposed on the deployed troops. Papers on this topic discussed not only the leadership issue but also the significant stressors, stress - strain relationships and some coping strategies for adapting to different operational conditions in Contingency Operations.

5.5.1 Contingency Operations: Leadership and management issues

Moloff (#55) described some of the challenges imposed by Contingency Operations on aeromedical personnel and capabilities, noting that the nature of these operations may be uncertain and the planning for them may be limited due to a variety of factors including the ill-defined nature of many of these missions. He stressed the importance of utilizing national and international data bases, rapidly accessing information through a variety of computer oriented and human sources, and, above all, remaining flexible mentally and physically if solutions are to be realized. He noted that aeromedical expertise will be a component of all future Contingency Operations.

Salisbury (#56) focused on the lessons learned in delivering health care to the multinational, NATO-led Implementation Force (IFOR) in Croatia. Some of the more important lessons learned included the following:

- Multinational medical staff training and joint exercises are essential.
- Standardization of, and compliance to, medical documentation by nations must be mandatory.
- Bilateral agreements between nations must be signed before deployment, if possible, to assure adequate medical support.
- A medical authority must be established early to provide advice to commanders and medical units.
- Medical intelligence must be available and timely to assess risk to health and establish unit effectiveness.
- NATO medical staff must have at least one dedicated communication system that covers the entire theatre of operations.
- Centralized tracking is essential to access patient status and coordinate evacuation.
- To enhance their return, patients must be evacuated to in-theatre medical facilities, and not out of theatre.

In Keynote Address #2, Jones discussed the issue of medical leadership in handling stress-related mental health problems. He noted that experiences from the Vietnam War regarding post-traumatic stress disorder (PTSD) have legitimized the study of the psychiatric effects of war on individuals. Consequently, much recent work has explored the relationship between acute stress and combat fatigue, and how to cope with the consequences of PTSD which may continue on for many years. To reduce the long-term effects of PTSD in peacekeeping missions, Jones recommended briefing troops before they leave that something may happen to them as a result of combat stress that may last a long time and may even require post-mission referrals. He also recommended providing immediate interventions to symptomatic individuals during operations and returning them to duty as soon as possible. He classified mental health problems as being of two types: 'acute adjustment disorders' which occur during active operations, and 'personality disorders' which happen when operations wind down.

Jones noted that lessons learned from previous operations and the recent psychiatric literature suggest that medical leadership requires that:

- stress-related care must be anticipated from the announcement of mobilization until troops have been reintegrated into the community following return from duty;
- health care workers must be prepared to be self-sufficient for at least 24 hours following deployment;
- a well-equipped ambulance may serve as an excellent portable dispensary;
- the use of local communication services must be learned quickly;
- a clear chain of command must be established;
- flexible leadership must be maintained; and
- past lessons learned may be tempered by technology changes and troop demographics.

Jones' paper gave valuable insights into the role of medical leadership in coping with stress from the perspective of 28 years of active experience as a military flight surgeon and psychiatrist. His paper should be mandatory reading for all health care workers and commanders that are part of a deployment mission in Contingency Operations.

Medialdea Cruz and Rios Tejada (#57) explored the stress factors in Spanish Air Force personnel assigned to humanitarian and peacekeeping duties. In order of frequency, family separation, language barriers, shift work, sleep deprivation, difficulties in communicating home, adverse climates, risk of physical injury, and the potential for disaster were the major stressors cited. Psychosocial stressors were more prominent than physical ones, leading the authors to propose that this should be taken into account in the selection criteria for peacekeeping and analogous duties. No evidence of PTSD was found.

Murphy and colleagues reported on recent

Canadian experience relating to stress in peace support operations in Bosnia-Herzegovina and Haiti (#59), and the current model employed by the Canadian Forces to assess stress and performance (#58). In the first paper, significant stressors, stress-strain relationships and moderating factors including satisfiers and coping styles were discussed. Psychological/behavioural strains were more prevalent than physical strains. Gender differences in coping strategies were evident in the data from Haiti but not in the sample from Bosnia-Herzegovina. The main satisfiers or motivating factors in peacekeeping commitments that may act to moderate the effects of stressors were humanitarianism, professionalism, personal development, social interactions and the novelty of the deployment. The model in the second paper incorporated stressor, intervention, moderator and outcome components at the individual, group and organizational levels. Data collection from the model is at an early stage.

Paper #60 was to have discussed the merits for and against having aeromedevac personnel as air crew versus having them as passengers. However, the authors were not able to give the paper.

Radova (#61) described the motivations of the three categories of Czech volunteer units that entered NATO-led IFOR and Stabilization Force (SFOR) services as follows:

- Foreign mission veterans joined primarily to enhance their professional skills and gain new experiences; joining for the financial aspects, though important, was a secondary reason.
- Active-duty Czech Army soldiers serving for the first time in a peacekeeping mission joined for financial reasons, but career enhancement and personal satisfaction also played a part.
- After-duty volunteers (from previous Czech Army services) joined primarily for financial reasons.

6. CONCLUSIONS

There is every reason to believe that Contingency Operations will become even more prevalent in the post 'Post-Cold-War' era than they have in the past. In fact, they will likely form the major focus of future NATO operations as General John de Chastelain indicated in his Keynote Address.

From a medical standpoint, the major impediments to an effective health care strategy in Contingency Operations may include any of the following logistic, support and environmental factors which may be interdependent in many instances:

- Hostile environment
- Harsh climate
- Deployment of health care facilities and supplies to forward areas
- Movement of seriously ill patients out of forward areas
- Lengthy evacuation and supply lines
- Poor host nation infrastructures
- Interoperability problems with non-NATO allies, and non-government organizations and consultants
- Maintenance of low casualties
- Impaired hygienic conditions
- Infectious disease management, both indigenous and introduced
- Battlefield and MOOTW trauma management
- Stress disorder management, both acute and chronic
- Sleep-loss and fatigue management to unnatural work conditions
- Indigenous population interactions
- Familiarization and adaptability to new technologies
- Accommodation to an inquiring and omnipresent media
- Decreased defence budgets
- Reduced medical personnel

These factors were addressed in this Symposium in terms of their impact on the following four broad areas:

- Sustained and Continuous Operations
- Medical Management in Remote Locations
- Medical Information

- Adaptation to Operational Conditions

6.1 Sustained and Continuous Operations

Key points noted regarding this topic included the following:

- Extended air operations involving multiple time zone changes, irregular work schedules, and stresses to workload will become the norm for air crew in Contingency Operations.
- Sleep loss and fatigue during extended operations affect performance. The judicious use of quick-acting pharmacological measures without having significant side effects, possibly combined with crew rest strategies such as strategic naps will be required to maintain sustained alertness. For some operations, such as intensive, night air operations, non-pharmacological measures are not practical.
- Modafinil and melatonin continue to demonstrate promising sleep management properties for maintaining air crew effectiveness during extended operations. The properties of these and other promising drugs used as sleep management tools should continue to be assessed and not used indiscriminately until more is known. In particular, the "overconfidence" phenomenon associated with modafinil should be investigated further as this may have an affect on cognitive decision making. Similarly, how melatonin works on the brain in terms of circadian rhythm adjustments and sleep induction, and the associative side effects on the immune and hormonal systems need to be established more thoroughly before this becomes an accepted method of prophylaxis.
- Early results suggest that the hypnotic drug, zolpidem may be a good sleep management tool having no deleterious side effects.
- The extent of, and recovery from, fatigue and sleeplessness varies from individual to individual. To optimize workload performance without compromising operational efficiency, strategies should be developed to identify individuals and effective crew formations to handle different flight regimes in extended operations.

6.2 Medical Management in Remote Locations

Key points noted on this topic included the following:

- Effective aeromedical support in Contingency Operations is dictated largely by a sound operational medical doctrine in regard to patient treatment and evacuation. Furthermore, providing extensive operational planning, being flexible, effectively using advanced technologies, especially, communications technology, as well as implementing lessons acquired from previous operational experiences are essential.
- Political realities and operational constraints in most countries dictate a smaller, but more versatile medical presence in the forward battlefield area. Rather than waiting for patients to stabilize, critically ill or injured patients will be evacuated aeromedically to out-of-area definitive care centers. Far forward resuscitative surgery will become a vital part of this new essential-care-only doctrine for in-theatre medical operations.
- To accommodate the increased need for evacuation requires highly trained critical and surgical care workers to move quickly, bringing modular and man-portable medical equipment and shelters to set up wherever needed; e.g., en route, in the forward area, etc.
- The provision of good critical care medicine en route or in far-forward areas increasingly depends on novel advances in technological devices and solutions. This includes point-of-care laboratory and clinical devices for bedside blood composition analysis and precision substance infusion; stretcher-based transport systems which incorporate vital signs monitoring and trauma management capabilities; effective transportable mechanical ventilators; and diagnostic portable imaging equipment.
- Severe trauma management in the field is contingent on having the necessary tools, experience and teamwork to act quickly and

decisively. This requires that procedures, equipment and team competency be extensively validated beforehand by way of animal studies or other simulations of trauma management in contingency conditions.

- Promising developments in blood substitutes, lung protection strategies and field resuscitative surgery will greatly facilitate trauma resuscitation management in Contingency Operations.
- NATO troops exposed to unusual infectious diseases for which they have negligible natural immunity are at a particular risk in acquiring lethal infections. The response of the World Health Organization to include the military in its worldwide surveillance program is an important step in controlling and containing these disease pathogens.
- Immunization programs based on the estimated incidence rate of various vaccine-preventable diseases in the area of conflict or disaster might be a more cost-effective approach to assuring immunization in deployed troops than one based on the severity of symptomatic infection in the region.
- The apparent lack, in many instances, of troop compliance with infectious-disease preventive measures during troop deployment is a concern. New disciplinary strategies and behavioural change programs need to be developed, validated and promoted to assure implementation. In this regard, a strong proactive medical leadership is essential.
- The rapid diagnosis and characterization of potentially highly lethal and communicable diseases for which there are no effective countermeasures is essential. The concept of an air-transportable diagnostic laboratory and pathogen containment facility in combination with a rapid response aeromedical team as developed by the US Army Medical Research Institute of Infectious Diseases to isolate the patient and conduct basic clinical research, is a viable method of minimizing the risk of disease transmission during air evacuation.

6.3 Medical Information

Key points noted on this topic included the following:

- Shared medical data among decision makers for the purpose of patient care must be a seamless operation applicable to all levels of command. This includes making use of command and control assets such as **TRAC^{2}ES**, telemedical advances, portable imaging devices, Smart Cards, portable computers and Internet computerized resources to achieve this objective.
- The facilitation of a global military and civilian telemedical service that is financially self-sustaining requires a step-by-step approach by building up an organizational infrastructure to ensure standard operating and medical procedures, standardization and maintenance of workable equipment, and proper training.
- Digital data compression and transmission techniques, portable video cameras and imaging devices, and powerful personal computers - much of it using COTS equipment - are beginning to enhance deployment telemedicine as a viable and cost-effective means of patient care in remote locations.
- Advanced man-portable, diagnostic imaging systems employing ultrasound, x-rays and other modalities at remote locations are key components to an effective telemedical strategy. They allow immediate visualization of trauma injury which enable good specialist interpretation by major medical centers.

6.4 Adaptations to Operational Conditions

Key points noted on this topic included the following:

- Aeromedical personnel will be part of all future Contingency Operations. They must be involved in all phases of operational planning. They will be required to adapt to unfamiliar surroundings, and, with the aid of computerized resources, assimilate and act on complex data quickly. Above all, they must provide flexible health care leadership in all stressful situations.

- The psychiatric effects of combat and other traumatic events may be permanent if coping strategies are not implemented at the appropriate time. Troops must be briefed before action takes place, and stress-related care given to symptomatic individuals during and, possibly, long after operations have ceased.
- There is evidence that psychosocial stressors are more prevalent than physical stressors in peacekeeping operations. Medical support and combat units should be selected that have a high capacity for coping with such stressors when participating in these and analogous types of missions. Some training for coping with stress should be a prerequisite to deployment. Gender differences in coping with stress may require different strategies.

7. RECOMMENDATIONS

7.1 Capturing Lessons Learned from Contingency Operations

Contingency Operations are complex and unique according to many factors such as the nature of the hostilities or actions taken, the place where the actions occur, the type of terrain occupied, the time of year of the operation, whether there is participation with NATO or non-NATO allies or both, and the behaviour of indigenous populations towards the occupying Armed Forces. These and other factors all have an effect on in-theatre medical care, and medical logistics including aeromedical evacuation. They impact on the varied requirements for medical management in remote locations; i.e., on the treatment of battle casualties, on managing endemic and communicable diseases, and on handling acute and chronic stress. These may require innovative, real-time technical solutions, which should be recorded since these experiences may be largely lost or forgotten with the passage of time, once the action is over.

A recurring theme in this Symposium has been the importance of lessons learned from past Contingency Operations. A number of examples may be cited. Dines in her paper on the UNSCOM operation in Iraq referred to the evolving nature of each mission and the challenge of accommodating to these changes. Gibson spoke of the implications of failing to apply lessons learned from previous operations. Jones warned that changes in technology and troop demographics temper dependence on past lessons. Salisbury cited numerous medical lessons learned from IFOR peace support operations.

The new RTO/Human Factors and Medicine (HFM) Panel (combines AMP and DRG Panel 8) has at its disposal a number of options for ensuring that medical lessons learned from past operations are captured, retained and upgraded for future NATO Contingency Operations. As a start, a computerized data entry and recording system must be developed and maintained to register the collective experiences of health and casualty care workers in each NATO Contingency Operation. A Workshop comprised of health and casualty care workers, field experienced in NATO Contingency Operations, should be held by the new RTO/HFM Panel to identify key collaborators, discuss the issues, identify the areas, and define the relevant parameters for pooling post-operational information into a comprehensive data base. This could form the basis of a subsequent Working Group that would develop the knowledge base and provide analyses of lessons learned for consideration for future operations. Most of the speakers and participants at this Symposium could contribute to such a Working Group. For example, the valuable efforts of D'Amelio and Heymann in developing a computerized network for the surveillance of infectious diseases could be one component of such a data base.

The information obtained from the Working Group could be distributed to the NATO countries and their allies, at timely intervals, by briefing the Committee of the Chiefs of Military Medical Services in NATO (COMEDS); and by making presentations at the annual NATO Flight Surgeons Course at Ramstein AFB, GE, at the Aerospace Medical Association Meetings in North America, and at other fora where such instructional

knowledge and experiences would facilitate international cooperation and promote health and casualty care. Essential lessons learned from this cooperative effort should be published in the appropriate open literature for the benefit of others. Also, training centers and industrial concerns in each country would benefit from this material. This information should be available to field medical units telemedically via the Internet. Such information could be disseminated to United Nations agencies such as the World Health Organization, and others such as Médecins Sans Frontieres that may wish to share the knowledge obtained to provide effective solutions for contingency commitments.

A Knowledge Watch could be instituted following termination of the Working Group to continue collecting international experiences from evolving NATO Contingency Operations in order to maintain and enhance a workable data base for future dissemination of this critical information. This Watch could consider not only new developments in technology as they relate to health and casualty care, but also the experiences gained in medical support issues. The challenge is there for the new RTO/HFM Panel to exploit!

7.2 Limitations on the Use of Technology in Contingency Operations

Finally, a few words should be said about placing too much reliance on technology for enhancing Contingency Operations. Much hope is being placed on new advancements in technologies to address deficiencies in manpower and the requirement of rapid response and mobility in NATO Contingency Operations. Without a doubt, new developments in materials, sensors, displays, information processing, communications, and biotechnology will significantly enhance disaster medicine and alter the way in which it is conducted. However, the question arises as to what happens when equipment, systems and concepts based on these elaborate technologies break down, are sabotaged, or are rendered useless from missile attacks? Will back-up spare parts be available for each critical item of equipment if there is a permanent malfunction? Will 'high-tech' solutions be promoted when 'low-tech' solutions are sufficient? Will power sources to operate equipment be readily available, sufficient, portable and compatible? Will COTS medical equipment be enduring and compatible with the military systems with which it must interface? Will military physicians be required to become systems engineers to conduct their operations? One is reminded of these issues after having heard the excellent contributions to this Symposium by Farmer, Lawlor, Pearce and their respective colleagues. Overriding all of this is the confusion and associated uncertainty - the 'fog of war' - which is an inevitable consequence of any military operation. Technology must be tailored to reduce chaos and ambiguity, it cannot further contribute to uncertainty! These examples illustrate some concerns that occur when too much reliance is placed on technology (or the wrong kind of technology) and not enough effort is placed on basic and long-standing critical care. Military physicians and surgeons must be flexible and innovative, but should never be placed in the position that technology dictates the primary mode of diagnosis and treatment. At best, technology should be used in an adjunctive manner.

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CONTINGENCY OPERATIONS: THE CHALLENGE OF THE POST 'POST-COLD-WAR' ERA

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1. SUMMARY

The Post 'Post-Cold-War' era is characterized by the enlargement of NATO and its co-operation with non-aligned countries in preparing for contingency operations aimed at maintaining peace and security in Europe and elsewhere. The period is likely to see a continuation of a series of national crises -- the legacy of the end of the Cold War -- as well as other natural or man-made emergencies calling for international intervention. Today the main challenge for NATO in preparing for contingency operations lies in the willingness of member and non-member states to maintain military forces trained to the professional levels required for war. Other and important challenges include: the need for specialised training to enable forces to respond to a wide range of roles short of war; a rapid-reaction capability that takes account of standardised procedures and effective logistic, administrative and medical-support requirements; and an understanding of the need to inter-act effectively with civilian and other Non Government Organisations (NGO), including the media. While the United Nations (UN), the Organisation for Security and Co-operation in Europe (OSCE) and the Western European Union (WEU) continue to be involved in contingency operations in Europe and elsewhere, the conduct of military or military-supported operations is not their principal *raison-d'être*. For NATO, it is While the threat of global or continental conflict has receded, the incidence of disasters or security-threatening crises continues. NATO is uniquely placed to respond to such contingencies and today it is addressing the challenges involved in doing so.

2. INTRODUCTION

I am grateful to the Aerospace Medical Panel (AMP) and to the Canadian Defence Civil Institute for Environmental Medicine (DCIEM) for inviting me to address this symposium and for giving me the chance to return to a NATO Forum after an absence of two years. It goes without saying I believe your topic is timely.

The title of this symposium -- "Aeromedical Support Issues in Contingency Operations" – places the context and emphasis of your discussion on medical activities, and it is true that medical support is an important factor in all categories of contingency operations, even when other resources may not be needed. That noted, I shall talk about the main challenges I believe face NATO today in its preparation for contingency operations, and while I shall say something about aeromedical issues – both because that is your interest and because Canada plays a major role in this area – my intention is to provide a general background for the detailed discussions of the next few days.

3. BACKGROUND

The Cold War began in the aftermath of Word War II, and involved the confrontation of military forces in an undeclared conflict with the potential to destroy the world. NATO's strategy to avoid such an outcome was deterrence, underpinned by tactical and strategic nuclear capabilities. It ensured a level of peace in Europe and elsewhere, but at the cost of large defence budgets and the world-wide effect of power bloc influence. Despite various crises and many undoubted hardships, the Cold

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War ended after forty years without a resort to global conflict.

The 'Post-Cold-War' period began with the 1990s. It involved the cautious dismantling of nearly half a century of military confrontation and the development of a security system in Europe based on trust and co-operation. It involved the promulgation of arms-reductions treaties and the implementation of troop withdrawals and force-level reductions. It witnessed the development of co-operation and consultation between NATO and non-NATO military forces through the Partnership for Peace (PfP), and their integration in training and in operations. It also witnessed an increase in tension and conflict in areas both within Europe and outside, brought about by the loosening of restraints previously imposed by Cold War powers, the break-up of the Soviet Union, increasing nationalism and economic migration.

In Madrid this summer, NATO opened the way to increase its membership through the entry of Poland, Hungary and the Czech Republic, with the possibility of more new members to follow. That decision heralded the beginning of a new period: the Post 'Post-Cold-War' era. That is where we are now. It is in the context of the challenges that NATO enlargement brings, and the complex nature of a range of future possible contingency operations that might involve NATO and its partners, that I make this address.

4. CONTINGENCY OPERATIONS

One definition of Contingency Planning is: "A process which takes account of contingencies by preparing likely courses of action to deal with a range of potential incidents or situations in specific geographic areas"[1]. The key words are "preparing likely courses of action", "potential incidents" and "specific areas". As to their nature, likelihood and location, contingency operations are ones we can predict only in general terms, but they are ones for which plans can and should be made.

Your Symposium brochure notes: "Contingency Operations constitute a diverse array of operations ranging from peacekeeping ... to humanitarian aid ... to peacemaking/enforcement ... to full scale offensive operations". The brochure makes the point that natural disasters and terrorist action also constitute Contingency Operations, whereas war does not.

Whether war is a contingency operation or not, the NATO General Defence Plan at the outset included a series of "contingency plans" designed, in the first instance to deter and prepare for war, and ultimately, if necessary, to fight it. The challenge NATO faced in making those plans work was formidable. It involved welding different nations into a political and military body capable of responding to a wide variety of land, sea and air operational contingencies across the huge geographic spectrum of Western Europe and the North Atlantic. It involved the need to standardise, to the degree possible, the organisation, training, equipping, funding and deployment of the military forces of these nations; the development of Standard Operating Procedures, communications procedures, nomenclature and doctrine; and the setting up of command structures and organisations capable of conducting operations effectively in spite of the numerous different languages of its members. The same challenges, and new ones, face NATO today given its expanded structure and additional roles.

The Post-Cold War period created different challenges. Cut-backs in defence funding, the reduction and withdrawal of stationed-troops, the search for peace-dividends, and the changing of national priorities, all coincided with the need to open avenues of co-operation with non-NATO countries and involvement in so-called "out of area operations". A feature of this co-operation

included the adoption of NATO procedures and doctrine by countries seeking partnership in the Alliance, as well as by those seeking only a closer co-operative stance. Its value was, and continues to be, demonstrated progressively in PfP exercises and in operations conducted by NATO.

Maintaining joint standards requires attention and practice and remains a challenge. There are others. With the likelihood of global or continental war receding, with reduced budgets for defence and international aid, and with a growing imperative for many individual countries to address national rather than international issues, the willingness and ability to respond to new operations becomes a question. Which is why it is in NATO's best interest to promote the involvement of others. Participation of non-NATO nations in NATO-led contingency operations lessens the load for those countries that do become involved. It brings the benefit of wider international involvement in problem-solving and it increases the sharing of costs. It offers the potential for special understanding of regional differences and the appropriate resources to handle those differences. Above all it coalesces the interests of a greater number of nations in the benefits of practical and effective collective security.

NATO is now but one of a number of organisations taking a leading role in contingency operations. The United Nations, the principal sponsor of peacekeeping and humanitarian missions during the Cold War era, has since been joined by the OSCE, the WEU and individual nations, in dealing with new international crises in the European area of influence.

The United States' proxy leadership of the UN-sanctioned multi-national operations in the Gulf and in Somalia demonstrates another dimension[2]. Leaving aside the very real and almost unique capability the United States maintains in global transport resources and Large-scale logistic capacity, one benefit of having the United States lead these two particular operations was its familiarity with standardised NATO procedures and its ability to incorporate those procedures effectively in planning and conducting operations in which Many non-NATO nations were involved.

It is certain the United Nations and other organisations will continue to conduct contingency operations worldwide. But it might be observed that for these organisations contingency operations are not the principle reason for being, whereas the military aim of NATO is to maintain peace and security in Europe and elsewhere through its ability to react to security-threatening contingencies, wherever and whenever that is necessary. For NATO an important challenge lies in not diluting its ability to maintain its historic role to deter and defend against an attack on Western, and now Central Europe, as it takes on missions involving crisis-management and peacekeeping. As one observer recently noted:

> *"Sustaining this new approach will require an unambiguous understanding of both tasks, an appreciation of their complementarity and their differences, and a clear enunciation of what the "new NATO" stands for. Communicating the emerging duality of NATO's role, particularly to new members, will be one of the pressing tasks awaiting NATO leaders"*[3].

The NATO Implementation Force (IFOR) and the NATO Stabilisation Force (SFOR) have recently demonstrated NATO's capability to conduct the new role. The challenge will be to maintain that effectiveness, and to improve it, in this new Post 'Post Cold-War' era.

5. THE PRINCIPAL CHALLENGE

It might be said that the necessary ingredients for the successful conduct of contingency operations include the ability to respond swiftly, with self-sufficient resources appropriate to the contingency and the location, adequately equipped, trained, organised and controlled, and with the flexibility to respond effectively to the unforeseen.

Swift response entails planning, reaction forces-in-being, readily-available transport, and rapidly-transportable support-capabilities. Self-sufficiency requires the same capabilities but stretches to include the whole range of logistic, administrative and medical competence. Adequate equipping, training, organisation and control, also calls for forces-in-being, with established standardised procedures, practised Command-Control and Communications capability (C3), rehearsed options, Civil Military Co-operation activities (CIMIC), and the ability to interface effectively with NGO and the media.

At the risk of special-pleading, and with the understanding that there are some contingency operations that call for a specific or limited reaction not requiring military participation, I would say that military organisations are the ones most capable of fulfilling the majority of requirements I have mentioned. I shall return to the vital role that NGO and the media play in many, if not most, contingency operations today; but the premise of my address, and the NATO context of this symposium, assumes the primacy of military organisations and capabilities in this area.

I would go further and say that military forces trained, organised, manned, and equipped for war, provide the most effective and capable response to the demands of today's contingency operations; which raises the challenge I consider to be perhaps the most daunting in meeting that requirement in this Post 'Post-Cold-War' era: that is, the maintenance of forces prepared to the professional standards required to fight.

I am no longer a soldier, but it remains my conviction that troops trained for war make the best peacekeepers, and constitute the military resources most suited for contingency operations. I believe that is true across the spectrum of each of the combat, combat-support and combat-service-support capabilities, and that the experience of the past fifty years has shown that to be so. Professional troops, or troops trained to a professional level in the conscript or reserve forces of nations that have contributed to peace-keeping operations regularly, have shown their superior ability to react to the broad range of requirements called for by such operations.

That is certainly not to say that additional and specialised training for peacekeeping is not a requirement, and I will say more on that. My point is that those who train for the worst eventuality are prepared to meet it when it arrives unexpectedly, and those who don't aren't.

One of the by-products of the 'Post-Cold-War' era, and it is the same today, was an understandable turning away from the expense and the commitment of resources required in deterring the outbreak of a Third World War. I have referred to the eager search for peace-dividends through reductions in defence-spending that characterized the activities of many NATO nations during this decade. That search was inevitable, understandable and right. But so is the caution of nations in not dismantling, wholesale, the very resources needed to provide their own security, and that of their allies, in this far-from-unthreatening new era. The guarding of sovereignty, and the protection of its citizens, remain the foremost obligations of all democratic governments. And few nations if any can afford to maintain one set of troops trained and equipped for war and another trained and equipped for what some see as the less demanding tasks of peacekeeping.

My own and other nations have, sensibly in my opinion, made readiness for war the principle *raison-d'être* of

their armed forces, while accepting that their most likely roles in the future will be in peace-keeping and other contingency operations. Nonetheless, the willingness of nations to maintain such capabilities, and to fund them to the degree they can meet the requirement, remains to my mind a continuing and serious challenge to the effective conduct of contingency operations.

6. OTHER CHALLENGES

Other important challenges include those issues I referred to as the ingredients of the successful conduct of contingency operations. All are fundamental, but some are worth underlining, not just to identify them, but to indicate what NATO and its partners are doing to address them.

7. TRAINING

Having said that training for war is the best training for peacekeeping and for other contingency operations, I accept that specialised training for those operations is also a necessity. Just as specific training is required for professionally-trained troops undertaking specialised war-time roles, and just as battle-hardening training is required for professionally-trained troops being committed to combat, so specialised and refresher training is required for contingency operations.

Countries regularly involved in the conventional peacekeeping operations of the fifties, sixties and seventies, set up specialised courses to instruct and refresh their troops in the peculiar requirements of peacekeeping, as well as in the socio-political situation in the operation's host-nation. Countries like Denmark, Norway and Sweden have long run such courses, as have, more recently, countries of Central and Eastern Europe.[4] Canada has long conducted work-up training at the home station of units tasked for individual operations. Some years ago Ottawa formalised individual training for Canadian and international officers and civilians at the Lester B. Pearson Canadian International Peacekeeping Training Centre in Cornwallis, Nova Scotia, and more recently for Canadian military personnel at the Canadian Peacekeeping Support Training Centre in Kingston, Ontario.[5]

The United States, whose super-power status during the Cold War made it largely ineligible to participate in peacekeeping operations other than at the individual officer level, has also identified the need for specialised training for such operations now they are routinely engaged in them. A review into Peacekeeping and Peace-Enforcement Policy conducted by the Inspector General of the United States Department of Defence in September 1994 concluded that:

> *"...well-trained, disciplined forces are a fundamental requisite for conducting successful peace operations. However, those qualities alone are insufficient to ensure adequate preparation for such operations. We found that individuals of all Military Services assigned to military observer duty, units deploying on peacekeeping or peace enforcement missions, and commanders and staffs at all levels, need some degree of additional preparation due to the different challenges peace operations present".*[6]

To ensure a standard of appropriate levels of specialised training, the NATO Partnership Coordination Cell (PCC) at Mons is establishing a database of units from NATO and other countries with the proven ability to work together, and has developed plans to conduct fourteen or fifteen PfP exercises each year, a schedule stretching nearly to the end of the century. This action will go a long way to meeting NATO's requirement to train to a common standard for contingency operations and then to assess that standard.[7] Funding the exercises will remain

a challenge.

8. RAPID REACTION

Rapid Reaction is a challenge increasingly solved by the willingness of individual nations to earmark and maintain the readiness of units for contingency operations within both the UN and in NATO. In the UN dozens of member states have committed large numbers of troops to UN standby forces.[8] Some NATO nations maintain standby units for UN operations and are prepared to see these used in support of NATO contingency operations as well. Others have committed units and capabilities to integral NATO Reaction Forces held at readiness for Chapter V operations, and have agreed to their use in non-Chapter V contingencies. And many NATO and PfP nations maintain units and organizations at high readiness for domestic contingencies, particularly humanitarian and disaster-relief emergencies, and many will make these available for NATO operations also.

For NATO the crucial requirement to provide effective C3 capability in the early stage of an operation is eased by the number and variety of operational headquarters kept in being and trained regularly as part of NATO's main operational roles. The swift degree of deployment and readiness of the IFOR and SFOR was due in large part to the fact they were commanded by headquarters-in-being, reinforced to meet representational multi-national requirements.

The challenge for NATO in Rapid Reaction has largely been met. What remains is to maintain the efficiency and readiness of existing tasked headquarters and units through frequent evaluation and practice.

9. MEDICAL SUPPORT

As I mentioned at the beginning, medical support plays an essential role in all contingency operations, if not always to look after victims of the circumstance, then certainly to provide care to those executing the mission. I am reluctant to say much about medical issues here, for fear of covering materiel you will receive in your many presentations over the next few days – or, worse, for fear of later having my statements contradicted by experts. But certain general challenges bear mentioning, and I want to say something about Aeromedical evacuation since this is an area where my country has developed considerable expertise.

The very nature of contingency operations calls for the likelihood of missions in locations far from those of the sending nations, areas that may have challenging factors of acclimatization, lack of infrastructure, or indigenous populations suffering from hunger, thirst, disease, trauma or disability. The involvement of medical support from nations with varying levels of capability, as well as of Government Organisations and NGO with different but overlapping mandates, provides the potential for duplication of effort as well as uneven levels of care to patients transferred from one organisation to another. The answer to these challenges lies in liaison, in co-operation, in standardisation where that is practicable, and in training.

The factor of distance has placed a premium on the requirement for aeromedical evacuation (AME) and NATO has responded by developing over the past two years a NATO AME Concept which has been approved and placed in the NATO planning cycle for implementation in 1998. Medical staffs of Canada's Air Command have been active participants in the development of this Concept, their extensive expertise in AME the consequence of domestic imperatives and a nation whose geography has made medical evacuation by air a standard procedure. Their involvement in the NATO project also drew on lengthy experience in Operation Airbridge in Yugoslavia, as well as lessons learned from aeromedevac experience in Exercise

Co-operative Challenge in Hungary last year.

Canada's Surgeon General, herself an experienced pilot and flight surgeon, has suggested to NATO the formation of strategic and tactical aeromedevac teams, for which Canada has offered to provide trained personnel as Liaison Officers or members of Casualty Staging Units and Transit Evacuation Facilities. At the same time, courses in AME conducted by Canada's Air Command have attracted great interest from outside, particularly from those countries which have no established AME training programs but which seek nonetheless to gain information about this increasingly essential function.

I will close on this topic by saying I believe the main medical support challenges presented by contingency operations today are well understood and are being addressed. New technology is being applied across a number of areas connected to medical support and new procedures are being developed to handle old problems more expeditiously and effectively. Surrounded as I am today by so many experts on this subject, I will say no more about it.

10. LOGISTICS

The complete range of logistic challenges posed by international military operations is huge and largely beyond the capability of the armed forces of most nations to address alone. But two areas continue to show great promise in reducing costs, improving efficiency, and relieving military organisations of the need and expense of maintaining specialised logistic capabilities and infrastructure. These are contracting-out functions to civilian agencies and the application of up-to-date information-handling technology.

The system of contracting-out capabilities such as air and sea transportation, housing, and the provision of rations and other supplies, has been employed for a number of years by the United Nations. Even the United States, with the most logistically-capable armed forces in the world, used such a system in 1995 during the deployment of its troops to Haiti for Operation Uphold Democracy. At that time a civilian contractor initially supplemented, and then took over, the entire logistics operations for all American military units in Haiti.[9]

Many countries have now adopted increasingly sophisticated information management systems to make improvements and create cost and personnel savings in the day-to-day running of their own military organisations. The same methods and systems are being applied to the employment of troops in contingency operations. In Canada, as in other countries, bar-coding, warehouse-automation, and the development of automated Table of Organisation and Equipment programs (TOE), is reducing costs, saving personnel, and cutting back on the size and number of warehouses. At the same time the use of Global Positioning Systems technology (GPS), and the miniaturization of transmitters and computers, has allowed the tracking of materiel-in-transit to be radically improved. Using such systems, not only can the location of containers in transit be instantly confirmed, but so can the contents, with all the operational benefits of swift re-routing that that entails.

The continued development and enhancement of such forward-looking systems and their routine incorporation into contingency operations, will greatly overcome many of the major logistic challenges that continue to surround those operations today.

11. RULES OF ENGAGEMENT (ROE)

One of the more difficult issues affecting the employment of multi-national forces in operations is the definition of the level of force permitted, the type of weapons that may be carried, and the circumstances in which participants in the operation can react other than

in their own self-defence. Unlike the UN which does not have a standardized use-of-force doctrine or ROE architecture, and must develop one for each individual mission, NATO has developed Rules of Engagement which its members have accepted as the basis on which refinements for operations can be made.[10] Getting agreement on what particular ROE will apply to a specific operation can be time-consuming and delay timely deployment; but many members of NATO have national constraints that affect what ROE they can use, and these must be taken into account. A NATO ROE that permits the use of deadly force to protect mission-essential equipment may be acceptable to some member-nations, but not to those whose own rules allow the use of deadly-force only in the protection of human life.

National constraints aside, NATO's development of standing ROE does provide a starting point and does reduce deployment-delays caused by the need to get full agreement on use-of-force levels. One compromise used in the early stages of developing plans for the IFOR was to establish NATO rules that set a ceiling for the operation, and to permit the use of national ROE that were no more robust than these. This compromise allowed countries with less robust rules to participate, while still meeting their own national requirements. As with most compromises there were drawbacks; commanders with troops from different nations assigned to them for the operation, had to deal with the problem of potentially different levels of reaction-capability in their multinational command. Nonetheless the plan worked.

It is clear there is unlikely to be a solution that will make last-minute adjustments to ROE unavoidable. No two operations are alike and rules will have to be tailored to the circumstances of the day. The challenge remains to keep to a minimum the time necessary to establish ROE, at the same time ensuring that rules which are put in place are as appropriate to the mission, and as acceptable to the nations executing it, as possible.

12. NGO

The relationship between Non Government Organisations and the military has not always been harmonious and remains difficult today (and here I would make an exception in the case of the civilian police forces – arguably not classified as NGO – which work alongside military ones in peace support operations. Traditionally co-operation and communication between the two has been excellent). The problem between NGO and the military may be largely one of perception. On the NGO side, the inherent humanitarian nature of their missions and the egalitarian nature of their organisations, lead them to regard military organisations, whose primary role is not humanitarian, with suspicion. On the military side, that suspicion is often reciprocated, and for opposite reasons. And yet experience has shown that effective co-operation between military organizations and NGO in contingency operations is essential.

The newly appointed International Secretary-General for CARE, Canadian Major-General Guy Tousignant, recently remarked that his experience as Commander of the UN Force in Rwanda made him recognise that military commanders need better training and greater sensitivity in dealing with civilians in humanitarian emergencies.[11] That conclusion is echoed by observers of other contingency operations today, where increasingly military and civilian agencies are working side-by-side. As one notes:

> *"The art of military/NGO liaison and cooperation will need to be developed by all Peace Support Operations personnel to shape a pattern of creative working relationships between PSO forces and NGOs. Effective Cupertino will have a major impact on the success of an operation"*[12]

Amongst NATO and PfP countries the need for better

co-operation with NGO is recognised. Increasingly, conferences and exercises include scenarios that bring the two together and permit a greater understanding of the need of each for the other. But some military commanders still do not acknowledge the importance of incorporating factors of CIMIC activities and relations with NGO in their planning at each of the strategic, operational and tactical levels, and there remains much to be done in convincing them of the requirement to do so. While it is not essential that these different groups end up liking each other, it is important that each understands the role the other plays in what is becoming a more and more frequent and necessary partnership.

13. MEDIA

The media is a part of almost every aspect of life today and an important factor in all national or international conflicts. But dealing effectively with the media remains a challenge, and like CIMIC activities and NGO relations, it is frequently treated as an ancillary, rather than a fundamental, factor in operations. During the conduct of military operations, the need to execute the mission takes priority over everything else, and relationships with the media are frequently accorded low priority by military officers. NATO has recognised the need to change this attitude. At the 1995 SHAPEX, SACEUR felt it important to have the senior NATO and PfP commanders and staffs addressed by the celebrated BBC War Correspondent, Kate Adie, who made clear to them the drawbacks entailed in military officers' reluctance to pay attention to the role the media plays in operations[13]. Elsewhere, courses conducted to prepare troops and leaders for contingency operations, now make media relations a part of their curriculum. The Pearson Peacekeeping Centre notes:

"A challenge for press officers of members of the New Peacekeeping Partnership in the field, is to maintain media interest when things go well. Because of their very nature and their function, the Media tend to act as both an asset and a liability to most peacekeeping operations."[14]

The challenge remains to maximise the asset and minimise the liability.

14. CONCLUSION

The world is not a peaceful place nor is it likely soon to be so. Sadly, evolution and technological development have not eliminated war or the causes of war, and the ability of man to put an end to natural disasters of earth, air, fire and water remains a dream. But the worst exigencies of man's inhumanity to man, and the worst effects of nature's fury, can be mitigated by the harnessing of human and technical resources, and their application to the contingency as swiftly and as appropriately as possible. It is to be hoped that the major wars of this century, and the terrible destruction that nuclear weapons can unleash, have frightened mankind sufficiently to preclude another conflict on the global scale. But conflicts and disasters of a lesser nature abound and they will continue to do so. At best, perhaps, we may hope to halt their expansion, address their cause, and influence their legacy. At worst, our failure to do so can lead to dangers that are greater by far. That is the challenge. But for every challenge there is a solution. We have only to find it.

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[1] Canadian Forces Operations Manual: Contingency Planning (B-GG-005-004/AE-000).

[2] "Peacekeeping by Proxy" is a term described in an article by Alex Morrison, Director of the Lester B. Pearson Canadian International Peacekeeping Training Centre, in the Brown University Journal of World Affairs, 1996

[3] Pellerin, Alain, "NATO Enlargement – Where we Came From and Where it Leaves Us", AURORA PAPERS 29, Canadian Council for International Peace and Security, 30 May 1997, Pp 46-47.

[4] In 1994 the Danish Commander of Allied Forces Baltic Approaches noted that; "The difference [between peace support training and normal combat training] is that in peace support training we teach the soldier new attitudes. We teach them to react differently, often directly contrary to normal combat reactions". Lieutenant General Kjeld G.H. Hillngso, "Peace Support Organization and Training: A Danish Perspective", in "Peace Support Operations and the U.S. Military", ed. Dennis J. Quinn (Washington DC, National Defense University Press, 1994), p.67.

[5] Canada has recently re-iterated its belief that general purpose military training remains the best basis on which to train for peace support operations. But while noting that "It is our demonstrated proficiency in this respect which establishes our military credibility and reputation among warring or belligerent factions and which reduces the risk to our personnel during confrontational situations and periods of increased hostility", Canada has also underscored the need for specialised training for peace support operations. National Defence Headquarters, Ottawa, NDHQ Instruction DCDS 5/96, "Training Requirements for Peace Support Operations", 6 December 1996, p.1.

[6] Brittin, Katherine A, Memorandum for the Deputy Assistant Secretary of Defense, "Specialized Military Training for Peace Operations", DOD IG No. K316, 1 September 1994, p. 1.

[7] Rogers, Marc, "NATO Plan for World Pool of Reaction Units", Jane's Military Exercise and Training Monitor, January-March 1997, p. 16. It is also noteworthy that the Pearson Peacekeeping Centre now writes political, diplomatic and peacekeeping scripts for major NATO as well as Canadian contingency operation exercises, as the need for such scenarios is reinforced by the experience gained in operations like IFOR and SFOR

[8] In his last Annual Report to the Security Council, the UN Secretary-General noted that as of 30 November 1996, 62 Member States had committed 80,000 personnel for standby tasks. Annual Report of the Secretary-General to the Security Council, "Progress Report of the Secretary-General On Standby Arrangements For Peacekeeping", Security Council S/1996/1067, 24 December 1996, p. 1

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[10] National Defence Headquarters, Ottawa, "Use of Force in Canadian Forces Operations", B-GG-005-004/AF-005, 1996-10-01, pp. 4-2 to 4-4.

[11] Tousignant said: "When I came into Rwanda I thought I was the boss. I had an overwhelming desire that none of my soldiers die. This was my military training and I was not going to take orders from anyone. I was going to tell the agencies where to go, when to go, and how to do the job. From that point of view, I was ill-prepared", Knox, Paul, "Retired Canadian General to lead CARE", Interview with Major General Tousignant, *Globe and Mail*, Toronto, August 1997.

[12] A Guide to Peace Support Operations, Ed. John Mackinlay, Thomas J. Watson Jr. Institute for International Studies, Brown University, p. 114

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SUSTAINED AIR OPERATIONS: PROLONGED DUTY OVERNIGHT

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Sustained air operations imply round-the-clock scenarios and, inevitably, prolonged duty overnight. The ability of crews to cope with such work-rest patterns depends to a large extent on obtaining sufficient sleep during critical rest periods. Hypnotics may be essential to ensure sleep as the rest periods themselves are limited in number and duration, and occur at all times of the day and night. However, even if good sleep is attained during all the available rest periods, there may still be much difficulty in sustaining alertness during duty overnight, particularly if the duty periods themselves are prolonged. This paper deals with the use of various potential interventions to sustain alertness during intensive air operations.

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

IRREGULARITY OF WORK AND REST

During the late 1970s the RAF Institute of Aviation Medicine was concerned with the capability of aircrew operating in the interdictor role, and laboratory studies were directed toward defining the issues involved in coping with the inevitable irregularity of rest (Nicholson et al, 1984). Such information was essential to ensure that means could be developed to assist squadrons in maintaining round-the-clock operations in which the high workload would be shared between all aircrew, and in which crews could be deployed in a flexible manner between night and day operations. The work and rest of such projected scenarios were simulated over periods of 9 days, which was the period over which aircrew would have been expected to operate at maximum output.

The simulated 9 day schedule of work and rest involved 24, 6-h periods of work and 12, 6-h periods of rest (Fig.1). The schedule was preceded and followed by 2 days of normal daytime duty and nocturnal rest, and these periods provided control data. It was the primary intention of the study to ensure that sleep deprivation was minimised, and so the schedule provided an average of 8 h rest each 24h - though in unequal parts from the 6h periods of rest. The rest periods were arranged over the 9 days so that the number of night and daytime sleeps were equal and runs of consecutive night or daytime sleeps avoided. The synchronising effect of sleep was also minimised by avoiding, as far as possible, consecutive periods of rest around the usual nocturnal time of sleep.

Over the period of 9 days, rest periods began at each of four times (0300, 0900, 1500 or 2100 h). There were three single work periods of 6 h, six double work periods of 12 h and three triple work periods of 18 h duration. The complete findings of the simulation have been published elsewhere (Nicholson et al 1984), and for the purpose of the present paper the information obtained relevant to prolonged duty overnight is reported.

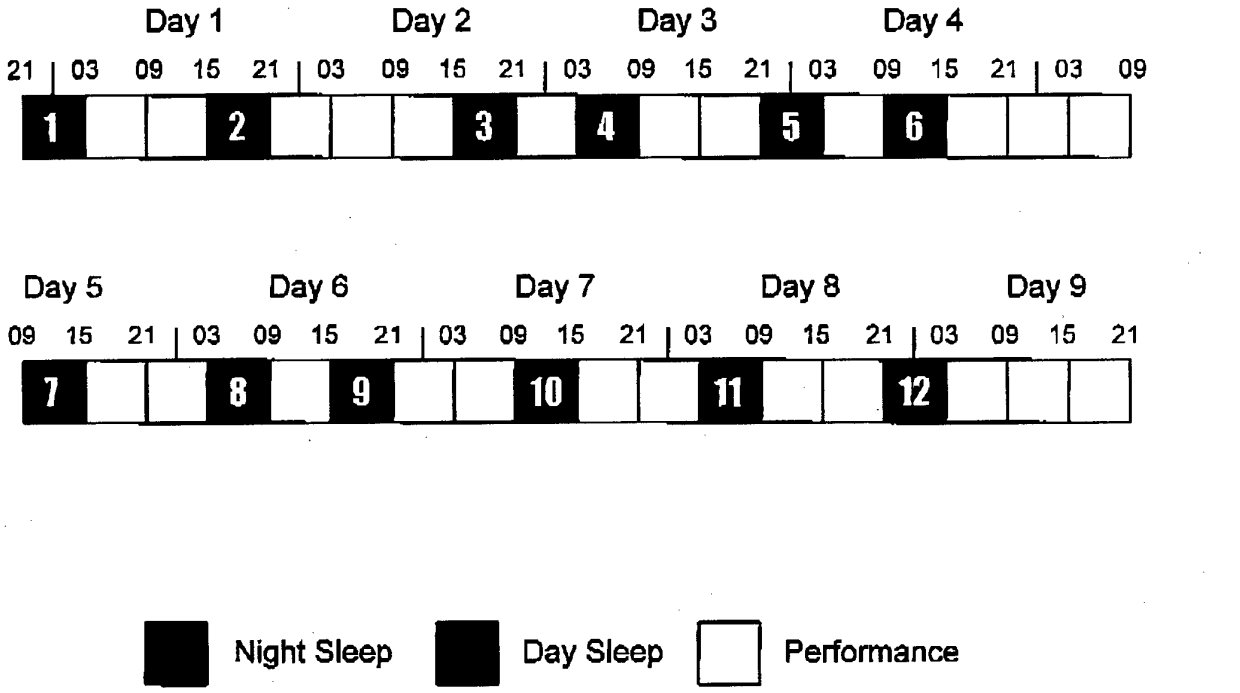


Fig 1. Schedule of work and rest

The quality of sleep during each rest period was measured by electroencephalography. Total sleep times (min) for each rest period are given in Figure 2. In the rest periods before and after the schedule the total sleep time almost accounted for the 6h period, but during the schedule total sleep time varied considerably. Sleep at 2100h and 0300h was always restful, but sleep during the day, ie at 0900h and particularly 1500h, was short unless it followed an interval of significant sleep deprivation. Further analyses were related to the time of day as well as to the preceding pattern of work and rest. These indicated that the greatest difficulty in falling asleep would occur around 2000h, whereas the longest sleep would have been most likely when the sleep began around 0100h. Duration of sleep during the day would be particularly short except when preceded by periods of wakefulness approaching 20 h. The most restful sleep would be obtained when it commenced between 2100h and 0300h and the quality would be improved at any time by a reasonable period of preceding wakefulness.

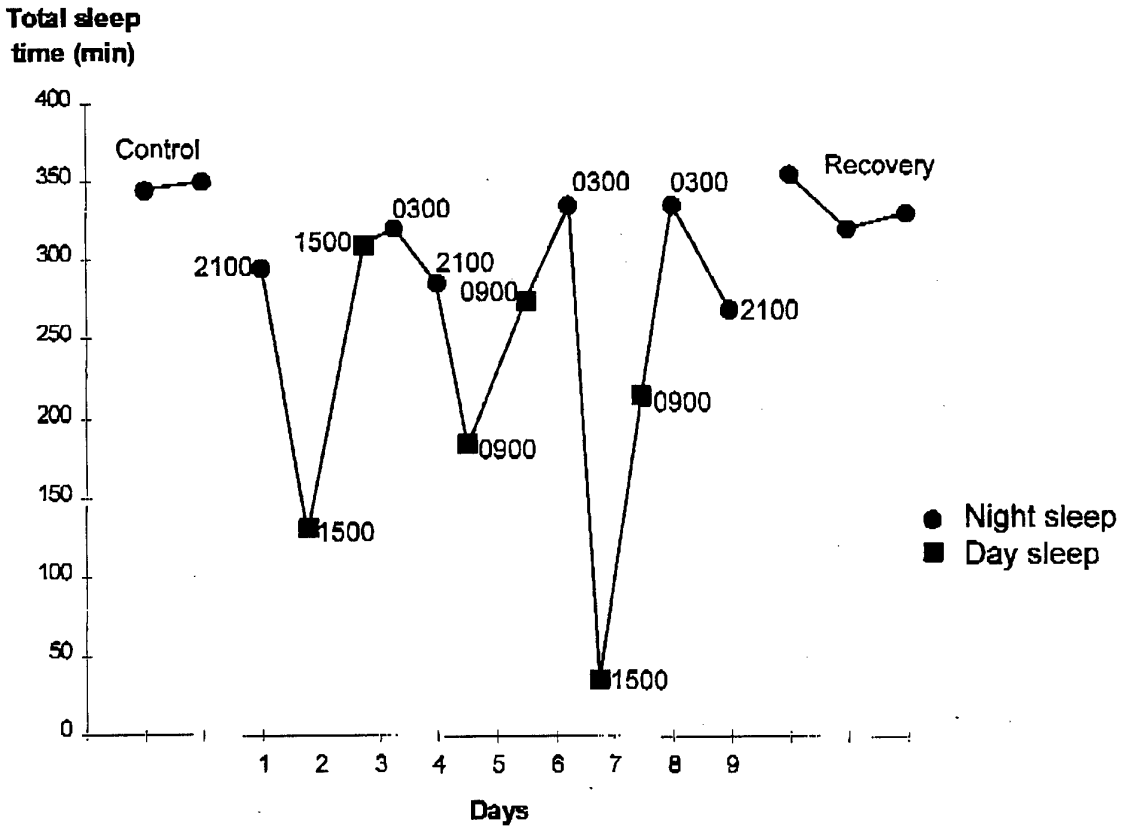


Fig 2. Total sleep time determined electroencephalographically for each rest period

As far as performance during the work periods was concerned, the usual circadian pattern with lowest scores in the early morning, was maintained throughout the schedule. Performance decreased with increasing time awake and for some tasks there was a trend towards impaired performance as the 9 day period proceeded. However, there was evidence of improvement in some tasks over the schedule, though caution must be exercised in the interpretation of this finding. The intensity of testing during the schedule clearly led to continued learning on some tasks, and so the effect of cumulative sleep loss was probably masked. Overall, the analysis established that impaired performance was related to circadian rhythmicity, duration on task, and cumulative sleep loss, and these three factors are fundamental to understanding how performance during duty against a background of irregularity of work and rest can be predicted.

Adaptation of the individual to irregularity of rest and activity was the primary concern of the study. It suggested that during a lengthy period of irregular work and rest the efficiency of individuals is likely to be

increasingly impaired, and that their performance will be influenced by their circadian rhythmicity and by the length of time on task, as well as by any cumulative loss of sleep. Above all, it was clear that, in complex schedules, a significant difficulty in maintaining capability would occur during prolonged periods of work extending to the latter part of the night. It must also be borne in mind that behavioural changes such as impaired interpersonal relations, which are difficult to measure, may be equally, if not more, important than decrements indicated by tests of performance.

The 9-day study confirmed the overriding importance of avoiding cumulative sleep loss and of poor performance during long periods of work overnight to sustaining intensive rates of work. In this context it must be appreciated that in sustaining such operations it is highly unlikely that any significant change to the work-rest patterns themselves will be possible. The schedule is determined by a host of, often immutable, operational constraints. Nevertheless, the study indicated that crews were likely to be able to cope with 12 x 6-h missions over a 9 day period, and that using the longer periods of wakefulness for double missions, 15 missions may be possible. Ensuring sleep is essential and this can be assisted by hypnotics, but overnight duty is the vulnerable component in operations designed to provide sustained capability.

PERFORMANCE OVER 24 HOURS

Our studies on irregularity of work and rest also provided data necessary to quantify the characteristics of periods of work which determine performance.(Minors et al 1986, Spencer, 1987) Several factors were shown to influence performance during a particular duty period; these were : the interval between the end of the previous sleep and the commencement of duty (time since sleep); duration of duty (time on task); and the clock time of duty (time of day). It was evident that the adverse juxtaposition of a long duty period and the timing of duty during the 24 hour period prejudiced the ability to sustain vigilance.

Further analysis of these data showed that as far as "time on task" is concerned, performance rises during the first few hours, falls to its initial value after around 5 hours, and then levels off around 12 to 16 hours after commencement of duty (Fig 3). As far as "time of day" is concerned performance rises during the day and falls during the late evening and overnight reaching its nadir around 0500 h in the morning (Fig 3). Hence, very low levels of performance are reached if the latter part of a prolonged duty period coincides with the circadian trough in performance. For example, if a 16 hour duty period commences around 0200 h it is likely that

performance will be maintained as the fall during the latter half of the work period coincides with the rising phase during the day. On the other hand, if duty commences around 1400 h the drop in performance during the latter part of the duty period would coincide with the circadian fall during the night, and so low levels may be reached (Fig 4).

This knowledge is crucial to the management of aircrew involved in high workload, round-the-clock operations. Assuming sleep loss is avoided it can be assumed that long periods of duty during the day lead to only limited deteriorations in performance, whereas similar periods overnight lead to serious decrements which may be accompanied by microsleeps. Further, it is possible to determine the duration of night and day periods of duty which would equate to the same degree of impairment. It is, therefore, evident that if prolonged duty overnight is essential to maintain a sustained operation, then some means must be developed to avoid the lowest levels of impairment. Various approaches have been studied including sleep prior to duty overnight, naps, during the period of duty itself if feasible , breaks during the duty period, and stimulants.

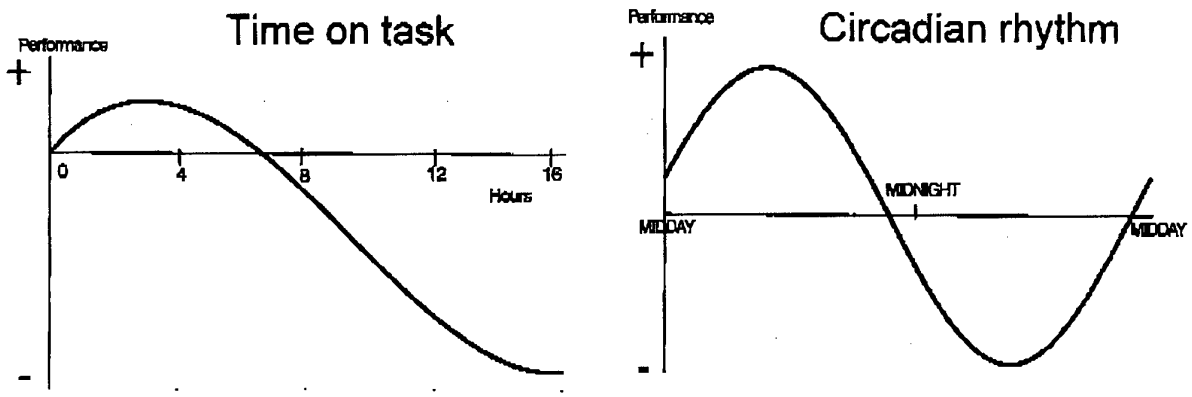


Fig 3. A model of change in performance with time on task (left) and time of day(right).

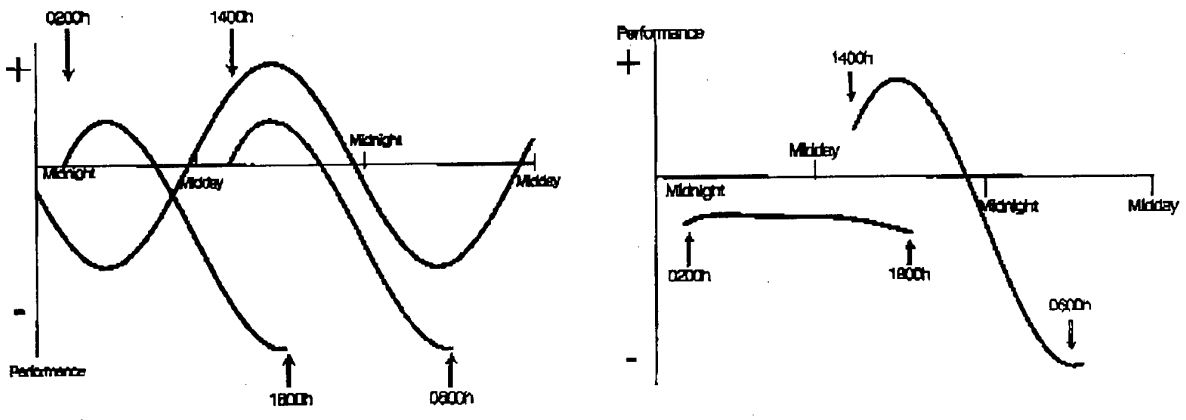


Fig 4. Time on task and time of day related to duty commencing at 0200 and 1400 h (left) and resultant of the time on task and time of day related to duty commencing at 0200 and 1400 h. (right). If a 16 h duty period commenced around 0200 h it is likely that performance would be maintained as the fall in performance during the latter half of the work period would coincide with the rising phase during the day. On the other hand if the duty period commences around 1400 h the fall in performance during the latter part of the dury period would coincide with the lowest level during the night related to the circadian rhythmicity of the individual, and so very low levels of performance may be reached. Such adverse juxtapositions of time on task and time of day should be avoided if crews are expected to remain continuously on their task. For this reason careful attention must be given to the length of duty periods in such operations, and the length should be determined in relation to the time of day. These considerations assume that the aircrew are fully rested at the commencement of their duty.

SLEEPS TO MINIMISE PERFORMANCE DECREMENTS

Short evening sleeps

Prolonged duty overnight is the sine qua non of sustained and intensive air operations, and that such duty periods have very low levels of performance due to the adverse juxtaposition of prolonged duty and the nadir of circadian activity. However, it is possible that an evening sleep period before a period of overnight duty may ameliorate the deterioration to some extent. It is in this context that the possible beneficial effect of an early evening sleep prior to overnight duty was studied (Nicholson et al 1985)

The subjects were six healthy male volunteers aged between 20 and 21 years. In the study subjects completed nine different schedules of work and rest, each separated by a week, though in this account we deal only with those schedules concerned with the effect of an evening sleep on overnight performance. Schedules were of 48 hours duration and began with an overnight sleep from 2300h to 0700h. During the day after the initial overnight sleep performance was measured over three hour periods from 0900h, 1400h, 1900h, and then through the night at 0000h and 0400h, and similarly through the next day. In the schedule with an evening

sleep the period of sleep was from 0800h to 2200h, and so replaced one of the performance periods preceding the overnight period of duty (Fig.5) .

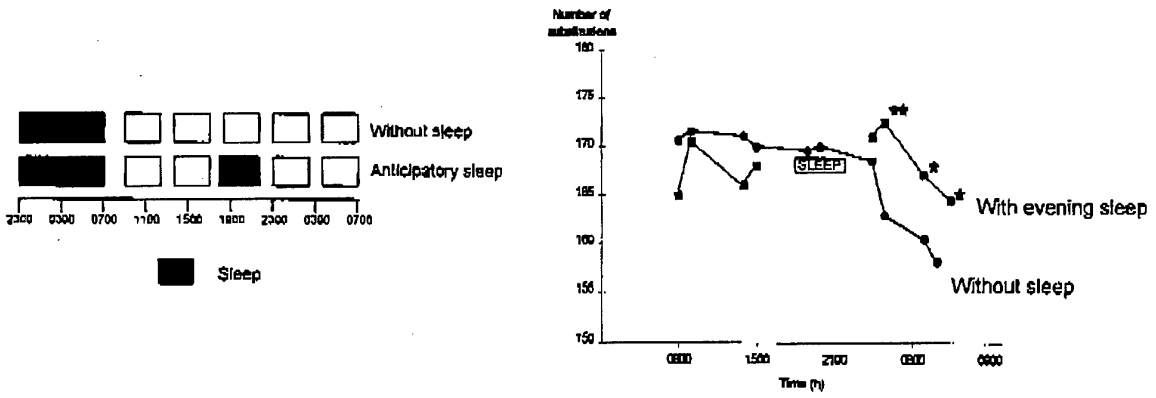


Fig.5 Schedule of work and rest related to anticipatory sleep (left) with performance on Digit Symbol Substitution with and without sleep (right)

Performance overnight (0000 - 0300h and 0400 - 0700h) with early evening sleep (1800 - 2200h) showed improved digit symbol substitution , symbol copying, mental arithmetic and cancellation in all subjects. There was also some evidence that visuo-motor coordination, critical flicker fusion, reaction times, tracking and auditory vigilance were improved. It, therefore, appeared that relatively short periods of sleep had a beneficial effect on subsequent performance even in the absence of a preceding sleep debt, and that sleep in the early evening could attenuate the circadian fall in performance overnight.

Naps during duty

Although impaired efficiency overnight may be ameliorated by an evening sleep of about 4h duration (Nicholson et al 1985), shorter sleeps within the period of duty may be beneficial in certain circumstances. However, any advantage that may be gained from short sleeps depends on several factors, including the length of the preceding period of sleep loss, the duration of the sleep, the phase of the circadian rhythm when the sleep was taken, and the relatively poor ability of individuals to perform soon after awakening, otherwise known as "sleep inertia". The circadian time of performance testing and the nature of the performance tests must also be taken into consideration. It was to establish the effectiveness of a short period of sleep in reducing the

progressive impairment of performance specific to overnight duty that the effect of a 1h nap taken at 0200h was investigated (Rogers et al. 1989).

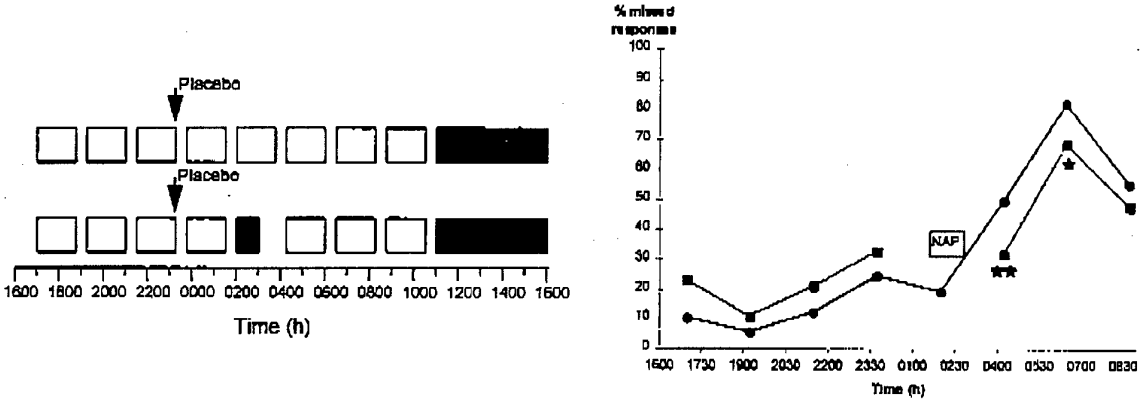


Fig.6 Schedule of work and rest related to naps during a duty period (left) and performance on a visual vigilance task with and without a nap (right).

The subjects were six healthy females, aged between 20 and 32 years (mean 25 years). Each schedule was of 17.5h duration and was preceded by a 4h rest period during which the subjects were awake but restricted to passive activities (reading, watching television etc.). Performance was measured during eight sessions, each lasting 1.75h, which began at 1700h, 1915h, 2130h, 2345h, 0200h, 0415h, 0630h and 0845h, with a 30 min break between sessions when the subjects were supervised to ensure that they remained awake. In the schedule which included a nap the subjects retired to bed at 0200h (Fig 6) . Sleep was measured by electroencephalography. Subjects were awoken 1h after sleep onset, (indicated by latency to the first unbroken 5 min of stage 2), and performance testing was resumed at 0415h.

Overnight, in the absence of the nap, performance on all tasks except short-term memory deteriorated. Sustained attention, digit symbol substitution, auditory and visual vigilance were impaired around midnight compared with the levels attained during the early evening, and the lowest scores appeared around 0630h, though decrements in complex vigilance, two-letter cancellation, and logic, did not appear until 0415h or 0630h. Within-run deteriorations in visual and auditory vigilance were evident around midnight, and were present within 12 min of commencing each task.

The nap was characterised by short latencies to slow wave sleep. As expected, the long period of prior wakefulness influenced the propensity for slow wave sleep in the nap, which occupied around half the sleep time. However, this was insufficient to influence the requirement for slow wave sleep during the recovery sleep, unlike other studies of post nap sleep at night where a 2h nap in the late afternoon reduced slow wave activity from 10% to 5% of the total sleep time. The 1h nap taken at 0200h had only a limited effect on the usual decrements in performance observed overnight. An improvement was discerned on auditory vigilance at 0415h and 0630h and on digit symbol substitution at 0630h, but impairments remained on all other tasks.

Previous studies have shown that a 1h or 2h nap taken around the nadir of the circadian cycle during a single overnight period of work may attenuate the expected decrements in performance, but it would appear that a sleep of much longer duration than 1h, which is unlikely to be practical is needed to have a persistent effect when testing sessions are particularly demanding. There is also the possibility that sleep inertia may have persisted beyond the nap and counteracted any possible improvement in subsequent performance.

Breaks in duty

In some circumstances it may be possible to break up periods of continuous work with short breaks, and this has been studied in work periods of 12 hours (Rogers, 1997). Eight performance sessions which lasted seventy five minutes were separated by 15 minute breaks. Within each session there were six runs of the tracking component of the task studied (Multi-attribute task battery). Performance overnight after an evening sleep, and during the day was measured under two workload conditions. The decrements associated with time on task and with working at night were more severe under conditions of high workload. Tracking performance deteriorated over the six runs within a session , particularly at night when significant decrements occurred by the third run compared with the fifth run during the day. Following a 15 minute break there was a general improvement in tracking performance at the beginning of a session compared with the last run of the previous session, particularly overnight (Fig. 7). As well as stopping work during these breaks, subjects were also able to eat, drink, walk around and interact with others. It is not yet clear what aspect of the break was responsible for the

recuperative effects.

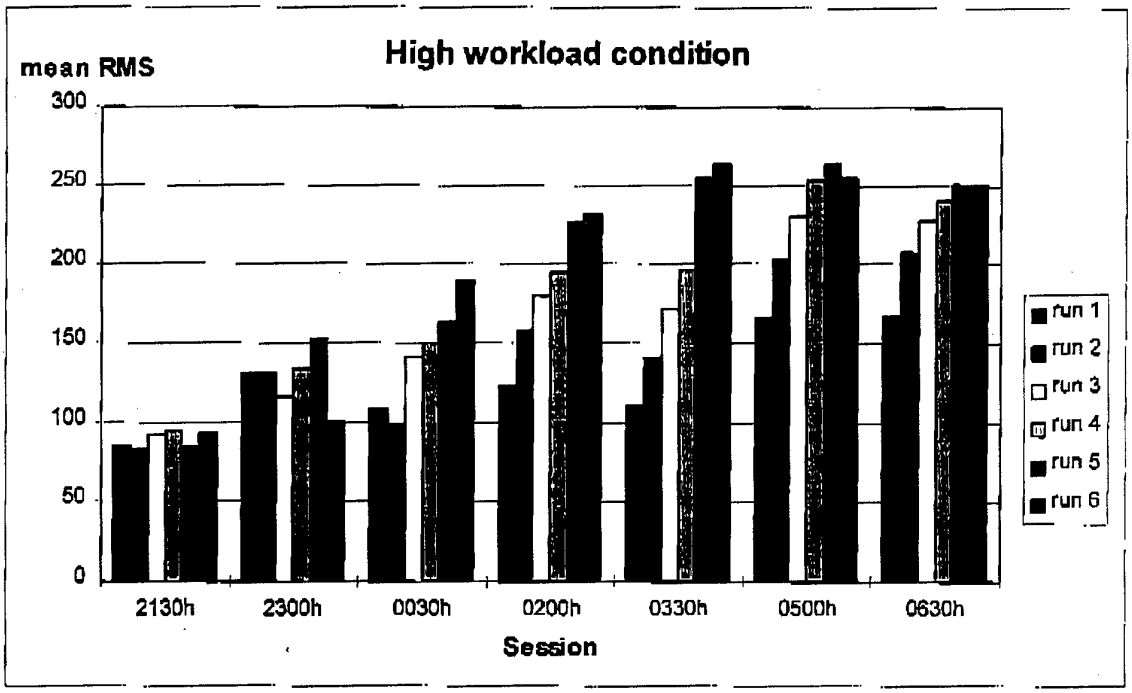


Fig. 7 Mean RMS for the tracking component of the MAT battery during the high workload condition overnight.

These and studies from elsewhere on the use of sleep preceding and a nap during duty show that the deterioration in performance overnight may be ameliorated under certain circumstances, but it must be borne in mind that in the management of intensive and sustained operations such techniques have practical difficulties, and they are unlikely to be appropriate unless they provide an overriding improvement in capability. During a sustained operation each overnight period of work will follow an irregular pattern of work and rest over several days and that good sleep preceding duty is an essential element to avoid cumulative sleep loss. It is unlikely to be possible to provide an extra sleep anticipating a duty period. Indeed, it is considered that impaired performance overnight against a background of intensive rates of work and irregularity of rest is unlikely to be ameliorated by such techniques. It is in this way that we have sought to establish whether stimulants would be more useful.

CONSIDERATIONS OF STIMULANTS

Our approach to this problem has been to identify a stimulant free of adverse effects on affective behaviour (Nicholson & Pascoe 1991, 1992, Nicholson et al 1989). In this context we do not support the use of amphetamines in military operations because of the well known euphoric effect. However, it is difficult to establish from experimental studies which stimulants would be free of such central effects. We have taken the approach that a stimulant free of effects on the noradrenergic and serotonergic systems, i.e. likely to be predominantly dopaminergic, is more likely to be acceptable. In the search for such a drug we have used the fact that noradrenergic and serotonergic drugs directly suppress REM sleep additionally to any decrease in REM activity which may be associated with increased wakefulness during sleep. We have observed that both caffeine and pemoline are free of such activity, and these observations are consistent with the drugs being free of adrenergic and serotinergic activity. It has been to pemoline that we have given most of our attention.

Pemoline is an indirect dopaminergic agent and is relatively free of sympathomimetic activity. It is known to increase alertness and improve performance during the day, and, for sleep deprived subjects, overnight. However, it is envisaged that a drug like pemoline would only be used overnight and, therefore, information is needed on the effects that such a drug would have on performance and alertness of duty periods which commence during the latter part of the day, and which are, indeed, likely to lead to very low levels of performance. There is no doubt that pemoline increases alertness, but there is uncertainty concerning the appropriate dose that should be used in a situation which may well prove to have critical time constraints. It was in this context that we have carried out studies on the effect of pemoline and on its potential use in a simulated overnight operation.

An initial study highlighted the persistent effect of pemoline. Indeed, 30, 60 and 90mg pemoline increased daytime alertness over periods of 8 hours, while 40mg pemoline prevented the deterioration of performance over 8 and 12 hour periods overnight, but also disturbed sleep which commenced up to 12 hours after ingestion. It was, therefore, decided that the studies pertinent to an operational scenario would be carried out with maximum dose of 40mg pemoline.

Two further studies (Turner and Mills, 1996, Nicholson and Turner,1998) have shown that a 20mg dose would be appropriate for maintaining performance overnight without disturbing recovery sleep the next

morning. In a high workload task all measures of performance were improved with 20mg pemoline as soon as performance was impaired when compared to control levels(Fig.).

CONCLUSION

Although modulation of the work-rest pattern can ameliorate impaired performance during prolonged duty overnight, it is unlikely that such an approach would be practical in intensive and sustained operations. It is in this context that stimulants may prove to be the most effective solution under operational conditions.

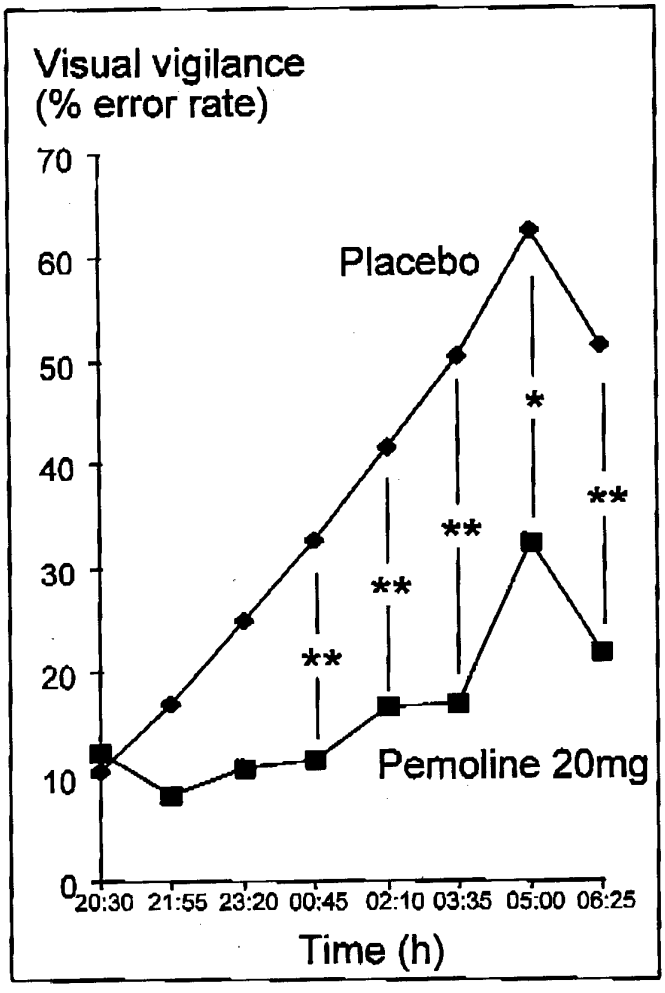


Fig. 8 Performance at a visual vigilance task showing improvements in performance with pemoline.

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AIRCREW PERFORMANCE DURING EXTENDED SIMULATED BOMBER MISSIONS

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SUMMARY

Research was conducted to determine if fatigue impacted the performance of aircrew during long-duration bomber missions. Sustained flight in excess of 36 hours with only a minimal crew aboard was examined in two studies. Sixteen male United States Air Force B-1B bomber aircrew participated in the study. The participants served in crews of four and performed three 36-hour experimental periods (missions) in a high-fidelity B-1B simulator. The missions were interspersed with 36-hour rest breaks. Speech, cognitive, physiological (EEG, temperature), and subjective fatigue data were collected approximately every three hours for 11 trials per mission. A MANOVA analysis revealed a significant effect of trials for the aggregated measures ($F(10,432) = 1.9885$, $p < 0.0001$). This result, along with trend analyses, indicated a strong diurnal pattern in nearly all of the dependent measures. End-mission performance was similar to beginning-mission performance. Crews were able to perform the missions successfully; however, several areas of increased risk due to fatigue were observed. Crew rest strategies prior to, during, and following a mission are discussed. A second study is described which evaluated three long-duration B-2 missions.

1 INTRODUCTION

This paper describes two studies. Each study examined simulated bomber-aircraft missions. The first study utilized a B-1B "Lancer" simulator and was concerned with repeated 36-hour missions. The second study utilized a B-2 "Spirit" simulator and was concerned with single missions of even longer duration. Each of the studies was designed from an operational and scientific perspective. This combined strategy meant that a certain amount of scientific control was relinquished (e.g., specifying naps at particular times, requiring a specific diet) to gain the realism required for a useful training mission.

The B-1 study examined the ability of aircrew to perform three long-duration realistic missions in close succession. Such a scenario could occur at the beginning of a conflict and the operational community wanted to know how it might affect the crews. To this end, particular attention was paid to both the 'low-points' in each of the missions, and the differences (if any) between Missions 1, 2, and 3.

The B-2 study was performed at the invitation of the B-2 test team. The three observed missions ranged in duration from 34.25 hrs to 44.25 hrs. A number of performance metrics were used to assess each crews performance during the simulations. The simulations also served as exercises for the B-2 wing. To this end, the simulations mimicked realistic scenarios in almost every way. Missions included aerial refuelings, weapons strikes, and realistic threats. The simulator was even modified to fit the operational toilet, allowing crews to remain in the cockpit for the entire mission. The missions were designed as realistically as possible and each crew's preparation was thorough and complete.

"I was so tired the coffee made me uneasy instead of alert."

2 STUDY I (B1-B Simulator)

METHOD

This study was a simple repeated measures design. Each participant participated with his flight crew in a single 10 day session. This session consisted of one day of practice on the cognitive tests (1) followed by three repetitions of a 36-hour on, 36-hour off cycle and concluded in one final day for recovery. Participants arrived at crew quarters at 10 a.m. the day prior to the first simulated mission. The following day they arrived at the weapons system training facility at 8 p.m. and remained there for approximately 36 hours. They were then allowed 36 hours of rest returning again to the simulator at 8 p.m. the following day (Figure 1).

Study I Schedule

Prep	Flight	Rest	Flight	Rest	Flight	Rest
24 Hr	36 Hr	36 Hr	36 Hr	36 Hr	36 Hr	24 Hr

Figure 1

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

Subjective fatigue, voice samples, EEG and cognitive performance scores were taken every three hours throughout each of the simulated flights. Voice was measured through the use of the phrase "Futility Magellan. This is 'name'. The time is 'time'." Two voice measures were calculated on the word "Magellan." Subjective fatigue was determined using a 7-point Likert scale, with 1 being low fatigue and 7 being extreme fatigue. Cognitive performance was measured using a computerized test battery consisting of the following tests: Logical Reasoning, Tracking, Matrix Comparison, and Attention Switching. Accuracy (Acc) measured as percent correct and reaction time (RT) to correct responses were measured for each test. Monopolar EEG activity was recorded for subsequent spectral analysis from the occipital region (O2), referenced to the mastoid bone.

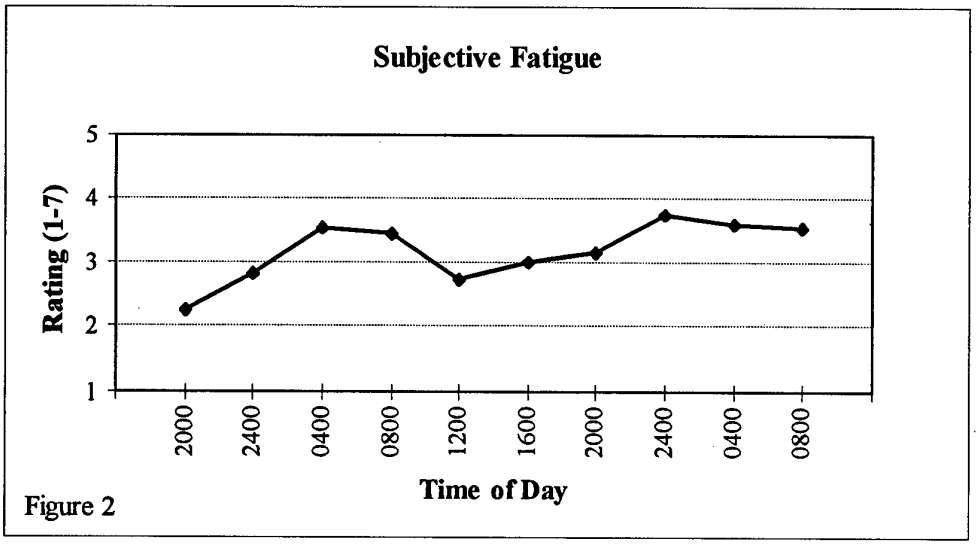


Figure 2

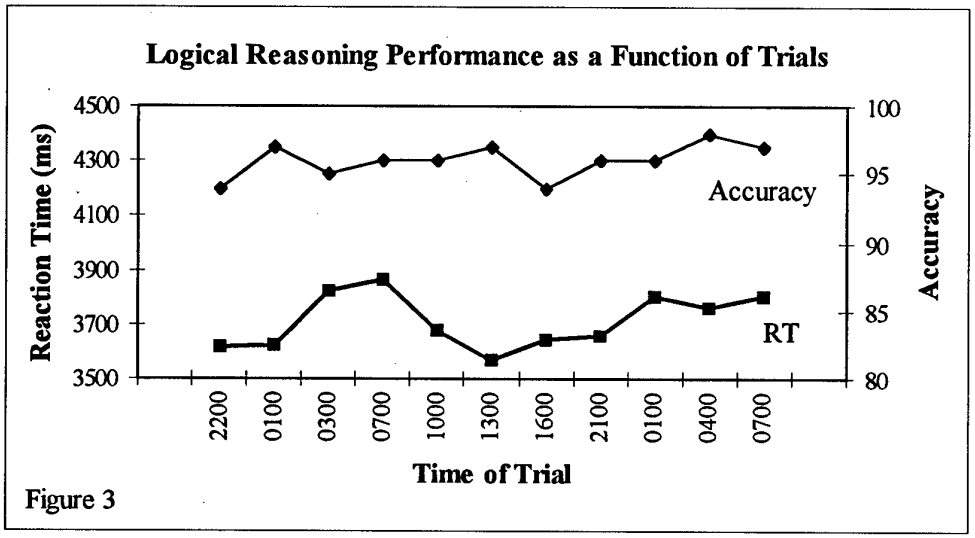


Figure 3

3 RESULTS

An alpha level of .05 was used for all statistical tests. A Two-Way Repeated Measures ANOVA was performed on the fatigue data. There was no significant interaction between missions and trials. The effect of missions was not significant. Subjective fatigue decreased for each successive mission, from 3.4 for the first to 3.2 for the second and 3.0 for the third. There was a significant main effect of trials ($F(9,81) = 5.54$, $MSE = 1.11$). Fatigue data for each mission showed a strong circadian cycle (Figure 2).

In general accuracy varied only slightly over trials, while RT showed greater and more consistent variation (Figure 3). A circadian pattern was seen in each of the RT measures. A Two-Way Repeated Measures ANOVA was performed for accuracy and RT

on each cognitive test. The significance test results are shown in Figure 4. There was no interaction of missions and trials for any of the measures. The Logical Reasoning Task results provide an example of the performance on the computer tests (Figure 3).

COGNITIVE TESTS RESULTS

TASK	MEASURE	MAIN EFFECTS	
		T- significant trial effect M - significant mission effect	
Logical Reasoning			
	RT	T $F(10,90) = 3.62$	$p=.0030$
	Acc	T $F(10,90) = 2.37$	$p=.0130$
		M $F(2,18) = 7.28$	$p=.0031$
Unstable Tracking			
	Hits	T $F(10,90) = 4.23$	$p=.0001$
		M $F(2,18) = 8.46$	$p=.0026$
Continuous Recognition			
	RT	T $F(10,90) = 6.25$	$p=.0001$
		M $F(2,18) = 15.31$	$p=.0003$
	Acc	no significant effects	
Attention Switching Task			
	Mannequin		
	RT	T $F(10,90) = 4.12$	$p=.0001$
		M $F(2,18) = 4.28$	$p=.0301$
	Acc	T $F(10,90) = 1.96$	$p=.0460$
	Math		
	RT	T $F(10,90) = 5.77$	$p=.0001$
		M $F(2,18) = 5.8$	$p=.0114$
	Acc	no significant effects	

Figure 4

A Two-Way Repeated Measures ANOVA was performed on the fundamental frequency data. There was no significant interaction between trials and missions and no significant effect of missions. There was a significant main effect of trials ($F(10,90) = 2.63$, $MSE = 70.59$). The results of the analyses on fundamental frequency were consistent with a circadian pattern (Figure 5).

The interaction between trials and missions was not significant for speech duration. There was a significant main effect of missions ($F(2,18) = 6.91$, $MSE = .0054$). There was also a significant main effect of trials ($F(10,90) = 2.50$, $MSE = .0026$). Speech rate averages were within the expected range of 4.5 to 7.5 syllables per second. The circadian trend present in all the earlier RT results was also present in the speech duration data.

"[Fatigue caused] a lot of thinking about how tired I was rather than what I was doing."

The predominant feature of the EEG spectral analysis was the loss of power in the 12-30 Hz range for the third mission compared to the first and second missions. As figure 6 shows, the average high frequency relative power decreased for the third mission at each sampling time. Significance tests have not yet been performed on the EEG data.

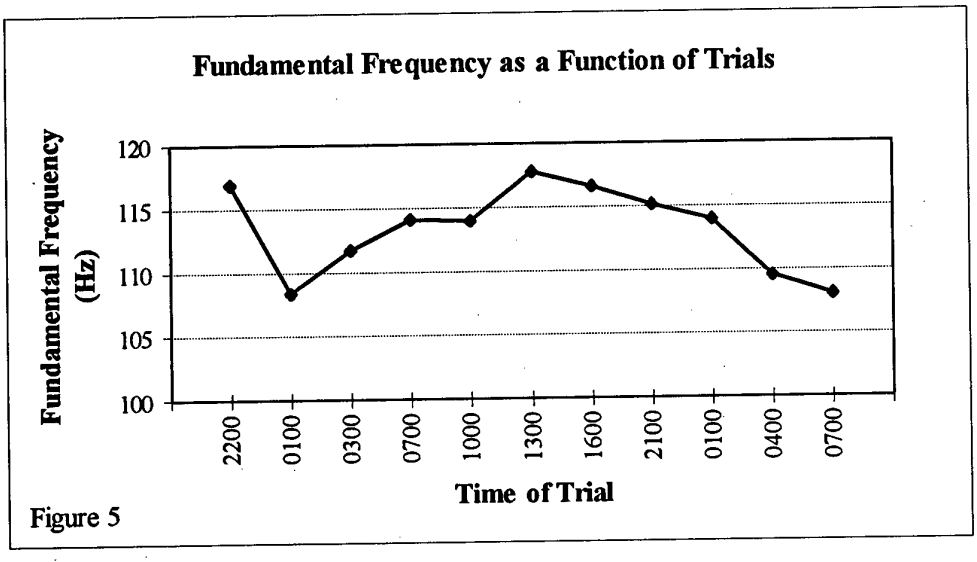


Figure 5

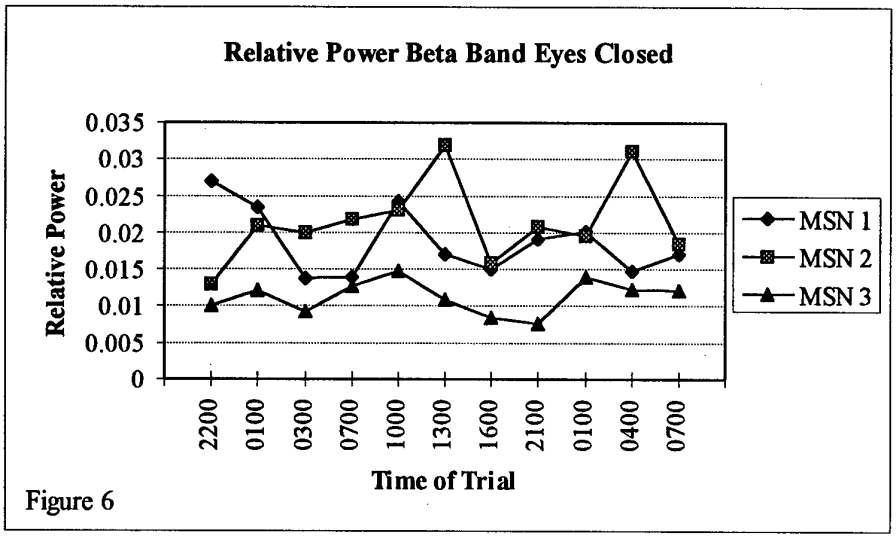


Figure 6

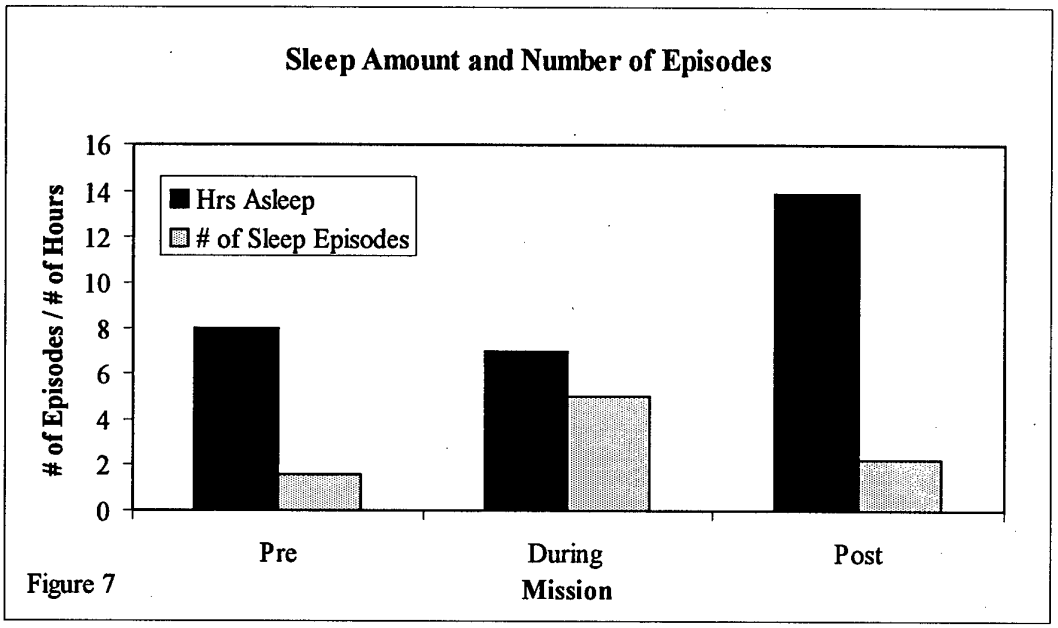


Figure 7

4 STUDY II (B-2 Simulator)

METHOD

Six crewmembers participated in teams of two. Each team flew a single long-duration mission, lasting between 34.25 hrs and 44.25 hrs. The crews were not allowed to leave the simulator during the mission. Twenty-four hours prior to, during, and 24 hours post mission, crews were monitored for sleep quantity through the use of actigraphs (2). In addition, an activity log was used to record subjective fatigue and subjective quality of sleep. During the mission, five electrodes were used to measure Electroencephalography (EEG) and Electrooculargography (EOG). Throughout the mission expert evaluators rated the crews performance on critical mission events. In addition, minor system failures were built into each mission to assess the crews ability to handle unanticipated events.

5 RESULTS

Sleep - Crewmembers slept an average of 8 hours pre-mission. The crewmembers attained 7 hours of sleep per mission on average. While the total sleep time during the mission compares favorably with the pre-mission sleep, it must be remembered each of the missions lasted through two nights. In addition, crewmembers averaged 1. 4 hours of sleep per sleep episode during the mission. This reduced sleep length

and reduced total amount of sleep per mission created a sleep debt in the crewmembers, as can be seen in the post-mission sleep. Post-mission, the crewmembers averaged 13.9 hours of sleep within 24 hours after landing (Figure 7). While the crews completed their missions successfully, it is important to recognize their relatively high level of fatigue post-mission as indicated by the much greater amount of post-mission sleep required.

Fatigue - The results for subjective fatigue turned out as expected. Subjective fatigue scores during the mission were higher during the night than during the day (Figure 8). Fatigue during the mission and post-mission was higher than fatigue pre-mission. While the average post-mission fatigue (2.68) was not greatly higher than the pre-mission fatigue (2.15), extreme fatigue scores were reported more often. From all crewmembers, a fatigue score of 6 was recorded only once prior to the mission. No scores of 7 were reported pre-mission. Post-mission however, 7-6s and 4-7s were recorded. These extreme levels of fatigue provide additional support that the crews were very tired following the mission.

Ergonomic - Anecdotal evidence suggest at least two areas for drastically improving the comfort aboard the aircraft. The headsets worn in the study were typically government issue standard headsets. These headsets were designed for an appropriate level of sound attenuation and comfort for a short mission. On longer missions however, they consistently developed 'hot spots' and probably provided insufficient hearing protection. It must be noted that there are no Air Force regulations for long-duration (20+ hours) noise exposure. The ejection seat was the other area of concern. The seat is relatively unadjustable and has a thin cushion. Seat comfort was improved by utilizing appropriate seat pads and cushions.

Simulation Measures/Expert Evaluations - Crew performance across all phases of flight, including system failures, was uniformly good. Some instances of simple judgment errors or minor deviations from procedures were observed. This behavior was attributed to fatigue or stress by the expert observers. Overall, these measures showed no meaningful decrement due to fatigue.

"I realized I was fatigued after I woke up in my seat."

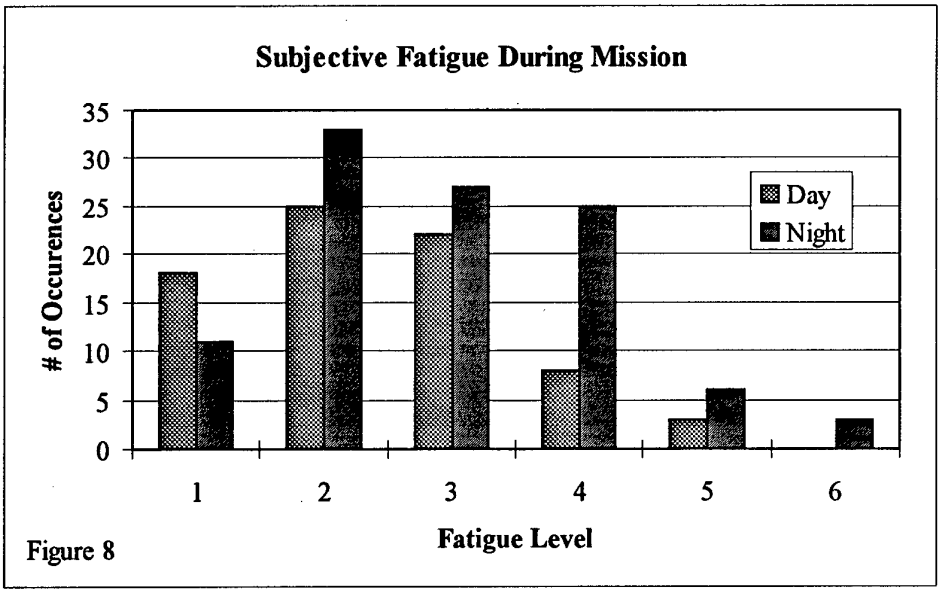


Figure 8

6 CONCLUSIONS

One of the most consistent findings, though not significant, in the first study is that cognitive performance tended to increase over missions, not decrease. Practice and adaptation to the somewhat novel environment of the simulator were the factors most likely responsible for changes in performance over the three missions. Within each mission the normal circadian cycle was present, where cognitive performance was lowest during the early A.M. hours. The voice measures paralleled these changes. A quartic trend analysis was performed on each of the RT measures and speech measures. This test was significant for all reaction time measures except Logical Reasoning. Both fundamental frequency and

speech duration returned significant values on this test as well.

In the first study, loss of high frequency beta activity was found for the third mission when compared to the first and second missions. This finding would be consistent with an interpretation of a loss of vigilance for the crews. This evidence is globally inconsistent with the computer performance data. Current analysis compares performance tests results with EEG data and separates the analysis into Pilot and Weapon's Officer results to evaluate position effect on the EEG.

Crews utilized the on-board sleeping area only sparingly during the second study. This could be due to a number of factors, such as the frequency of mission events (e.g., aerial refueling), the anxiety of performing the mission, or environmental stimuli (e.g., noise). The crewmembers were able to average about 3.5 hours of sleep per night. While this amount of sleep is probably enough to maintain performance during the more stimulating portions of flight, it is probably insufficient to prevent inadvertent sleeping and potentially reduced performance during the calmer portions (3). Crews should be particularly cautioned about maintaining vigilance during the post-strike portion of the mission. This is particularly true between aerial refuelings and when external communication is low.

The B-2 contains an adequate amount of space for one crewmember to position themselves comfortably for sleep. Use of an airmatress and separate sleeping bags is highly recommended. Crewmembers have reported disliking to use anothers sleeping bag, more importantly the second sleeping bag may be used as an additional cushion and provide additional vibration attenuation.

B1-B crews spent the nights prior-to and between the missions in on-base billeting. B-2 crews were required to sleep the night before the mission in on-base billeting. This requirement allowed them to be removed from their normal home environment where they might have been unnecessarily awakened or might have performed chores/tasks which reduced their sleep opportunity. Therefore, the data presented should be regarded as information on a well-rested group of flyers. Pre-mission crew rest is critical to mission performance. If crews do not receive a 'reasonable' nights sleep prior to the mission then their fatigue levels can be expected to be considerably higher than those reported in the second study.

Fatigue management schedules were developed for the crews in each of the studies. These schedules listed the entire mission (critical events and relative aircraft location) in a chronological sequence on a single sheet of paper. In addition they contained recommendations on sleep times. The principal benefit of these schedules was to heighten the crews attention to fatigue. The schedules induced the crews to develop a crew rest plan which allowed all crewmembers to obtain sleep during critical periods.

These studies allowed a 'first-look' at long-duration performance for B-1B and B-2 aircrews. Following each of the studies the respective operational community instituted long-duration training missions as part of every flyers training.

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Gestion des Repos et Evolution des Manifestations de Fatigue chez les Pilotes selon les Rotations

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1. INTRODUCTION

La fatigue des pilotes d'avions constitue l'un des facteurs le plus souvent cité parmi les causes susceptibles de réduire la performance. L'une des sources d'information disponible concerne le système ASRS (Aviation Safety Reporting System) qui permet aux équipages américains de reporter de manière confidentielle des incidents. L'analyse de ces réponses indique que la fatigue est explicitement citée dans 4% des événements. Néanmoins, on peut considérer que la fatigue se trouve en partie à l'origine de plus de 20% de ces incidents puisque d'autres facteurs tels que l'inattention, les difficultés de communications se trouvent fréquemment évoqués. Par ailleurs, lorsque des pilotes font référence à la fatigue, les causes associées se révèlent très diverses. Certains l'assimilent à un manque de sommeil alors que pour d'autres, les temps élevés de service ou une charge de travail constituent les principales causes de fatigue. L'une des confusions les plus fréquentes concerne le concept de somnolence. En fait beaucoup d'études réalisées en situations réelles suggèrent que la somnolence et la fatigue représentent des notions différentes. En aéronautique, la fatigue associée à la privation de sommeil et à la désynchronisation des rythmes biologiques a été étudiée dans plusieurs recherches (1), (2), (3). Ces privations de sommeil se traduisent essentiellement par une réduction du niveau d'éveil des équipages comme l'indiquent les résultats des enregistrements électrophysiologiques effectués en vols lors d'une recherche précédente (4). L'une des solutions les plus efficaces pour réduire les effets des privations de sommeil demeurent la sieste (5). Néanmoins, ces recherches présentent deux limites essentielles : elles concernent souvent uniquement les vols long-courriers et restent très centrées sur la somnolence. Une enquête sur la fatigue récemment menée auprès de 728 pilotes de diverses compagnies aériennes indique que les pilotes évoquent deux causes principales : le manque de sommeil et la charge de travail (6). Parmi les manifestations de fatigue, l'altération des fonctions cognitives et notamment de l'attention se trouvent fréquemment citées. La fatigue ne pouvant se résumer à une diminution du niveau d'éveil, des évaluations de la fatigue ont été réalisées en vol afin de caractériser les manifestations de la fatigue ainsi que la récupération en fonction de différentes rotations (7).

Cet article présente la synthèse de résultats obtenus en situation réelle de manière à illustrer trois aspects essentiels de la fatigue en aéronautique :

- le décalage horaire et la gestion du sommeil au cours de rotations long-courriers,
- les manifestations de la fatigue au cours de vols long-courriers et court-courriers,
- la récupération de la fatigue à la suite de rotations long-courriers et court-courriers.

2. DECALAGE HORAIRE ET GESTION DU SOMMEIL AU COURS DE ROTATIONS LONG-COURRIERS

L'une des principales causes des symptômes du décalage horaire repose dans l'inertie de l'horloge biologique . En d'autres termes, l'adaptation du cycle veille-sommeil à un nouvel horaire n'est pas immédiate ce qui entraîne une dégradation de la durée et de la qualité du sommeil, des manifestations de fatigue, une réduction des performances ainsi que par des troubles digestifs. Généralement, ces troubles apparaissent après des durées d'escale supérieures à 48 heures. Néanmoins, dans le cas d'escales plus courtes, le décalage entre l'horloge biologique et les synchroniseurs externes tels que le cycle lumière-obscurité et les rythmes sociaux se traduit pour les équipages par une altération importante de la durée et de la qualité du sommeil. Cet aspect a été étudié dans le contexte de la recherche menée sur la vigilance et le sommeil des pilotes d'avions long-courriers (4). Dans cette recherche, les durées de sommeil à l'escale étaient évaluées à la fois à partir d'enregistrements actométriques et d'agendas de sommeil. Par ailleurs, des enregistrements électrophysiologiques, l'électro-encéphalogramme (EEG) et l'électro-oculogramme (EOG) on été recueillis de manière à évaluer les variations du niveau d'éveil des équipages au cours de leurs activités. Dans l'une des phases de ce travail, une série de recommandations concernant la gestion du sommeil et le décalage horaire a été testée sur des rotations à destination de Singapour et Taïpei comportant une escale de 24 heures. Les résultats présentés ci-après ne constituent qu'une partie des données obtenues. La synthèse de l'ensemble des résultats, portant sur 156 vols, est présentée dans d'autres articles (8).

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

Compte tenu de la courte durée de l'escale, il est recommandé aux équipages de ne pas tenter de se synchroniser sur l'horaire local afin d'éviter les troubles liés au décalage horaire. La figure n°1 présente les résultats de deux groupes de pilotes n'appliquant pas et appliquant les recommandations. Pour ceux les appliquant, on observe une tendance à se synchroniser sur l'horaire local, même si l'escale est très courte. Ceci entraîne des durées de sommeil relativement faibles et surtout des durées très élevées d'éveil.

Les pilotes appliquant les recommandations conservent un rythme veille-sommeil synchronisé sur les horaires de Paris, ce qui se traduit par une moindre privation de sommeil et surtout une meilleure qualité pour ce dernier.

Sur le plan de la vigilance au cours des vols, les résultats moyens, en terme de durée et de pourcentages d'hypovigilance, confirment l'efficacité des recommandations fournies aux pilotes. En effet, lors des phases de montée et de croisière, les pourcentages d'hypovigilances sont significativement inférieurs lors des vols avec recommandations par rapport aux vols sans recommandations (figure n°2).

Compte tenu de l'intérêt des recommandations proposées, notamment sur le plan de la gestion du sommeil aux escales, il a été retenu de les regrouper dans un guide à l'attention des pilotes de long-courriers. Ce guide est disponible en version française (9), anglaise et chinoise (10).

3. MANIFESTATIONS DE LA FATIGUE AU COURS DE VOLS LONG- ET COURT-COURRIERS -

A la suite des constats effectués sur la vigilance des pilotes d'avions long-courriers, il est apparu que l'hypovigilance ne constituait cependant que l'une des manifestations de la fatigue des équipages. D'autres travaux, actuellement en cours, ont pour objectifs d'identifier les différentes causes de la fatigue en aéronautique ainsi que ses diverses manifestations selon le type de vol considéré : long-, moyens- ou court-courriers l'objectif étant d'arriver à des recommandations en matière de réglementation des temps de service et de repos, de planification des rotations et de formation des équipages.

La méthode d'étude mise en place pour répondre à cet objectif repose sur le recueil des données suivantes pour chaque membre d'équipage :

- les durées de sommeil et des siestes éventuelles, sur la période concernant les deux jours précédant le départ jusqu'au deuxième jour de repos après la fin de la rotation,
- les évaluations de la fatigue globale et de la somnolence, au coucher et au lever ainsi qu'au cours des différentes phases de vol et pendant les repos,
- les évaluations des manifestations de la fatigue pour ce qui concerne la fatigue physique, la fatigue mentale et la fatigue sensorielle ainsi que les troubles de l'humeur ; ces données sont recueillies avant, pendant et après la rotation,
- des évaluations de charge de travail, à l'aide de la NASA Task Load indeX (TLX).

En l'état actuel d'avancement des travaux, 7 rotations ont été étudiées. Elles se répartissent en :

- deux rotations en long-courrier de nuit, à destination de l'Afrique, en équipage à 3,
- deux rotations en long-courrier de nuit à destination de la Réunion, en équipage renforcé,
- une rotation comportant des vols court- et moyens-courriers de nuit,
- deux rotations comprenant des vols court-courriers réalisés de nuit.

Aucune de ces rotations n'entraîne de décalage horaire significatif.

A titre d'exemple, les résultats d'une rotation effectuée entre Paris et la Réunion sont présentés sur la figure n°3. Au cours des phases de croisière, alors que la charge de travail reste modérée, on note une augmentation progressive des sensations de fatigue et de somnolence ainsi que de l'ensemble des manifestations de fatigue. A la fin du vol, lorsque la charge de travail augmente, la fatigue demeure élevée contrairement à la somnolence qui tend à diminuer. Cette dissociation entre la fatigue et la somnolence, concomitante d'une augmentation de la charge de travail se révèle typique des vols long-courriers étudiés.

Pour les vols court-courriers multitronçons, les résultats dépendent du rang du vol dans la rotation (figure n°4). La dissociation fatigue-somnolence en fin de vol n'est observée que pour les étapes intermédiaires (deuxième ou troisième vol de la rotation). Pour la première étape de la rotation, les niveaux de fatigue et de somnolence demeurent identiques. En d'autres termes, plus le temps de service augmente, plus la dissociation entre la fatigue et la somnolence se révèle importante.

De manière à préciser les relations entre la fatigue et la charge de travail, une comparaison des niveaux moyens de fatigue en fin de vol pour les pilotes se trouvant aux commandes et les pilotes ne se trouvant pas aux commandes a été effectuée (figure n°5). On constate que les valeurs restent identiques entre les deux pilotes à la fin des vols long-courriers et des premières étapes des rotations court-courriers. Seul le niveau de fatigue, évalué à la fin des dernières étapes des rotations court-courriers, se révèle plus élevé pour le pilote aux commandes par rapport au pilote non aux commandes. La même tendance se retrouve sur les évaluations de la charge de travail pour les échelles de demande mentale, de pression temporelle et d'effort. Ces résultats traduisent probablement une répartition des tâches plus homogène entre les deux pilotes lors des vols

long-courriers par rapport aux vols court-courriers. Ils confirment également l'implication de la charge de travail dans l'apparition de la fatigue.

4. RECUPERATION DE LA FATIGUE APRES DES ROTATIONS COURT- ET LONG-COURRIERS

Dans le contexte de cette recherche, la récupération de la fatigue au cours des repos a été abordée à l'aide des mêmes évaluations que celles utilisées pendant les vols. Ces évaluations étaient réalisées à différentes périodes, lors des deux journées qui suivent le retour à la base : au coucher, au lever, puis 2 heures et 4 heures après le lever. La comparaison des vols long- et court-courriers (figure n°6) montre des profils de récupération bien différenciés. Le besoin de récupération en sommeil étant naturellement très marqué à la suite des rotations long-courriers qui comprenaient toutes deux vols consécutifs de nuit, les niveaux de fatigue et de somnolence au coucher demeurent plus élevés après ces vols qu'à la suite des vols court-courriers. Lors de la deuxième journée de récupération, il est frappant de constater que les niveaux de fatigue et de somnolence demeurent élevés au lever après les vols long-courriers, contrairement aux valeurs observées pour les rotations court-courriers. Ceci suggère qu'après des rotations long-courriers, deux nuits de repos pourraient s'avérer insuffisantes pour obtenir une récupération totale.

5. CONCLUSIONS

Les résultats présentés permettent de dégager plusieurs implications concernant la fatigue en aéronautique. La première est qu'une gestion appropriée des repos permet de lutter efficacement contre les effets du décalage horaire sur la durée et la qualité du sommeil. Cet aspect constitue un point essentiel de la récupération de l'équipage puisqu'il conditionne pour une part importante la vigilance de l'équipage lors des vols retour. Rappelons que ces recommandations relatives aux décalages horaires ont fait l'objet d'un guide à l'usage des équipages long-courriers des compagnies aériennes. D'autres aspects tels que l'hygiène de vie, l'organisation des activités en vol, la monotonie sont abordés de manière à apporter des réponses pratiques aux pilotes dans leur préparation.

Les résultats obtenus sur des vols long- et court-courriers confirment l'implication de la charge de travail dans l'apparition de signes de fatigue, comme l'indique la dissociation fatigue-somnolence lors des phases finales de vol. Cet aspect, souvent sous-estimé dans les travaux sur la fatigue en aéronautique, doit être pris en considération d'autant plus que ces manifestations surviennent lors de phases critiques, la descente et l'approche, au cours desquelles les effets combinés de la charge de travail et de la privation de sommeil apparaissent les plus élevés.

Enfin, l'étude de la récupération de la fatigue dans les jours suivant les rotations suggère que la vitesse de récupération dépend étroitement du type de rotation long- ou court-courrier. Au vu des rotations effectuées, deux journées de repos ne permettent pas une récupération complète à la suite de vols long-courriers comportant des escales courtes. Un recueil de données complémentaires sur un plus grand nombre de rotations est actuellement en cours afin de vérifier ces premières tendances. Si ces résultats se confirmaient, ils devront être intégrés à la réflexion sur la réglementation des temps de repos.

6. REMERCIEMENTS

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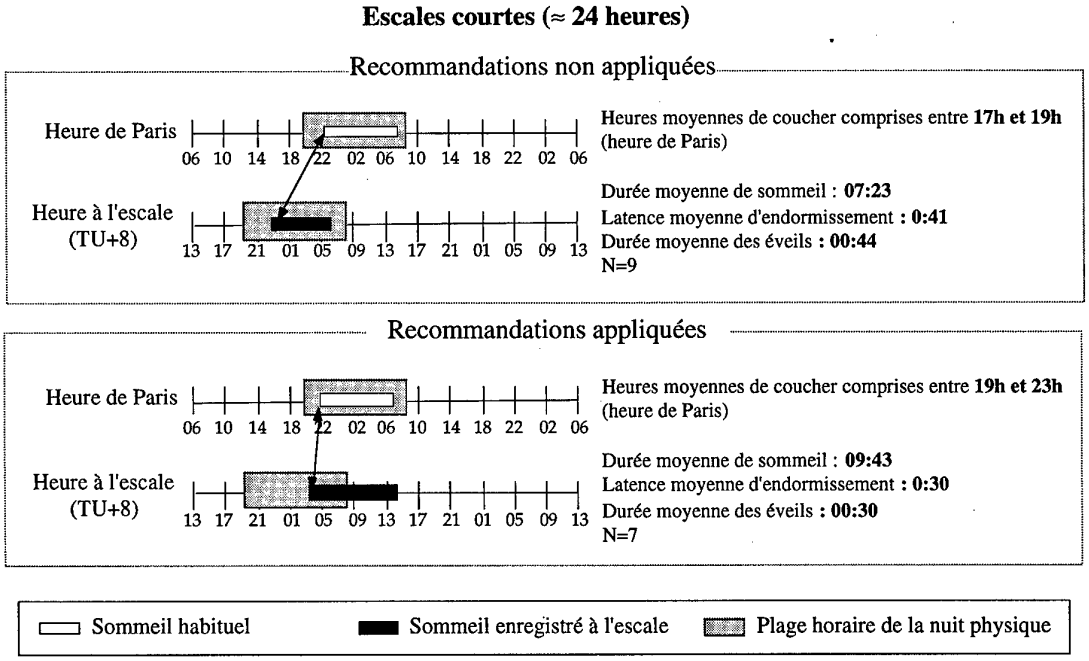


Figure n°1
Durées et qualités moyennes du sommeil à l'escale (Taipei) en fonction de l'heure de coucher. Pilotes d'avions long-courriers
(d'après Mollard et coll., 1997).

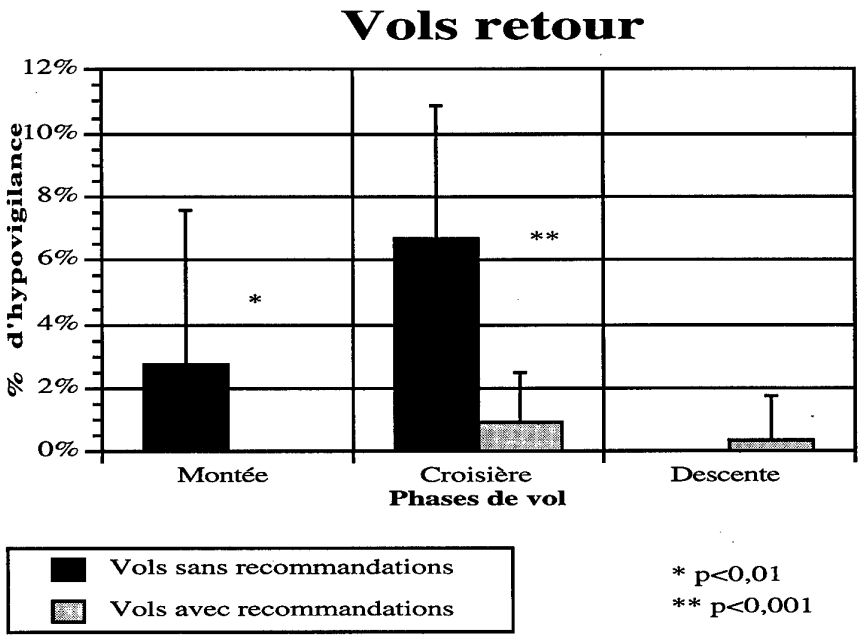


Figure n°2
Pourcentages d'hypovigilance au cours des vols Paris-Singapour (sans recommandations, n=8) et Paris-Taïpei (avec recommandations, n=18)
(d'après Mollard et coll., 1997).

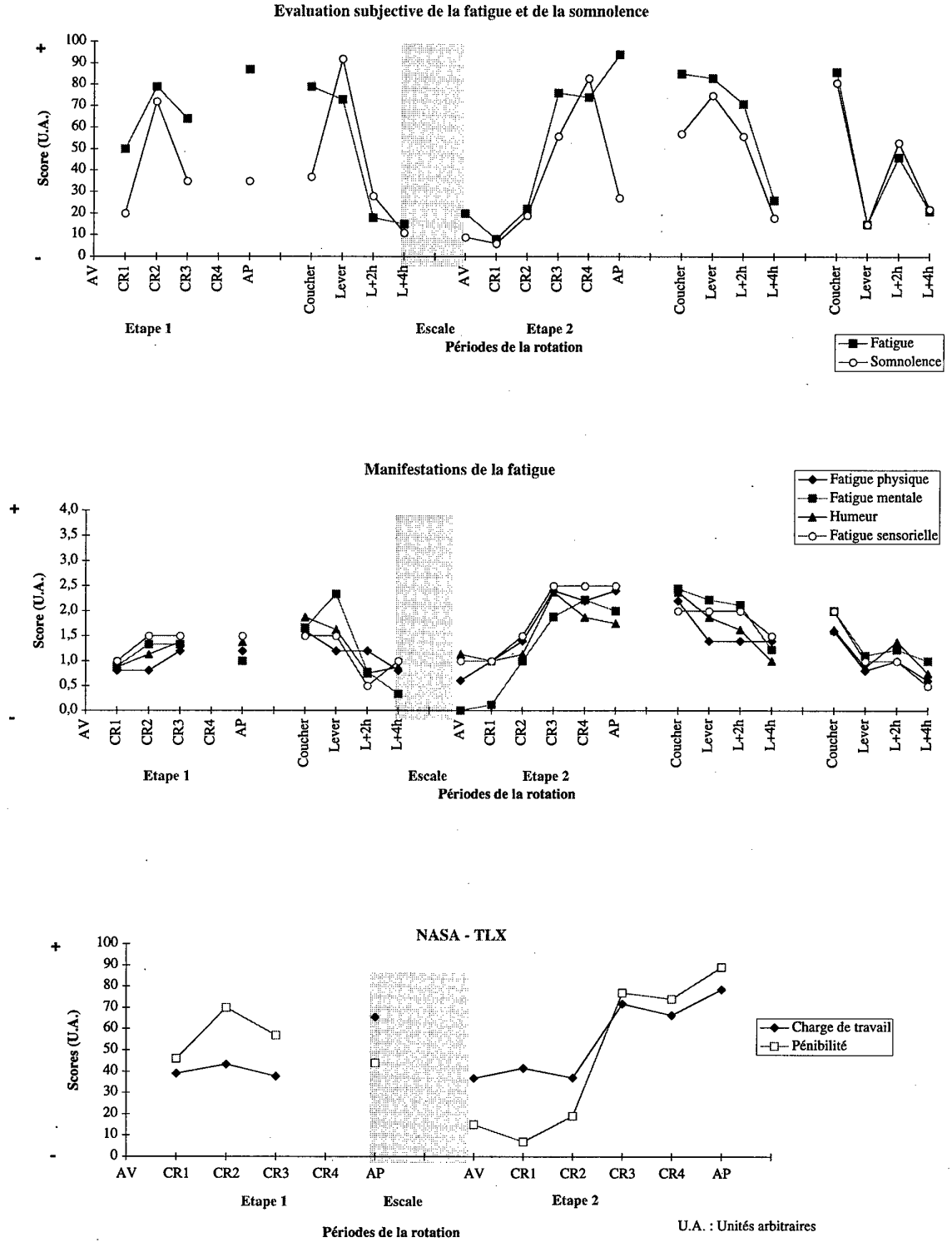


Figure n°3
Evolution des sensations de fatigue, de somnolence et charge de travail au cours d'une rotation Paris - La Réunion (vols de nuit). Résultats d'un pilote.

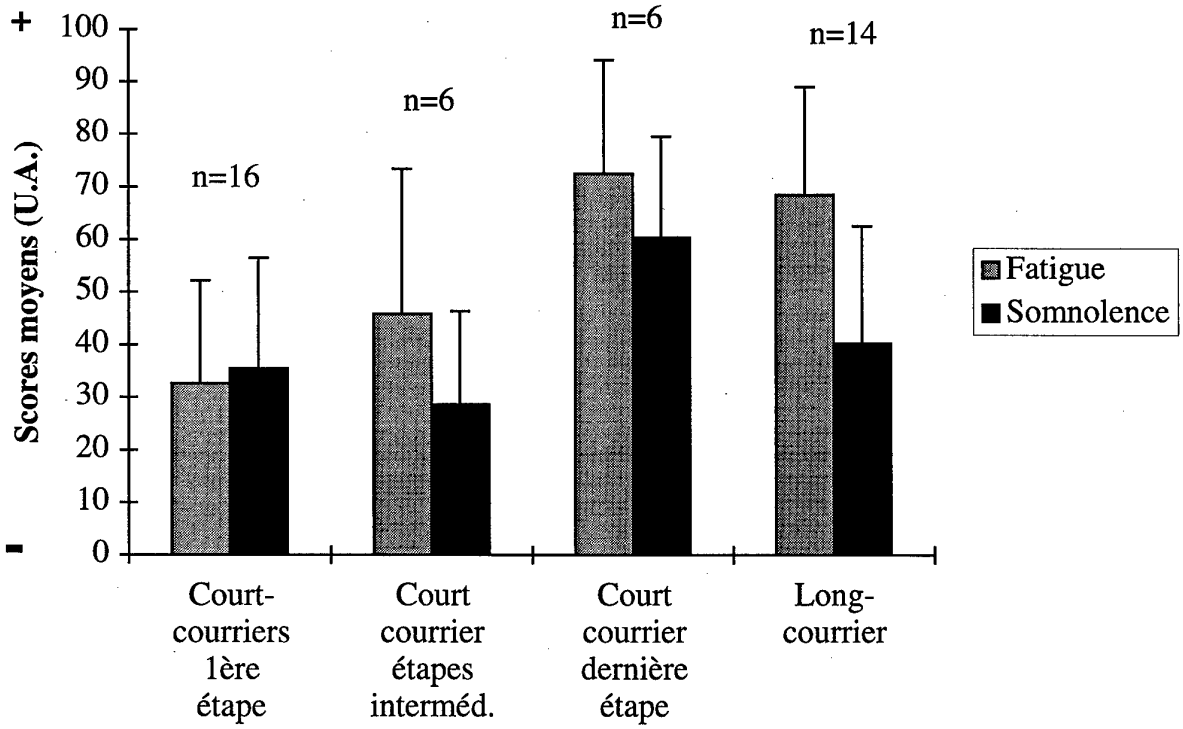
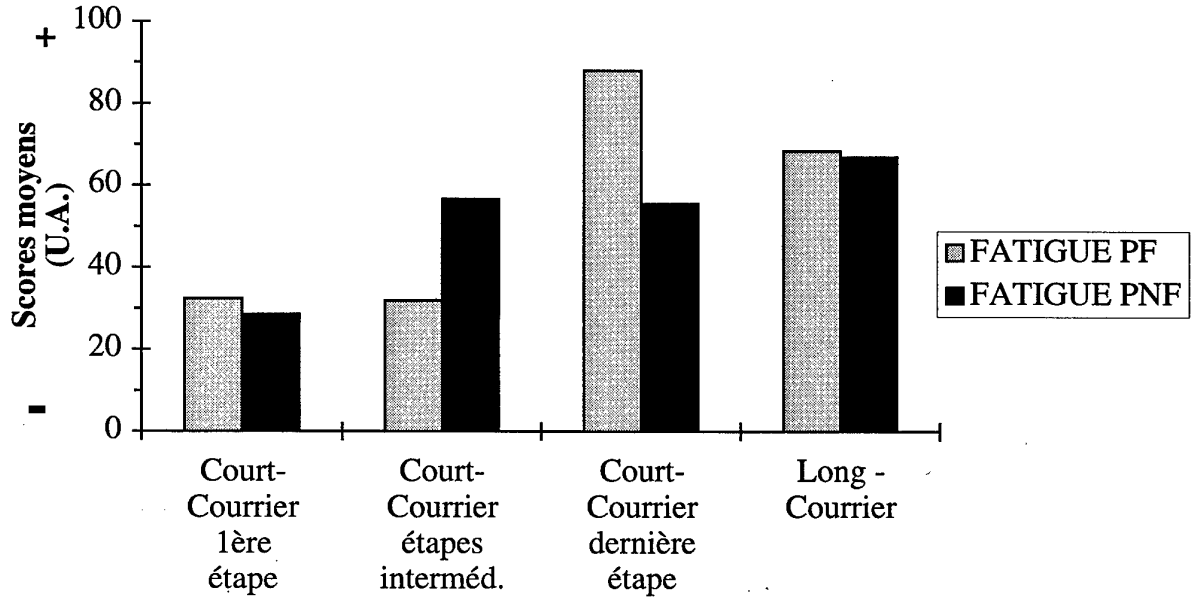
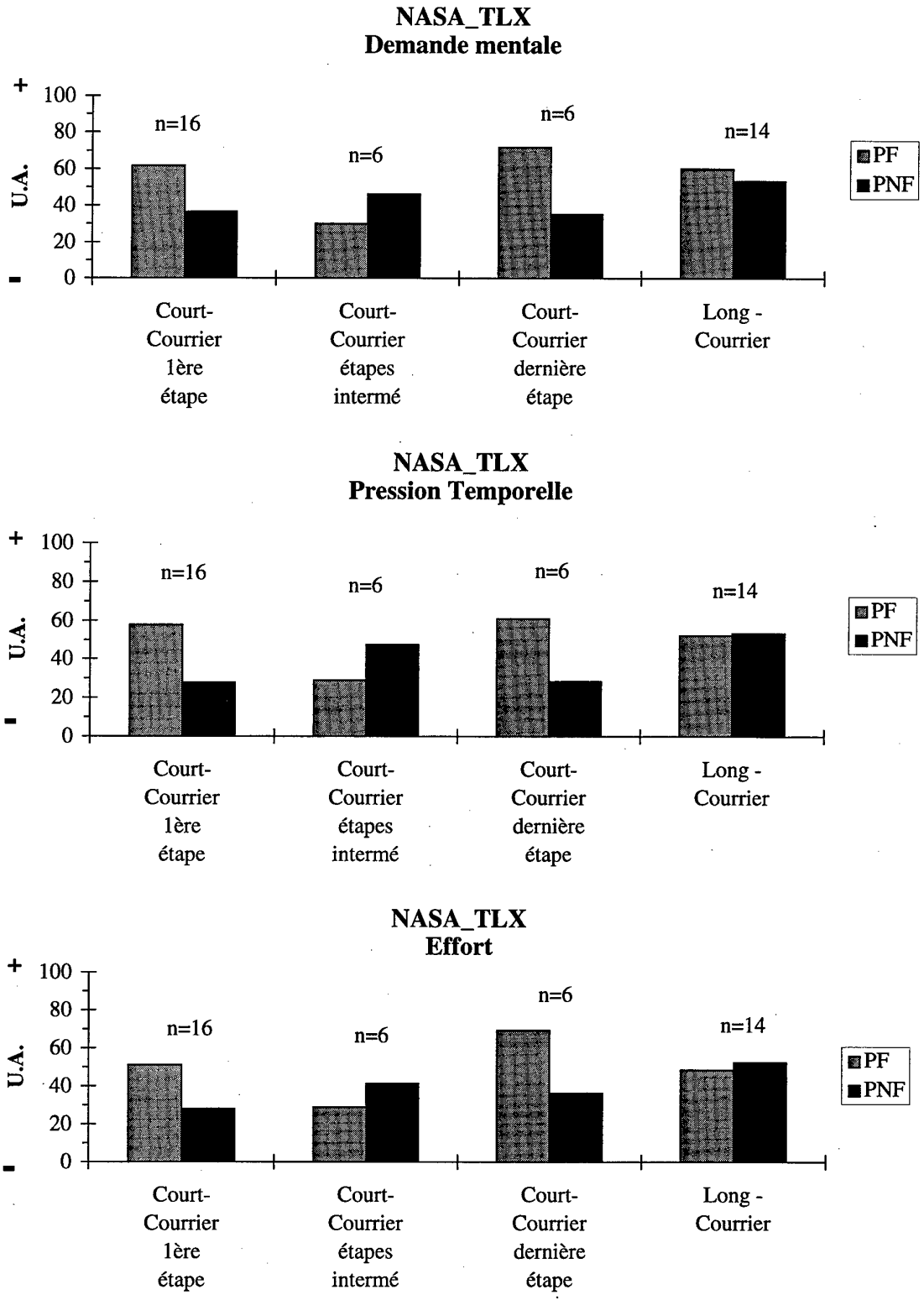


Figure n°4
Sensations moyennes de fatigue et de somnolence
à la fin de différents types de vols.



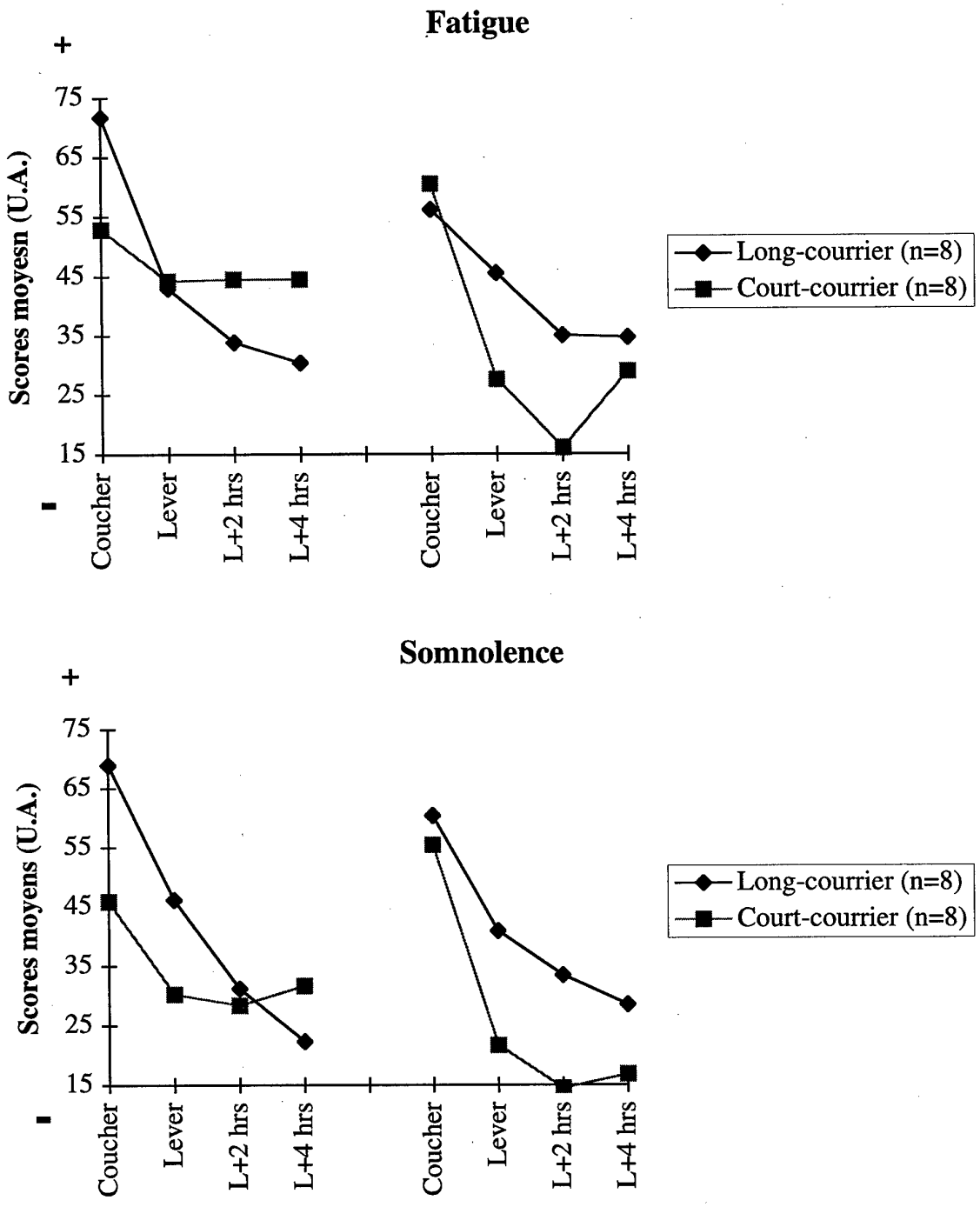
U.A. : Unités Arbitraires

Figure n°5
Sensations moyennes de fatigue à la fin des vols
pour les pilotes aux commandes (PF) et les pilotes non aux commandes (PNF).



U.A. : Unités Arbitraires.

Figure n°6
Evaluation en fin du vol de la demande mentale,
de la pression temporelle et de l'effort pour les pilotes aux
commandes (PF) et les pilotes non aux commandes (PNF).



L : Lever.

Figure n°7
Evaluation de la fatigue et de la somnolence au cours des deux journées de récupération qui suivent les rotations - Scores moyens.

Evasive Maneuvers and High-G Flight Safety after Sleep Deprivation

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1. SUMMARY

It is a common situation in the current global reach/global power mission to require fighter pilots to deploy overseas on short notice and to require immediate duty. Up to thirty six hours of sleeplessness is a common status in this environment. The objective of this study was to assess the performance of trained simulator pilots performing flight relevant tasks in the stressful environment of high G under two conditions; rested and 24 hours of sleeplessness. Performance was also compared to self-assessment and self-reported effort and fatigue. Limited data was collected concerning a 2-4 week lay-off from the task. APPROACH: Volunteers (eight men & eight women) were trained to fly the Dynamic Environment Simulator in a closed loop configuration air combat maneuvering up to 9 Gz. Before and after each session, their total body isometric strength was measured. During each sortie, thirty performance measures at simultaneous multiple tasks were measured. After each session, subjects completed a subjective questionnaire and a standardized subjective workload assessment. RESULTS: Neither male nor female overall performance was significantly affected by sleep status, although individual tasks showed sensitivity; call-sign reaction time was longer by 33% and missile survival was considerably less likely. Also, perceived effort and physical demand were higher while perceived performance was lower when sleepless. Greater self-reported effort on the anti-G straining maneuver correlated with better task performance and less post-G fatigue. Men are naturally stronger than women, however there was no significant decrease in strength due to G exposure in either the rested or sleepless conditions for either gender. CONCLUSIONS: Though sleep deprived pilots' subjective sensations may be that they are fatigued and unable to perform, objective measures show that their ability to conduct offensive maneuvers remains unchanged after 24 hours without sleep. However, when conversion to uncertain and spatially demanding defensive maneuvers occurs, survival may be compromised.

2. INTRODUCTION

Physiological changes under high-G include primarily a redistribution of the blood supply to various organs [1]. The most commonly encountered acceleration ($+G_z$) causes a shift of blood from the head to lower parts of the body. Because of this blood shift, loss of vision and even loss of consciousness may result. These effects have been well studied and have been shown to be both without permanent effects and spontaneously reversible when the $+ G_z$ force is reduced [2].

Some ground-based research has investigated the loss of cognitive function in the extreme conditions of G-induced loss of consciousness (G-LOC), however, little is known about pilots' abilities to maintain cognitive performance throughout prolonged conscious exposure in the high G environment. The recent deployment of positive pressure breathing for G (PBG) systems in the US Air Force, as well as the pending deployment of advanced technology full-coverage anti-G suits, is resulting in longer duration high-G exposure. Gz doses of greater than a million G-seconds are being anticipated [3]. There have been only a few experiments concerning crew performance with these advanced suits in the military arena [4, 5, 6] and few have been published in the open literature.

In 1944, the first experiment documenting impairment of cerebral function during exposure to G forces described subjects with confusion and momentary memory loss [7]. Since then there have been dozens of studies of performance under G. Grether reviewed the effects of acceleration on performance, and concluded that simple and choice reaction times to visual signals generally increase during increased levels of +Gz. However, these effects tend to diminish or disappear as humans become more accustomed to acceleration environments [8].

While there have been no previous sleep deprivation studies conducted under high-G, there has been a G-layoff study conducted. The issue was the effect of

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G-layoff on tolerance, not performance. No medical risks were identified from having subjects exposed to +9 G_z after 2 and 4 weeks of G-layoff; however, a four week layoff was found to reduce G endurance from 220 to 163 seconds during an alternating 5 to 9 G profile [9].

3. METHODS

This research was conducted on a ground-based human centrifuge, the Dynamic Environment Simulator (DES), located at Wright-Patterson AFB, OH and shown in Figure 1. The DES is a unique research facility which couples simulated high-G with a flight simulator capability that provides the means to measure psychophysiological, behavioral, and subjective reports of mission performance, workload, and situational awareness [10].

Subjects, Qualification and Training

Out of nearly 70 individuals that applied at Wright Patterson AFB, over half could not pass the medical screening criteria and half of the remaining attritted out of the subject pool prior to useful data collection. Sixteen active duty non-rated Air Force subjects (8 men, 8 women) were retained and passed the rigorous medical screening procedures including spinal and cranial radiographs, blood analysis, and neurological examination. All were briefed on the study, signed an informed consent, and received suit, helmet, and mask fitting and anti-G straining maneuver training. Coincident with an eight visit indoctrination series that introduced motion sickness coping strategies, anti-G straining techniques, positive pressure breathing, and DES safety procedures, subjects completed 8 to 20 classes in the static simulator learning to fly and complete the multiple tasks. Then each subject underwent a minimum of three days of training that blended high G endurance with the flight simulation.

After each subject demonstrated their ability to safely and reliably fly the closed loop simulation, they were assigned to the experiment. The schedule was mapped out for weekly runs to include a minimum of 3 blend days (blending G tolerance with flight simulation) or until their performance was consistent (SEM of tracking score < 1000 ft, approximately, as scheduling allowed). Assignment to the experimental design was balanced for order, gender, and skill level.

Protective Equipment

COMBAT EDGE (Combined Advanced Technology Enhanced Design G Ensemble) was selected as the protective equipment because that is what is now required in the F-15 and F-16.

Protective equipment was customized to accommodate both men and women. In operational scenarios these types of modifications are common practice [11]. Five women and six men reduced the height of their anti-G suit abdominal bladders. Arm pain has been a by-product of PBG protection, especially in the centrifuge, thus four women and six men elected to wrap their arms to avoid arm pain. Due to the oxygen sensing transducers on the forehead, some subjects required larger helmets than normal and the high-style bayonets had to be used to get a good mask fit.

Flight Task and Metrics

The Dynamic Environment Simulator is equipped with a wide field-of-view visual display for presentation of a closed-loop flight task where subjects control the onset/offset of high-G according to the requirements of the flight. A computer generated, projected, instrument panel is controlled by specialized software. During this experiment, the subjects were tasked to perform the following:

- Maintain controlled flight
- Follow lead, maintain 3000 ft range (tail chase)
- Discriminate call-sign and correctly respond
- Report any 5000 ft altitude breaks
- Upon klaxon, find and evade missile (Attitude, Chaff, Direction, max G)

Metrics for both effects of fatigue and G-layoff included the measurement of closed-loop flight performance, overall + G_z dose, and reaction times/error rates to secondary tasks related to the mission. Performance metrics were measured for two initial 1G runs (normal 1G environment) followed by four real G runs (DES arm active) with three minute rest periods between each run. Each 3 minute engagement was designed to emulate an air-to-air targeting sortie. The target profile was randomly selected from a library of profiles prerecorded to contain similar G dose and maneuvers of equivalent difficulty. Metrics recorded for the primary task included mean RMS error from the target and G dose (both as an integral, and as a distribution).

The multifaceted task included not only pursuit tracking, but speech discrimination, choice response, altitude reporting, and missile evasion. The missile was always the final portion of the sortie and required situational awareness, spatial and cognitive decision making, and high G tolerance.

HUD Task

Throughout the flight task, the subject reported (via a switch on the throttle) every time that the engagement altitude floor was violated. Profiles were constructed so as to break the floor approximately every 30 seconds during each sortie. Data recorded were the number of breaks occurring, the number to which the subject responded to within 10 seconds, and the average reaction time of responses.

Head Down Task

The head down task was coupled with the flight task. It consisted of the radar warning receiver display that told the subject which direction the target aircraft was when it was no longer visible on the forward visual scene and the direction from which the missile had been launched. Missile metrics recorded included reaction time to trigger chaff button, peak G pulled, and successful solution (kept missile abeam long enough to evade).

Communications Task

The profile software included computer recordings of three different call signs and instructions. These occurred every five seconds. If the subject recognized his/her call-sign, he/she responded by following the instructions indicating which of three buttons on the flight stick to engage. Example: "Bird 2, Squawk Charlie", if the subject was Bird 2 on that day, he/she should push the right-most (Charlie) button. Metrics recorded included number of calls to the subject, number correctly responded to, and average reaction time from start of instruction word to button push (must be correct button to count).

Subjective Workload Measures

In addition to the various quantitative measures of performance, subjective measures of workload and performance were also obtained using both a computerized version of the six dimensional NASA-TLX and a locally developed paper questionnaire.

Physiologic Measurements

A Nellcor N-200 pulse oximeter was used to measure arterial oxygen saturation at head level via a RS-10 oxisensor. These data were collected 15 seconds prior to, during Gz, and for 30 seconds post G exposure.

A Somanetics INVOS 3100 cerebral oximeter measured transcranial regional cerebral oxygen saturation using a near infrared Somasensor. Both the N-200 and the INVOS 3100 devices have undergone extensive clinical validation at 1Gz.

Experimental Procedures - Fatigue

During nights in the sleepless condition, subjects reported to the DES facility at 10 PM and were supervised throughout the night. There were no specific activities required, as long as they stayed awake. Caffeine intake was restricted to only what they would normally consume (e.g. 1 cup in AM). No more. Closed-loop performance was measured the following morning at 7 or 8 AM.

Experimental Procedures - G-Layoff

Subjects were divided into four groups of equal number: 1) males with G-layoff of two weeks, 2) females with G-layoff of two weeks, 3) males with G-layoff of four weeks, and 4) females with G-layoff of four weeks. After the prescribed layoff period, subjects once again underwent the standardized high-G sortie and performance metrics were collected. The final subject counts completing the layoff portion of the study were 7 men (4 on two-week layoff, 3 on four-week layoff) and 4 women (2 on two-week layoff, 2 on four-week layoff).

Data Analysis

Performance, physiologic, and workload data were tabulated in a large Excel database with each observation identified by all treatment conditions. Combined score was produced using the weighted sum as follows:

Combined score =

60% of normalized RMS
+ 5% of percent calls correct
+ 5% of normalized call RT
+ 5% of percent breaks reported
+ 5% of normalized break RT
+ 20 (if missile evaded)
100 % total

Analysis on score was also performed on the continuous tasks separate from the binary task of missile survival. Several significant response metrics were also analyzed individually.

A single factor, 4-level analysis was performed to examine run order effect. Data were then examined using a combination of:

- two-way ANOVA, within gender, blocked by subject
- three-way ANOVA with subject averages
- the Chi-squared test for binomial data
- linear regression

Results were considered statistically significant with a p value of less than 0.05. Power of a test was considered acceptable if greater than 0.8.

Strength Test Procedures

The strength test equipment used was a custom made semi-automatic static ergometer which measured isometric strength of subjects manipulating simulated aircraft controls. Isometric forces were measured via strain gauge force transducers.

This assembly measured forces when subjects pushed forward and pulled backward on a vertical column yoke. The yoke also measured forces generated while turning the yoke. Leg strength was measured using a foot pedal assembly which pivoted on a roller bearing about a vertical axis. The seat was adjusted so that the subject's knee angle was between 130 and 140 degrees.

Each test condition was repeated three times with a one minute rest period between trials. The highest force value generated during the three trials was used. Test conditions were randomized across subjects. Strength tests were performed prior to entering the centrifuge and immediately following centrifugation.

4. RESULTS

Effect of Fatigue on Performance

Figure 2 shows the results of just the primary task, pursuit tracking, shown here in inverse log units such that a higher bar represents better range tracking. Neither male nor female tracking was significantly affected by sleep status.

Individual task analysis showed two significant components affected by sleep status:

- call-sign reaction time was longer by 33% in the sleepless condition (3.1 vs 2.4 sec)
- missile survival was significantly less likely in the sleepless condition (50% survival sleepless vs 75% survival rested)

Percent correct of either the call-sign task or the altitude breaks was unaffected by sleep status. These differences were not sufficient to affect the overall score. Figure 3 shows the results in the combined score. Neither males nor females were affected by sleep status, overall. Using the mean square error attributed to the sleep factor, the degrees of freedom of the factor, the degrees of freedom of the sample space, and the pooled variance, the power of the test was found to be 0.92.

The NASA Total Workload Index (TLX) responses were combined into a weighted sum by the automated administration program. Statistically significant differences were found in a few of the dimensions; perceived effort and physical demand are higher when sleepless while perceived performance is lower when sleepless. Somewhat unexpectedly, reported frustration level was lower when sleepless. Overall, though, the weighted workload was not different in either sleep condition or between genders.

Effect of Layoff on Performance

The single factor (baseline vs laid-off) ANOVA on each of the four conditions (female two-week, female four-week, male two-week, and male four-week) showed no statistically significant differences in RMS tracking, call-sign reaction time, G dose, time > 8 G, or combined score. A slight tendency appeared for the males to have a drop in score after 4 weeks of layoff. The lack of significant results is likely due to the small N-size, since the power of most of the tests was less than 0.4.

Self Induced G Dose

Figure 5 shows the results of the three-way ANOVA on G dose, that is the integral under the profile curve but above 3 G. The 3 G lower limit is necessary due to the non-linear relationship of the aero-model and the DES response below 3 G. These results show, again, that sleep status had no effect on the amount of G that the subjects commanded.

Effect of G on Physiologic Measurements

Regional cerebral oxygen saturation dropped throughout each sortie and the minimum value was typically (almost always) at the end of the profile. Examination of this minimum as a function of time spent at G is shown in Figure 6. Both linear regressions were significant with the slope being approximately twice as steep for the men.

The physiological measurements showed some statistically significant changes after layoff. Table 1 summarizes the effect of layoff on each of these variables. The most striking result is the lower peak pulse after 4 weeks of lay-off.

		Peak Pulse Rate	Post-G Pulse Rate	Min SaO2 (%)	Post SaO2 (%)	Min rSO2 (%)	Post rSO2 (%)
2-Week Layoff							
Male	Current	155	144	**88.7**	94.2	52.0	53.0
	Layoff	148	140	**90.5**	94.8	53.0	52.6
Female	Current	156	**144**	91.3	**94.4**	59.0	60.1
	Layoff	161	**126**	93.0	**96.7**	57.9	61.4
4-Week Layoff							
Male	Current	**153**	119	92.8	97.1	56.0	56.9
	Layoff	**123**	127	91.2	95.4	54.5	60.1
Female	Current	**144**	137	87.7	92.7	57.7	63.7
	Layoff	**123**	124	91.8	91.4	55.2	49.4

Table 1. Physiological Measures Compared Between Current and Laid-Off Conditions. **Bold** indicates statistically significant difference at $p \leq 0.05$

Results of Isometric Strength Testing

Upper body strength data for men and women for the rested pre-G and rested post-G were examined. Also, these same data for the strength values collected during the sleepless phase of the experiment both pre- and post-G. Statistical analysis of these data revealed no significant changes in any of the upper body strength conditions measured. Figure 4 illustrates male and female post-G sleepless lower body strength data which were not statistically different from rested pre-acceleration values.

One interesting subjective result from this study was the response of test subjects when asked if they had performed better or worse on the strength test after having been up for 24 hours and after having been exposed to high-G. Twelve of the fourteen subjects responded they had performed worse in the post-G sleepless condition. Quantitative strength data showed that subjects performed about the same or better in the post-G sleepless condition compared to the pre-G rested data.

5. DISCUSSION

The lack of effect on overall performance of 24 hours of sleeplessness is the primary result of the study and further analysis indicated several significant findings concerning the value of performance research conducted in conjunction with physiological tolerance measures.

The women in this study were willing to pull the G, as much as men, even spending significantly more time in the highest G ranges. One might expect a negative correlation between arterial saturation and time-at-high-G. Our data did not reflect this. Those who spent the extra time at the higher G were still able to keep oxygen saturation at levels comparable to those with less time at high G. This speaks well for the level of protection provided by COMBAT EDGE.

The lack of significant change in performance after a two or four week layoff is likely due to the small N-size, since the power of most of the tests was less than 0.4. The extended time- frame of this study and individual schedules of volunteer subjects makes it difficult to control, however subjective reports, anecdotal incidents, and preliminary adaptation results indicate that beyond two weeks of layoff workload is increased, and beyond four weeks layoff performance is decreased. In addition, this study showed a reduction in peak heart rate after a 4 week lay-off , suggesting that some physiological deconditioning has occurred.

Performance metrics must include situational awareness and complex decision making to be sufficiently sensitive to operational issues such as fatigue or layoff. Within this simulated sortie, the missile evasion task showed a significant sensitivity to fatigue.

6. CONCLUSIONS

Twenty four hours of sleeplessness had little or no effect on the basic psychometrics of pursuit tracking combined with discrimination-choice-reaction-time tasks in either gender. However, a complex task involving situational awareness of attitude, altitude, airspeed, and heading, both of self and of the enemy, was twice as likely to fail in the sleepless condition.

Though women demonstrated significantly less isometic strength, they were able to endure just as much G as the men. Neither gender showed a loss of physical strength due to G exposure or sleep deprivation.

Although none of the subjects were pilots, they all learned to fly an F-16 simulation closed loop on a human centrifuge and were able to command as much G as the F-16. This research found no dire effects regarding men and women performing complex cognitive tasks in the high G environment after the loss of a night's sleep.

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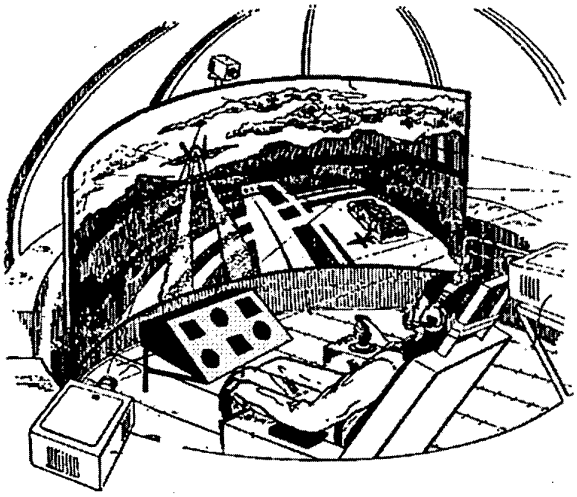


Figure 1. The Dynamic Environment Simulator Crewstation

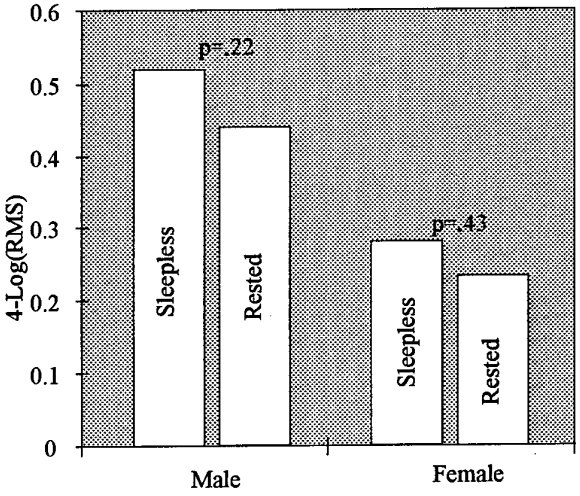


Figure 2. Tracking Performance not significantly affected by sleep status

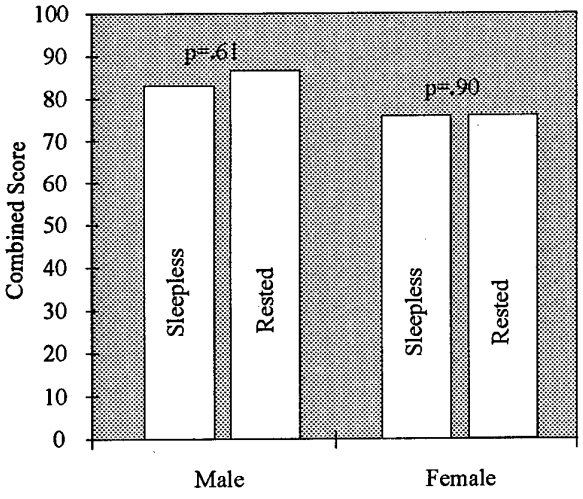


Figure 3. Combined Score was not significantly affected by sleep status

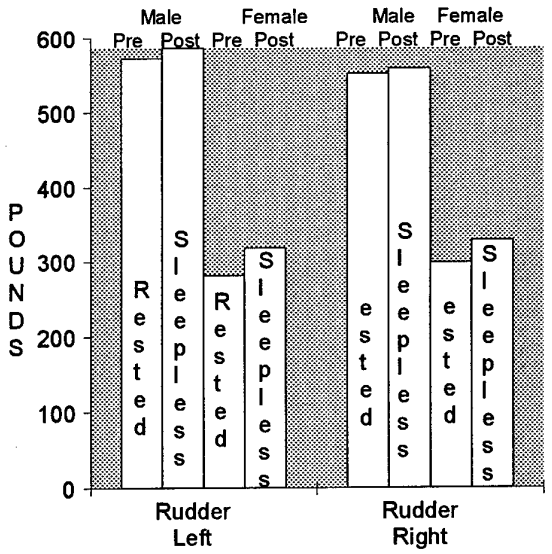


Fig. 4 Mean lower body strength men and women in both the rested and sleepless conditions

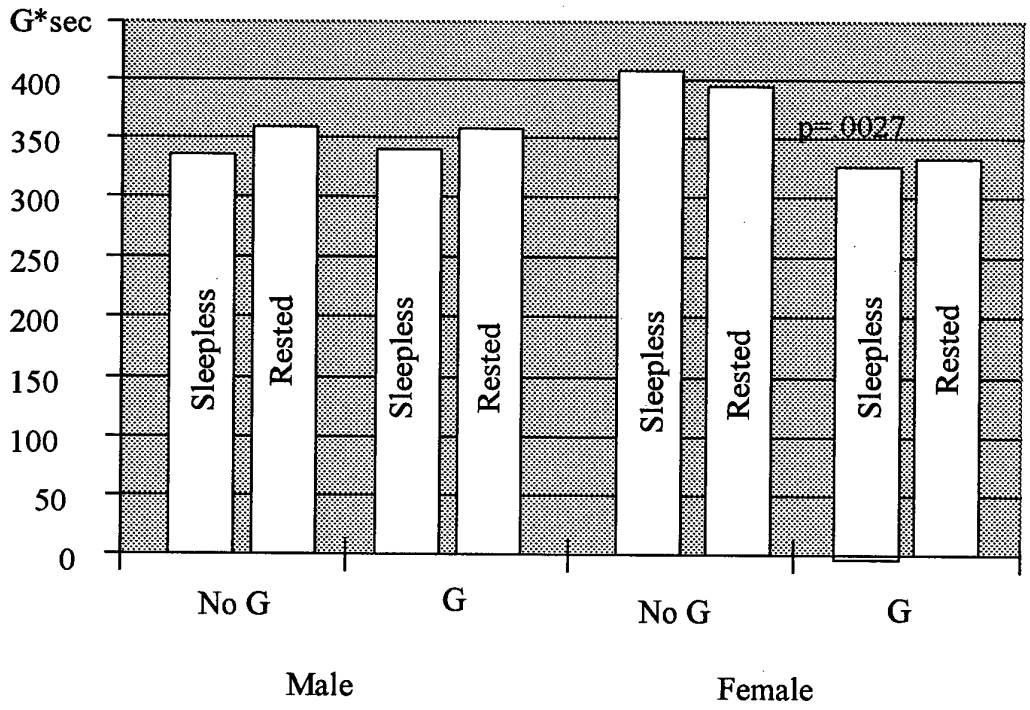


Figure 5. Three way analysis of G dose. Sleep deprivation had no effect on G dose.

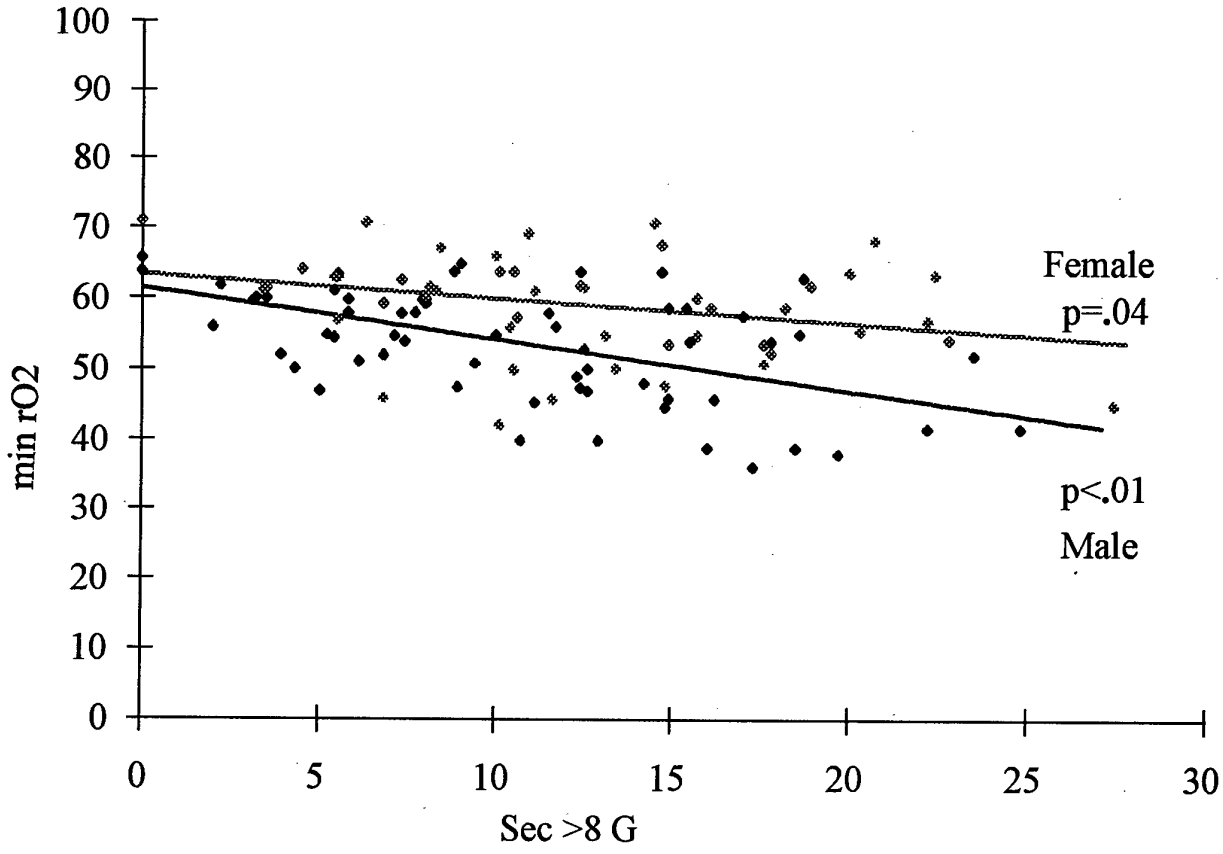


Fig 6. Oxygen desaturation compared to time spent above 8 G.

Discussion #1

CALDWELL, US: Dr Chelette, in terms of the effects of, or lack of effects of sleep, could you clarify the time of day of your testing and how long did the simulated mission take (in reference to Paper #4)?

CHELETTE, US: All tests were performed in the morning between 7 and 9 am. It was the first activity in the morning for the subjects after having been up all night. The testing took about a half-hour in the centrifuge.

CALDWELL, US: The reason I ask is that we often find that the interval between about 5 am and about 11 am represents some of the worst times for sleep deprived individuals if they've been up since 7 am the previous morning. We also find that the duration of that type of mission has a great effect too. Often, subjects at the beginning of the mission do just fine; later on, we see deterioration setting in. Perhaps, if your mission had been an hour in duration as opposed to 30 minutes, then the effects may have been more severe.

CHELETTE, US: In future studies, we may do experiments where the subject is not pulling G but is actively flying a simulator. However, we are really at the limit in what we can do in terms of G. Doing 3-minute sorties back-to-back like that is exhausting even in the rested condition, so that end point will determine how long a subject can perform in the centrifuge.

ALONSO-RODRIGUEZ, SP: If you had conducted the experiments without the assistance of positive pressure breathing (PBG), how would that have affected the end results, i.e., how much do you consider that PBG contributed to the results that you have presented?

CHELETTE, US: Because our F-15s and F-16s are deployed with PBG, the conditions in which we do our measurements employ the same protective system as the one in these aircraft. We did not conduct the experiments without using PBG. From previous comparisons though, I can say that PBG is a very important factor. We would not have been able to do the four sorties for 3 minutes with our volunteers without PBG. It certainly enhances their performance, so, perhaps, if you didn't have PBG, one would see a more dramatic effect of fatigue, I would guess.

BROOKS, CA: You mentioned that some of your subjects wrapped their arms about themselves; presumably, that was to reduce arm pain. How many subjects wrapped their arms, and what effect do you think that had on the experiment?

CHELETTE, US: Almost all subjects wrapped their arms; the few that may have chosen not to learned their lesson quickly. With these long term exposures to G on a centrifuge where there is a gradient of G, most people experienced arm pain if they did not wrap their arms about themselves.

WILLIAMS, UK: Your study was primarily an offensive 3000-foot, tail chase pursuit rather than a defensive manoeuvre from a missile. Is there any way to do the same study where the pilot is defensive in the 3000-foot range, whether in the "check-six" position trying to evade, or "out turn" an opponent under the same kind of conditions?

CHELETTE, US: Certainly it is possible to set up the simulator to do what you suggest. The difficulty is in maintaining a standardized G dose. We wanted all subjects to experience about the same G dose in all conditions and that's why we used the pursuit task. If subjects are free to fly whatever

Cockpit rest guidelines
In order to guarantee safety of the flight operations, in this study the following rules were applied with respect to the controlled rest on the flight deck:

1. Controlled rest is only permitted during cruise-flight in a low workload phase of flight
2. The duration of the rest period will not exceed 40 minutes
3. Planning should take into account individual needs
4. When planning, existing CRM-principles have to be followed
5. Only one crewmember is permitted to rest at a time, while the other pilot (and FE) maintains flight operations
6. The designated waking pilot should be adequately briefed prior to the rest period of the designated resting pilot. Prior to resuming flight duties, the rested crewmember should be briefed
7. The flight deck alarm clock should be set to a period of maximal 40 minutes
8. All rest periods should be terminated at least 1 hour prior to Top of Descent
9. The use of eye shades, neck supports, and ear plugs is permitted

Assessment methods
The use of methods which necessitate the presence of one or more investigators in the cockpit was avoided, because presence of investigators on the flight deck might alter the regular flow of cockpit conversation and interaction (5). Therefore, in this study only 'pilot-friendly', non-interfering, and cost-effective objective and subjective methods were used to assess the effects of a 40-minutes controlled rest period on alertness and performance of both the resting and the waking pilot. Specific measures were chosen to evaluate sleep, alertness, and performance.

Data on cockpit rest and sleep
With respect to the controlled rest period in the cockpit, pilots used a Psion-3a palmtop computer to log subjectively estimated duration of the rest period, sleep latency, total sleep time, and quality of sleep. The quality of sleep was scored on a 5-point rating scale (Nap Quality Scale: very good, rather good, neither good nor bad, rather poor, very poor). Objective data on cockpit rest was recorded using an actigraph device. Using the event button, subjects marked beginning and end of rest and sleep periods. In addition, the quality of sleep during the pre-trip night (at home) and the stopover night was assessed (results not presented in this paper).

Sleepiness/alertness
The Stanford Sleepiness Scale (8) was used to assess subjective alertness throughout the trip (Table 2). This subjective rating scale has proven to be sensitive in detecting any significant increase in sleepiness or fatigue. Furthermore SSS measures showed to be highly correlated with flying performance and threshold of information processing speed during periods of intense fatigue (9).

Performance
During long cruise-flights, pilots have to sustain attention and to maintain vigilance under relatively monotonous conditions. These capacities are particularly vulnerable to the effects of fatigue and sleepiness (9,10).

Table 2: Stanford Sleepiness Scale (SSS)

1. Feeling active and vital; alert; wide awake
2. Functioning at a high level, but not at peak; able to concentrate
3. Relaxed; awake; not at full alertness; responsive
4. A little foggy; not at peak; let down
5. Foggy; beginning to lose interest in remaining awake; slowed dow.
6. Sleepy; prefer to be lying down; fighting sleep; woozy
7. Almost in reverie; sleep onset soon; losing struggle to remain awake

Therefore in this study, emphasis was laid on the assessment of vigilance. The performance task used in this study (VigTrack; Fig.1) is a dual-task, which measures vigilance performance under the continuous load of a compensatory tracking task (11). This task was successfully applied in studies on the effects of irregular early reporting times on alertness of pilots in short-haul operations (12), sedative effects of antihistamines, and alcohol (13,14). The VigTrack probes two important aspects of the behavioural capability of aircrew, and is not a measure of overall operational performance. However, high levels of performance on the VigTrack require sustained attention for 5 minutes, while attention is distracted by the tracking task. To the extent that attention and adequate tracking are critical features of many tasks involved in the safe operation of aircraft, the VigTrack data provide information about operational readiness and vigilance.

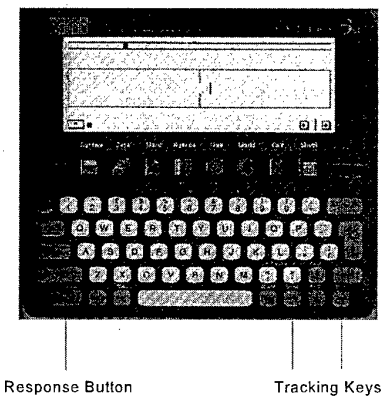


Fig. 1. Psion 3a: Vigilance and Tracking task (VigTrack)

Procedure and experimental design
A schematic overview of the procedure is presented in Table 3. Before the trip, pilots were instructed how to use the actigraph and the Psion-3a palmtop computer. They were trained on the performance task and briefed on the subjective rating procedures. Each pilot was equipped with his own actigraph and Psion-3a. Furthermore, it was decided which pilot was designated to have the controlled rest on the outbound flight and which on the inbound flight. Thus, during the two stretches of the trip, each of the pilots was once designated as 'resting pilot' and once as 'waking pilot'. During the outbound

flight, test sessions were performed just before and circa ¼ hour after the cockpit rest, and half an hour before top of descent. All sessions included SSS and VigTrack. In addition, in the 'post-rest' session the resting pilot had to rate quality of sleep during the rest period (NQS), while the waking pilot had to rate his sleepiness during this period ('Nap-SSS'). This rating was retrospective over the period in which the waking pilot had to maintain alertness while the resting pilot was resting. The test procedure during the inbound flight was identical to the procedure applied on outbound flights. Subjects had the opportunity to make written comments on non-standard flight circumstances and conditions that favoured or interfered with the quality of onboard rest (such as seat comfort, noise, cockpit visits). After their return at Amsterdam, actigraph and Psion-3a were collected and data were downloaded in a database.

Table 3. Overview of test procedure. SSS: Stanford Sleepiness Scale; VigTrack: vigilance and tracking task; NQS: Nap Quality Scale; Nap-SSS: SSS rating retrospective over rest period; rp = resting pilot, wp = waking pilot.

Before Trip	instruction and training on task
Outbound	
Pre-Rest	flight data / SSS / VigTrack
Post-Rest	NQS (rp) / Nap-SSS (wp) / SSS / VigTrack
Top of Descent	SSS / VigTrack
Inbound	
Pre-Rest	flight data / SSS / VigTrack
Post-Rest	NQS (rp) / Nap-SSS (wp) / SSS / VigTrack
Top of Descent	SSS / VigTrack

RESULTS

Timing of the controlled rest period

Subjects were free as to when the nap was planned during cruise-flight. The mean time period between take-off and the start of the nap was 04:16 hr (±00:54) on outbound flights, which is approximately after 53% of the total flight time. Inbound cockpit rest was planned 03:52 hr (±00:55) after take-off, which is after 55% of the total flight time.

No significant correlations could be demonstrated between the timing of the cockpit rest and parameters of sleep during the controlled rest period (NQS scores, sleep latency, total sleep time, and sleep efficiency).

Sleep during controlled rest on the flight deck

As appeared from the comments of the pilots, 18% of them complained about shortcomings of the cockpit seat, such as lack of leg space and limited recline, and explicitly mentioned the lack of a head rest on the seat as the reason for not being able to make optimum use of the controlled rest opportunity. Other comments were interference of rest by noise, turbulence, and cockpit visits by cabin crew. On outbound flights 48% and on inbound flights 41% of the pilots did not sleep at all during the controlled rest period. Characteristics of those pilots, who subjectively had any amount of sleep during the 40-minutes rest period are presented in Table 4.

No significant differences in nap sleep variables were found between outbound and inbound flights and no significant correlations could be demonstrated between subjective and actigraphy measures. On outbound flights 27% of the pilots rated the quality of sleep as rather good and 42% as rather poor or very poor. On inbound flights 18% rated quality as very good or rather good and 38% as rather poor or very poor.

Table 4. Characteristics of sleep during controlled rest on the flight deck: total rest time (TRT), sleep latency, total sleep time (TST), sleep efficiency, and sleep quality (NQS) as estimated by subjects and measured by actigraphy on outbound and inbound flights. Scores are presented as means (±SD).

	TRT (min)	**latency** (min)	**TST** (min)	**efficiency** (%)	**NQS**
OUTBOUND ✈					
subjective	37 (4.3)	12 (7.8)	19 (10.6)	51 (25.7)	3.0 (0.9)
actigraphy	39 (5.6)	3 (2.3)	16 (13.7)	69 (14.5)	
INBOUND ✈					
subjective	38 (5.0)	13 (7.4)	19 (9.3)	49 (21.3)	2.8 (0.8)
actigraphy	42 (7.5)	9 (12.4)	14 (12.7)	56 (20.6)	

Effects of cockpit rest

To assess the effects of the controlled rest on the flight deck, scores of the pre-rest session were used as reference values. Difference-scores were computed between post- and pre-rest scores. These scores represent the effect of the nap on alertness and performance as measured a ¼ hour after the rest period. To assess whether a controlled rest on the flight deck had beneficial effects on performance associated with critical phases of flight (approach and landing), also difference-scores between top of descent and pre-rest scores were computed. Mean difference-scores on sleepiness (ΔSSS), vigilance (Δ%omissions), and tracking (ΔRMS) are presented in Figs. 2, 3 and 4. On outbound flights, no significant difference in the post-rest ΔSSS (Fig. 2) scores was found between resting pilots and waking pilots, while at top of descent the difference was significant ($U=151$, $p<.001$): sleepiness in resting pilots had decreased, while sleepiness in waking pilots had slightly increased. On inbound flights, the difference in ΔSSS scores between the two groups was significant both at post-rest ($U=249$, $p<.05$) and top of descent ($U=139$, $p<.001$): sleepiness in resting pilots was not affected (post-rest) or had decreased (top of descent), while sleepiness in waking pilots had increased.

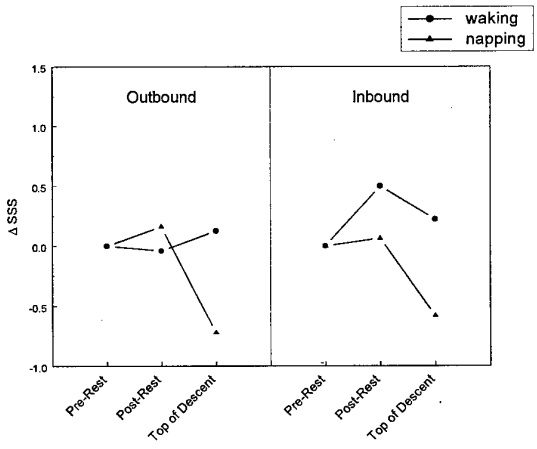


Fig. 2. Mean difference scores on sleepiness (ΔSSS) of resting and waking pilots for outbound and inbound flights.

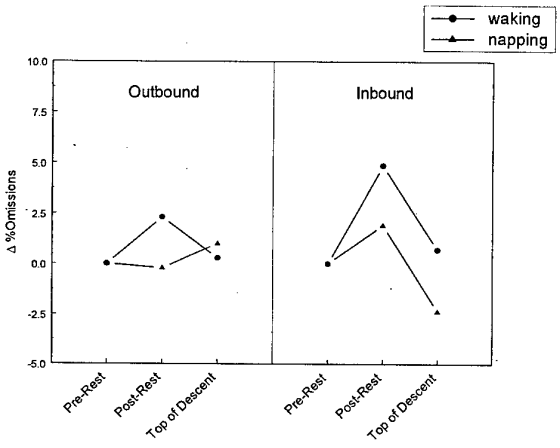


Fig. 3. Mean difference scores on vigilance (Δ %omissions) of resting and waking pilots for outbound and inbound flights.

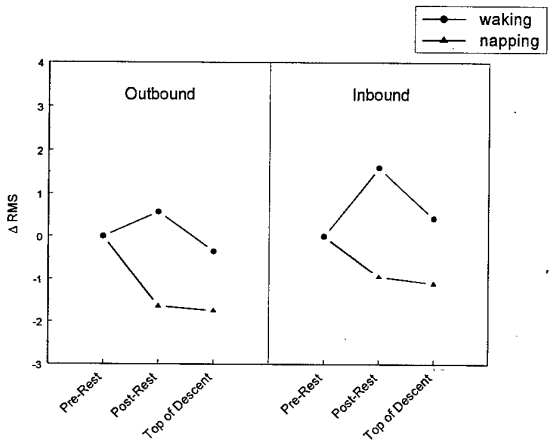


Fig. 4. Mean difference scores on tracking (ΔRMS) of resting and waking pilots for outbound and inbound flights.

Although resting pilots showed an overall better vigilance performance, no statistically significant differences were found (Fig. 3: Δ%omissions). Post-rest difference scores on tracking performance (Fig. 4: ΔRMS) showed significant differences between resting and waking pilots both on outbound ($F(1,47)=4.97$, $p<.031$) and inbound flights ($F(1,55)=7.97$, $p<.007$): resting pilots showed improved tracking performance after the rest, while performance of waking pilots had impaired. At top of descent, differences found were statistically not significant, although performance of resting pilots showed improvement while tracking performance of waking pilots remained on reference level.

To assess the effects of sleep per se, the resting pilots group was divided into two subgroups: sleepers (any amount of subjective sleep) and non-sleepers (no subjective sleep). Sleepers showed significantly lower sleepiness scores after the cockpit rest (inbound: $U=88$, $p<.01$) and at top of descent (out- and inbound: $U=40.5$ and 82.5 respectively, $p<.05$). Furthermore, it was observed that longer sleep duration resulted in lower sleepiness levels at top of descent ($r=-.59$, $p<.05$). No significant differences in performance between the two subgroups were observed.

Alertness of the waking pilot

During the period that his colleague was resting, the alertness of the waking pilot was assessed by means of a retrospective SSS rating (Nap-SSS); viz. at termination of the rest period the waking pilot was asked to rate his sleepiness during this preceding period. When comparing mean Nap-SSS scores with pre-rest, post-rest, and top of descent SSS scores, it was found that Nap-SSS scores were slightly higher (ns) on both outbound and inbound flights (outbound: 2.5, SD=±.96; inbound: 2.9, SD=±1.55.).The frequency distribution of Nap-SSS scores for outbound and inbound flights is presented in Fig. 5.

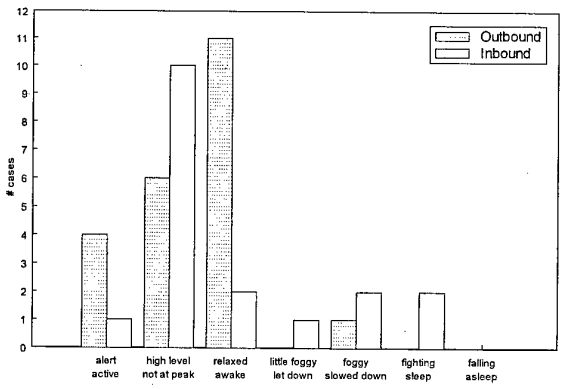


Fig. 5. Frequency distribution of Nap-SSS ratings for outbound and inbound flights.

On outbound flights 1 pilot was identified with a Nap-SSS score of 5 (foggy, slowed down) and on inbound flights there were 2 pilots who rated 5, and 2 pilots rated 6 (fighting sleep). Nap-SSS scores were significantly correlated with the quality and efficiency of the pre-trip and stopover sleep (with quality scores: $r=.27$, $p<.05$; with efficiency: $r=-.49$, $p<.05$). This indicates that good pre-trip sleep quality and efficiency are associated with less sleepiness (higher alertness) during the rest period. Furthermore, pre-rest sleepiness scores showed significant correlation with sleepiness of waking pilots during the rest period ($r=.58$, $p<.001$). On outbound flights, pre-flight and pre-rest tracking performance (RMS) was significantly correlated with Nap-SSS scores ($r=.46$, $p<.05$ and $r=.50$, $p<.05$ respectively). There was no relationship between the timing of the controlled rest period and the Nap-SSS scores.

CONCLUSIONS

1. A controlled rest period in the cockpit is a useful countermeasure for the effects of fatigue and sleepiness, as experienced by a majority of pilots engaged in long-haul flying. A 40-minutes rest period provides improvement in alertness and performance up to top of descent.

2. A substantial number of resting pilots did not sleep during their rest period. Pilots who slept showed more improvement of alertness and performance after the nap and before top of descent, than pilots who did not sleep during their rest period.

3. A number of pilots had difficulties in maintaining alertness during the rest period of their colleague pilot. Higher levels of sleepiness of the waking pilot during the rest period were associated with lower quality and efficiency of pre-flight sleep, lower pre-flight and pre-rest performance levels, and higher pre-rest sleepiness.

4. Data on total sleep time, quality and efficiency of pre-flight sleep, pre-flight and pre-rest performance, and pre-rest sleepiness are useful to predict the designated waking pilot's capacity to maintain a sufficient level of alertness during the controlled rest period.

OPERATIONAL ISSUES

Measures to improve sleep opportunities of the resting pilot

Pilots who slept showed more improvement of alertness and performance after the nap and before top of descent, than pilots who did not sleep during their rest period. Therefore, sleep opportunities should be optimized. The pilots in this study indicated, that measures which improve the comfort of the cockpit seat, such as fitting a head rest and improving reclination will lead to better opportunities for sleep during the rest period. Furthermore, disturbance of sleep due to noise should be limited by instructing cabin crew to carry out the necessary cockpit visits during the rest period as silently as possible, and by wearing suitable ear plugs. Designated resting pilots should avoid coffee before the rest period. Moreover, ample time should be taken for pre-rest briefings. Only a complete briefing will give a resting pilot the opportunity to 'reset' his mind and to get mentally 'ready for sleep'.

Measures to improve alertness of the waking pilot

It can be assumed that both pilots equally benefit from the preventive effects of a cockpit nap. In the context of maintaining optimal alertness in designated waking pilots, it should be emphasized that cockpit rest periods should be preplanned. Planning of rest periods at times, when maximal sleepiness of both pilots is anticipated, should be avoided. The sequence of rest periods should be determined by the needs of both pilots. The most fatigued pilot should use the first rest opportunity, to be taken at a time when the waking pilot will still be able to maintain his alertness on a sufficient level. After this rest period, the rested pilot will be better prepared, in terms of alertness and performance, for the next controlled rest period in which he will be designated as waking pilot.
The results of this study indicate that high quality and efficiency of pre-flight sleep will lead to higher levels of alertness in waking pilots. Therefore, optimal pre-flight sleep of sufficient duration (>8 hrs) should be pursued.
Further improvement of the ability to maintain sufficient levels of alertness during night flights can be achieved by increasing the level of illumination in the cockpit, while the resting pilot (using eye shades) is having a nap (15,16). In addition, coffee could be used to optimize alertness of the waking pilot (17).

Monitoring alertness of the waking pilot

An insufficient level of alertness of the designated waking pilot should be identified before the controlled rest period starts. This is important, because even if an effective cockpit alarming system would exist (which is at present not the case; 18), it would be hazardous to allow a pilot, whose alertness is insufficient, to be the only pilot to monitor the aircraft systems. When a pilot with degraded alertness, is designated as the waking pilot during the controlled rest period, he might still be able to satisfy a cockpit alarming system, while neglecting relevant tasks (18).
To identify the level of alertness/fitness before flights and before acting as the waking pilot during planned rest periods, it is recommended to use a 'Fit-to-Fly Checklist', which will be designed in analogy with the 'CFIT Checklist' of the Flight Safety Foundation (19). At present, most cockpit crew uses 'common sense' and CRM principles when planning a (unofficially tolerated) rest period during cruise flight. In most cases this 'common sense' will lead to a justified decision. However, the 'Fit-to-Fly Checklist' can provide a systematic and protocolized method to the process of decision making. Particularly in 'borderline' cases this method will be a useful tool for the flight deck crew. It is common practice that pilots have to check their flight systems at regular intervals, and it is remarkable that no mandate exists on checking personal fitness at regular intervals during a trip. For this purpose the 'Fit-to-Fly Checklist' will be developed.

ACKNOWLEDGEMENTS

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Early Starts: Effects on Sleep, Alertness, and Vigilance

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SUMMARY

Early starts and irregular work schedules might lead to disruption of sleep-wake rhythms with consequent sleep loss and fatigue. Fatigue is known to be a contributing factor to operational errors. The aim of this study was to determine the effects of early reporting times and irregular duty schedules on sleep, alertness and performance of pilots flying short-haul operations. *Method*: 6 Captains flying short-haul charters were measured during two 4-week periods. Subjects were equipped with a palmtop computer and an actigraph for subjective and objective measurement of sleep parameters, alertness, and performance on a vigilance dual-task. Each day subjects had to perform measurements before, during, and after flights and before and after the main sleep period. *Results*: It was found that pilots reporting before 06:00 a.m. had a significant shorter total sleep time, impaired sleep quality, and impaired performance both pre-flight and at top of descent. To a lesser degree, this also applied for reporting between 06:00 and 09:00 a.m. Degradation of sleep was most significant during the night prior to the start of a new duty period. *Conclusion*: Performance was primarily affected by inadequate sleep related to reporting times before 06:00 a.m. It is recommended that reporting times before 06:00 a.m. should be avoided, whenever possible. Pilots who have to report early, should try to anticipate insufficient sleep by advancing their sleep phase. This can only be achieved when early starts are planned on a regular basis. When irregular early starts are unavoidable, it should be considered to compensate for sleep reduction by planning sufficient time for recovery sleep.

1 INTRODUCTION

Due to increasing congestion of the European airspace and maximal utilization of aircraft, pilots of European short-haul charter operations are confronted with irregular shift work and early starts. Early morning starts require pilots to go to bed in the early evening, when their biological clock is not ready for sleep. This might lead to reduction of total sleep time and quality of sleep. Although pilots engaged in short-haul operations can be considered as shift workers, their schedules are often more irregular than those of shift workers in other industries. Irregularity may hinder habituation of the internal biological rhythm, and therefore problems in short-haul pilots might be more complicated than in regular shift workers. In regular shift work, it was evidenced that performance decrements were more frequent during the night shift, than during the morning shift (1).

In the case of short-haul pilots, sleep-wake rhythms will be disrupted with consequent sleep loss and fatigue. Fatigue and sleepiness are recognized as contributing factors to operational errors and aircraft accidents (2,3,4,5). Pre-dawn operations between 3:00 and 6:00 a.m. require pilots to perform in a period when their circadian rhythm dictates sleep and alertness is minimal (6). Sleep loss exacerbates this situation by increasing the level of sleepiness (7).

Few field studies have addressed the effects of irregular early starts in short-haul operations. Studies by Gander & Graeber (8), James, Green & Belyavin (9), Kecklund, Åkerstedt & Lowden (10) provided evidence for sleep restriction in aircrew of short-haul commercial operations. Experiments on the effects of sleep restriction on the quality of sleep have consistently shown reductions in stage 2 and REM sleep (11,12,13). However, the results of experiments on the effects of sleep restriction on performance and daytime sleepiness are less clear. Performance on prolonged vigilance tasks seems to be more adversely affected by sleep reduction than other types of performance (11,14,15). In the context of flight duty time limitations and rest requirements, knowledge of the relationships between sleep, alertness, and performance in short-haul operations is of great importance. Therefore, the present study was designed to assess the effects of early reporting times on sleep, alertness, and vigilance of pilots engaged in short-haul charter operations.

2 METHOD

As measurements of subjects during a single flight will not produce data that are representative for the average workload of short-haul pilots, it was decided to measure each subject continuously during two periods of four weeks (8 weeks total). The use of methods which necessitate the presence of one or more investigators in the cockpit was avoided, because this precludes a regular flight operation (7). Therefore, in this study only 'pilot-friendly', non-interfering, and cost-effective objective and subjective methods were used, which did not necessitate the presence of an investigator onboard the aircraft.

Subjects

Participants of the study included 6 experienced captains (5 male, 1 female) flying short-haul charters within their regular duty rosters. Mean age was 36.6 years (range 31-47), mean flying experience 10.2 years (5-24), and mean total flight hours was 8336 hrs (range 3900-14.500). All participants considered themselves as good sleepers while at home. Subjects lived within 1 hour travelling time to the home base crew centre.

Assessment methods

Subjective and objective measures were used to determine the effects of short-haul operations during two 4-week periods on quantity and quality of sleep, alertness and performance. An actigraph device was used to record objective data during sleep at home and during

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stopover nights. Subjective and performance data were collected using a Psion-3a palmtop computer (Fig. 1). Each pilot was equipped with a personal actigraph and Psion-3a and all tests were self-administered.

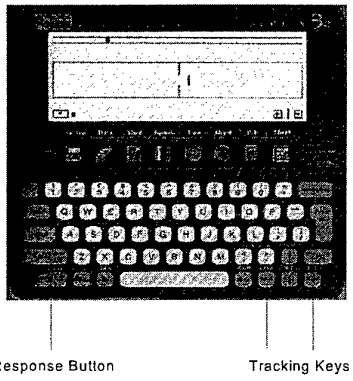


Fig. 1. Psion 3a: Vigilance and Tracking task (VigTrack)

The computer program (16) was menu driven and consisted of 4 main modules:

Sleep module
The sleep module consisted of a questionnaire including questions on sleep at home. Subjects had to record bedtime, latency, wake-up time, get up time, the subjectively estimated sleep length, and the use of sleeping aids. The quality of sleep at home and during stopovers was assessed by means of the Groningen Sleep Quality Scale (17). This scale has been used in a variety of studies on sleep disturbances among Dutch airline pilots (15, 18, 19). GSQS scores range from 0-14; higher scores indicate poorer sleep quality.

Alertness module
The Stanford Sleepiness Scale (20) was used to assess subjective alertness while at home/hotel or during flight operations. This subjective rating scale has proven to be sensitive in detecting any significant increase in sleepiness or fatigue. SSS measures showed to be highly correlated with flying performance and threshold of information processing speed during periods of intense fatigue (21). SSS scores range from 1-7. Higher scores indicate higher levels of sleepiness, equating lower levels of alertness.

Vigilance module
Fig. 1 shows the VigTrack task (16), which was used to measure vigilance performance while at home/hotel or during flights. This dual-task measures vigilance performance under the continuous load of a compensatory tracking task and was applied in studies on sedative effects of antihistamines, and alcohol (22, 23), and effects of cockpit naps (24). The duration of this test was 5 min. and performance measures included root mean square tracking error (RMS) and percentage omissions.

In-flight module
This module consisted of questions about napping strategies related to flight operation. Furthermore relevant flight data were stored.

Experimental design
During two 4-week periods, subjects were studied continuously under both rest and working conditions. Each day, subjects had to perform a test session after waking up and at bedtime. The wake-up test session consisted of the abovementioned sleep, alertness, and vigilance module. The bedtime test session included questions about napping, and the alertness and vigilance module. Wake-up and bedtime test sessions were classified into 4 different categories depending on duty status, 1) day off, 2) start duty period, 3) during duty period, and 4) end duty period. Furthermore a distinction was made between nights at home and during stopovers (hotel). During flight operation, subjects had to perform a test session just before top of descent. This in-flight test session consisted of the alertness, and vigilance module.

Statistical analyses
All variables were analysed using descriptive techniques. Those variables that were considered to be interesting for further analysis were tested using separate applications of a one-way analysis of variance (ANOVA). Post-hoc analyses (Duncan) were performed for comparison between the means of the different experimental conditions. Subjective ratings were analysed using non-parametric techniques (Wilcoxon Matched Pairs Signed-Ranks, Mann-Whitney U). Relationships between different variables and methods were investigated by using correlational computations (Pearson product-moment correlation coefficients or Spearman Rank correlational coefficients).

3 RESULTS

Sleep quantity and quality
Significant differences between the different duty status categories were found for bedtime ($F(3,254)=14.12$, $p<.001$), wake-up time ($F(3,254)=18.35$, $p<.001$), and total sleep time ($F(3,253)$, $p<.0001$). With respect to sleep, it was found that pilots slept 1-1½ hour shorter when on duty or starting a duty period, as compared to off-duty periods. It was demonstrated that pilots switching from a rest period (days off) to a duty period, experienced a significant shortage of total sleep time, increased sleep latency, and impaired sleep quality.

Alertness
Pilots were most alert at top of descent and most drowsy before going to bed. During and at the end of the duty periods pilots were significantly more drowsy at bedtime as compared to off-duty periods. Moreover, after waking up, pilots on duty felt more sleepy and less alert, as compared to waking up sessions during the off-duty periods ($F(2,752)=256.18$, $p<.001$).

Performance
Effects of fatigue on performance were most clearly demonstrated by the tracking component of the VigTrack task. Tracking performance was 10-15% better during the wake-up session, as compared to in-flight and bedtime values ($F(2,745)=8.32$, $p<.001$). Tracking per-

formance was worst at bedtime at the end of duty periods. Pilots tended to have a higher percentage of omitted targets on the vigilance component of this task after waking up as compared to bedtime values. This effect (5%) was primarily caused by the difference between wake-up and bedtime values at the start of, and during the duty period.

Duty schedules

During duty periods pilots had an average of 9 hours duty time and 6 hours flight time per day. Duty periods lasted 4 consecutive days on average. Pilots reported 1 hr prior to the scheduled start of the flights. It was found that reporting time was of major influence on total sleep time, sleep quality, alertness, and performance. The earlier pilots had to report, the shorter they slept, and the more sleep quality, alertness, and performance were impaired (Table 1).

Table 1: Correlation coefficients between reporting time, flight time, duty time, and total sleep time (TST), sleep quality (GSQS score), alertness (SSS score), and performance measures (VigTrack: tracking and % omissions).

	reporting time	flight time	duty time
TST	.441***		
GSQS	-.367***		
SSS	-.198*	-.009	.048
tracking	-.243**	-.034	.036
% omissions	-.228*	-.205*	-.173

*: p<.05; **: p<.01; ***: p<.001

Taking into consideration the frequency distribution of reporting times, data were analysed using 4 categories, depending on reporting time:

Group 1 (32 cases): reporting before 06:00 hrs
Group 2 (24 cases): between 06:00 and 09:00 hrs
Group 3 (21 cases): between 09:00 and 15:00 hrs
Group 4 (35 cases): after 15:00 hrs.

Effects of reporting time on sleep, alertness, and performance

Effects of reporting time on sleep are presented in Table 2. Significant differences between reporting time groups were found for bedtime ($F(3,111)=32.95$, $p<.0001$), sleep latency ($F(3,111)=5.63$, $p<.001$), total sleep time ($F(3,104)=18.25$, $p<.0001$), and sleep quality ($F(3,111)=7.68$, $p<.001$).

Pilots who had to report before 09:00 hrs (groups 1 and 2) went significantly earlier to bed as compared to those who had to report later (groups 3 and 4). Reporting before 06:00 hrs resulted in a significant longer sleep latency and significant shorter total sleep time as compared to later reporting times.
Furthermore, group 2 showed significantly shorter total sleep time as compared to groups 3 and 4. GSQS scores in groups 1 and 2 were significantly higher as compared to groups 3 and 4, indicating impaired sleep quality.

Pre-flight sleepiness was significantly higher in the group who had to report before 06:00 am ($p<.05$). As compared to the before 06:00 and 06:00-09:00 group, at top of descent levels of sleepiness were significantly higher in the group who reported after 15:00 ($p<.05$). This might be explained by the fact that most pilots in that group performed their top of descent tests in the late evening or during the night (late arrivals).

Effects of reporting time on vigilance performance during pre-flight and top of descent sessions, are presented in Fig. 2 (%omissions), and Fig. 3 (RMS tracking).

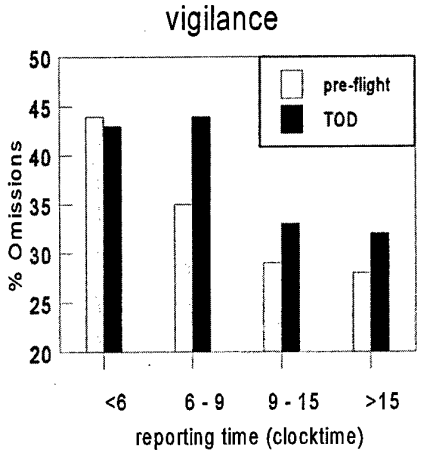


Fig. 2. Vigilance performance of the different reporting time groups: means of %omissions at 1 hr before reporting (pre-flight) and prior to top of descent (TOD).

Table 2: Bedtime, latency, total sleep time as measured by actigraphy, and sleep quality scores (GSQS) for the 4 different reporting time categories. Data are presented as means (±SD).

	Group 1 before 06:00	Group 2 06:00 - 09:00	Group 3 09:00 - 15:00	Group 4 after 15:00
Bedtime (local)	21:50 (00:55)	22:38 (01:12)	00:45 (01:50)	01:35 (02:21)
Latency	00:38 (00:33)	00:24 (00:22)	00:17 (00:17)	00:17 (00:17)
Total sleep time	05:09 (01:01)	05:52 (01:15)	07:06 (01:27)	07:11 (01:12)
Sleep quality score	6.1 (4.0)	5.0 (3.6)	2.2 (2.9)	2.7 (3.3)

As is shown in Fig. 2, reporting before 06:00 was associated with significant impaired vigilance performance (%omissions) pre-flight ($p<.05$) and at top of descent ($p<.05$). At top of descent, the same effect was found for the group that reported between 06:00 and 09:00 ($p<.05$).

In Fig. 3, it is shown that pre-flight and top of descent tracking performance (RMS) was significantly impaired in the group reporting before 06:00, as compared to the groups reporting between 09:00 and 15:00, and after 15:00 (pre-flight: $p<.05$, top of descent: $p<.05$).

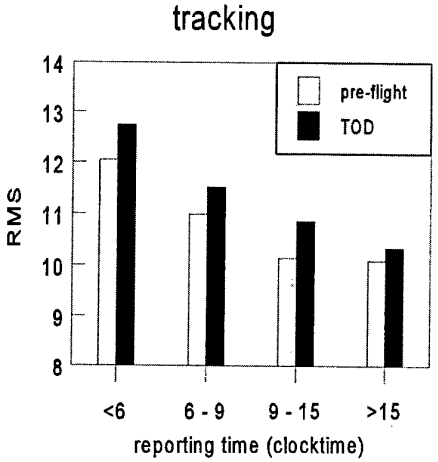


Fig. 3. Tracking performance of the different reporting time groups: means of RMS of tracking error at 1 hr before reporting (pre-flight) and prior to top of descent (TOD).

4 DISCUSSION AND CONCLUSIONS

It was found that reporting time was of major influence on total sleep time, sleep quality, alertness, and performance. The earlier pilots had to report, the shorter they slept, and the more sleep quality, daytime alertness, and performance were impaired. These effects were most significant when pilots had to report before six o'clock in the morning, but could also be demonstrated when they had to report between six and nine o'clock a.m. Reporting before 06:00 a.m. was associated with significant decreased total sleep time, sleep quality, decreased daytime alertness, and impaired performance. This impairment of performance was equally demonstrable during pre-flight and top of descent sessions. The degrading effects on pre-flight performance and performance at top of descent are of particular concern to flight safety. In this context, the results of the present study indicate that irregular early starts may have harmful effects on performance during critical phases of flight, such as take-off, approach, and landing.

The findings of the present study are in agreement with literature indicating that adverse effects of acute or chronic sleep reduction on subjective and performance measures might be expected when sleep is restricted to less than about 6 hours/day (11, 13).

In a healthy Dutch population, average sleep quality (GSQS) scores range between 1 and 3 (17). While literature generally emphasizes transmeridian operations as a major factor to cause sleep disturbances in aircrew (average sleep quality score: 5.4; (18)), the present study demonstrates that irregular early reporting times are at least as important in causing impaired sleep quality (average sleep quality score in the present study: 6.1).

Reduction of total sleep time and impairment of sleep quality were most significant during the night prior to the start of a new duty cycle. After an off-duty period, most pilots had to report early on the first duty day. They anticipated early rising by going to bed earlier than they were used to. This resulted in significantly longer sleep latencies, shorter total sleep times, and impaired sleep quality in the first night prior to a new duty period.

Although, daytime alertness was significantly affected by reduced sleep, most pilots appeared to compensate these negative effects, and showed to be able to maintain an adequate level of alertness during flight. However, frequent reduction of sleep might lead to a cumulative sleep debt, which pilots may no longer be able to compensate. This situation may lead to unacceptable levels of alertness and performance. Alertness and performance might be further degraded by pre-dawn reporting times between 03:00 and 06:00 a.m., which require pilots to perform in a period when their sleepiness is maximal. Sleep loss exacerbates this situation by increasing the overall level of sleepiness. Ideally, very early starts should be avoided. However, the present situation in the airline industry or demanding military missions will necessitate scheduling of early starts in a substantial number of cases. Pilots who have to report early, should try to anticipate insufficient sleep by advancing their sleep phase. This can only be achieved when early reporting times are planned on a regular basis. Thus, it is important to reduce irregularity whenever possible, in order to enable pilots to adapt to a regular work-rest pattern, which may consequently lead to prevention of sleep loss. In the case circumstances do not allow regular scheduling, it should be considered to compensate for sleep debt by planning sufficient time for recuperative sleep. In this context flight and duty time limitations and rest requirements should be evaluated. Implementation of new guidelines should include follow-up research to evaluate effects on sleep, performance, and alertness. The assessment methods applied in this study have proven their feasibility, practical relevance, and cost-effectiveness, and should be included in follow-up research.

5 ACKNOWLEDGEMENTS

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Discussion #2

COMPERATORE, US: Dr Valk, how did you determine sleep onset using actigraphy? Did you do a correlation study with electro-encephalography (EEG)? Generally, actigraphy is somewhat difficult to use for determining sleep onset time because of its ability for error.

VALK, NE: The problem with actigraphy is that it is not a good measure for assessing sleep onset during short sleep. That is especially true for assessing sleep onset during napping as you only have about 40 minutes of data available. We tried to use several other rhythms to define sleep onset and correlate them with our subjective data. We found, in other studies, that there is no relationship between actigraphy data and subjective measures in very short sleep or disturbed sleep.

SIMONS, NE: Other than that, actigraphs were helpful. The main item, the event button, was used when subjects started the rest period and, again, at the end of the rest period. In this way, we were always able to determine when subjects were supposed to sleep. But we didn't use it for assessing sleep quality or sleep duration.

COMPERATORE, US: Could you tell which of your participants were actually sleeping deeper than others, particularly since sleep prior to the flight was not controlled? You might have had some subjects having only 5 to 6 hours of sleep and they might have gone into stage four, or, perhaps, deeper sleep than others. That may have affected performance. I realize that you can't tell that with actigraphy but I wonder if you were concerned with that or not?

VALK, NE: We are concerned about that but in the study that I mentioned, we measured EEG only during flight, not during stop overnight at a hotel. Our problem is that we have only a limited amount of money, and putting EEG in as a measure in the design can be very costly.

COMPERATORE, US: I agree with you.

VALK, NE: We also saw, for instance, that Rosekind (see Reference in Papers 5 and 6) measured EEG during his nap study, and during the 40-minutes of sleep didn't find stage four sleep too often. Moreover, our subjects were rested quite well; on average, they had seven and one-half hours of sleep of rather good quality on stopover.

COMPERATORE, US: Dr Simons, I noticed that the performance in RMS tracking of those subjects who reported for work after 1500 hrs was better than it was for the ones who reported early in the morning, before six. Did I see it correctly that the subjective evaluation of sleepiness, in fact, is reversed in terms of that relationship; i.e., the performance of the 1500-hour group is better, but they feel more tired at the end than does the before-six group.

SIMONS, NE: Yes, that is correct. Most scores were taken late at night or in the early hours in the morning before landing the aircraft, but, then again, when there is a good correlation between subjective and objective performance, one should find a worse performance. However, we didn't so although overall the correlation between the objective performance measures and the subjective sleep ratings were significant, we had a lot of cases where the correlation, though significant, was rather low.

VALK, NE: Furthermore, what you saw were the measurements at the top of the aircraft's descent. We have already mentioned that the subjective ratings are based on the pilots rating the scores as being desirable, so they have to be fit when they land the aircraft. If you look at the scores when pilots go to bed at night, in all studies,

we see a very good relationship between performance measures and very sleepy or fatigued pilots.

COMPERATORE, US: I really appreciate the operational relevance of your study in considering both the countermeasures and approach to the design. This is difficult to accomplish but you are taking into account wakefulness, reporting time and all the factors that are sometimes ignored in the laboratory.

DOIREAU, FR: Dr Valk, do these pilots readily accept the napping strategy, especially when they are aware of the deleterious effects of sleep inertia in the flight deck in case of emergency, for example?

VALK, NE: It's very individually determined; some pilots believe that napping is required to become well rested for performing better at the end of the flight. On the other hand, some individuals are concerned about sleep inertia. We don't know if there is sleep inertia if pilots have slept too long, slept too short or didn't sleep that well. We are well aware of defective sleep inertia; therefore, we have introduced a nap period that is terminated within an hour of Top of Descent. We think pilots waking up from controlled rest on the flight deck need some time to refresh themselves so that they are fit to take over the flight operation again.

DOIREAU, FR: Is there any conflict between this napping strategy and official company policy? Some companies will allow rest but not sleep on the flight deck.

VALK, NE: We were able to do the experiment within our regulations in The Netherlands. What is not allowed yet is to introduce controlled rest legally on the flight deck. Pilots are doing it already, so we suggested a procedure for controlling it. We particularized it so that one can say when the nap should occur during the flight. This has to be done before commencing to fly the aircraft, and not when flying the aircraft and the pilots are both tired and are falling asleep, and saying: "Oh, oh, I'm so tired, I need a nap".

Bases neurologiques de la gestion pharmacologique de l'éveil

Neurobiological Basis of the Pharmacological Management of Sustained Alertness
(Résumé/Abstract)

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Since waking and sleep are regulated by two distinct systems, there are two different methods to increase the duration of waking, either by stimulating the waking systems or by inhibiting sleep-inducing mechanisms.

Some advances in the understanding of the mechanisms of drugs acting upon the nervous system have been recently obtained by the development of immunohistochemistry of early genes. Among them, the immunohistochemistry of CFos protein is a good index of the neural systems which are activated after injection of drugs in animals. these data will be summarized together with the study of sleep which occurs after sustained wakefulness.

a) Drugs which stimulate the waking systems (amphetamine - methylphenidate, caffeine).

The sustained alertness which follows injection of these drugs in animals is always followed by a compensatory rebound of both Slow Wave Sleep and Paradoxical Sleep. There is a common aspect in the topography of CFos-containing neurons after injection of these drugs, i.e., the targets of dopaminergic systems (striatum, limbic cortex) are strongly CFos positive. It is likely that the excitation of ascending dopaminergic systems is responsible for the rebound of sleep.

b) Drugs which decrease the activity of sleep-inducing mechanisms.

Modafinil is known to present a pharmacological profile totally different from amphetamine. on the one hand, sustained alertness which follows Modafinil administration, both in the rat or in the cat, is not followed by a subsequent rebound of either Slow Wave Sleep or Paradoxical Sleep. On the other hand, contrary to amphetamines, the administration of Modafinil does not induce CFos-containing neurons in the targets of dopaminergic systems but induces a restricted population of CFos-containing neurons located in the anterior hypothalamus, an area known to be involved in sleep mechanisms. Thus it is likely that Modafinil increases waking by inhibiting sleep mechanisms originating from the anterior hypothalamus.

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

The Efficacy of Dextroamphetamine for Sustaining Helicopter Pilot Performance: An In-Flight Evaluation

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SUMMARY

The capability to operate 24 hours per day on the battlefield creates a tactical advantage over enemy forces. However, staffing shortages necessitating long work hours devoid of sleep eventually produce overwhelming fatigue, impairing performance and safety. In these situations, the only effective means to sustain performance may be the administration of stimulants. Unfortunately, studies of stimulants such as dextroamphetamine on the actual flight performance of aviators are virtually nonexistent. The present study assessed actual in-flight performance, mood, and alertness of UH-60 pilots during sleep-deprivation periods in which they were given either a 10-mg dose of Dexedrine or a placebo at 0000, 0400, and 0800 within the last 23 hours of each period. Results indicated better control (smaller RMS errors) of several flight parameters (i.e., heading, altitude, airspeed, etc.) under Dexedrine than placebo during straight-and-levels, climbs, descents, right turns, and a left-descending turn. Tendencies toward Dexedrine-related improvements also occurred in the left turns and the Instrument Landing System approach. The Profile of Mood States revealed reductions in fatigue, confusion, and depression concurrent with increases in vigor as a function of Dexedrine. Electroencephalographic data indicated enhanced central nervous system arousal under Dexedrine relative to placebo. No significant side effects occurred. It can be concluded that dextroamphetamine effectively sustained aviator performance during short-term sustained operations.

BACKGROUND

Because sustained operations make it difficult for aviators to receive adequate sleep during combat, the military is exploring countermeasures to offset problems associated with sleep debt. Pharmacological measures may be the only viable alternative in some situations, and the stimulant Dexedrine appears to be very promising for this purpose (1).

Senechal (2) reported that EF-111A Raven jet crews who were administered 5 mg Dexedrine during an Air Force strike on Libya experienced positive effects in terms of overcoming the fatigue of the mission itself and the sleep deprivation which occurred during preparation for the mission. There were no in-flight or landing problems, and all of these electronic-jamming aircraft returned safely to base. Cornum (3) reported that dextroamphetamine also was used with 35 F-15C pilots who were flying combat air patrol missions during Operation Desert Shield/Storm. These pilots were not only flying long missions (6-11 hours), but were sleep deprived and suffering from circadian desynchronosis as well. Pilots were issued 5-6 dextroamphetamine tablets (5 mg) at the beginning of flights and were told to self-administer one tablet every 2-4 hours as needed to maintain alertness. The aviators reported clear benefit from the drug, and the unit commander concluded that dextroamphetamine administration contributed significantly to the safety of operations. There were no reported adverse effects, even in personnel who took 10 mg at a time, and no aviators reported a need to continue the drug once proper work/sleep schedules were reinstated.

Emonson and Vanderbeek (4) indicated that Air Force pilots effectively used dextroamphetamine during Operation Desert Storm to maintain acceptable performance during continuous and sustained missions. The medication was found to be both safe and beneficial in terms of overcoming fatigue without producing unwanted side effects. These results were later supported by Cornum, Cornum, and Storm (5) who surveyed F15-C squadrons deployed in Operation Desert Shield. Fifty-seven percent of respondents indicated they used dextroamphetamine, mostly on long, low-task, night missions. This medication was considered beneficial in terms of flight safety without inducing the feelings of hyperactivity associated with caffeine.

These anecdotal reports have been supported in controlled laboratory investigations of the effects of Dexedrine on the simulator flight performance of sleep deprived aviators (6,7). These investigations were placebo-controlled studies of 12 Army helicopter pilots who completed UH-60 simulator flights, psychological evaluations, and electrophysiological assessments throughout 36-hour periods of continuous wakefulness. Flights occurred at 0100, 0500, 0900, 1300, and 1700. One hour prior to each of the first three flights, aviators were given 10 mg of Dexedrine or placebo. Dexedrine improved aviator control on the majority of flight maneuvers including descents, straight-and-levels, standard-rate turns, low-level navigation, and a left-descending turn. Performance was not enhanced on hovering turns or formation flight. Dexedrine most noticeably facilitated flight performance at 0500, 0900, and 1700 (after 22, 26, and 34 hours of continuous wakefulness). Slow-wave electroencephalographic (EEG) activity and ratings of fatigue and confusion were reduced after Dexedrine administration, indicating a positive effect on general alertness. Although recovery sleep after Dexedrine was somewhat compromised, there were no clinically significant behavioral or physiological effects. Thus, it appeared that Dexedrine was safe and effective for sustaining helicopter pilot performance during short periods of sleep loss. However, a definitive conclusion about sustaining flight performance with Dexedrine required actual in-flight investigation.

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

METHODS

Subjects

Ten UH-60 pilots (between the ages of 28 and 36, with a mean age of 31.9) were tested. Five used tobacco (only during breaks between sessions), but none used alcohol or other drugs during the protocol.

Apparatus

Drug administration. At dose times on Dexedrine days, subjects received 2 capsules, each containing 5 mg Dexedrine. On placebo days, subjects received matching capsules containing lactose.

UH-60 helicopter. Flights were conducted in a specially-instrumented Sikorsky UH-60A helicopter. Aspects of aircraft control including heading, airspeed, slip, roll, vertical speed, and altitude control were recorded by computer during flights.

EEG evaluations. EEG activity (from Fz, C3, Cz, C4, Pz, O1, and O2) was collected between flights with a Cadwell Spectrum 32. The low filter was set at 0.53 Hz and the high filter was set at 70 Hz. Electrodes were secured to the subjects' scalps with collodion.

Profile of Mood States (POMS). Subjective ratings of tension-anxiety, depression-dejection, anger-hostility, vigor-activity, fatigue-inertia, and confusion-bewilderment were made with the POMS.

Procedure

Tests were conducted at 0900, 1300, and 1700 on Monday, Tuesday, and Thursday; and at 0100, 0500, 0900, 1300, and 1700 on Wednesday and Friday (the sleep deprivation periods). On Wednesday and Friday, drug or placebo doses were administered to subjects at 0000, 0400, and 0800. At dose times, subjects received either 10 mg Dexedrine or placebo. Sessions began with a flight in the UH-60 helicopter and ended with a cognitive test (not reported here).

UH-60 flights. Each flight was 30 minutes in length and consisted of straight and levels, standard-rate turns, climbs and descents, and an ILS. During each maneuver, subjects maintained control parameters (headings, altitudes, airspeeds, etc.), based upon safety-pilot instructions. The first several maneuvers were conducted with the UH-60's automatic flight-path control system (AFCS) engaged, and the remaining maneuvers were flown without the AFCS. Root mean square (RMS) errors were calculated for each control parameter during each maneuver.

EEG evaluations. Evaluations were conducted after flights. Data were recorded for 1.5 minutes with eyes open and 1.5 minutes with eyes closed. Power was calculated for delta (1.5-3.0 Hz), theta (3.5-8.0 Hz), alpha (8.0-13.0 Hz), and beta (13.0-20.0 Hz) bands based upon 3, artifact-free 2.5 second epochs.

POMS. The POMS was administered about 45 minutes after the EEG. Subjects completed a checklist in which they indicated how well each of 65 mood adjectives described their present feelings. The data were scored to produce ratings on six factors.

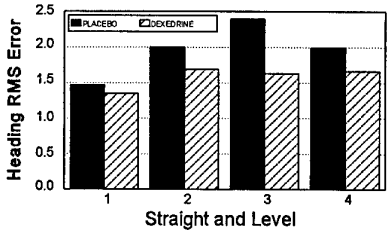
RESULTS

Flight performance

The effects of drug (Dexedrine, placebo) and time (0100, 0500, 0900, 1300, and 1700) on RMS errors were analyzed with analysis of variance (ANOVA). Only drug-related effects are reported here.

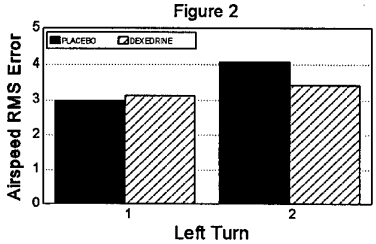
Straight and levels. Analysis of heading, altitude, airspeed, slip, and roll control in the four iterations of straight-and-level (SL) flight, indicated a drug-by-iteration interaction on heading ($F(1,9)=18.36$, $p<.01$) and drug main effects on heading ($F(1,9)=19.79$, $p<.01$) and airspeed ($F(1,9)=5.24$, $p=.05$). The interaction was due to larger errors under placebo than Dexedrine during SLs 2-4, with no difference in SL 1 (see figure 1). Drug main effects were due to decreased errors under Dexedrine versus placebo. Heading errors were 1.6 and 2.0 degrees respectively, and airspeed errors were 2.9 and 3.2 knots.

Figure 1



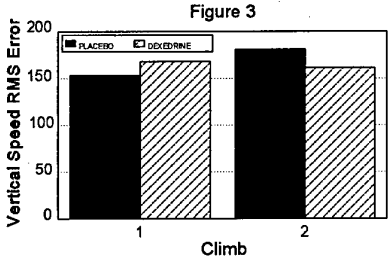
Left standard-rate turns. Analysis of turn rate, altitude, airspeed, slip, and roll control in the two left turns showed two marginal effects--a drug-by-iteration interaction on airspeed ($F(1,9)=4.37$, $p=.07$) and a drug main effect on roll ($F(1,9)=3.26$, $p=.10$). As shown in figure 2, the interaction was due to larger airspeed errors under placebo than Dexedrine in the second turn (conducted without the AFCS). The main effect on roll was due to larger errors under placebo than Dexedrine (2.1 versus 1.7 degrees).

Figure 2



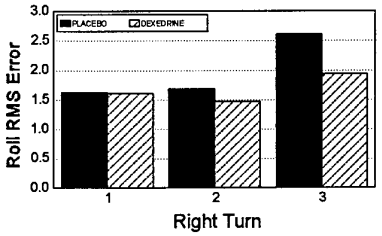
Climbs. Analysis of heading, airspeed, slip, roll, and vertical speed in the two climbs revealed a drug-by-iteration effect on vertical speed ($F(1,9)=5.35$, $p=.05$) and drug main effects on heading ($F(1,9)=6.36$, $p=.02$) and slip errors ($F(1,9)=6.02$, $p=.04$). The interaction was due to an unexpected increase in errors under Dexedrine in the first but not the second climb (see figure 3). The drug main effects were due to smaller errors under Dexedrine relative to placebo. Heading errors were 1.5 and 1.7 degrees, and slip errors were .21 versus .25 ball widths.

Figure 3



Right standard-rate turns. The ANOVA on turn rate, altitude, airspeed, slip, and roll control in the three right turns indicated a drug-by-iteration interaction on roll control ($F(2,18)=3.54$, $p=.05$). This was due to larger RMS errors under placebo than Dexedrine during only the third turn (conducted without the AFCS). This interaction is depicted in figure 4.

Figure 4



Descents. Analysis of heading, airspeed, slip, roll, and vertical speed control in the two descents indicated drug main effects on heading ($F(1,9)=5.64$, $p=.04$), airspeed ($F(1,9)=5.44$, $p=.04$), roll ($F(1,9)=9.98$, $p=.01$), and vertical speed control ($F(1,9)=9.90$, $p<.01$). All were due to smaller RMS errors under Dexedrine than placebo--means were 1.6 versus 1.8 degrees of heading, 3.0 versus 3.4 knots of airspeed, 1.3 versus 1.6 degrees of roll, and 192 versus 224 feet per minute of vertical speed.

Left descending turn. Analysis of turn rate, airspeed, slip, roll, and vertical speed control during the left-descending turn indicated drug-by-time interactions on roll ($F(4,36)=2.87$, $p=.04$) and vertical speed ($F(4,36)=3.98$, $p<.01$). In addition, there was a drug main effect on vertical speed ($F(1,9)=7.12$, $p=.03$). The interactions were due to smaller roll errors under Dexedrine versus placebo at 0900 and a similar effect on vertical speed errors at 0500 and 0900 (see figures 5 and 6). The drug main effect on vertical speed also was due to smaller errors under Dexedrine versus placebo (225 and 264 feet per minute, respectively).

Figure 5

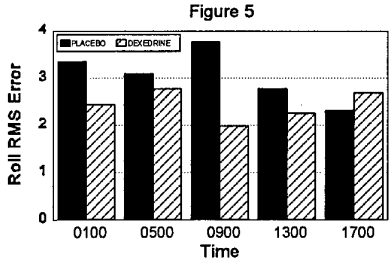
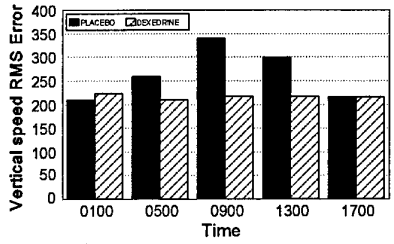
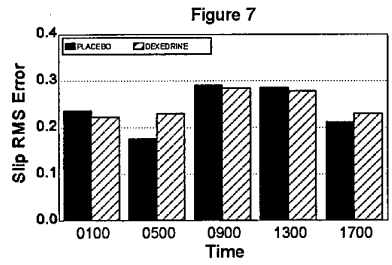


Figure 6



ILS approach. The ANOVA on airspeed, slip, and roll control, and localizer and glide-slope tracking accuracy on the ILS revealed a drug-by-session interaction on slip control ($F(4,36)=2.94$, $p=.03$) and glide-slope tracking ($F(4,36)=2.19$, $p=.09$). Also, there was a drug main effect on localizer tracking ($F(1,9)=3.98$, $p=.08$). The slip interaction was due to an unexpected increase in errors under Dexedrine at 0500 but not elsewhere (see figure 7). The glide slope interaction was due to smaller errors under Dexedrine at 1300. The drug main effect on localizer tracking was due to better accuracy under Dexedrine than placebo (1.1 and 1.4 dots, respectively).

Figure 7



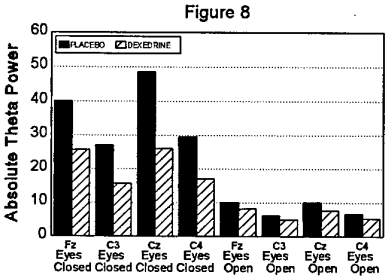
EEG activity

EEG power was assessed with ANOVAs for drug (Dexedrine, placebo), time (0220, 0620, 1020, 1420, and 1820), and eyes (closed, open). The data from 7 electrodes were analyzed separately.

Delta activity. There were no interactions or other drug effects. Although tendencies ($p=.10$) were seen suggesting slight increases in delta at Fz, Cz, C4, and C3, none were statistically significant.

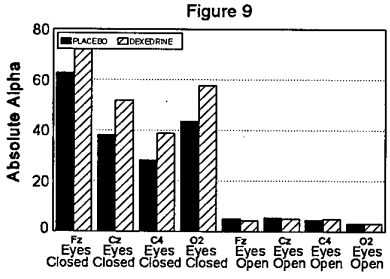
Theta activity. Drug-by-eyes interactions occurred at Fz ($F(1,9)=9.14$, $p=.01$), C3 ($F(1,9)=6.41$, $p=.03$), Cz ($F(1,9)=8.74$, $p=.02$), C4 ($F(1,9)=7.56$, $p=.02$), and marginally at Pz ($F(1,9)=4.80$, $p=.06$) because of greater theta under placebo versus Dexedrine at eyes closed (see figure 8). Drug main effects were found at C3 ($F(1,9)=7.84$, $p=.02$), Cz ($F(1,9)=8.45$, $p=.02$), C4 ($F(1,9)=6.72$, $p=.03$), and Pz ($F(1,9)=6.04$, $p=.04$) because of increased theta under placebo.

Figure 8



Alpha activity. Drug-by-eyes interactions occurred at C4 ($F(1,9)=7.93$, $p=.02$), Cz ($F(1,9)=8.40$, $p=.02$), Fz ($F(1,9)=11.80$, $p<.01$), and O2 ($F(1,9)=6.38$, $p=.03$) due to more alpha under Dexedrine than placebo with eyes closed (see figure 9). Drug main effects at Fz ($F(1,9)=9.93$, $p=.01$), Cz ($F(1,9)=6.51$, $p=.03$), C4 ($F(1,9)=7.01$, $p=.03$), and O2 ($F(1,9)=6.36$, $p=.03$) were also due to increased alpha under Dexedrine.

Figure 9



Beta activity. No drug-related interactions or main effects were observed. Thus, beta activity (13-20 Hz) was unaffected by Dexedrine administration.

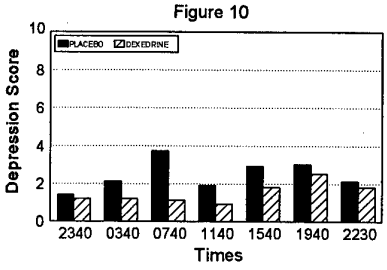
POMS

POMS data were analyzed with ANOVA in which the factors were drug (Dexedrine, placebo) and session (2340, 0325, 0725, 1125, 1525, 1925, and 2225). Each of the six factors was examined separately.

Tension-anxiety scale. There were no interactions or main effects which would reflect differences in musculoskeletal tension under placebo versus Dexedrine.

Depression-dejection scale. Despondence and sadness was affected by the combination of drug and session ($F(6,54)=2.92$, $p=.02$) in that more depression was seen under placebo relative to Dexedrine at 0725. There were no drug-related differences at the other times (see figure 10).

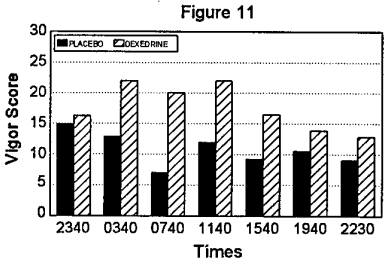
Figure 10



Anger-hostility scale. There were no significant main effects or interactions which would reflect differences in anger and antipathy towards others under placebo versus Dexedrine.

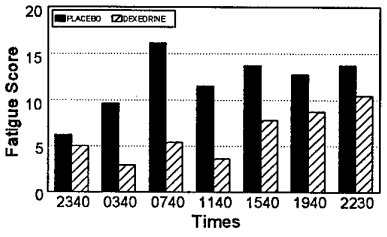
Vigor-activity scale. Energy levels were affected by the combination of drug and session ($F(6,54)=5.05$, $p<.01$) in that vigor scores were lower under placebo than Dexedrine at 0325, 0725, 1125, and 1925, but not at 2340 (before deprivation) or at 2225 (at the end of deprivation). This can be seen in figure 11. A drug main effect ($F(1,9)=46.50$, $p<.01$) was due to reduced vigor ratings under placebo versus Dexedrine (10.7 for placebo and 17.6 for Dexedrine).

Figure 11



Fatigue-inertia scale. Weariness and tiredness ratings showed a significant interaction between drug and session ($F(6,54)=2.75$, $p=.02$) and a significant effect on the drug factor ($F(1,9)=28.20$, $p<.01$). The interaction was due to higher levels of fatigue under placebo than Dexedrine at 0325, 0725, 1125, and 2225 but not elsewhere (see figure 12). A drug main effect resulted from higher fatigue scores under placebo than Dexedrine (11.9 versus 6.3).

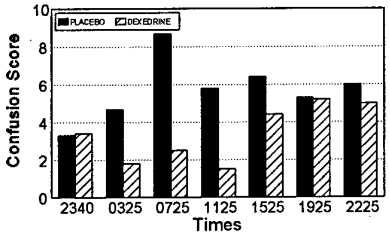
Figure 12



Confusion-bewilderment scale. Scores reflecting increased difficulties in mental abilities showed a drug-by-session interaction ($F(6,54)=4.83$, $p<.01$), and a drug main effect

($F(1,9)=33.51$, $p<.01$). The interaction was due to more confusion under placebo than Dexedrine at 0325, 0725, and 1125, but not at other times (see figure 13). The drug main effect was attributable to a reduction in self-perceptions of confusion under Dexedrine in comparison to placebo (the means were 3.4 versus 5.7).

Figure 13



DISCUSSION

Dexedrine improved flight performance during the final 23 hours of a 40-hour period of continuous wakefulness. Several helicopter control parameters were more precisely maintained under Dexedrine than placebo in the straight and levels, left turns, climbs, descent, left descending turn, and ILS. A similar effect also occurred in one of the right turns. During the left descending turn, Dexedrine was particularly helpful at 0500 and 0900. There were 2 instances out of 19 in which a reversal of the expected drug effects occurred (vertical speed control was better under placebo on the first climb, and slip control was better under placebo at 0500 on the ILS); but these were exceptions. Overall, these results are consistent with those from an earlier simulator study (6,7). However, there were fewer significant in-flight drug effects than simulator effects, probably because of the variance-producing impact of turbulent weather, traffic delays, radio distractions, and environmental temperature changes present in the real aircraft. Also, in-flight-study participants benefitted from the alerting effects of frequent sunlight exposures, periodic walks outside of the Laboratory, and changes in scenery associated with traveling from the Laboratory to the airfield every 4 hours.

EEG changes were consistent with performance effects in that theta activity, which increases as a function of sleep deprivation (8), was reduced by Dexedrine. Since cognitive impairments are related to increased theta (9), changes in this slow-wave EEG suggests Dexedrine-related improvements in performance were partially due to enhancements in central nervous system (CNS) arousal. This interpretation was supported by the fact that EEG alpha activity was increased by the drug in comparison to placebo. Since alpha suppression is an indicator of sleep onset, the alpha increases show that Dexedrine reduced the potential for sleepiness-related performance errors.

Subjective mood states were improved after Dexedrine, especially in the morning and the middle of the day. In comparison to placebo, depression-dejection ratings on the POMS were lower at 0725; fatigue-inertia scores were reduced at 0325, 0725, 1125, and 1925; and confusion-bewilderment scores were lower under Dexedrine at 0325, 0725, 1125, and 2225. Vigor-activity ratings were improved by Dexedrine from 0325 to 1125 and at 1925. Thus, in addition to improvements in objective performance and alertness under Dexedrine, it is clear that feelings of alertness were sustained by the drug throughout the majority of the sleep-deprivation test sessions. These results are consistent with those of Newhouse et al. (10) and Caldwell, Caldwell, and Crowley (11).

In conclusion, this in-flight evaluation supports the results from simulator studies in which Dexedrine maintained flight performance, CNS arousal, and mood during prolonged wakefulness. These results support previous suggestions that dextroamphetamine should be considered a viable countermeasure for fatigue and sleep deprivation in operational environments (3,5,6,7,11,12). Although Dexedrine produced general cardiovascular stimulation and slight impairments in sleep quality (13), these negative effects are inconsequential compared to the improvements in flight performance, mood, and alertness associated with this medication. Dexedrine, administered prophylactically, is particularly beneficial for preventing dangerous reductions in aviator performance and alertness that are most evident between 0300 and 1000 in the morning. Thus, when sleep deprivation is unavoidable, short-term Dexedrine administration is recommended.

Future research should address the issue of whether longer-term use of dextroamphetamine is a viable option for personnel who may be sleep deprived for 3-4 days. It may be that the short-term benefits disappear after 1-2 days because of sleep-pressure, drug tolerance, or physiological stresses. However, until these factors can be investigated, it may be concluded that Dexedrine is a good countermeasure for sleep deprivation in operations that require up to 40 hours of continuous wakefulness.

ACKNOWLEDGMENTS

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PHARMACOLOGICAL SLEEP MANAGEMENT
Interest of Modafinil
(Gestion pharmacologique du Sommeil : Intérêt du Modafinil)

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ABSTRACT

During sustained and continuous operations the sleep-wakefulness cycle is often disturbed : jet-lag, shift lag, prolonged sleep deprivation. The vigilance management in operational conditions includes pharmacological and non-pharmacological counter-measures. Sometimes non-pharmacological counter-measures, i.e, preventive, ergonomic and physical measures become inefficient or are inapplicable, so in these cases, military research teams are looking for pharmacological measures.

There is a great variety of susbstances which may be used to reduce the effects of these sleep disturbances. These substances have to take place in a straight rule which could be resumed in 4 points :
- an easy ingestion
- a quick effect after treatment
- a modulating time duration effect, dose-function
- without side effects

Generally, three kinds of substances could be used :
- hypnotic substances to induce a recovery sleep
- wakening substances to maintain a good level of vigilance
- synchronizer to resynchronize biological rhythms after jet-lag

In this work, the author presents an interesting synthetic substance called Modafinil (MODIODAL®). This substance is a medicine used to treat narcolepsy and hypersomnia. But modafinil could also act in healthy subjects, for example during a long sleep deprivation, and maintain a good level of vigilance and performance during 60 hours of continuous wakefulness. A neuroprotector effect at high dose has been demonstrated. The action mechanism of modafinil is complex. Modafinil modulates (as agonist) central post-synaptic alpha 1 noradrenergic receptor (wakefulness effect). At high doses, it increases dopamine level in nucleus accumbens (locomotor effect). It has also an indirect participation in the serotoninergic system (wakefulness effect). It induces a decrease of cortisol liberation of the GABA (wakefulness effect), and induces moderate transient increase in aspartate and glutamate (wakefulness effect) followed by long lasting decrease of extra-cellular excitatory amino-acids (neuroprotector effect). Modafinil increase a brain metabolic energetic compound : the phosphocreatine, and it induces an activation of proto oncogen c-fos in anterior hypothalamic nucleus.

Modafinil (MODIODAL®) appears as an interesting substance in SUSOPS and CONOPS, easy to take, with a dose-effect to modulate the action. No major side effect was described. It is a wakening substance and not anti-sleep drug. Modafinil could be a very useful substance during real sustained operations but we have to take care of the wrong use.

RESUME

Pendant les opérations soutenues et continues, le cycle veille-sommeil est souvent perturbé, qu'il s'agisse de décalage horaire, de travail posté ou de privation prolongée de sommeil. La gestion de la vigilance en situation opérationnelle comprend des mesures pharmacologiques et non pharmacologiques. Parfois les mesures non pharmacologiques, c'est-à-dire ergonomiques et physiologiques deviennent inefficaces ou inapplicables. C'est alors que des mesures pharmacologiques prennent toute leur importance.

Il existe une grande variété de substances qui peuvent être utilisées pour réduire les effets de ces perturbations du sommeil. Ces substances doivent répondre à un certain nombre de critères définissant le concept d'aide pharmacologique légère, et qui peuvent être résumés en 4 points :
- une administration facile
- un effet rapide après la prise
- un effet modulable en fonction de la dose
- l'absence d'effet secondaire

Généralement trois types de substances peuvent être utilisées :
- les substances hypnotiques pour induire un sommeil de récupération
- les substances éveillantes pour maintenir un bon niveau de vigilance
- les resynchroniseurs pour resynchroniser les rythmes biologiques après décalage horaire.

Dans ce travail, l'auteur présente une substance de synthèse intéressante, le Modafinil (MODIODAL®). Cette substance est un médicament utilisé dans le traitement de la narcolepsie et des hypersomnies. Mais le modafinil peut également agir chez le sujet sain, par exemple à l'occasion d'une privation de sommeil de longue durée, et maintient un bon niveau de vigilance et de performance pendant 60 heures d'éveil continu.Un effet neuroprotecteur à forte dose a été mis en évidence. Le mécanisme d'action du modafinil est complexe. Le modafinil agit comme agoniste au niveau des récepteurs

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noradrénergiques alpha 1 post synaptiques centraux (effet éveillant). A forte dose, il élève le niveau de dopamine dans le noyau accumbens (effect locomoteur). Il induit aussi une participation indirecte du système sérotoninergique (effet éveillant). Le modafinil provoque une réduction de la libération corticale de GABA (effet éveillant), ainsi qu'une augmentation transitoire de l'aspartate et du glutamate (effet éveillant), suivie par une diminution lente des amino-acides excitateurs extra-cellulaires (effet neuroprotecteur). Le modafinil entraîne un accroissement d'un composé métabolique énergétique cérébral, la phosphocreatine. Il provoque, enfin, une activation du proto oncogène c-fos au niveau du noyau de l'hypothalamus antérieur.

Le modafinil est une substance intéressante lors des opérations soutenues et continues, facile à prendre, produisant un effet-dose modulant son action. Aucun effet secondaire majeur n'a été décrit. Il s'agit d'une substance éveillante et non anti-sommeil. Le modafinil peut être une substance très utile lors d'opérations soutenues réelles mais une attention particulière doit être portée à un éventuel mésusage.

INTRODUCTION

Si dormir est une nécessité physiologique, rester éveillé et efficient est un impératif opérationnel exigé dans certaines situations aéronautiques militaires dites "opérations soutenues". Si la tâche confiée se prolonge au-delà des limites physiologiques habituelles, la seule motivation et le seul stress engendrés par ces situations ne suffisent pas pour permettre à un pilote de piloter de façon optimale, à un surveillant de contrôle radar de surveiller sans faille, à un combattant de combattre efficacement.

La défaillance des mesures dites physiologiques, comme la prise d'un petit somme récupérateur, est à l'origine du concept d'aide pharmacologique légère.

Ce concept repose sur trois principes fondamentaux :

1) préserver l'utilisateur des effets pénalisants et dangereux pour sa sécurité, de la dette de sommeil ;
2) être d'utilisation aisée et modulable ;
3) ne pas créer par sa seule mise en oeuvre d'autres effets pénalisants.

S'il peut être relativement facile de trouver des substances pharmacologiques répondant à une de ces conditions, il est exceptionnel qu'elles répondent aux trois simultanément. La recherche menée, à partir de ce nouveau concept, à l'Institut de Médecine Aérospatiale du Service de Santé des Armées, bénéficie de plusieurs avantages : l'expérience, puisque depuis plus de 20 ans médecins et vétérinaires se sont succédés accumulant de nombreuses données ; la mise au point d'un modèle animal, en l'occurrence le Macaque Rhésus ayant permis le "screening" de nombreuses molécules, et enfin les rapports très étroits entretenus avec le milieu aéronautique militaire et civil. En effet, ce dernier point permet de disposer d'un vaste champ d'observation où la privation plus ou moins prolongée de sommeil est associée au travail de nuit, aux vols de longue durée, aux décalages horaires et à l'environnement très spécifique de l'aéronautique que représentent notamment les accélérations ou l'hypoxie relative.

Ces avantages ont ainsi permis, en dépit des difficultés liées à la définition du concept lui-même, et énumérés plus haut, d'aboutir à l'évaluation et à la mise au point d'une substance éveillante opérationnelle utilisable en cas de conflit réel. D'autres recherches sont actuellement en cours, dans le but de mettre à la disposition du commandement d'une part, des substances éveillantes utilisables comme "booster" pour finir une mission sensible pendant quelques heures, ou comme resynchroniseur des rythmes biologiques, d'autre part des substances inductrices d'un sommeil réparateur de courte durée et autorisant une reprise rapide d'activité.

La pharmacopée actuellement disponible et utilisable dans le cadre d'une gestion pharmacologique des cycles veille-sommeil en opération est constituée d'hypnotiques, d'éveillants et de resynchroniseurs. Parmi les hypnotiques, on retiendra le temazepan, benzodiazépine utilisée en 1982 lors du conflit de l'Atlantique Sud par les anglais, mais surtout le zolpidem et le zopiclone nouvelle génération d'hypnotiques dits non-benzodiazépiniques, à demi-vie courte et aux effets secondaires moins marqués.

Les stimulants les plus utilisés sont les amphétamines et la caféine. Depuis peu existent le modafinil, substance eugrégorique, et la caféine à libération prolongée. Le resynchroniseur le plus répandu est la mélatonine, dont l'usage est à ce jour interdit en France.

MODAFINIL : Effet éveillant

Les expérimentations réalisées chez le sujet humain restent relativement peu nombreuses. Les données actuellement disponibles proviennent tout d'abord de sujets pris comme référence par rapport à des sujets hypersomniaques. C'est ainsi que Benoit et coll. (1) mettent en évidence chez 12 sujets jeunes de sexe masculin que l'administration de 200 mg de modafinil à 2 heures du matin entraîne une réduction de la somnolence nocturne, mais avec un niveau de vigilance inférieur à celui de référence, et une amélioration des performances psychomotrices nocturnes. Goldenberg et coll (6), en 1987, montrent chez 12 sujets sains (5 hommes et 7 femmes) que la prise de 200 mg de modafinil trois heures après le petit déjeuner n'entraîne aucune différence significative par rapport au groupe placebo en ce qui concerne le test de mesure des latences itératives d'endormissement (T.I.L.E.), l'électroencéphalogramme quantifié et les échelles visuelles analogiques.

La majeure partie des données disponibles proviennent d'expérimentations réalisées chez le sujet en privation de sommeil plus ou moins prolongée. La première fut celle de Puech et Bensimon (15), en 1987, qui montra chez 12 sujets sains, lors d'une privation de sommeil de 36 heures, que le modafinil (à 100, 200 et 300 mg/kg) antagonisait les effets de la privation de façon proportionnelle à la dose. Les travaux de Lagarde et coll, réalisés en 1990 et 1992 et publiés plus tard (7, 9, 10) mirent en évidence la puissance de l'effet éveillant du modafinil administré à la dose de 200 mg pendant trois jours consécutifs (figures 1 et 2) et la potentialisation de l'effet récupérateur du petit somme lorsqu'il est associé à la prise diurne du modafinil. L'absence de différence entre la structure de l'EEG sous modafinil et sous placebo fut confirmée par Saletu et coll (16), ainsi que l'absence

d'effets secondaires lors de l'administration de doses de 100 et 200 mg de modafinil (2, 16). En 1994, Bourdon et coll (3) démontrèrent l'absence d'effet du modafinil sur la balance thermique dans des conditions de neutralité, et sur la thermorégulation de sujets exposés au froid. Enfin, plus récemment, en 1995, Pigeau et coll (14) et Buguet et coll (4) ont comparé modafinil et d-amphétamine et montré, entre autre, l'efficacité très proche de ces deux substances, tant sur le plan du maintien de l'humeur que celui des performances.

L'évaluation du modafinil chez le sujet sain a ainsi permis de mettre en évidence la puissance de l'effet éveillant de cette molécule qui autorise le maintien des capacités optimum lorsque celles-ci sont dégradées, ne provoque pas d'effets secondaires aux doses utiles et possède la propriété originale d'être une substance éveillante mais non anti-sommeil.

MODAFINIL : Effet neuroprotecteur

Les neurotoxiques organophosphorés, agents de guerre chimique potentiels, tels que le soman, ont pour cible l'acétylcholinestérase (AChE) et provoquent l'accumulation d'acétylcholine (ACh). L'administration aigüe de soman chez l'animal de laboratoire provoque la survenue de crises convulsives généralisées et de séquelles neuropathologiques chez les animaux survivants, dans toutes les zones limbiques, en particulier l'hippocampe. La survenue de ces crises convulsives est sous la dépendance de mécanismes cholinergiques muscariniques. Des travaux récents (11) ont montré que les acides aminés excitateurs, glutamate en particulier, libérés massivement après intoxication par le soman, jouaient un rôle prépondérant dans la propagation, la maintenance des crises convulsives et les dommages neuronaux retardés à cause de l'activation des récepteurs NMDA. L'intoxication par le soman semblait donc être un excellent modèle de neurotoxicité afin de tester de façon objective les propriétés neuroprotectrices du modafinil. Les sites ω 3 sont des récepteurs aux benzodiazépines de type périphérique, essentiellement présents dans les cellules gliales et les macrophages, mais peu dans les neurones. L'augmentation de la densité des sites ω 3 est une reflet de la réaction gliale et de la colonisation macrophagique, conséquences d'une souffrance neuronale aigüe ou chronique. La mesure de la densité des sites ω 3 constitue donc un index indirect de lésions cérébrales. Une première série d'expériences menée chez la souris (figure 3) a montré que le modafinil, administré à la dose de 600 mg/kg par voie i.p. antagonisait l'augmentation de la densité des sites ω 3 dans l'hippocampe, après intoxication par le soman (2 DL50 = 220 g/kg, s.c.). Au contraire, aux doses de 150 et 300 mg/kg i.p., le modafinil n'antagonise pas l'augmentation des sites ω 3. Une seconde série d'expériences a consisté en un examen microscopique de coupes d'hippocampes, après coloration au crésyl violet, chez des rats intoxiqués par le soman, prétraités ou non par le modafinil. En raison des résultats précédents obtenus chez la souris, seule la dose de 600 mg/kg a été testée. L'hippocame des rats intoxiqué non prétraités est le siège de lésions histologiques caractérisées par une rupture de l'intégrité de la couche de cellules pyramidales avec cytolyse. Lorsque les rats ont été prétraités par le modafinil, il n'existe aucune lésion histologique visible dans les aires CA1 et CA3 et l'intégrité de la couche de cellules pyramidales est conservée. Les coupes histologiques d'hippocampes de rats prétraités par le modafinil ne montrent pas de différence visible avec celles des rats non intoxiqués. Les deux études précédentes, menées au sein du Service de Santé des Armées (25), démontrent clairement que le modafinil exerce un effet neuroprotecteur, à la dose de 600 mg/kg, contre les lésions hippocampiques induites par les composés neurotoxiques organophosphorés.

MODAFINIL : Mécanisme d'action

La principale propriété pharmacologique du modafinil est la propriété éveillante distincte de la propriété stimulante stimulante qui n'est obtenue chez la souris et le singe que pour des doses élevées (5, 8). Cette observation distingue le modafinil des psychostimulants amphétaminiques, substances éveillantes de référence, dont il ne partage ni le mécanisme d'action ni les effets secondaires. Son mécanisme d'action est particulièrement complexe et implique la majorité des neurotransmetteurs mis en jeu dans les voies neurochimiques de l'éveil.

On peut schématiser ce mécanisme d'action en disant que :

- la présence d'un tonus alpha 1 adrénergique central "physiologique" est indispensable à la manifestation des effets stimulants ou éveillants du modafinil ;
- une augmentation indirecte de la neurotransmission dopaminergique (résultant de la levée de l'inhibition GABAergique et/ou d'une inhibition de la recapture de dopamine) pourrait participer aux effets du modafinil administré à forte dose ;
- la neurotransmission sérotoninergique semble aussi impliquée ;
- en revanche, l'implication des systèmes histaminergiques et cholinergiques semble peu probable
- le modafinil régule la libération de GABA cortical selon un équilibre entre les neurotransmissions sérotoninergiques et alpha 1 adrénergiques centrales ;
- les propriétés neuroprotectrices du modafinil pourraient être médiées par la diminution prolongées du taux d'acides aminés excitateurs extra-cellulaires qu'il provoque, ainsi que par ses propriétés d'antagoniste des récepteurs NMDA et d'agoniste métabotrope.
- Enfin, le noyau de l'hypothalamus antérieur serait le site d'action privilégié et spécifique du modafinil, et induirait l'éveil par des mécanismes distincts de ceux des autres substances éveillantes classiques (13).

EN CONCLUSION

La place du modafinil (MODIODAL®) dans une gestion pharmacologique du cycle veille-sommeil en opération paraît importante. Son intérêt dans le cadre des opérations soutenues et des opérations continues réside dans son administration aisée (un comprimé à 100 mg per os), l'existence d'un effet-dose permettant de moduler son action, l'absence d'effets secondaires majeurs. Mais son plus grand intérêt est peut-être celui d'être une substance éveillante puissante et non une substance anti-sommeil. Son utilisation possible lors d'opérations militaires ne doit pas faire oublier un éventuel mésusage résultant d'un détournement de son indication thérapeutique.

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Modafinil: an enhancer of vigilance

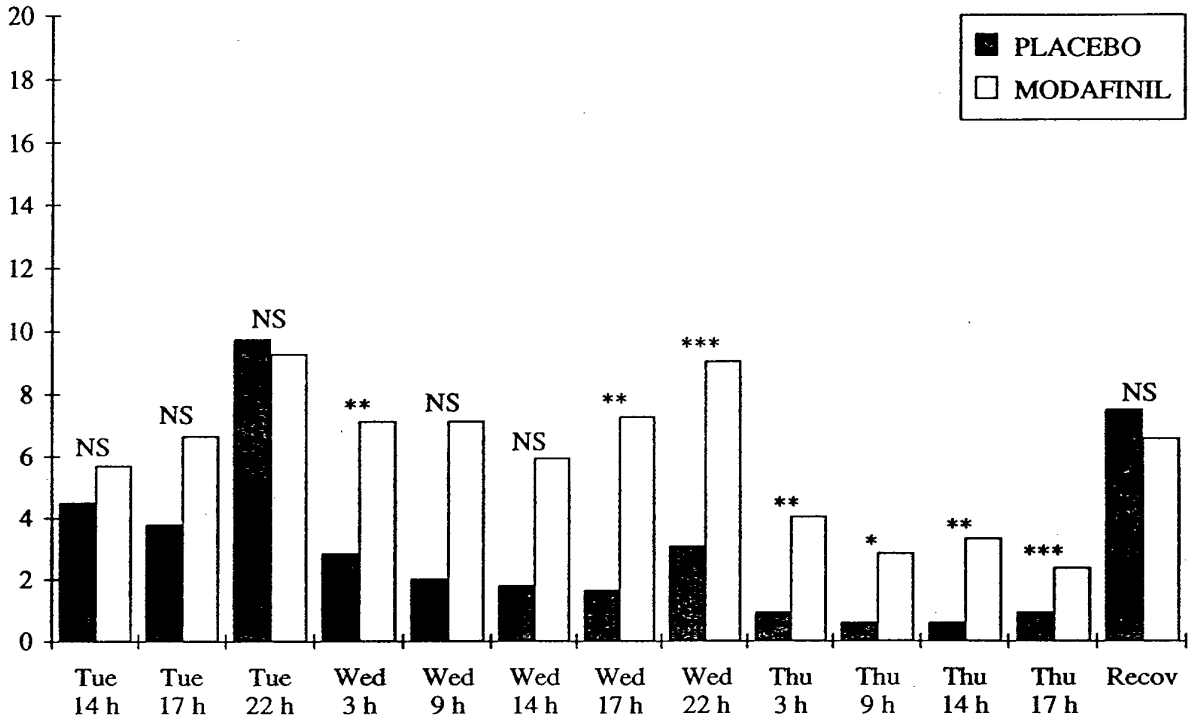


Fig Sleep latencies obtained during the 60 hour sleep deprivation in placebo ■ and modafinil □ situation, by MSLT method. Observation of the fast decrease of sleep latencies with placebo and the maintenance of a good level of arousal with modafinil. * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

Figure 1

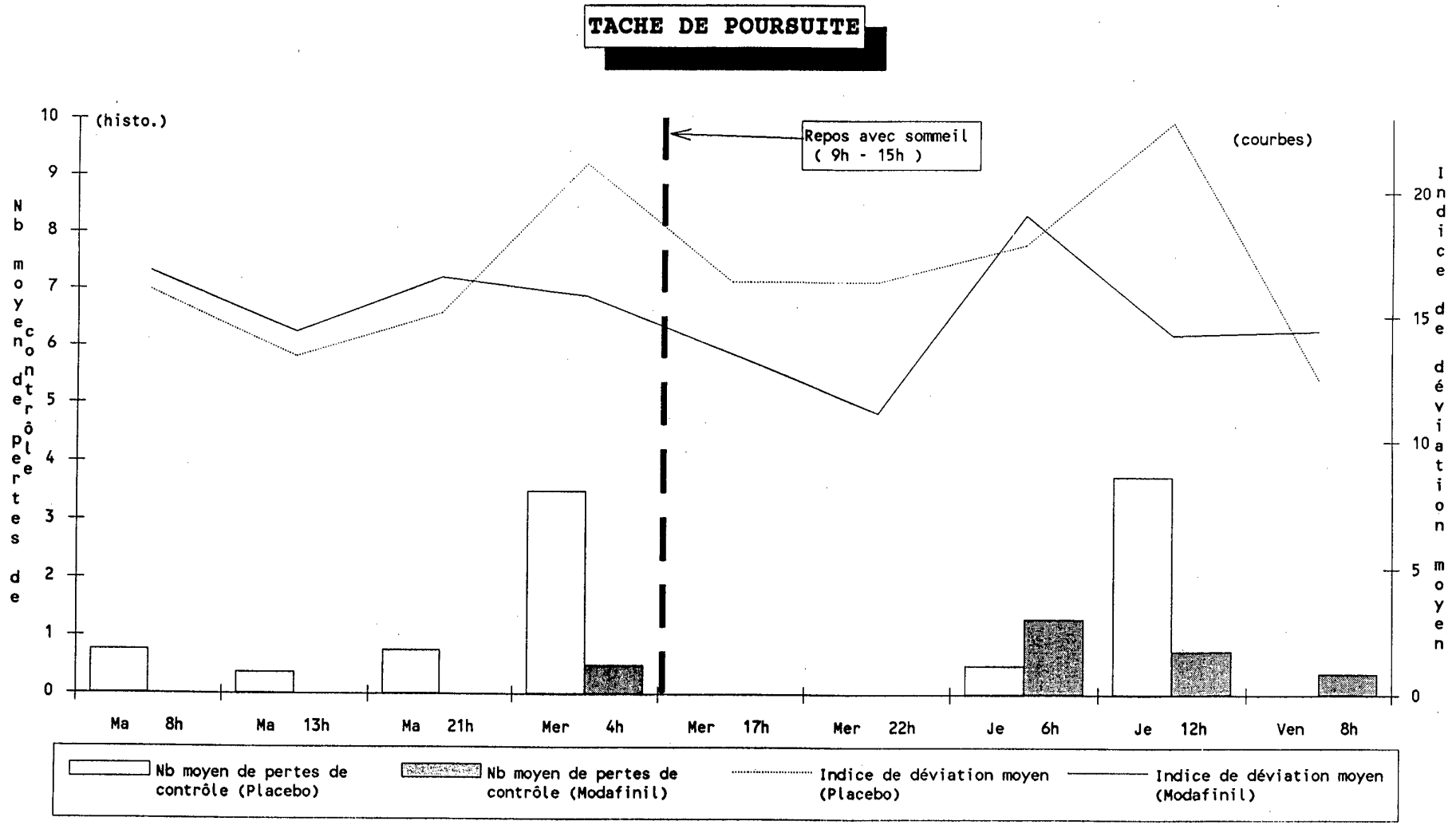
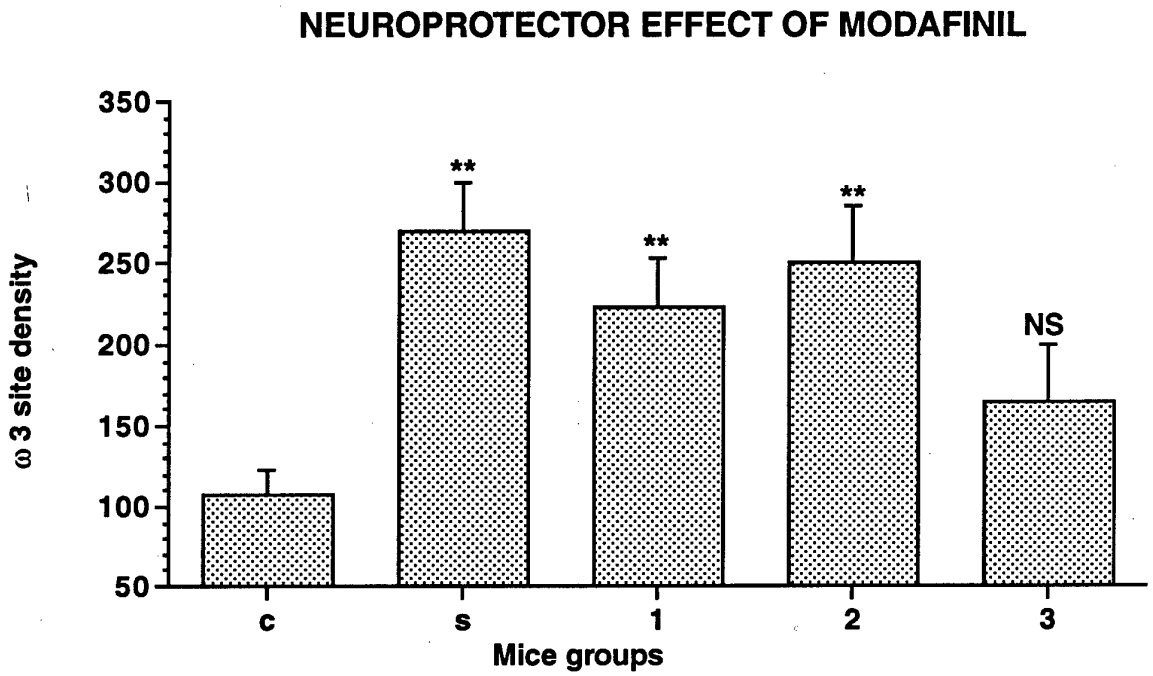

TACHE DE POURSUITE
(histo.)
(courbes)
Repos avec sommeil
(9h - 15h)
Nb moyen de pertes de contrôle
Indice de déviation moyen
0
1
2
3
4
5
6
7
8
9
10
0
5
10
15
20
Ma 8h
Ma 13h
Ma 21h
Mer 4h
Mer 17h
Mer 22h
Je 6h
Je 12h
Ven 8h
Nb moyen de pertes de contrôle (Placebo)
Nb moyen de pertes de contrôle (Modafinil)
Indice de déviation moyen (Placebo)
Indice de déviation moyen (Modafinil)

Figure 2



ω 3 site density in the hippocampi of mice 48 hours after soman intoxication C : control ; S : soman ; 1 : soman + modafinil (150 mg/kg) ; 2 : soman + modafinil (300 mg/kg) ; 3 : soman + modafinil (600 mg/kg). **p<0.01

Figure 3

MODAFINIL EFFECTS ON SPATIAL COGNITION DURING 60 HOURS OF SLEEP DEPRIVATION

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SUMMARY

Modafinil is currently being investigated in the context of sustained military operations as a potential countermeasure to the effects of extensive sleep deprivation (SD) on human cognitive performance. The aim of this present study is to analyze SD and dose-related effects of Modafinil on spatial cognition according to information processing patterns. Six normal healthy French military personnel participated for 4 one-week testing sessions involving double-blind, placebo-controlled manipulation of three doses of Modafinil (50, 150 and 300 mg/24hrs) during 60 hours of SD. Cognitive tasks investigated spatial abilities.

Information processing data analysis indicates that Modafinil effectiveness is to be qualified based on the dose of Modafinil and psychological processes. Thus, Modafinil has more important beneficial effects on the serial processes which govern the speed of attentive spotlight scanning of the visual field, but a lower effect on the decision making processes involved in the same task. Regarding sensory interactions between vestibular system and vision, low doses (50 et 150 mg/24hrs) of Modafinil have beneficial effects, while a dose of 300 mg/24hrs produces effects which are similar to those observed with a placebo. Lastly, Modafinil have beneficial effects on mental imagery processes, however its effectiveness on mental image accuracy seems to be restricted to 48 hours of SD while vigilance is still well-preserved. This experiment suggest that sensorial integration processes, working memory and control operators are the preference target site for SD and Modafinil.

INTRODUCTION

Though Modafinil's originality and pharmacological properties justify the part it now plays in the treatment of vigilance diseases (3, 4, 6), the interest its use generates in non-therapeutic applications raises many questions. Our field of interest is the operational field where prolonged wakefulness no longer meets the necessary requirement of safety - as was the case when there was a risk of major confrontation in Central Europe between the East and the West - but that of military technology and state of the art where continuous operations has a strategic dimension.

Under such conditions, research dealing with the use of such a psychostimulant substance - or any other substance for that matter - should under no circumstances be modeled on the conventional pharmacological approach aimed at treating a disease, i.e. reducing or even eliminating the pathological symptoms which burden the life of a patient while incurring minimum risk and side effects. Indeed, the military's approach is to meet other requirements which are much more demanding in the area of accurate knowledge of the action of the compounds.

It is within this prospect that we have developed an original psychopharmacological method which relies on cognitive psychology whose purpose differs from that of conventional behavioral psychology currently used in psychopharmacology. The latter focuses on the link between the stimulus and the response in a given situation thus likening the brain to a black box whose operation is deliberately ignored. The point of interest is performance and only performance as a function of possible variations under differing conditions whether it be in terms of attention, memory or decision options for instance.

With cognitive psychology, the focus is mainly on identifying and understanding the functional structure of the psychological processes occurring between data input from sensory organs and the output behavioral reactions. The cognitive approach to mental functions is based on an overall theoretical model, that of the Information Processing System (IPS, Fig. 1), involving several stages - between sensory encoding and system response - common to all activities which the subject may have (9). Therefore, whether it be memorization, logical reasoning or sensory-motor pointing task, all of these tasks do include : sensory encoding, perception, representation, mental operations in their widest acceptation, decision making and behavioral response. This is all in interaction with management and control operators as well as with working memory and long-term memory.

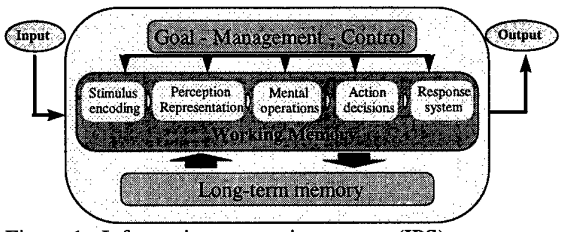


Figure 1 : Information processing system (IPS)

The purpose of our research was to compare three Modafinil dosages - 50, 150 and 300 mg/24 taken three times a day every 8 hours - over a period of 60 hours of Sleep Deprivation (SD) using cognitive analyses to study psychological effects

METHOD

Modafinil was studied in a double-blind, placebo-controlled manipulation on subjective fatigue, alertness, cognitive performance and physiological recordings in normal healthy adults.

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

Subjects

Because of the experimental design complexity, the number of subjects was limited to six French military personnel. These volunteers males - 20-35 years old - were fully informed about the purposes of the study and the procedures to be employed.

Psychological materials

The psychological tests combined both conventional behavioral tests such as those used in batteries of computer tests, and tests specific to the research conducted at CRSSA in the field of spatial cognition. Five tests were set up for this purpose : attentional search, mental rotation, mental scanning, sensory-motor pointing and spatial perception involving interactions between vestibular and visual systems.

procedure

The study included four experimental one-week sessions separated by a minimum wash-out of 15 days. For one session, the psychological investigation included two control sessions - one before SD with pharmacological medication, the other after stopping the medication and a night of recovery sleep. During SD, four sessions of psychological tests were organized - two at night and two in the afternoon (fig. 1)

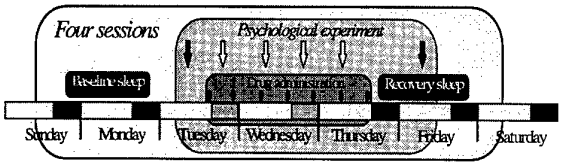


Figure 2 : Graphical description of the experimental time-line.

RESULTS

We have collected a lot of data and information in this experiment (1, 2, 5, 7, 8, 10). Therefore, as the main target was to show the relevance of the cognitive approach, only are presented the results pertinent to attentional research and mental scanning as an illustration of our subject matter.

The attentional task is standard in behavior psychology. It consists in detecting the presence or absence of a target among distractors (Fig. 2). The target is either a Q amongst Os, or, conversely, an O amongst Qs. In both cases, the number of distractors may vary (3, 6 or 9).

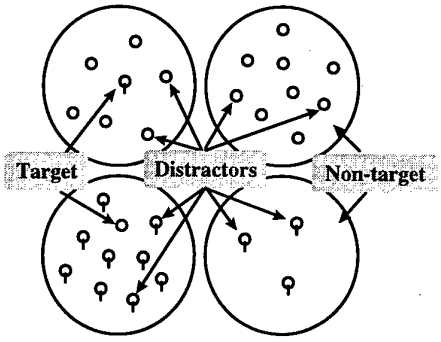


Figure 3 : examples of the attentional task.

For behavioral approach, the performance is equal to the average of all reaction times. With cognitive psychology, identification of the underlying processes of the task is performed based on the diversity in response times in relation to the features differentiating the items (Fig. 4). When identifying the presence or absence of a target Q among O distractors, it is therefore observed that the response times are independent of the number of distractors. This is called parallel processing, and involves an automatic detection process. When identifying an O amongst Qs, the response time increases with the number of distractors. This is called serial processing, and involves an attentional spot shift mechanism for task performance.

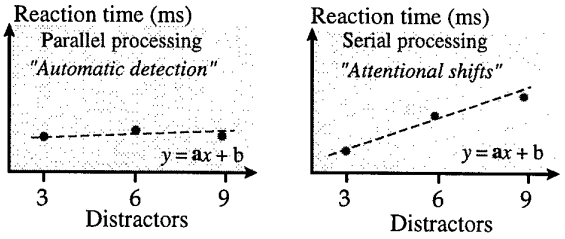


Figure 4 : Response times and slopes for Q (parallel processing) and O (serial processing) relative to the number of distractors.

Thus, two different processes may be implemented for the same task depending on the item to be processed whereas the instruction is the same. The linear regression slope between response times and number of distractors is a dual source of information : one, qualitative, on the nature of mental processing - parallel or serial - the other, quantitative, is pertinent only to serial processing since it is the speed of movement of the attentional spot expressed in number of items processed per millisecond. The error percentage is used to monitor both the subject's compliance with the instruction and the effects of SD.

Results show that neither SD nor Modafinil have any effect on parallel processing, i.e. this is an automatic process which resists to SD and is not modified by Modafinil (Fig. 5).

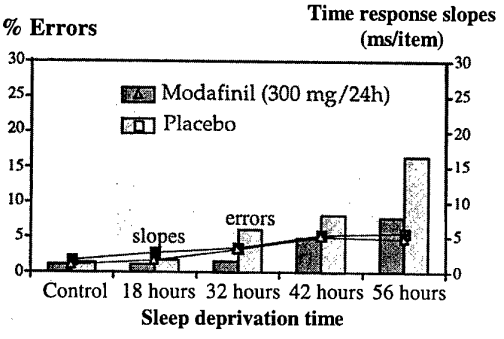


Figure 5 : Time response slopes and errors of parallel processing during SD for Modafinil (300 mg/24h) vs. placebo

For serial processing, the speed of the attentional spot slows down from the 32nd hour of SD with the placebo ($p<.02$), whereas it remains constant until the end of 60 hour of SD with 300 mg of Modafinil (Fig. 6). Moreover, errors increase significantly with SD (placebo, $p<.02$)

whatever the type of processing - serial or parallel - whereas there is no significant variation with 300 mg of Modafinil although errors do tend to increase.

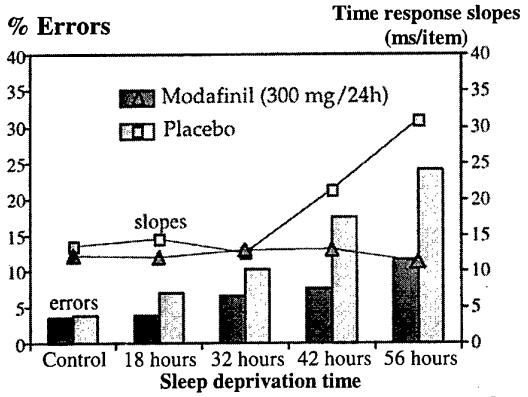


Figure 6 : Time response slopes and errors of serial processing during SD for Modafinil (300 mg/24h) vs. placebo

The mental imagery task consists in memorizing the physical structure of the Kosslyn's island, more particularly the spatial relations between the various locations (hut, beach, well, etc.). Then, based on the instructions given orally through the headset, the subject mentally scans a spot between locations taken two by two (Fig. 7). There is a linear relation between the physical distance separating the various locations taken two by two, and the time spent by the subject to mentally cover the distance.

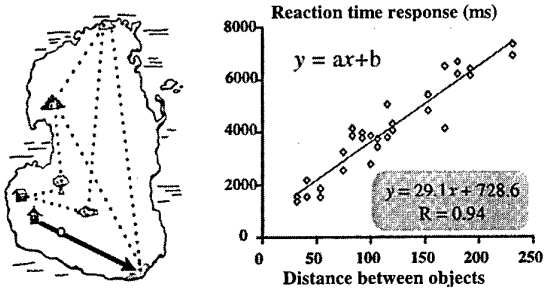


Figure 7 : The mental imagery task of Kosslyn's island.

Here, the cognitive variables are of a quantitative nature - i.e. the speed of mental exploration, and of a qualitative nature - i.e. the accuracy of the exploration shown by the value of the regression coefficient. A vigilance index can be used to assess the attentional wakefulness of the subject : it consists in introducing, every so often, fake destinations which do not exist on the island (e.g., a church), and which the subject is to identify as quickly as possible.

Results show that 150 and 300 mg of Modafinil are sufficient to maintain a constant vigilance index over the 60 hours of SD (Fig. 8). Also, only 300 mg of Modafinil are needed to maintain the accuracy of mental exploration at a good level (i.e. $r > .7$), however, this effect drops beyond the limit of 42 hours of SD (Fig. 9).

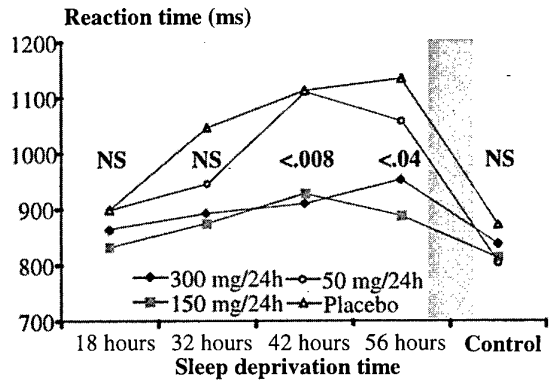


Figure 8 : Evolution of the vigilance index of the mental imagery task for the four drug conditions during SD and after recovery sleep.

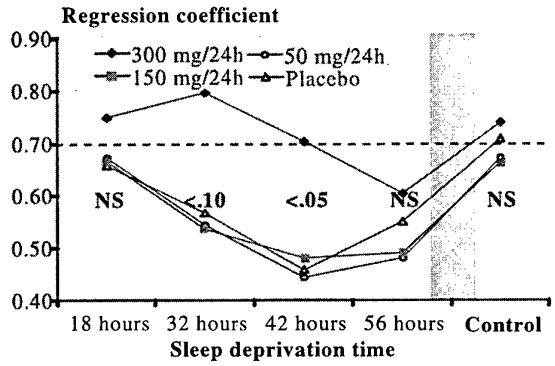


Figure 9 : Evolution of the accuracy index of the mental imagery task for the four drug conditions during SD and after recovery sleep.

DISCUSSION

The analysis of the cognitive tasks results - attentional search, mental rotation, mental scanning, sensory-motor pointing and spatial perception - point to the sensorial integration processes and working memory as the target site for SD and Modafinil, rather than the peripheral sensorial sites. As for the processes governing vigilance, it seems that the action of SD as well as that of Modafinil preferentially targets more sophisticated processes, i.e. directly connected to the management and control of mental tasks.

CONCLUSION

The psychopharmacological and cognitive approach permits to highlight the complexity of Modafinil's effects on mental functions since they show specific variations in operative mode, in efficacy and duration depending on the processes and dosage. Moreover, the interest of diversity is that it allows the construction of functional hypotheses as to the ***where*** and ***how*** of the psychopharmacological effects of Modafinil.

However, this also requires constantly evolving the aim of the researches, the experimental situations and the psychological measures to come ever closer to the mechanisms of action of SD and Modafinil on the brain.

The behavioral approach usually implemented in psychopharmacology thus appears to be too restrictive to properly study and understand the effects of Modafinil within the prospect of operational use. Indeed, it is important to always advise that personnel liable to use it are exposed not only to extremely exacting conditions - such as SD - but, above all, to complex activities and a significant mental workload.

CONCLUSION

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CAFEINE A LIBERATION PROLONGEE : UNE CONTRE-MESURE PHARMACOLOGIQUE EFFICACE

SLOW RELEASE CAFFEINE : A VALID PHARMACOLOGICAL COUNTERMEASURE

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RESUME

Les opérations continues, les déploiements aériens rapides, les veilles de nuit, sont source de privation de sommeil et de désynchronisation qui peuvent induire fatigue et dégradation des performances. Dans de telles circonstances la caféine peut être une Contre-Mesure efficace. Nous avons évalué une forme de Caféine à libération prolongée, qui retarde et diminue le pic maximum de concentration de caféine circulante. Une première expérimentation réalisée en double aveugle contre placebo, chez 120 hommes jeunes, a permis d'étudier la tolérance d'une dose unique de 600 mg de cette Caféine, en dehors de toute privation de sommeil. Les paramètres pharmacocinétiques n'étaient pas influencés par le phénotype d'acétylation des sujets, ni par leurs habitudes de consommation de café. Seules la quiétude et la qualité de l'endormissement étaient altérées chez ces sujets bien reposés. Dans une seconde étude, nous avons évalué en 4 séances les effets sur la vigilance et les performances de différentes doses (150, 300 et 600 mg) de cette Caféine LP et d'un placebo chez 12 hommes et 12 femmes en situation de privation de sommeil. La vivacité et les performances des sujets ont été améliorées par la Caféine à libération prolongée. La sensibilité plus importante des femmes au traitement est à rapprocher d'une plus grande susceptibilité à la privation de sommeil, et aux taux de caféine circulants plus élevés, corrélés avec un poids moyen inférieur et la prise de contraceptifs oraux. L'utilisation de 300 mg de cette Caféine LP chez des sujets en situation de privation de sommeil améliore donc significativement les performances, et offre une tolérance et une acceptation certainement supérieure aux autres types de psychostimulants tels que les amphétamines.

1. INTRODUCTION

La caféine est largement utilisée comme psychostimulant dans des situations de privation de sommeil, de fatigue, de désynchronisation des rythmes biologiques (décalage horaire, travail de nuit). Alors que des psychostimulants plus puissants existent, elle est préconisée et utilisée dans des opérations militaires (1). Nous avons évalué une nouvelle forme de Caféine à libération prolongée (LP). Comparée à une caféine en solution, cette Caféine LP présente un pic de concentration plasmatique significativement réduit et retardé (Tableau I) (2). Une première étude réalisée chez 120 sujets masculins, sans privation de sommeil, nous a permis d'affiner la pharmacocinétique et de tester la tolérance de 600 mg de cette Caféine LP. Une deuxième expérimentation chez 12 hommes et 12 femmes, avec privation de sommeil, évaluait les effets sur la vigilance, l'humeur et les performances psychomotrices de 150 mg, 300 mg et 600 mg de Caféine LP.

Tableau I: pharmacocinétique de la caféine à libération prolongée. Moyenne ± sem.

caféine 300 mg /60Kg	**Cmax** µg/ml plasma	**Tmax** h	**T ½** h	**AUC** µg/ml plasma h
solution aqueuse	6.9 ± 0.3	1.2 ± 0.2	5.4 ± 0.6	57.8 ± 4.9
libération prolongée	5.5 ± 0.3 $p < 0.05$	4.1 ± 0.3 $p < 0.05$	5.1 ± 0.6	54.2 ± 6.4

2. SANS PRIVATION DE SOMMEIL

L'étude effectuée en double aveugle avec deux groupes parallèles comparait en dose unique 600 mg de caféine LP à un placebo. Les 120 marins, volontaires, caucasiens, de sexe masculin, étaient répartis en deux groupes randomisés: 100 dans le groupe caféine et 20 dans le groupe placebo. Leur âge était compris entre 18 et 26 ans (moyen 21.2 ans), leur poids entre 52 et 100 kg (moyen 70.7), et leur taille moyenne était de 176.8 cm (compris entre 159 et 200). Le métabolisme de la caféine étant presque exclusivement hépatique, leur phénotype d'acétylation a été déterminé avant l'essai. La répartition en 51 % d'acétyleurs lents et 49 % d'acétyleurs rapides était conforme aux données biographiques connues chez les caucasiens (3).

2.1 protocole

Après une nuit normale, les sujets prenaient à 07h00, à jeun, soit le placebo, soit 600 mg de Caféine LP. Les taux plasmatiques de caféine étaient estimés par des dosages salivaires répétés, le ratio caféine salivaire/ plasmatique étant de 0.74 ± 0.08 (4). La vigilance, l'humeur et le sommeil étaient évalués par les échelles visuelles analogiques de Bond et Lader jusqu'à 24 h après la prise du traitement (5).

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2.2 Résultats (5)

Effets indésirables

Seulement trois sujets ont présenté des effets indésirables: un cas avec le placebo (asthénie aiguë) et deux avec la caféine (nausées, tremblements des extrémités). Ces effets sont apparus dans les quatre heures après la prise et ont disparu spontanément en moins de deux heures.

Pharmacocinétique

Les habitudes de consommation de caféine et le phénotype d'acétylation n'ont pas influencé les paramètres pharmacocinétiques de la Caféine LP. Les fumeurs de tabac habituels avaient des taux salivaires de caféine significativement diminués par rapport aux non-fumeurs.

Vigilance, humeur et sommeil

Il n'est pas apparu de différence dans les deux groupes pour la **vivacité** et le **bien-être**. Seul un item sur les neufs qui composent le facteur vivacité montrait une augmentation de l'éveil 5 heures après la prise de Caféine LP . Les sujets du groupe placebo présentaient un score de **quiétude** supérieur aux sujets sous Caféine LP, 2, 5 et 10 heures après la prise du traitement. Les taux salivaires de caféine étaient corrélés avec ce facteur quiétude ($p<0.01$), mais indépendant de la vivacité et du bien-être. L'endormissement était meilleur pour les sujets du groupe placebo. La qualité du sommeil, le nombre de réveils nocturnes et la qualité de l'endormissement n'ont pas été influencés par le traitement.

La prise unique de 600 mg de Caféine LP est donc bien tolérée chez des hommes jeunes sans privation de sommeil. Le phénotype d'acétylation et les habitudes de consommation de café n'influencent pas la pharmacocinétique, contrairement au tabac. Il convient donc d'évaluer les effets de cette Caféine LP dans une population mixte, avec privation de sommeil. L'influence des contraceptifs oraux qui augmentent la demi-vie et le Cmax de la caféine pourra être ainsi étudiée.

3. AVEC PRIVATION DE SOMMEIL

Cette expérimentation réalisée en double aveugle et selon un plan croisé avait pour but de comparer 3 dosages de Caféine LP (150 mg, 300 mg et 600 mg) à un placebo. Les 24 sujets, 12 femmes, toutes sous contraceptifs oraux, et 12 hommes se sont volontairement soumis à une session d'apprentissage des tests suivie de quatre séances expérimentales, une pour chaque dose (Caféine LP ou placebo). Une fenêtre thérapeutique de 5 à 10 jours séparait les séances. Les sujets, tous caucasiens, étaient âgés de 18 à 38 ans (moyenne 24.4: 24.5 chez les hommes et 24.3 chez les femmes) et présentaient un poids moyen de 68 kg (hommes 76.7 kg et femmes 59.3 kg) et une taille moyenne de 171 cm (177 pour les hommes et 165 pour les femmes). La répartition des fumeurs était égale dans les deux sexes, 10 sujets étaient non fumeurs.

3.1 protocole

Les sujets se présentaient le premier jour (J1) à 06h00 au centre où se déroulait l'essai, et étaient maintenu éveillés jusqu'au lendemain 17h30 (J2), marquant la fin des tests. Ils pouvaient alors rentrer chez eux pour une nuit de récupération, et revenaient le lendemain (J3) à 08h00 pour une dernière évaluation. Ils prenaient le traitement (Caféine LP 150, 300 ou 600 mg, ou placebo) au temps H0, qui était décalé de 30 minutes entre 00h00 et 01h30 (J2) afin de séparer les sujets en quatre équipes. Trois séries de tests de 90 minutes chacune étaient administrées à H2, H9, et H13, soit une privation de sommeil de 34 h maximum à la fin de la dernière épreuve de J2. Chaque série de test comprenait des tests psychomoteurs, forme réduite de la Standardized Tests for Research with Environmental (STRES) battery (6), une mesure électroencéphalographique de la latence d'endormissement (MSLT) pendant 20 minutes maximum, et des échelles visuelles analogiques évaluant subjectivement la vigilance et l'humeur. Des mesures de fréquence cardiaque, de pression artérielle et des prélèvements salivaires pour doser la caféine circulante étaient effectués de H0 à H15, et à H32 (J3).

3.2 résultats

Effets indésirables

Parmi les 24 sujets, huit dont un homme, ont présenté des effets indésirables. Sous placebo, des nausées et vomissements sont apparus chez deux femmes, entre H1 et H6. Ces symptômes ont nécessité l'administration de paracétamol et métoclopramide chez l'une d'elle. Sous Caféine LP 150 mg, trois sujets féminins ont rapportés des tremblements discrets (H3 à H9) ou des palpitations (H3 à H42). Sous 300 mg de Caféine LP, un homme s'est plaint de troubles digestifs légers entre H11 et H14, et quatre femmes ont présenté des signes fonctionnels à type de tremblements, nausées, palpitations , entre H1.5 et H18. Durant la séance avec prise de 600 mg de Caféine LP, le même sujet masculin et deux femmes se sont plaints du même type de symptômes mineurs et transitoires que précédemment.

paramètres hémodynamiques

La fréquence cardiaque et la pression artérielle fluctuaient au cours de la journée, mais il n'y avait aucune différence entre les groupes thérapeutiques.

Pharmacocinétique

Les paramètres cinétiques de la Caféine LP sont reportés dans le tableau II. Les femmes présentaient un pic de concentration salivaire (C_{max}) de caféine et une biodisponibilité (AUC) significativement plus élevés que les hommes. La demi-vie ($T_{½}$) était équivalente dans les deux sexes pour la dose de 150 mg, mais elle significativement rallongée chez les femmes aux doses de 300 et 600 mg. Toutes ces différences statistiques sont retrouvées si on intègre la différence de poids et que l'on retrace les courbes cinétiques en ramenant les sujets à un poids identique. Cette élimination retardée de la Caféine LP chez la femme est à rapporter à la prise d'oestroprogestatifs.

Tableau II. paramètres cinétiques salivaires de la Caféine à libération prolongée. moyenne ± sem.

Caféine LP		**Cmax** µg/ml salive	**AUC** µg/ml.h salive	**T ½** h
150mg	hommes	1.3 ± 0.08	16.9 ± 2.44	5.9 ± 0.67
	femmes	2.1 ± 0.21	29.3 ± 4.77	6.0 ± 0.53
	h + f	1.7 ± 0.14	23.1 ± 2.44	5.9 ±0.42
300mg	hommes	2.4 ± 0.18	30.3 ± 3.49	4.8 ± 0.32
	femmes	4.7 ± 0.36	77.6 ± 9.77	7.6 ± 0.87
	h + f	3.5 ± 0.30	53.9 ± 7.07	6.2 ± 0.54
600mg	hommes	5.4 ± 0.38	69.5 ± 7.12	4.5 ± 0.49
	femmes	9.4 ± 0.71	144.3 ± 22.6	6.4 ± 0.80
	h + f	7.4 ± 0.58	106.9 ± 14.0	5.4 ± 0.50

Latence d'endormissement
Les temps d'endormissements sont reportés dans le tableau III. L'analyse de variance indique qu'il y a un effet significatif du facteur traitement ($p<0.01$) et du facteur horaire ($p<0.0001$) tous sujets et horaires confondus.

Tableau III. Temps d'endormissements (MSLT) mesurés en minutes et secondes.

horaires H 0 = prise traitement	**placebo**	**LP 150 mg**	**LP 300 mg**	**LP 600 mg**
H 2.5 moy ± sem	6:05 ± 1:50	9:00 ± 1:58	11:40 ± 1:02	10:20 ± 1:54
H 9.5 moy ± sem	3:22 ± 0:45	3:30 ± 0:15	4:40 ± 0:18	5:40 ± 1:08
H 13.5 moy ± sem	2:50 ± 0:49	2:30 ± 0:39	4:30 ± 0:56	4:40 ± 0:16

Tests psychomoteurs (STRES Battery)
Trois critères de réponse ont été pris en compte pour les différents tests: temps de réponse moyen pour les bonnes réponses, pourcentage d'erreurs et de non-réponses. A l'exception du traitement mathématique,
dont les scores n'étaient pas significativement différents entre le placebo et la Caféine LP, les autres tests (raisonnement grammatical, traitement spatial, recherche en mémoire, poursuite, double tâche poursuite-mémoire) révélaient un effet significatif de la caféine, toujours dans le sens d'une amélioration. Pour certains tests il y avait un effet sexe lors de la session sous placebo avec des performances plus dégradées chez les femmes pour le raisonnement grammatical, le traitement spatial et la double tâche. Avec la Caféine LP, les femmes présentaient un plus grand nombre d'améliorations significatives ($p < 0.10$) des performances que les hommes. Chez l'homme, la majorité des améliorations se situaient à la séance H9, et chez la femme à H9 et H13 (tableau IV).

Tableau IV. Distribution des améliorations ($p<0.10$) selon les séances des tests de performance.

H 0 = prise du traitement	**H 2**	**H 9**	**H 13**
hommes	8 % (3/38)	61 % (23/38)	31 % (12/38)
femmes	18 % (12/68)	40 % (27/68)	42 % (29/68)

(nombre d'améliorations à une heure donnée / nombre total d'améliorations toutes heures confondues)

Chez l'homme et la femme, le nombre d'améliorations augmentait avec la dose de Caféine LP. La proportion des améliorations était sensiblement la même à la dose prescrite de 300 mg (Tableau V).

Tableau V. Distribution des améliorations des performances ($p < 0.10$) selon les doses de caféine LP.

doses de caféine LP	**150 mg**	**300 mg**	**600 mg**
hommes	11 % (4/38)	26 % (10/38)	63 % (24/38)
femmes	19 % (13/68)	29 % (20/68)	51 % (35/68)

(nombre d'améliorations à une dose donnée / nombre total d'améliorations toutes doses confondues)

Vigilance, humeur et sommeil
Sous placebo les sujets féminins ont rapporté par l'intermédiaire des échelles visuelles analogiques des sensations de **quiétude** et de **bien-être** équivalentes aux sujets masculins, alors que la **vivacité** était significativement dégradée. Tous sujets confondus, la **vivacité** était améliorée par le traitement. Cette amélioration prédominait lors de l'autoévaluation réalisée à H3, comparée à H10 et H14, et était corrélée avec la dose de Caféine LP. L'influence du traitement et du temps sur les items qui composent les facteurs **quiétude** et **Bien-être** était contrastée.
La durée moyenne du **sommeil** lors de la nuit de récupération était augmentée par rapport à la nuit de référence. Les latences d'endormissement étaient plus courtes que lors du sommeil de référence, mais il n'y avait pas d'effet traitement. La qualité du sommeil moins bonne lors de la nuit de récupération, n'était pas influencée par le traitement. Sous caféine le réveil était plus précoce que sous placebo, mais pas plus difficile.

4. CONCLUSIONS

Cette dernière étude, en situation de privation de sommeil de 20 à 34 heures, confirme la bonne tolérance de cette forme de Caféine à libération prolongée. La récupération des sujets n'est pas pénalisée. Les performances et la vigilance sont améliorées, avec un effet sur les performances plus prononcé pour les tâches complexes et retardé par rapport à la perception de l'augmentation de la vigilance. Les améliorations des performances sont corrélées avec les taux de caféine circulant et sont d'autant plus importantes que la détérioration de la vigilance engendrée par la privation de sommeil est prononcée. L'efficacité plus prolongée et à des doses plus faibles de la Caféine LP chez les femmes semble être multifactorielle. Les femmes dans nos conditions expérimentales sont plus sensibles que les hommes à la privation de sommeil, et du fait d'un poids corporel inférieur et de la prise d'oestroprogestatifs présentaient des taux de caféine circulant plus élevés. L'utilisation en dose unique de 300 mg de Caféine à

libération prolongée semble suffisante pour allier maintien de la vigilance et des performances en situation de privation de sommeil et bonne tolérance clinique. Contrairement aux psychostimulants type amphétamines ou à l'eugrégorique modafinil, le café est largement consommé dans le monde, ainsi la Çaféine LP bénéficie d'un a priori culturel favorable, qui ne peut que faciliter l'emploi d'un tel produit. Cette forme de caféine représente donc une contre-mesure pharmacologique efficace pour lutter contre les troubles de la vigilance en situation de privation de sommeil ou de désynchronisation, et adaptée à l'environnement opérationnel.

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SLOW RELEASE CAFFEINE : A VALID PHARMACOLOGICAL COUNTERMEASURE

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ABSTRACT

Sleep deprivation and desynchronization due to night watch, continuous operations or jet lag induce sleepiness and a decrement in performances: studies have shown that caffeine can be an effective countermeasure in such circumstances. We evaluated a slow release caffeine (SRC), which delays the mean peak plasma concentration and lowers the plasmatic Cmax. Tolerance of 600 mg SRC was assessed in a double-blind, placebo controlled, parallel-group study, involving 120 young adult males. This single dose of SRC was well tolerated by these rested subjects. Pharmacokinetic parameters were not influenced by acetylator status or caffeine use; however calmness and sleep onset were disturbed. Then in another experiment we evaluated in four sessions, 150, 300, 600 mg SRC and a placebo in 24 sleep deprived male and female subjects. Alertness and psychomotor performance were enhanced in both sex. The higher sensitivity to caffeine doses observed in the female group was related to greater susceptibility to sleep deprivation, and to increased salivary caffeine levels correlated with inferior body weight and use of oral contraceptives. Therefore the use of 300 mg SRC by fatigued subjects may significantly improve alertness and performance, with a wider acceptance and tolerance than other psychostimulants like dextroamphetamine.

1. INTRODUCTION

As a psychostimulant, caffeine has been widely used in situation of sleep deprivation, fatigue, and circadian desynchronization.. Due to its acceptance and safety (1), it is recommended by the military during continuous operations, even if more efficient performance maintenance medications are available. The present studies evaluate a new Slow Release Caffeine (SRC). Compared to an aqueous solution of caffeine, this SRC increases the mean delay to peak plasma concentration (T_{max}) and lowers the C_{max} (peak drug concentration) (Table I) (2). At first we evaluated the pharmacokinetics and tolerance of a single oral administration of 600 mg SRC, on 120 young healthy male adults, without sleep deprivation. Then we experimented 150 mg, 300 mg and 600 mg SRC on 12 male and 12 female sleep deprived subjects. Effects on blood pressure, pulse, mood, alertness and performance were monitored.

Table I: Caffeine pharmacokinetic parameters: aqueous solution and Slow Release. Mean ± sem.

caffeine 300 mg /60Kg	**C_{max}** µg/ml plasma	**T_{max}** h	**T ½** h	**AUC** µg/ml plasma h
aqueous solution	6.9 ± 0.3	1.2 ± 0.2	5.4 ± 0.6	57.8 ± 4.9
slow release	5.5 ± 0.3 $p < 0.05$	4.1 ± 0.3 $p < 0.05$	5.1 ± 0.6	54.2 ± 6.4

2. WITHOUT SLEEP DEPRIVATION

In this double blind, parallel-group study, 120 enlisted male Caucasian sailors, who volunteered, were randomly assigned either to a caffeine (100 subjects) or a placebo (20 subjects) group. Ages ranked from 18-26 yr (mean: 21.2), weights from 52-100 kg (mean: 70.7) and heights from 159-200 cm (mean: 176.8). In order to evaluate their caffeine metabolism, virtually confined to the liver, acetylation phenotype of all subjects was determined. Our population consisted of 51 % slow acetylators and 49 % rapid acetylators, ratio consistent with the proportion of acetylator phenotypes known in Caucasian population (3).

2.1 protocol

After a normal night, at 0700 hours each subject took either placebo, or 600 mg of SRC, on an empty stomach. Circulating caffeine was estimated by salivary caffeine assays performed on recurrent salivary samples. The concentration of caffeine in saliva is correlated with plasmatic caffeine in a ratio of 0.74 ± 0.08 (4). Mood, alertness and subjective sleep were evaluated by repeated Bond and Lader analog scales (VAS) and sleep questionnaire up to 24 h after treatment (5).

2.2 Results (5)

Adverse events

Subjects reported 3 adverse events: 1 with placebo (acute fatigue) and 2 with SRC (nausea, hand tremor). They appeared within 4 h of drug intake and spontaneously ceased in less than 2 h.

Pharmacokinetics

Caffeine habits and acetylator status did not influence pharmacokinetc parameters of SRC. Compared to non smokers, habitual tobacco users had lower circulating caffeine levels .

Mood, alertness and sleep
Between placebo and SRC group, there were no significant differences for alertness and contentedness. Only one alertness rating item indicated a significant awakening effect 5 h after treatment. Calmness was significantly increased in placebo subjects 2, 5 and 10 h after treatment intake. Salivary caffeine levels were correlated with calmness ($p<0.01$), whereas alertness and contentedness had no significant relationship with caffeine ratio. Sleep onset was scored better for placebo subjects. No significant differences appeared for quality of sleep, number of awakenings and quality of sleep onset. A single oral dose of 600 mg of SRC is therefore well tolerated in young male adults, without sleep deprivation. Smoking tobacco influenced the pharmacokinetic parameters, whereas acetylator phenotypes and caffeine habits did not significantly modify them. Further evaluation must be done in order to evaluate the effects of this SRC in sleep deprived subjects, including female using oral contraceptives known to prolong caffeine half life.

3. WITH SLEEP DEPRIVATION

The main purpose of this double blind, placebo controlled, crossover Latin square design study, was to evaluate 3 doses of SRC (150 mg, 300 mg and 600 mg). The 24 Caucasian subjects, 12 female adults using oral contraceptives, and 12 male volunteers, were submitted to 4 sessions, each with a different treatment. The sessions were separated by 5 to 10 days wash-out period. Ages ranked from 18-38 yr (mean: 24.4, 24.5 in male group and 24.3 in female group), mean weight was 68 kg (males 76.7 kg and females 59.3 kg) and mean heights was 171 cm (177 in males and 165 in females). Smoking habits were recorded, and smoker/non smoker ratio was the same in female and male (10 subjects were non smokers.

3.1 protocol
Subjects came at the laboratory on day 1 (D1) at 0600 h and were maintained awake until the end of the session on D2 at 1730 h. Then they were allowed to go back to their home for a recovery night, and had to come back to the laboratory on D3 at 0800 h for the last tests. They took the treatment (SRC 150, 300 or 600 mg, or placebo)at time zero (H0), which took place between 0000 h and 0130 h every 30 minutes (D2) in order to separate the different groups of subjects. Three tests sessions, each one lasting 90 minutes, were administered at H2, H9 and H13. By the end of the last test sessions on D2, the subjects had a 34 h maximum sleep deprivation. Each tests session included psychomotor tets, short version of the Standardized Tests for Research with Environmental Stressors (STRES) battery (6), a multiple sleep latency test (MSLT) with EEG recording, conducted during a maximum of 20 minutes, and visual analog scales to assess mood and alertness. From H0 to H15 (D2) and at H32 (D3) blood pressure and heart rate were monitored and salivary samples obtained to assess cardio vascular tolerance and circulating caffeine levels.

3.2 results
Adverse events
Seven female and one male subjects presented adverse events. With placebo, nausea and vomiting occurred in 2 female volunteers, between H1 and H6; one received paracetamol and metoclopramide to control the symptoms. With SRC 150 mg, 3 female subjects reported moderate tremors (H3 to H9) or palpitations (H3 to H42). With SRC 300 mg, one man complained of mild gastrointestinal disorders between H11 and H14, and 4 female subjects reported tremor, nausea, palpitations between H1.5 and H18. During the 600 mg SRC session, one male and 2 female subjects had the same minor temporary side effects.

Cardio vascular parameters
Variation of heart rate and blood pressure was not influenced by SRC.

Pharmacokinetic
Pharmacokinetic parameters are reported in table II. Women had a salivary peak drug concentration (C_{max}) and bioavailability (AUC) higher than men. Half life ($T_{½}$) was much the same in both sexes for the 150 mg SRC dose, and was longer in female for SRC 300 and 600 mg. These statistical differences remained after compensation for weight. This delayed caffeine elimination is related to the oral contraceptives intake.

Table II. SRC salivary pharmacokinetic parameters. mean ± sem.

SRC		Cmax µg/ml salivary	AUC µg/ml.h salivary	T ½ h
150mg	males	1.3 ± 0.08	16.9 ± 2.44	5.9 ± 0.67
	females	2.1 ± 0.21	29.3 ± 4.77	6.0 ± 0.53
	m + f	1.7 ± 0.14	23.1 ± 2.44	5.9 ±0.42
300mg	males	2.4 ± 0.18	30.3 ± 3.49	4.8 ± 0.32
	females	4.7 ± 0.36	77.6 ± 9.77	7.6 ± 0.87
	m + f	3.5 ± 0.30	53.9 ± 7.07	6.2 ± 0.54
600mg	males	5.4 ± 0.38	69.5 ± 7.12	4.5 ± 0.49
	females	9.4 ± 0.71	144.3 ± 22.6	6.4 ± 0.80
	m + f	7.4 ± 0.58	106.9 ± 14.0	5.4 ± 0.50

Sleep latency
Sleep latency is reported in table III. There is a significant treatment ($p<0.01$) and time ($p<0.0001$) effect.

Table III. Multiple Sleep Latency Test (MSLT) in minutes and seconds.

time **H 0** = drug intake	placebo	SRC 150 mg	SRC 300 mg	SRC 600 mg
H 2.5 mean ± sem	6:05 ± 1:50	9:00 ± 1:58	11:40 ± 1:02	10:20 ± 1:54
H 9.5 mean ± sem	3:22 ± 0:45	3:30 ± 0:15	4:40 ± 0:18	5:40 ± 1:08
H 13.5 mean ± sem	2:50 ± 0:49	2:30 ± 0:39	4:30 ± 0:56	4:40 ± 0:16

Psychomotor tests (STRES Battery)
Performance was evaluated by mean response time, error levels and no response ratio. Mathematical processing scores were not essentially different between placebo and SRC. However in all the other tests (grammatical reasonning task, spatial processing, memory search, unstable tracking, dual task tracking -memory search) performance was improved by SRC. Female subjects exhibited a decrement of performance for grammatical reasonning, spatial processing and dual task with placebo, whereas their scores with SRC showed greater significant improvement ($p < 0.10$) than their male counterpart. Most of performance improvements occured at H9 in men and at H9 and H13 in women (table IV).

Table IV. performance improvement distribution within the 3 different test sessions. ($p < 0.10$)

H 0=drug intake	H 2	H 9	H 13
males	8 % (3/38)	61 % (23/38)	31 % (12/38)
females	18 % (12/68)	40 % (27/68)	42 % (29/68)

(number of improvements at one test session / total number of improvements in the 3 test sessions)

Number of performance improvements were positively correlated with SRC doses in male and female subjects with similar results for the 300 mg dose (Table V).

Table V. Performance improvement distribution within SRC doses ($p < 0.10$) .

SRC	150 mg	300 mg	600 mg
males	11 % (4/38)	26 % (10/38)	63 % (24/38)
females	19 % (13/68)	29 % (20/68)	51 % (35/68)

(number of improvements with one dose / total number of improvements with the 3 SRC doses)

Mood, alertness and sleep
With placebo, female and male subjects reported similar scores for calmness and contentedness, whereas a decrement in alertness appeared in the female group. In both sexes, alertness was enhanced by the SRC. This improvement was larger at H3, compared to H10 and H14, and was correlated with SRC doses. Influence of treatment and time on calmness and contentedness was not significant. Mean recovery sleep time was augmented compared to reference sleep. Sleep onset latency was shorter but not statistically different in the SRC or placebo groups. The lower quality of sleep during the recovery night was not influenced by the treatment. With SRC, morning awakening was advanced but not more difficult than with placebo.

4. CONCLUSIONS

These data suggest that under sleep deprivation (20 to 34 h) this Slow Release Caffeine is well tolerated, and do not alter the recovery night. Psychomotor performances and alertness benefit from the treatment. The positive effect on performance is more patent with complex tasks and after awareness of alertness improvement. The performance gains are correlated with circulating caffeine and are more pronounced with the most fatigued subjects. SRC action is extended in female and at lower doses. In our experimental conditions, female subjects were more sensitive to sleep deprivation. They exhibited higher circulating caffeine levels, which was consistent with lower body weight and oral contraceptives intake. Therefore a single oral dose of a well tolerated 300 mg SRC, is sufficient to maintain alertness and performance in a sleep deprivation situation. Also the world wide consumption of coffee may facilitates SRC acceptance, whereas psychostimulants like amphetamines or eugregorics like modafinil may face legal or sociological restrictions. This caffeine form represents a valid pharmacological counter measure for alertness and performance decrements caused by sleep deprivation or sleep-wake rythm disruption, and is adapted to operational use.

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"COGNITIVE PERFORMANCE DURING A 64-HOURS SLEEP DEPRIVATION: INTEREST OF A SLOW RELEASE CAFFEINE"

"Performances cognitives de sujets soumis à une privation de sommeil totale de 64 heures : interêt d'une forme à libération prolongée de caféine"

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ABSTRACT:

Sleep deprivation is a consequence of modern military warfare. It leads to mental and physical performance decrement. Historically, psychostimulants have been widely used in the military context. Among them, caffeine is the most commonly taken - thus not prescribed - substance to cope with fatigue. Caffeine increases the level of alertness and the cognitive performance of fatigued personnel. Nevertheless, this effect is transitory and leads to chronic consumption and well known side effects. Recently, a slow release (SR) caffeine has been designed by NESTEC to improve its « usability » in sleep deprivation context.

We present some data of an experiment conducted to answer the two following questions :
- firstly, is SR caffeine an effective substance to maintain a good level of alertness during a 64-hours sleep deprivation ? (the results have been presented at the NATO - DRG - Workshop on "Sleep management in the military ", held in Roma 21-22 April 1997)
- secondly, is it able to alleviate the performance decrement of subjects ?
We will focus here on the results of the last objective.

Methodology:

Sixteen healthy young male volonteers have participated to a 64-hours sleep deprivation double blind cross over study (SR caffeine versus placebo). After one day dedicated to training, sleep deprivation has occured between monday morning and wednesday evening. During that period, subjects have taken 300 mg SR caffeine every 12 hours from monday 9 PM to wednesday 9 AM. They have performed test sessions including a focused attentionnal test (BATP) and the AGARD Stres Battery. BATP test lasts 10 minutes and consists in crossing targets embedded in a page of signs. AGARD Stres Battery includes complex reaction time, various tasks (mathematical, memory, spatial, tracking, grammatical, dual ones) and leads to a total of 46 different results. The test session schedule was: each day at 10/12 AM and 02/04 PM; each night at 10/12 PM and 02/04 AM. A recovery period has followed from wednesday evening (11 PM) to friday evening (5 PM). During that period, subjects has been allowed to sleep two 8-hours nights and has been diurnally tested only. This means a total of 14 test sessions for the entire experimental period.

The data have been analysed with PCSM software in a two way

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ANOVA (session x treatment) with one repeated factor (session). In the case of a statistical significance, a Newman-Keuls test has been performed.

Results :

Sleep deprivation period:

* Attentionnal performance is better with caffeine than with placebo from 15 to 55 hours of sleep deprivation ($p<0.01$). Nevertheless, there is a deep of performance after 41 hours of continuous awakening for both treatment.
* Stres Battery: considering response time and / or percentage of error and / or percentage of non response, performance of subjects is better under caffeine than under placebo, whatever the task of the battery. These results appears until 39-45 hours of sleep deprivation (even more for some data) with statistical significance ($p<0.05$).

Recovery period:

* Attentionnal performance shows no difference between placebo and caffeine for that period. But a certain gain of performance appears - for both treatment - compared to the reference period, possibly due to a learning or motivation effect.
* Concerning the Stres Battery, there is no difference between placebo and caffeine condition for all data (except for the percentage of non response of the grammatical reasonning task which is higher for the caffeine group).

Conclusion :

Previous data obtained with SR caffeine are confirmed. These results indicate that 300 mg SR caffeine is an effective substance to maintain cognitive performance during limited (45 hours) sleep deprivation. It does not impair recovery performance. Potential use concerns the treatment of Jet Lag syndrom and the pharmacological management of limited sleep deprivation or extended duty, either in military or civilian context.

RESUME :

La privation de sommeil est une des conséquences des opérations militaires modernes. Elle conduit à une dégradation des performances physiques et mentales. Historiquement, le recours aux psychostimulants existe depuis longtemps en milieu militaire. Parmi ceux-ci, la caféine est probablement la substance la plus consommée - à défaut d'être prescrite - pour diminuer la sensation de fatigue. La caféine élève le niveau d'éveil et les performances cognitives des sujets fatigués. Néanmoins, cet effet est transitoire et entraîne une consommation chronique avec des effets secondaires bien connus. Récemment, une forme à libération prolongée de caféine (caféine LP) a été mise au point par la société NESTEC afin de faciliter l'emploi de cette molécule dans des contextes de privation de sommeil. Une expérimentation a été conçue de façon à tester son pouvoir éveillant et sa capacité à éviter la dégradation des performances cognitives des opérateurs lors d'une privation de sommeil totale de 64 heures.

Méthodologie :

Seize jeunes volontaires sains, de sexe masculin, ont participé à une étude de privation de sommeil totale de 64 heures avec prescription en essai croisé et double aveugle de caféine LP versus placebo. La privation de sommeil débute le lundi matin pour se terminer le mercredi soir. Pendant cette période, les sujets prennent 300 mg de caféine LP toutes les 12 heures du lundi soir 21h00 au mercredi matin 9h00. Ils réalisent un test d'attention concentrée (BATP) et l'ensemble des tests de l'AGARD Stress Battery selon les horaires suivants : le jour de 10h00 à 12h00 et de 14h00 à 16h00, et la nuit de 20h00 à 22h00 et de 2h00 à 4h00. Suit une période de récupération de deux nycthémères allant du mercredi soir au vendredi soir pendant laquelle les sujets sont testés

uniquement le jour et ont droit à deux nuits de sommeil limitées à 8 heures.

Résultats :

Période de privation de sommeil :

* La performance au test d'attention concentrée est meilleure sous caféine que sous placebo pendant toute la durée de la privation. Mais un bon niveau de performance ne peut être maintenu après 45 heures de privation de sommeil.
* Concernant la batterie de tests de l'AGARD, si l'on considère les temps de réponses, les nombres d'erreurs et les nombres de non-réponses, les performances des sujets sont meilleures sous caféine que sous placebo quelle que soit la tâche expérimentale. Les différences sont significatives pour des durées variables suivant les différentes tâches mais se situent aux alentours de 45 heures d'éveil continu.

Période de récupération :

* Il n'existe pas de différence entre les conditions caféine et placebo pour la performance au test d'attention concentrée. Cependant, un gain de performance apparaît pour l'ensemble des sujets par rapport à la situation de référence traduisant un effet d'apprentissage ou de motivation.
* Concernant la batterie de tests de l'AGARD, il n'y a pas de différence entre les conditions placebo et caféine à une seule exception : pour la tâche de raisonnement grammatical, le nombre de non-réponses est plus important chez les sujets ayant reçu la caféine.

Conclusion :

Cette expérimentation confirme les données obtenues précédemment avec la caféine LP. Ces résultats démontrent que la Caféine LP 300 mg est efficace pour maintenir les performances cognitives durant des privations de sommeil limitées à 45 heures. Elle ne perturbe pas les performances lors de la récupération. Son utilisation potentielle peut être envisagée pour le traitement du syndrome lié au franchissement de fuseaux horaires (Jet Lag) et pour la gestion pharmacologique des privations limitées de sommeil en contexte militaire ou civil.

"Performances cognitives de sujets soumis à une privation de sommeil totale de 64 heures : interêt d'une forme à libération prolongée de caféine"

1 - Introduction :

La privation de sommeil est une des conséquences des opérations militaires modernes. Elle conduit à une dégradation des performances physiques et mentales (Tilley.et Brown, 1992.). Historiquement, le recours aux psychostimulants existe depuis longtemps en milieu militaire (Lagarde et Batejat, 1995). Parmi ceux-ci, la caféine est probablement la substance la plus consommée - à défaut d'être prescrite - pour diminuer la sensation de fatigue. La caféine élève le niveau d'éveil et les performances cognitives des sujets fatigués (Lieberman et col. 1987 ; Zwyghuizen-Doorenbos et col. 1990 ; Debry 1993 ; Lorist et col. 1994). Néanmoins, cet effet est transitoire et entraîne une consommation chronique avec des effets secondaires bien connus (Griffiths et Woodson 1988, Rogers et al 1995).

Récemment, une forme à libération prolongée de caféine (caféine LP) a été mise au point par la société NESTEC afin de faciliter l'emploi de cette molécule dans des contextes de privation de sommeil. Cette forme galénique originale permet une diminution de la vitesse d'absorption de la caféine. Cette vitesse assure un taux plasmatique de caféine n'entraînant pas une accumulation de la molécule susceptible de donner des effets indésirables lors d'administration

réitérées. Les facteurs de variations pharmacocinétiques de la caféine LP sont identiques à ceux de la caféine en solution. Pour la dose recommandée de 300 mg, les taux circulants et les variations observées restent bien inférieures à ceux susceptibles d'engendrer des effets indésirables (Louguet, 1997). Une première étude en privation de sommeil a permis de déterminer que la dose de 300 mg présente le meilleur rapport bénéfice / risque par rapport aux doses de 150 ou 600 mg. L'effet éveillant est efficace immédiatement, celui sur les performances psychomotrices est un peu plus tardif tout en assurant une tolérance clinique et biologique satisfaisante (Lagarde et col. 1996).
Notre expérimentation avec la caféine LP 300 mg a été conçue de façon à tester son pouvoir éveillant et sa capacité à éviter la dégradation des performances cognitives d'opérateurs soumis à une privation de sommeil totale de 64 heures. Seuls la méthodologie générale et les résultats concernant les performances des sujets seront évoqués ici. Le protocole expérimental a reçu l'accord d'un comité d'éthique, dans le respect des lois Françaises sur l'expérimentation biomédicale humaine.

2 - Méthodologie, données recueillies et traitements :

Seize jeunes volontaires sains, de sexe masculin, ont participé à une étude de privation de sommeil totale de 64 heures avec prescription en essai croisé et double aveugle de caféine LP versus placebo. Après une première journée destiné à la familiarisation avec les tests psychotechniques, la privation de sommeil débute le lundi matin pour se terminer le mercredi soir. Pendant cette période, les sujets prennent 300 mg de caféine LP toutes les 12 heures du lundi soir 21h00 au mercredi matin 9h00 (4 prises au total). Ils réalisent un test d'attention concentrée (BATP) et l'ensemble des tests de l'AGARD Stress Battery selon les horaires suivants : chaque jour de 10h00 à 12h00 et de 14h00 à 16h00, et chaque nuit de 20h00 à 22h00 et de 2h00 à 4h00. Suit une période de récupération de deux nycthémères allant du mercredi soir 23h00 au vendredi fin d'après midi (17h00) pendant laquelle les sujets sont testés uniquement le jour et ont droit à deux nuits de sommeil limitées à 8 heures. Pendant toute la durée de l'expérimentation, les sujets bénéficient d'une surveillance médicale constante avec, à leur demande, la possibilité d'un entretien psychologique.

Les tests psychotechniques comprennent :
* le test d'attention concentrée BATP de Toulouse et Piéron, qui consiste en une tâche de détection et barrage de signes cibles mélangés au sein d'une page à des signes distracteurs. Sa durée est de 10 minutes. Le score s'exprime par une valeur comprise entre -1 (minimum) et +1 (maximum).
* La Stres Battery, qui comprend sept tests psychomoteurs, a été élaborée par un groupe de travail de la commission de Médecine Aérospatiale de l'AGARD pour permettre la standardisation de l'évaluation des effets de tout facteur de stress sur la performance. Ces tests, sélectionnés parmi les épreuves les plus couramment utilisées répondent aux conditions de validité, fiabilité et sensibilité, et sont implantés sur micro-ordinateurs. Il s'agit:
- d'une tâche de temps de réaction qui permet l'évaluation des cinq étapes de traitement suivantes: traitement de la stimulation ou codage, choix de la réponse, programmation de la réponse motrice, activation motrice et enfin exécution de la réponse avec la mise en place de quatre variables correspondant aux caractéristiques visuelles du stimulus, à la compatibilité entre le stimulus et la réponse, au degré

d'incertitude dans l'apparition de la stimulation et enfin à la complexité de la réponse que le sujet doit fournir, ce test comporte six modules, un module de base, un module avec stimulation codée, un module avec délai incertain, un module avec réponse complexe, un module avec réponse inversée et un deuxième module de base en fin de test destiné à mesurer la performance de base après 10 minutes de test,

- d'une tâche de traitement mathématique qui permet l'évaluation des ressources des processus centraux primaires (mémoire à long terme) associés à la mémoire de travail,
- d'une tâche de recherche en mémoire qui comprend les étapes suivantes: détection et reconnaissance du stimulus cible, recherche en mémoire et comparaison, sélection de la réponse, composée d'un module avec 2 lettres et d'un module avec 4 lettres,
- d'une tâche de traitement spatial qui correspond à une mesure des capacités de rotation mentale et de mémoire visuelle à court terme,
- d'une tâche de poursuite destinée à mesurer les ressources utilisées dans l'exécution d'une tâche de contrôle visuo-moteur continu,
- d'une tâche de raisonnement grammatical qui mesure l'habileté à manipuler des informations grammaticales en utilisant la mémoire de travail,
- d'une double tâche utilisant simultanément la tâche de poursuite et la tâche de recherche en mémoire qui permet la mesure des capacités d'attention divisée, ce test comprend deux modules correspondant aux conditions de recherche en mémoire 2 et 4 lettres.

Les critères évalués sont le temps de réponse moyen pour les bonnes réponses, le pourcentage d'erreurs et le pourcentage de non-réponses pour l'ensemble des tâches sauf pour les tâches de poursuite dans lesquelles sont mesurés: un indice de déviation correspondant à l'écart moyen du curseur par rapport au centre de la cible et un nombre de pertes de contrôle, nombre de fois où le curseur sort de l'écran. Au total, l'ensemble des épreuves aboutit à 46 résultats pour une passation.

Compte tenu de l'état de certains sujets, observé au cours de la réalisation des tests, des corrections ont été apportées aux données brutes recueillies. Ces corrections correspondent à des temps aberrants, temps trop courts obtenus en gardant le doigt appuyé sur une des « touche-réponse » par des sujets somnolents. Le nombre total de ces corrections est faible comparé au nombre total de stimulations traitées par les sujets pendant l'expérimentation.

Les données numériques des tests psychotechniques sont traitées sur le logiciel statistique PCSM par ANOVA à deux facteurs dont un à mesures répétées avec un facteur « traitement » à deux modalités placebo/caféine et un facteur répété « horaire ou session ». Lorsque les conditions de validité sont réunies, un test de comparaison multiple de moyennes de Newman-Keuls est effectué de façon à pouvoir classer les scores.

3 - Résultats :

3.1 - Période de privation de sommeil :

* le test d'attention concentrée BATP :

La performance au test d'attention concentrée est meilleure sous caféine que sous placebo pendant toute la durée de la privation ($p<0.01$). Mais il apparaît une chute de performance nette après 41 heures d'éveil continu quelle que soit la condition pharmacologique (voir schéma n°1). Au delà de 45 heures, la performance du groupe caféine rejoint les valeurs du groupe placebo en début

voire milieu de privation et ne peut plus être considérée comme optimale.

* La Stres Battery informatisée de l'AGARD :

L'ensemble des résultats statistiquement significatifs est résumé dans le tableau n° 1 se trouvant plus bas. Sont indiquées les différentes tâches pour lesquelles le score sous caféine sont supérieurs aux scores sous placebo, la nature de ces scores, les intervalles temporels pendant lesquels ils sont obtenus et les valeurs correspondantes du p.

3.2 - Période de récupération :

* Test d'attention concentrée BATP :

Il n'existe aucune différence statistiquement significative entre les sujets sous placebo et sous caféine. Tous sujets confondus, la performance des sujets en récupération est supérieure à celle en période de référence et démontre un profil rythmique à tendance ascendante (voir schéma n° 1). Ce résultat peut s'interpréter soit comme un effet d'apprentissage préalablement masqué par la privation de sommeil, soit comme un biais de motivation à l'approche de la fin de la semaine expérimentale.

* La Stres Battery informatisée de l'AGARD :

Il n'existe pas de différence significative entre les groupes caféine et placebo pour les modules « temps de réaction », « traitement mathématique », « recherche en mémoire 2 et 4 lettres », « traitement spatial », « tâche de poursuite instable », et « double tâche ». Concernant la tâche de raisonnement grammaticale, le score de non-réponses du groupe placebo est supérieur au groupe caféine pour l'ensemble de la période de récupération ($p = 0.026$).

4 - Discussion :

Les résultats sous caféine en période de privation sont constamment meilleurs que sous placebo pour la majorité des tests employés. Ceci conforte l'idée selon laquelle la caféine LP est capable de maintenir un niveau de performance supérieur à celui de la situation placebo. Pour le test d'attention, une conclusion identique s'affirme aux vues des résultats. Il est intéressant de remarquer la nature des scores significativement meilleurs sous caféine LP. Sur les 21 résultats significatifs obtenus, le temps de réponse n'est pas ou peu modifié (4 résultats sur 21). Au contraire, les pourcentages d'erreurs et de non-réponses sont majoritairement améliorés (respectivement 8 et 9 résultats sur 21). Si le fait de faire moins d'erreur peut facilement être rattaché à une performance brute, le pourcentage de non-réponse constitue un indice plus directement lié à l'éveil du sujet.

Concernant la durée d'action du produit sur les performances cognitives des sujets, elle varie d'un test à l'autre pouvant parfois couvrir la totalité de la période de privation.

Deux tendances générales se dégagent néanmoins :

- Premièrement, la caféine LP n'est pas immédiatement efficace. Les données de la littérature sont ici retrouvées (6, 7, 12, 1, 7 et 10). Il faut attendre la chute normale des performances due à la privation de sommeil pour voir les sujets sous caféine LP se différencier des sujets contrôle. L'effet bénéfique de la caféine LP s'exerce donc seulement lorsque les sujets sont fatigués, c'est à dire à partir de la première nuit de privation (dès 15/19 heures d'éveil continu).
- Deuxièmement, les valeurs de performance sont à mettre en relation avec les données psychophysiologiques recueillies par ailleurs et non présentées ici. Au cours de cette expérimentation,

l'effet éveillant de la caféine LP se manifeste clairement jusqu'à 45 heures d'éveil continu (5). Ce point d'inflexion se situe en deçà de la majorité des résultats de performances obtenues (à l'exception du test de traitement mathématique). Sa valeur peut être retenue comme la limite d'emploi du produit garantissant un niveau de performance acceptable.

En période de récupération, les sujets caféine et placebo ne se différencient pas en terme de performances attentionnelles ou cognitives. Le seul résultat significatif concerne le facteur "traitement" dans la tâche de raisonnement mathématique. C'est aussi le seul résultat en défaveur de la caféine LP pour toute la durée de l'expérimentation. Son caractère unique, isolé par rapport à l'ensemble de la batterie de test permet de le considérer comme négligeable.

5 - Conclusion :

Cette expérimentation confirme les données obtenues précédemment avec la caféine LP. Ces résultats démontrent que la Caféine LP 300 mg est efficace pour maintenir les performances cognitives durant des privations de sommeil limitées à 45 heures. Elle ne perturbe pas les performances lors de la récupération. Son utilisation potentielle peut-être envisagée pour le traitement du syndrome lié au franchissement de fuseaux horaires (Jet Lag) et pour la gestion pharmacologique des privations limitées de sommeil en contexte militaire ou civil.

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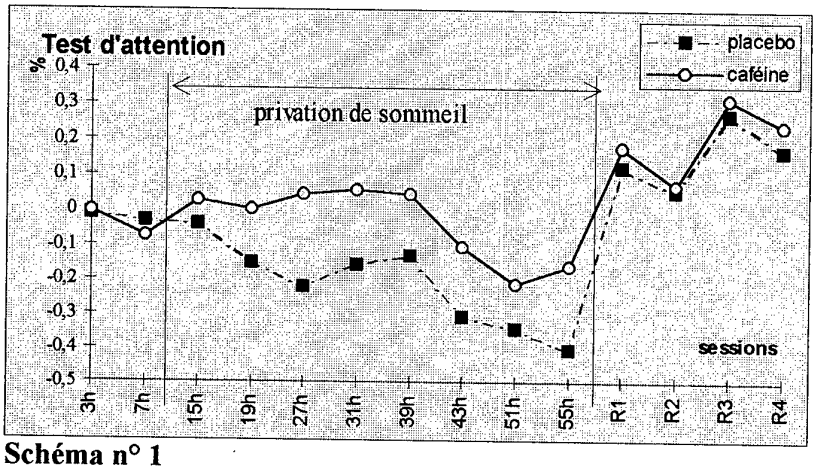


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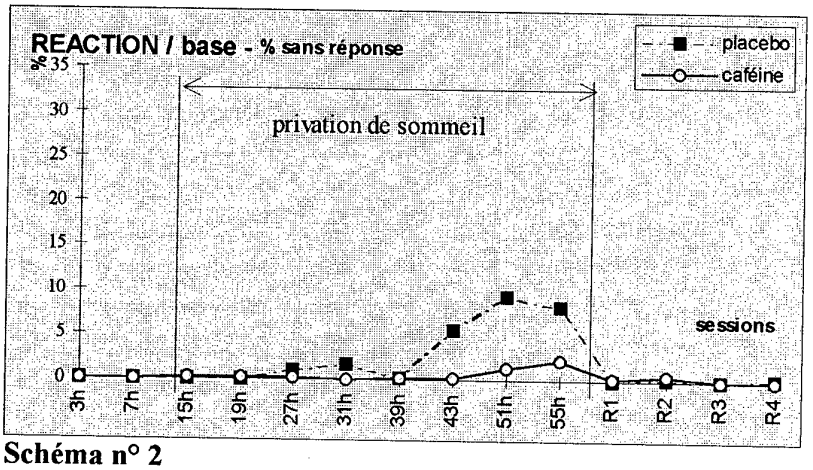


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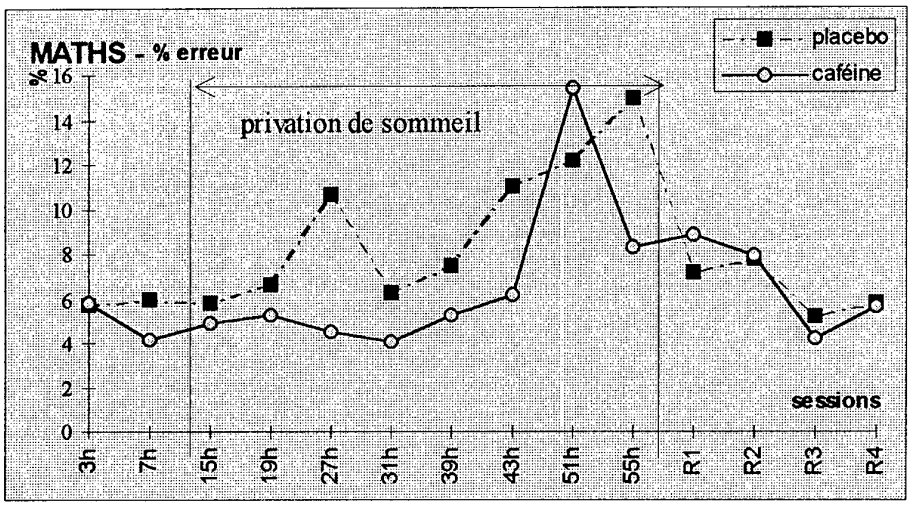


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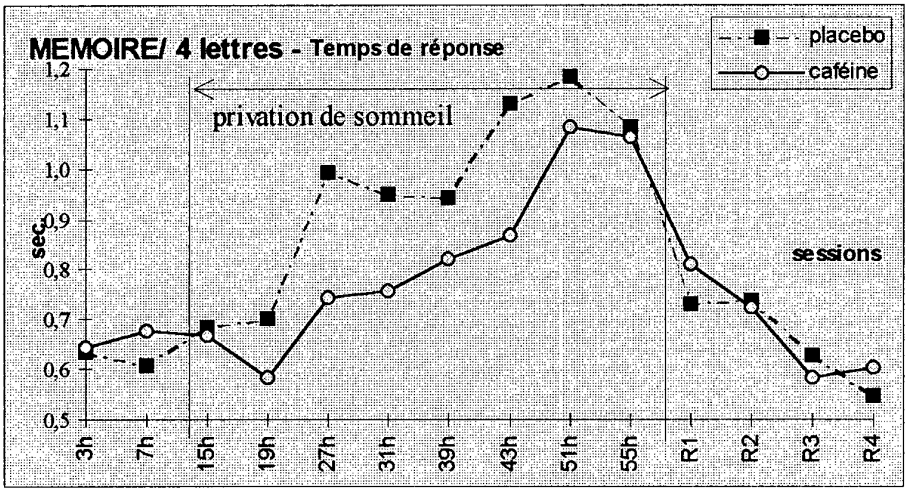


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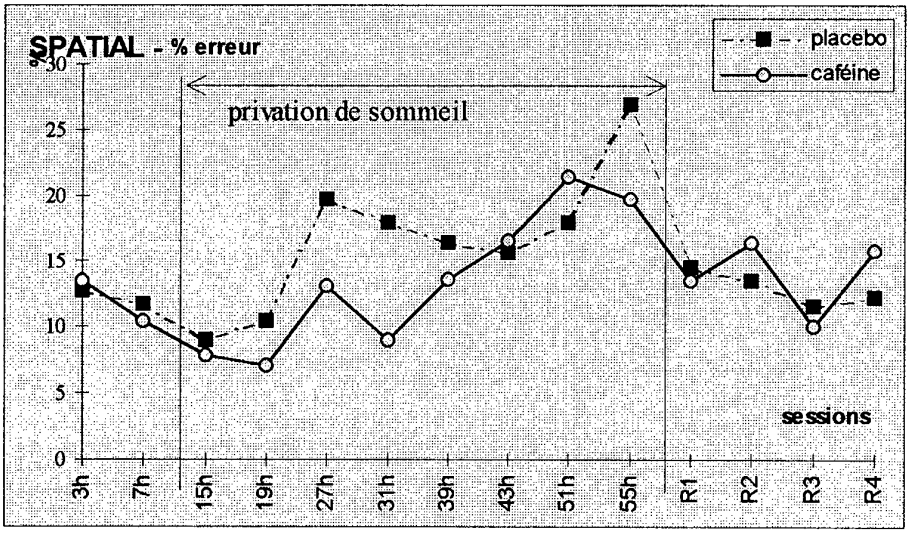


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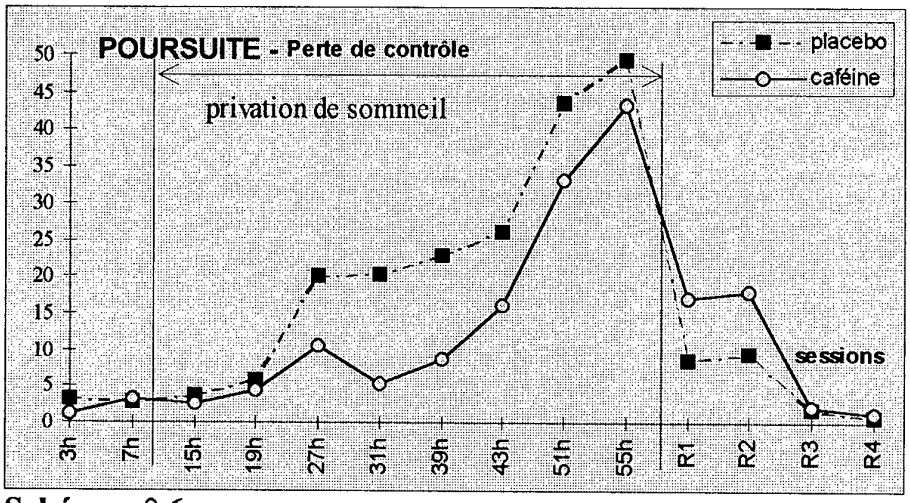


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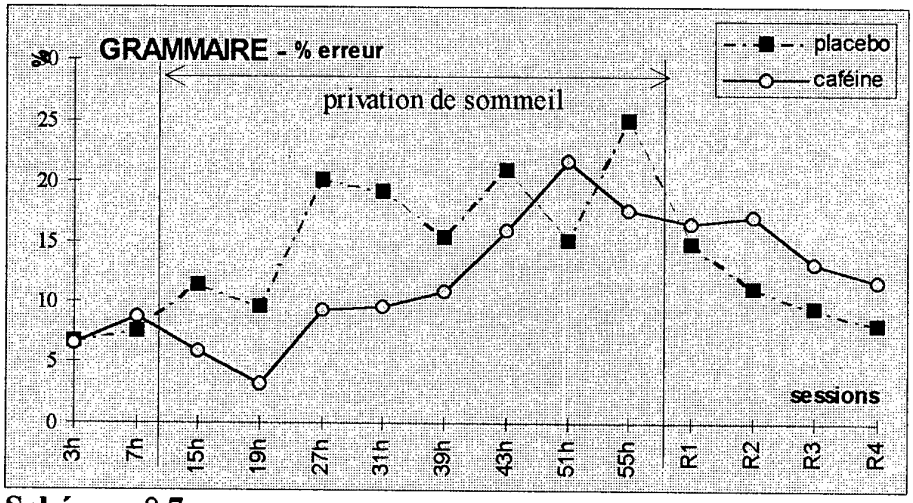


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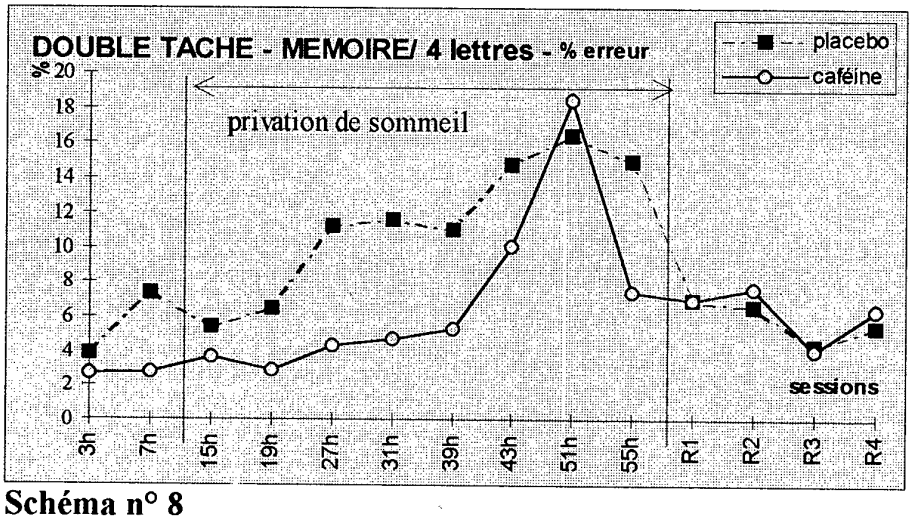


Schéma n° 8

Tâche pour laquelle la performance est supérieure sous caféine par rapport au placebo	Horaires pendant lesquels un résultat significatif en faveur de la caféine est obtenu	Valeur du p
Temps de réaction de base % non-réponse **(schéma n° 2)**	de 39 à 57 heures	p = 0.027
Temps de réaction codé % d'erreurs	de 27 à 45 heures	p = 0.041
Temps de réaction codé % de non-réponses	de 51 à 57 heures	p = 0.022
Temps de réaction (délai incertain) % de non-réponses	de 27 à 53 heures	p = 0.043
Temps de réaction complexe % d'erreurs	de 39 à 57 heures	p = 0.47
Temps de réaction complexe % de non-réponses	de 27 à 53 heures	p = 0.023
Temps de réaction inversé % de non-réponses	de 19 à 53 heures	p = 0.029
Temps de réaction de base 2 % de non-réponses	de 19 à 53 heures	p = 0.03
Traitement mathématique temps de réponse	de 19 à 33 heures	p = 0.034
traitement mathématique % d'erreurs **(schéma n° 3)**	de 27 à 45 heures	p = 0.048
Recherche en mémoire 2 lettres Temps de réponse	de 19 à 57 heures	p = 0.045
Recherche en mémoire 2 lettres % de non-réponses	de 3 à 57 heures	p = 0.025
Recherche en mémoire 4 lettres temps de réponse **(schéma n° 4)**	de 19 à 53 heures	p = 0.049
Recherche en mémoire 4 lettres % d'erreurs	de 19 à 57 heures	p = 0.008
Recherche en mémoire 4 lettres % de non réponse	de 15 à 57 heures	p = 0.013
Traitement spatial % d'erreurs **(schéma n° 5)**	de 15 à 41 heures	p = 0.019
Traitement spatial % de non-réponse	de 15 à 57 heures	p = 0.0001
Poursuite instable (tracking) nombre de perte de contrôle **(schéma n° 6)**	de 15 à 53 heures	p = 0.029
Raisonnement grammatical % d'erreurs **(schéma n° 7)**	de 15 à 45 heures	p = 0.01
Double tâche mémoire 2 lettres % d'erreurs	de 15 à 45 heures	p = 0.039
Double tâche mémoire 4 lettres % d'erreurs **(schéma n° 8)**	de 15 à 57 heures	p = 0.023
Double tâche mémoire 4 lettres % de non-réponse	de 15 à 45 heures	p = 0.022

Tableau des résultats significatifs de la Stress Battery en période de privation de sommeil.

EVALUATING CREW PERFORMANCE AFTER ANTI-EMETICS: A SCREEN FOR ASSESSING MILITARILY RELEVANT MEDICATIONS

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SUMMARY

Prophylactic, pharmaceutical countermeasures hold the potential to protect aircrew from a wide variety of threats during contingency operations, ranging from fatigue to radiation exposure. In order to assess the impact of these potential countermeasures on cognitive abilities, a 2-phase drug screen was developed. A battery of cognitive, affective and physiological measures was utilized in Phase I of testing to rapidly evaluate the performance liability of militarily relevant compounds. The carefully controlled Phase I lab study incorporated diurnal and nocturnal performance trials to assess potential drug interactions with circadian and sleep deprivation effects. During Phase II, flight performance was tested in a high fidelity aircraft simulator using embedded operational tasks, expert evaluation and subjective metrics. The Phase I screen evaluated two novel anti-emetic compounds, granisetron (2 mg) and ondansetron (8 mg), compared to placebo and a positive control, prochlorperizine (10 mg), in a double blind, crossover study of 24 subjects. Performance was assessed hourly from 1800 until 0200. All Phase I metrics were degraded during nocturnal performance trials for all drug conditions, presumably due to circadian and sleep deprivation effects. The positive control was identified by the divided attention task in terms of accuracy ($p < 0.05$) and reaction time ($p<0.05$) and by the mean lambda for the tracking task ($p<0.05$), but only during a time when blood levels of prochlorperizine were elevated. None of the affective state questionnaires were able to identify the positive control, suggesting that the dose was low enough that the participants were unable to discern it. None of the target anti-emetic compounds differed from placebo suggesting that they were not likely to affect sensitive performance. Phase II also revealed no differences between target anti-emetic compounds and placebo in any of the segments of an F-16 defensive counter-air mission flown by 9 pilots. Based on these tests, the target compounds were considered safe to use prophylactically, with respect to cognitive ability, for crews in danger of radiation exposure. The utility of the drug screen as a rapid and thorough means to assess the cognitive impact of militarily relevant compounds was established.

1 INTRODUCTION

There are many pharmaceutical agents of interest to the armed forces because they may improve human effectiveness during physiological stress imposed from a range of threats like hazardous environments or during long duty days. For example, compounds such as anti-malarials or anti-histamines or anti-nerve agents are important for symptomatic treatment and as prophylactics against entities that might degrade military preparedness. There are other classes of compounds that can extend the range of human effectiveness for short durations such as the stimulants and sedatives. Often these drugs are approved for field use purely on the basis of their clinical profile. However, pharmaceutical houses are not equipped to study the compounds in militarily relevant settings. For example, it is rare that a new compound will be tested throughout the nycthermeron, thereby ignoring any chronopharmacodynamic effects (1). It is conceivable that compounds may not have any deleterious effects in normal populations but during acceleration or at high altitude, such effects might be present. The Sustained Operations Branch at Brooks Air Force Base was interested in developing a series of drug screens for militarily relevant compounds that would test for potential chronopharmacological cognitive effects using aeromedically relevant tests. Protocols for phased testing of compounds were established. In addition to a standard series of computer generated cognitive tests developed by the US military (2), if warranted, a compound of interest could be tested for performance effects during high Gz acceleration, hypobaric and hyperbaric altitude chambers as well as in a series of high fidelity flight simulators, ranging from long duration bombers to combat sorties in fighter aircraft.

The opportunity to test militarily relevant compounds came about at the request of NATO Project Group 29. They were interested in discovering any cognitive performance effects from two novel anti-emetic drug that might be useful as prophylaxis against radiation induced emesis for military as well as emergency personnel. The two compounds of interest

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were granisetron (Kytril; Smith-Kline Company) and ondansetron (Zofran; Glaxo-Welcome Company), both selective serotenergic antagonists (3,4). Both granisetron (GSN) and ondansetron (ODN) were considered to have similar clinical profiles (5) and since both were being considered for NATO use, both were transitioned through two phases of the drug screen. Both drugs have about a 5-hour plasma half-life availability. In Phase I, a carefully controlled laboratory study was conducted that incorporated chronopharmacological testing for cognitive effects, mood effects and physiological effects (see Table 1). In Phase II, complex cognitive effects associated with a high fidelity fighter aircraft simulated mission were tested. The fighter aircraft mission was selected because it was considered most similar to a NATO-type scenario for these compounds. No other screening phases available, such as spatial disorientation, acceleration or altitude effects were considered essential since no indication in the literature suggested such effects.

Since no cognitive effects had ever been reported for these compounds already in use clinically, the need for a positive control was critical to demonstrate that if the target compounds had an effect on cognition or mood, the screens would discern it. Prochlorperazine (Compazine; Smith-Kline Company) was selected because it met three criteria for an appropriate positive control to determine if the tests would be sensitive enough to ascertain an effect if one were there. First, prochlorperazine (PRP) has a similar mechanism of action to the 5-HT anti-emetics (6). Although it is primarily active at dopaminergic sites, prochlorperazine can influence 5-HT3 receptor sites. Indeed, the effectiveness of dopaminergic compounds, such as prochlorperazine, as anti-emetics may relate to their effectiveness as 5-HT3 antagonists. Second, PRP is also used for the same purpose medically as the target drugs, an established anti-emetic (7). Finally, as a major tranquilizer (8), although at higher doses than used for anti-emesis, PRP was expected to produce an effect on the cognitive and mood tests.

The purpose of Phase I of the experiment was to establish the impact on cognition, mood and physiology of the target compounds, GSN and ODN. No effects were expected. Additionally, the positive control, PRP, was expected to have an impact on the test batteries. The purpose of Phase II was to demonstrate the absence of an effect in a complex cognitive task associated with an operationally relevant fighter aircraft simulator mission.

2 METHODS

All tests in both phases of the experiment were double blind to dose condition and a utilized repeated measures design. Dose administration was counter-balanced using a modified latin square to control for order effects. All doses were orally administered at the manufacturer's recommended anti-emetic dose; GSN (2 mg), ODN (8 mg) and PRP (10 mg).

PHASE I

Training and testing occurred in a large performance habitat (Lt 54.7 ft x Wt 8.6 ft x Ht 10.1 ft) that was configured to test 8 subjects at a time in individual computer stations in sound attenuated booths at the performance end of the habitat. A complete phlebotomy facility was at the opposite end of the habitat. Lighting was kept to below 100 lux in the performance section. Subjects were assigned to individual computers for the duration of the study. The subjects were 24 active duty military personnel (20 males, 4 females; 19 enlisted, 5 officers) between 19-31 years old and 125-210 pounds. All had recently passed a standard military physical. They were financially reimbursed for their participation. The requirements of the study minimized social interactions.

Each group of 8 subjects was tested over 1 week in 4 exposures with one evening for each of the 4 drug conditions followed by a 40 hour drug washout period.. Each subject got either a test compounds (GSN, ODN, PRP) or placebo during each of the exposures sessions. During the week before the first drug exposure, all subjects were trained on the cognitive tasks for 2 hours every day after work at 1700 hours for 4 consecutive days before testing began. This allowed for 4 cycles of the 12-minute cognitive test battery and 3 cycles of a complex cognitive task (Table 1) daily. On each exposure session, subjects reported to the testing facility at 1700. Pre-dose symptoms were assessed by a survey and compared to a post dose symptom survey administered 2 hours after dosing to isolate drug effects from pre-existing symptoms. Symptoms for all drugs were compiled from the Physicians Desk Reference (1995) and included in a pre and post mission symptom survey.

The test batteries in Phase I required about 55 minutes to complete the cognitive and physiological tests. Blood samples were taken every hour beginning at 1940 until 2140 and then again at 0140. Profile of Mood Surveys (POMS) were given every hour through first 4 hours and again during the 8th hour.

The grammatical reasoning, continuous recognition, pattern recognition (matrix) and critical tracking test required 2 minutes each to complete. Continuous recognition and matrix were used to test short term memory function. Critical tracking is a psychomotor skills test. These were taken from a standard test battery developed for tri-service use (9).

The attention switching test was developed separately and measured dual processing task skills (10). The dual tests consisted of the maniken test of spatial recognition and an addition test and the display screen for this representative test is shown in Figure 1. This test was the most affected by the

positive control and is shown as an example of the cognitive test battery screens. The maniken test is on the left hand side of the figure. It stands on a pedestal with the target object, and facing away or towards the viewer or right side up oriented towards or away from he viewer. The math tests consists of the addition problem shown on the right of the figure. If the numbers add to more than 5 one key is touched, if less than 5, another key is touched. The small icon in the bottom center of the figure instructs the subject to do either the maniken or the math test. In this figure, it is pointing to the maniken test. The attention switching test required 4 minutes to complete and a new screen was put forward after every subject input or would time out after a few seconds if no keys were pressed. For all of the cognitive tests, three measures were extracted; response time, overall accuracy and throughput (responses per minute). The Defensive Systems Officer (DSO) analog task was intended to represent the decision skills required of a DSO on a B-1B bomber and required 20 minutes. The results of this task are still being considered.

The tracking test was also sensitive to PRP and consisted of a computer mouse controlled cursor which would attempt to

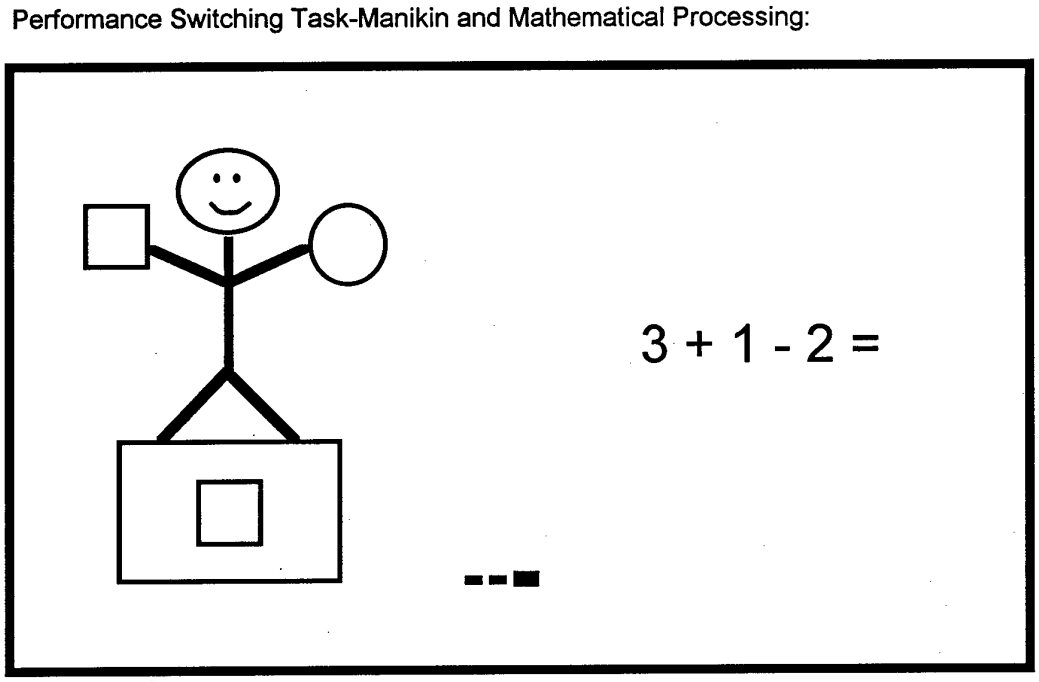


Figure 1. The computer screen from one of the tests, a divided attention task called Switching, used in the Phase I. tests. See text for details.

either a ball or a rectangle; in this case a rectangle. The subject must decide in which hand the maniken figure holds the target symbol. The maniken can be oriented upside down move from the vicinity of the center of the screen to the right or left borders. The speed with which it would move was not set and would increase in speed as the subject improved. Thus, the test got more and more difficult within each 2 minute test trial.

The critical flicker fusion test is considered a measure of visual information processing that is reported to be sensitive to fatigue. This test consisted of adjusting a knob on a binocular viewing visor until a flashing light stopped flashing. It was administered three times and generally took about 2 minutes to complete. Oral temperatures were collected every hour and recorded on log sheets along with a School of Aerospace Medicine (SAM) fatigue score. This procedure required about 2 minutes. The POMS is a standard survey for assessing drug effects and took about 3 minutes to complete. Finally, Air TRAffic CONtrol (TRACON) commercially available software was used to complete the remainder of each hour. Previous experience with these tests indicated that fatigue effects should be seen.

The tests were conducted from 1800-0200 to determine if sleep deprivation induced fatigue might enhance any

cognitive impairment produced by the drugs. By comparing early evening results with early morning results, any chronopharmacological effects of the drug might be ascertained. Phase I was conducted from November 1994 – March 1995

Table 1. Cognitive, mood, symptom and physiological assessment techniques used in the Phase I laboratory study.

COGNITIVE	PHYSIOLOGICAL	MOOD and SYMPTOMS
Grammatical Reasoning	Critical Flicker Fusion	Profile of Mood
Continuous Recognition	Serum Samples	Pre-test symptoms
Pattern Recognition	Oral Temperature	Post dose symptoms
Attention Switching		SAM fatigue
Critical Tracking		
COMPLEX COGNITIVE	OTHER	
TRACON	Actigraphy pre and post test sleep	
DSO Analog	Sleep survey pre and post test nights	

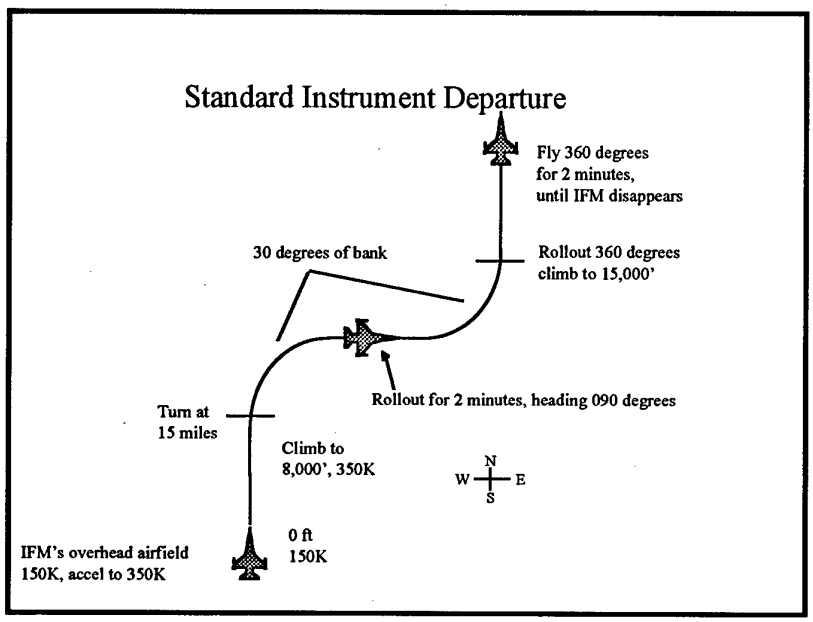


Figure 2. Flight requirements for one of the embedded tasks in Phase II of the screen. See text for details.

PHASE II

A total of 9 active duty US Air Force Reserve pilots, participated in groups of two, one flying lead and one wingman, during August - September 1995. A simulator operator assisted as wingman but did not receive any drug during one week when only one pilot was available. The high fidelity F-16 simulator facilities at Williams–Gateway airport were used. No positive control was used since results were clearly seen in Phase I and it was considered unlikely that F-16 crews would take prochlorperazine while flying.

The pilots arrived on Monday and were given an orientation flight on the simulator and the conditions of the test between 0900 and 1100. The first mission/dose condition was given in the early afternoon. Day 2 was a drug washout day. Mission 2 was conducted on the third day afternoon and day 4

was a drug washout day. The last mission was given on the afternoon of Day 5. Pilots were given either GSN, ODN or placebo during each of the missions. All doses were given 2 hours pre-mission. Prior to each mission the crews were given pre-mission symptom surveys. Immediately after each mission, crews were given POMS and a post mission symptom questionnaire identical to that used in Phase I.

All missions were identical. The two-plane formation took off singly and followed an intelligent flight model according to the design shown in Figure 2. Deviations from expected altitude, heading and airspeed as well as expert evaluations from the sim operators were used to assess the results of each drug/mission combination. A tactical scenario provided the combat engagement phase of the mission. An air-refueling task, shown in Figure 3, was also used to assess piloting skills. Finally, the crews proceeded to an Instrument Landing System (ILS) approach for touchdown after the mission according to the diagram. The entire mission lasted about 1 hour.

Table 2. Complex performance assessment techniques used in Phase II F-16 simulator study

Flight following during take-off, instrument landing system approach to landing,
Metrics : Heading, altitude, airspeed at critical stages of flight; RMS error

COMBAT ENGAGEMENT
Number of kills
Wingman protection

AIR REFUELING
Amount of gas received
Time on boom
Number of disconnects

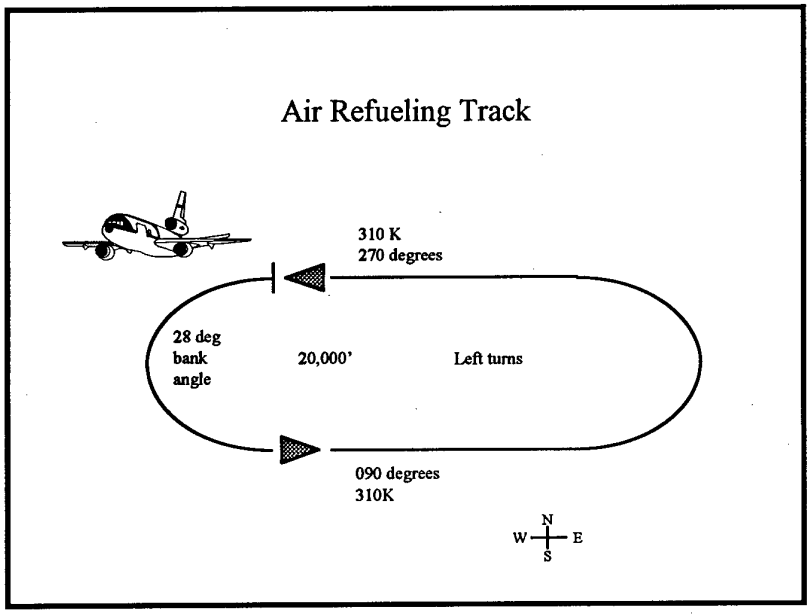


Figure 3. One of the embedded tasks required of Phase II subjects in the screen. See text for details.

3 RESULTS

None of the tests registered any performance or mood degradation as a result of the target drugs. Both the laboratory study in Phase I results and the flight performance results from Phase II agreed that the target compounds were free of debilitating side effects. No chronopharmacological effects of the target compounds were found and no compounding of normal fatigue effects on these tests were noticed. Either of the target compounds, based on these tests, could be used prophylactically as a counter measure to radiation induced emesis. In contrast, Phase I tests revealed that the positive control drug, PRP, was identified by 2 of the 5 cognitive tests and 7 of the 23 possible dependent measures.

All of the cognitive tests demonstrated a fatigue effect in that performance declined in the last half of the test session compared to the first half for 21 of the 23 dependent measures.

Phase I

Two examples are shown in the figures to follow, from the two tests that were the most sensitive to the positive control; Switching and Tracking. In Figure 4, the average throughput score for the maniken section of the Switching test is shown. Figure 5 is the average throughput score for the math section of this divided attention task.

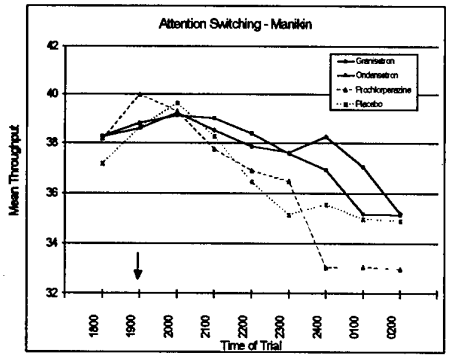


Figure 4. Correct responses / minute (throughput) Maniken test (Prochlorperazine ($p<0.05$)

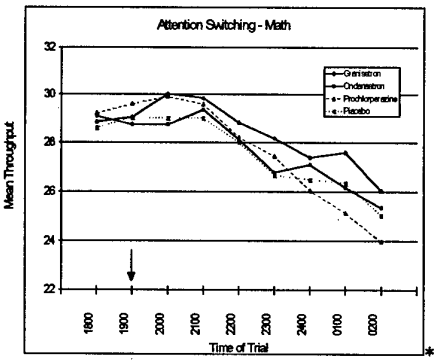


Figure 5. Correct responses / minute (throughput)for math test (Prochlorperazine ($p<0.05$)

The maximum lambda score is shown in Figure 6 for the tracking test. This was the highest lambda score achieved by each subject in a session. PRP degraded performance in a drug x trial interaction effect ($p<0.05$) for all of these effects. The subjects were able to identify when they had received the positive control drug at only chance levels. The complete results from Phase I of this study are available for review elsewhere (11).

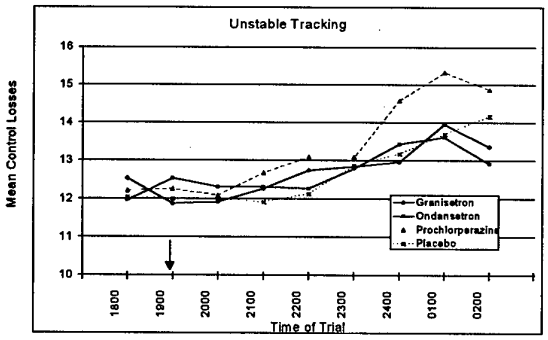


Figure 6. The number of control losses in the tracking test (Prochlorperazine $p<0.05$)

Phase II

No significant differences were found for either target drug

compared to placebo on any of the flying performance nor mood (POMS) measures. Neither could the expert evaluation of the crew's performance ascertain any target drug effects. Similarly, crews could not identify when the received target drug or placebo. Finally, there were no drug-related symptoms evident. The complete results of Phase II of this study are available for review elsewhere. (12)

Table 3. Summary of key results in Phase II screen with anti-emetic compounds.

No significant differences between the target drugs and placebo on any of the 7 objective

- flying performance measures.
- No differences in flight instructor evaluations
- No differences based on POMS results
- Pilots could'nt distinguish active drug from placebo
- No obvious drug related symptoms or side effects.

4 DISCUSSION

There were no effects of the target drugs on any of the tests used in both Phases of the experiment. This means that operational field tests might be the next place for these compounds to be tested in a Phase III study. The lack of effects for the target drugs is compared to the significant degradation produced by the positive control in Phase I. The fact that no one was able to discern the prochlorperazine suggests that the correct dose was used to demonstrate that some of the tests were sensitive to the tranquilzer/anti-emetic but the dose was not too high.

There is a need to test compounds beyond clinical efficacy for the extreme conditions in which they will be used in the aerospace environment. Many drugs were not studied under operational conditions but have been introduced into the operational military setting; amphetamines and Angiotensin Converting Enzyme (ACE) inhibitors like lisinopril are examples. Some times drugs are not studied thoroughly enough and admitted immediately into field operations because of expediency. Finally, compounds are not often tested at various times of day and night to determine if there is a chronopharmacological difference in their uptake and metabolism.

A drug screen is described which progresses from laboratory to operationally relevant simulator metrics. Two novel anti-emetic compounds, a positive control, and placebo were the first compounds tested in the laboratory screen . A second phase was used to assess operational questions about the two novel anti-emetic compounds and placebo. Other Phases could have been implemented if there were indications that the compound would be affected by altitude or acceleration. Positive controls in the Phase I paradigm should, if possible, meet three criteria: have a similar mechanism of action to the target compounds, have similar medical uses and should be likely to produce an effect.

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Discussion #3

NICHOLSON, UK: With the authors who are dealing with modafinil and with amphetamines, I felt that quite a large number of the tests were rather mechanical and that issues such as decision making and judgement and interpersonal relations were not assessed. I wonder if they could indicate what their view is of these more subtle effects on performance as far as those drugs are concerned, because both modafinil and amphetamines are, of course, amphetamine-like compounds (in reference to Papers #8, 9 & 10).

CALDWELL, US: We didn't look at a judgement task per se because of the psychometric problems that that entails. If one introduces an emergency procedure into the task a sufficient number of times for subjects to do it consistently, then it is no longer an emergency procedure. So it's hard to know how they would respond to such a task. What was clear was that for those subjects that were on the placebo condition what was often seen were these huge lapses in performance as observed if you broke down the flight performance, for instance, and just graphed how well they were able to maintain altitude for a period of a minute. They seemed to be doing just fine and then there would be this large deviation in performance, then they would get their mind back on the task and correct the problem. In the operational environment, if they're not in one of those lapses when they have to do something; for example, make a quick decision, then maybe they can do it just fine. However, they seem to spend a lot of their time in those lapses once they become sleep deprived, especially in the morning hours between about 4:00 am and 11:00 am. Then there is also the command and control issue of being able to interact with others. I was quite viciously attacked verbally a couple of times by some of our subjects by just simply walking in and saying: "Could you focus on the TV screen a little bit better during the EEG recordings?" I got yelled at and was told: "I'm doing the best I can, leave me alone.". So they can become very difficult to get along with and, often, just withdraw interpersonally from the situation when they are in the placebo condition. In contrast, subjects on dextroamphetamine essentially maintained their performance at a reasonably normal level even though they were significantly sleep deprived.

NICHOLSON, UK: One of the issues with amphetamine that I have noticed over many years - research going on for over 50 years - is that it may have detrimental effects, particularly at high doses. I know of subjects that ingested 30 mg over a period of eight hours - very high doses of the drug - and, although performance on well-learned tasks or mechanical tasks was improved, higher level activities, perhaps, could easily have been prejudiced. That's what worries me most.

CALDWELL, US: There seems to be this concern that people under the influence of amphetamines will respond faster but are not able to think as well about what they want to do. There is very little statistical evidence that that is the case. We certainly didn't see any evidence that people were becoming more careless so that being alert made them awake but yet they couldn't do their job any better. In fact, we saw just the opposite: They were more awake, were able to interact with others and did their jobs better.

JONES, US: I have some comments for Dr Caldwell and, perhaps also, for Dr Nicholson. I too came up in the era when dextroamphetamine was a lot more commonly used than it is today. I was assigned for two years to a base that routinely used dextroamphetamine for fighter squadrons rotating across the Atlantic where they had very early morning rises and then had two or

three or even four mid-air re-fuelings before they landed at dusk. Giving dextroamphetamine to twenty or thirty pilots at a time was an operational commonalty in those days. To my recollection, we never had any adverse medical effects. We used 100 mg of secobarbital to help them sleep. Today, I think it was a very poor thing to do, but it did work very well, and we never had any ill effects. The protocol that we used for that operation is given in Keynote Address #2 in which we discuss how we did it, what we did to ground test the fighter squadrons and how we documented it with the squadron commanders and so on. It was also used before the raid on Libya in the mid-80s in an operational setting without any difficulty.

JONES, US: I have some comments/questions for Dr French also. You mentioned in passing that you were developing a series of drug test protocols for the US Air Force. I've had a number of discussions with the US Federal Aviation Agency (FAA) about that because of questions we have about the use of Prozac, Zoloft and other drugs in civil aviation. I wonder if what you are doing could be published as a technical note, perhaps indicating how one can test any drug, and the philosophy behind the use of positive controls. One of the basic scientific questions that needs to be answered is: To what are you comparing the outcome of the drugs? I think that in the use of anti-emetic drugs one should compare the performance to airsick aviators who didn't take the drug. Like the use of dextroamphetamine, the time to use it is when it's more dangerous not to use it. That is, we use it in spite of its side effects because the alternative is even less acceptable. So I wonder if you have any feeling about the performance of very nauseated vomiting aviators doing that task (in reference to Paper #13)?

FRENCH, US: In response to the first question, we have a paper in press on our Phase I and Phase II studies in Aviation Space and Environmental Medicine. The use of the technique as a drug screen will be published in the RTO Conference Proceedings resulting from this meeting. Your second comment is a very good point. I can think of nothing more disgusting than pilots throwing up while one is trying to measure their performance. Fortunately, I think one can almost guarantee that an effect would be seen because the pilots are completely prevented from being able to respond correctly. It's a condition that we have considered, but decided against, because it would be a little too messy. Perhaps this is something that could be done with animals rather than pilots.

NICHOLSON, UK: Dr French, I think one of the problems of simulation is that it may itself be a relatively insensitive technique compared with working with psychometric tests. So I am rather surprised that, when you moved on to simulation, you didn't need a positive control. I would have thought, because of the complexity of the analysis, that it's much less likely to prove an effect on a simulation and that a positive control was even more necessary.

FRENCH, US: It's a good point. I can't address it because we didn't use it. We have an AWAC simulator at Brooks AFB that would allow us to test team dynamics and team decision making in an information warfare environment. We are planning to add that to our profile for the next compound that we are interested in testing, and we will certainly include a positive control. We felt confident that if the two drugs that we tested (granisetron and ondansetron) had shown us an effect on simple laboratory tests under very carefully controlled conditions, we would have seen it. However, you are correct that we should have used a positive control in the simulator.

MELATONIN AND ITS ROLE IN CIRCADIAN RHYTHM DISRUPTION

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SUMMARY

Melatonin, the hormone of the pineal gland, is secreted during the hours of darkness with virtually no secretion during light and has therefore been called the hormone of darkness. Its secretion is controlled by an endogenous rhythm generating system that is entrained by light. Melatonin has a role in cuing circadian rhythms, notably the sleep-wake rhythm, promoting sleep, and contributing significantly to the circadian rhythm in body temperature. Specific receptors for melatonin have been cloned recently which mediate these and other effects. (Melatonin can be given orally, intravenously, by nasal spray or transbucally and has a wide safety margin.) Administration of melatonin orally (in a dose of 0.5 to 5 mg) or light treatment (300 to 5000 lux) has established therapeutic actions in circadian rhythm sleep disorders, including disorders associated with jet lag, shift work, delayed phase sleep disorder, periodic sleep disorder in blindness and sleep and behavioural disorders in children with multiple brain damage.

Treatment of circadian rhythm disorders with light or melatonin requires an understanding of the manner in which these agents produce effects on body rhythms. Effects of light and melatonin treatment follow a phase response curve. Evening light treatment causes a phase delay in the sleep-wake cycle while morning light causes a phase advance. As is befitting the hormone of darkness, melatonin treatment produces effects which are nearly the mirror image of light.

1. INTRODUCTION

In sleepiness during extended operations there are two different major factors at work, a homeostatic pent up demand for sleep because of sleep loss and a circadian factor (1-3). These two factors have been named by Borbely: process S and process C respectively (1). These processes must be considered separately; because their causes differ the treatments may also be different. According to this model, which is supported by experimental evidence, daytime vigilance is due to an additive interaction of homeostatic and circadian regulation (4). In the previous chapters, there has been discussions of sleep loss and of countermeasures for sleep deprivation; these are all related to homeostasis. This chapter will review the role of melatonin in circadian rhythm disruption and its treatment.

2. REGULATION OF MELATONIN

Melatonin is produced by the pineal gland in a rhythmic fashion and immediately secreted into the blood stream. Under normal circumstances it is present in blood in high concentrations at night and in vanishingly low levels during the daytime. This rhythmic secretion of melatonin is controlled by the light-dark cycle. Information from the retina travels via the retino-hypothalamic tract to the suprachiasmatic nucleus of the hypothalamus (5,6) which is the major circadian rhythm generating system (endogenous oscillator or body clock) in the brain. From the suprachiasmatic nucleus information travels by a very indirect route, down the spinal cord and then up via the sympathetic fibres to the pineal gland.

Light synchronizes circadian rhythms by resetting the body clock (7-10). Bright light in the evening causes a phase delay in body rhythms while it causes a phase advance in the morning. Studies in the rat (11), supplemented by a limited number of human studies, support the concept that there are two endogenous oscillators, a evening and an morning clock, controlling the onset and decline in melatonin production respectively. These clocks appear to have different sensitivities to light (11).

3. MELATONIN ACTIONS

Melatonin also has major phase shifting effects on circadian rhythms. As might be expected of the "hormone of darkness" these effects are almost the mirror image of those produced by light (7). Melatonin administered in the evening can cause a phase advance in body rhythms while in the morning it may produce a delay. These effects are seen both in nocturnal species such as the rat (12,13) and diurnal ones including man (7). Thus melatonin production is associated with the wake phase of the sleep- wake

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cycle in the rat while the converse holds in man. In addition to its entraining effects, melatonin also has sleep promoting actions in man (14,15). Low doses of melatonin (0.1 to 10 mg) at midday cause decreased sleep-onset latency, oral temperature and reduce the number of correct responses on the Wilkinson auditory vigilance task. The two lowest doses (0.1 and 0.3 mg) produce melatonin levels in the normal nocturnal range of serum melatonin in untreated people. In keeping with the concept that melatonin is an endogenous sleep promoter, suppression of endogenous melatonin by light during sleep deprivation produces a decrease in sleepiness (16). In addition to these effects melatonin has potent effects lowering core body temperature. These effects appear to account for about one half of the body temperature rhythm (17-20).

Melatonin acts via melatonin receptors which have recently been cloned. Two melatonin receptor subtypes have been identified in mammals including man (Mel1a and Mel1b) (21,22) while three have been found in the chicken (Mel1a, Mel1b and Mel1c) (23,24). Both Mel1a and Mel1b receptors are present in the mouse suprachiasmatic nucleus (25). The Mel1a receptor is responsible for acute inhibitory actions of melatonin in mouse SCN slices. In mice with a disrupted Mel1a receptor the acute phase shifting effects of melatonin persist implicating the Mel1b receptor in the phase shifting response (25). The site of the sleep promoting actions may be elsewhere as melatonin receptors are widespread in the central nervous system (26-28).

Thus, in the regulation of the sleep-wake cycle in man, light is a potent cue which has both direct effects on the body oscillator via the retino-hypothalamic tract and indirect effects by regulation of the rhythm in melatonin. Melatonin in turn acts at melatonin receptors to influence the timing of the sleep-wake cycle and promote sleepiness.

4. BRIGHT LIGHT AND RHYTHM DISORDERS

Light treatment has been used for a variety of disorders (29-31). Adaptation to rotating shift work is facilitated by exposure to sunlight or bright artificial light during those working times which were formerly sleeping hours (9,32-36). In delayed sleep phase disorder morning bright light treatment is a useful treatment causing a phase advance in both sleep onset and wake time (37). In contrast, early morning waking insomnia is responsive to evening bright light treatment (37,38). Light therapy has also been shown to be useful in the insomnia that accompanies dementia (39,40).

5. BRIGHT LIGHT AND JET LAG

Jet lag may be defined as a condition of desynchronisation of the circadian rhythm induced by rapid transmeridian travel. It is a condition that is entirely man-induced and is a result of improvement and speed of air travel. The symptoms of jet lag are sleepiness at inappropriate times of the day, disturbed sleep patterns, impaired mental alertness, and increased fatigue. The severity of the symptoms is proportional to the number of time zones traversed and eastward flight. Whereas some large corporations in the past had policies which required their executives to rest at least one day in Europe after traveling from North America, these policies seem to be largely forgotten today. The military because of rapid deployment of troops for e.g. peace keeping operations and continued logistical support requires effective strategies for dealing with rapid transmeridial flight. Various strategies have been tried to alleviate the symptoms and bring the circadian rhythm in synchrony with external cues. These strategies have included diet adjustment ("feast and famine") in which breakfast should be high protein and the evening meal low on protein and high in carbohydrates, exposure to bright light early in the mornings, and more recently exogenous melatonin to help reset the internal clock. In a search using medline no controlled studies of diet adjustment were found.

A very limited number of field studies have been done on the effect of bright light on jet lag (41,42). In one trial two subjects were studied who were exposed to light after eastward flight across nine time zones for three h starting at 0700 h local time at the destination, the other at 1000 h. The subject exposed at 1000 h synchronized by day 6 while the other subject had still not adapted by day 13 (43). In another protocol a single subject was examined who returned from Tokyo to Boston, and was then exposed to bright light for three consecutive afternoons. Two days later a delay of over 11 hours was found (44). Two other studies examined effects of bright versus dim light on sleep in a total of 23 subjects after travelling from the Orient to California. Those in the bright light group appeared to have better consolidation of sleep in one study (45) and better sleep efficiency in the other study (46). With so few studies completed, much more needs to be done to clarify optimal timing, duration, intensity and number

Table 1. Bright Light & Jet Lag: Field Studies with Normal Volunteers

Authors Year	Study Design and Conditions	Bright Light at Destination	Outcomes
Daan and Lewy, 1984 (43)	Two subjects: eastward across nine time zones	daylight for 7 days: first subject at 0700 h, second at 1000 h	First not fully adapted at 13 days, second advanced in 6 days
Czeisler and Allan, 1987 (44)	One subject: Tokyo to Boston	7000 to 12000 lux for several hours for 3 days in early afternoon	Temperature phase delayed by 11.25 h five days after flight
Cole and Kripke, 1989 (45)	19 subjects: Orient or South Pacific to California	Either 2000 lux or <200 lux for 2-3 h for 3 days on awakening	bright light appeared to consolidate sleep
Sasaki et al., 1989 (46)	Four subjects from Tokyo to San Francisco	Either >3000 lux or <500 lux for 3 hours at 1100 h for 3 days	Higher sleep efficiency and less wake after sleep onset with bright light.

of treatment days for light treatment to be of practical utility. Moreover, the "bright light" strategy may not always be feasible because of the season at destination and for business people who usually have meetings in rooms where the ambient light is far below optimal.

6. MELATONIN AND RHYTHM DISORDERS

Melatonin has been found to be useful in correcting a variety of rhythm disorders (29). In chronic insomnia melatonin consolidates sleep and improves alertness (47). In the delayed sleep phase syndrome, melatonin treatment in the evening is reported to be effective in causing a significant phase advance of both sleep onset and wake time (48-50). In children with periodic sleep disorder and brain damage, melatonin treatment is able to correct the sleep cycle in about 80% of cases (51-54). In many blind subjects with periodic sleep disorder melatonin is capable of stabilizing sleep cycles (55-58). In a small group of police officers working a night shift, melatonin at the desired bedtime was shown to alleviate sleep problems and improve work alertness (59).

7. MELATONIN AND JET LAG

This brief review will concentrate on the melatonin strategy for the alleviation of jet lag in actual flying conditions.

Although treatment of jet lag has been of interest in both the scientific and the lay press, the latter in connection with the wide-spread availability of melatonin in health food stores in the USA, very few controlled studies have been done and of these fewer still had objective performance tests, see Table 2.

The first study by Arendt and collaborators (60) showed impressive results on the subjective evaluation of jet lag with subjects crossing eight time zones eastwards in one non-stop flight from San Francisco to London while measurements of endogenous melatonin and cortisol excretion showed that the melatonin treated group normalized quicker. In 1988 Arendt and Aldhous reported on a large study involving 52 subjects traveling to Australia and back to London (61). The protocol was slightly different in that on the eastward leg melatonin was administered 2 days prior to departure in order to phase advance the subjects and for another 4 days after arrival and on the westward leg for 4 days at destination bedtime. The results showed again that melatonin was beneficial over placebo in all but 4 subjects. These studies were no doubt an impetus for Petrie and his colleagues in New Zealand to evaluate the effects of melatonin on cabin crews flying between Auckland, NZ and London, UK, 12 time zones in each direction (62). The protocol was similar to that in the first Arendt study: 5 mg pre-conditioning doses of melatonin for 3 days prior to departure at the bedtime of destination, the day of departure, and for 2 days after arrival. Evaluation of treatment effects was by means of daily visual analogue scales and a profile for mood states questionnaire, as well as, a retrospective evaluation 10 days after arrival. Overall, the findings were that melatonin significantly alleviated the feelings of jet lag and return to normal patterns was shortened. Interestingly the subjects reported that jet lag was more severe in the westward direction, i.e.

Table 2. Melatonin & Jet Lag: Controlled Studies with Normal Volunteers

Authors Year	Study Design and Conditions	Melatonin p/o, at Destination Bedtime	Outcomes
Arendt et al. 1986 (60)	17 subjects: double-blind, placebo-controlled, parallel San Francisco to London	5 mg for 3 days prior and 5 mg for 4 days after arrival	Melatonin decreased subjective feeling of jet lag p=0.009
Arendt and Aldhous, 1988 (61)	52 subjects: double-blind, placebo-controlled, X-over. Australia-London return	5 mg for 2 days prior and 4 days after arrival	melatonin decreased subjective feelings of jet lag
Petrie et al. 1989 (62)	20 air crew: double-blind, placebo-controlled, X-over Auckland, NZ to London return	5 mg for 3 days prior to departure, once during the flight, and for 3 days after	Melatonin favored, p<0.05, for subjective relief of tiredness, normal sleep, and return to normal "energy"
Claustrat et al. 1992 (64)	30 evaluable subjects: double-blind, placebo-controlled and parallel	8 mg on day of departure and for 3 days after arrival	subjective evaluation 7 days after arrival: in favor of Melatonin for morning fatigue, evening sleepiness
Petrie et al. 1993 (63)	52 air crew: double-blind, placebo-controlled, parallel Auckland, NZ to London return	Group 1: placebo 3 days prior and 5 days after Group 2: Melatonin 3+5 days Group 3: placebo for 3 prior and Melatonin 5 days after	No statistically significant differences between placebo and Melatonin. Trend was in favor of Melatonin for subjective evaluations
Comperatore et al. 1996 (65)	29 Army aviation personnel: double-blind, placebo-controlled and parallel. From USA Central Time to Middle East.	10 mg for 3 days prior to departure, once during the flight, and for 5 days after arrival	Objective Criteria: Melatonin improved sleep duration, decreased error rate and better vigilance.

London to Auckland, NZ, than in the eastward direction; for transatlantic travel the eastward direction is associated with more severe jet lag. In both instances departures, going to Europe from the USA or Canada and going from Europe to New Zealand or Australia, are in the evening. It may well be that the disturbed night "sleep" , i.e. process S added to process C resulting from evening departures results in more severe jet lag. In 1993 Petrie et al followed up with a larger study with cabin crew (63). In addition to the previous protocol they also studied the effect of starting melatonin on the day of arrival and for 4 days afterwards. The overall results were similar to those reported earlier but the latter group reported significantly less jet lag and sleep disturbance than the placebo group, and they recovered faster than the group which received pre-conditioning melatonin. This latter group actually fared worse than the placebo group. It is important to note that the study subjects in the Petrie studies were working and active during the night whereas the subjects in the Arendt study and those in the Claustrat study (below) were passengers. In the Claustrat et al. study 30 evaluable subjects received 8 mg melatonin on the day of departure and then for 3 days after; they traveled from the USA and Canada to Lyon, France (64). Unfortunately, subjects were not evaluated until day 8 (7 days after arrival). Evaluation was by subjective self-ratings for global treatment efficacy, morning fatigue, and evening sleepiness. Significant treatment differences were observed for the morning tiredness and evening sleepiness. Finally, Comperatore and colleagues reported in 1996 a complex study of the effect of melatonin on air crew (not operational during transport) traveling from the Central Time zone in the USA to the Middle East (65). Time of departure was noon and traveling time was 14 hours. The complexity of the study lies in the requirements for deployment of the air crews in that they were required to work at night. The protocol was similar to the ones used by Arendt and Petrie: melatonin was given in a

dose of 10 mg on destination bedtime for three days prior to departure, on the day of departure, and for 5 days after arrival. Activity was monitored throughout, cognitive testing was carried out for each of 4 days prior to departure and again daily for the last 4 days of the study. The results showed that both bedtimes and rise times were significantly advanced by melatonin and sleep duration was increased. Testing for errors in a dual task vigilance test showed that the melatonin treated group made significantly fewer errors than the placebo treated group. There were no significant differences between the two groups for mood changes or in reports of fatigue. Also, with the dose of 10 mg there was no "hang-over" effect.

Although this is a review of the effect of melatonin on jet lag, there is an interesting report which while not published is available, of the effect of l-tryptophan on jet lag (66). This double-blind. placebo controlled study which was carried out by the Naval Health Research Center in San Diego, California, involved 51 Marines traveling from southern California to Okinawa, Japan (17 hours ahead of San Diego), via Anchorage, Alaska. The dose of l-tryptophan was 2 grams and was administered en route and for the first three nights after arrival. A battery of performance tests was administered 1 week prior to departure, during the flight and on 2 days after arrival. The results showed a significant benefit of l-tryptophan on sleep time and other objective measures of performance. Interestingly, the authors of the report did not link l-tryptophan to melatonin for which the former is the precursor. There is evidence that tryptophan is converted to melatonin in the gastrointestinal tract thereby causing a prolonged elevation of melatonin blood levels (67). Thus, effects of orally administered tryptophan, like those of melatonin, may be due to elevation of melatonin in blood.

8. DISCUSSION

The above studies have shown that a reasonable case can be made that melatonin is of benefit in the alleviation of the symptoms of jet lag. None the less it should be recognized that only 200 subjects have been treated in double-blind, placebo-controlled, parallel studies; 161 have actually been exposed to melatonin (Petrie's subjects and Arendt's second study participated in both eastward and westward flights). Moreover, the subjects were not comparable in that there were passengers (60,61,64), working cabin crew (62,63), and military personnel deployed on night time missions upon arrival (65). Finally, there are different treatment protocols and dosages of the active drug. However, there is a large body of supportive evidence of the role of melatonin in treating synchronization disorders. The administration of melatonin appears to be safe as no significant adverse reactions were reported. Thus there is presumptive evidence that should encourage a refinement of further studies. In the latter there should be clear definitions of the subjects, i.e. are they "passive" participants, i.e. passengers, or are they working cabin crew or air crew, and what are the pre-departure and post-arrival activities. In the treatment protocol there is a need to take into account not only the type of passenger but also their activities and the timing thereof before departure and after arrival as these will affect the timing of drug administration and the interpretation of the data. Pre-departure activities which require maximum alertness up to the point of departure should preclude pre-conditioning as this will induce undesirable sleepiness or symptoms of jet lag. It is surprising that lighting conditions have not been taken more into account because light is a prominent cue synchronizing body rhythms and treatment with bright light can produce phase shifts. Thus lighting conditions could oppose effects of melatonin or act in concert with it depending on the timing of lighting. Moreover melatonin in combination with an appropriate lighting regimen might result in a more rapid adaptation. The dose is another consideration, a dose of 5 mg may seem sufficient, however, this dose shows results that are only just statistically significant on self-reporting visual analogue scales, a dose of 7.5 to 10 mg might be considered more reliable depending on the circumstances of the flights, i.e. what time of day the flight departs and type of aircraft. Finally, a study of jet lag, without any treatments, in which the time of day departures is varied may yield some very interesting results. Such a study can be done comparing jet lag on "daytime" flights and "evening/night time" flights between the USA or Canada and Europe.

In reviewing these studies it became clear that in some process S predominates over process C e.g. in eastward commercial transatlantic flights and westward flights from London to New Zealand and Australia, in others disturbances in Process C appear to be the culprit, e.g. westward transatlantic flight and eastward flights from Australia and New Zealand. The reason for this is that eastward transatlantic flights depart, as a rule, after 1800 hours and likewise westward flights to Australia and New Zealand. It is a general given that eastward travel induces more severe jet lag, however, this may well be an artifact

which has nothing to do with the direction of travel but rather the time of day the flight departs. In the latter condition the passenger experiences sleep disturbance, i.e. it affects process S. In westward transatlantic flight the day is prolonged but only process C is affected as sleep can easily be postponed till after arrival. It would seem necessary to sort out the relative contributions to the experience of jet lag of the effects of eastward and westward flight on processes S and C. The results could be of help in devising the most appropriate treatment strategies. It would appear that many current, transmeridian airline schedules are non-physiological.

9. CONCLUSIONS

In the above review of relevant trials of melatonin for the treatment of jet lag a number of issues have surfaced which should be taken into account when designing new protocols:

1. Selection of subjects, passengers or working cabin crew.
2. Pre-flight and post-flight activities, and especially sleep-wake and light-dark schedules.
3. Distinguishing between the relative contributions of processes S and C.
4. Dose of melatonin.
5. Pre-flight and post-flight melatonin treatment schedules.
6. Objective measures of performance as well as of sleep parameters.
7. Examining the combination of melatonin and bright light treatment.

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URINARY MELATONIN EXCRETION IN AIRLINE PILOTS SUBMITED TO TRANSMERIDIAN FLIGHTS.

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SUMMARY

Endogenous biological circardian rhythms are present in the majority of behavioural and physiological variables of all living organisms. These rhythms are entrained to the external environment in which they live, and get desynchronized as a consequence of transmeridian flights. This study has investigated changes occurring in various biological markers in air line pilots during and after westbound (Madrid-Mexico) and eastbound (Madrid-Tokyo) flights. The results have been compared to those of a non flying control group over a 6 day period. A clear cut activity rhythm adapted to the local "Zeitgeber" was present over the whole period in controls as well as an evident rhythm in the urinary excretion of 6 sulfatoxy melatonin. Pilots showed alterations of the melatonin rhythm already on the day before of the flight, probably due to the desynchronizing effects of previous transmeridian flights. To Mexico, the rhythm remained adapted to Madrid in the first day and started to get adjusted to local time the second day. Pilots older than 50 years showed a higher resistance to change their excretory rhythm, to adjust to the local environment.The return flight to Madrid occurred in the middle of maximal 6 sulfatoxy melatonin excretion. Experimental subjects flying to Tokyo showed a complete disruption of the hormonal excretory, and of the activity rhythms. All subjects showed tiredness and anxiety at the end of the flights, being this effect maximal when arriving to Tokyo. Pilots did not completely recover before the return flight.

INTRODUCTION

All living organisms show rhythms of approximately 24 hours in their behaviour, physiology and biochemistry, which are named "circadian ". These rhythms are due to the existence of specific structures which organize the circadian system: The biological "clocks" (1, 2, 3, 4, 5, 6, 7, 8, 9).

This system has two main functions. It is responsible for the generation of rhythms in the temporary biological organization. At the same time, it is also responsible for the synchronization of the endogenous organical system with the periodical variation of the external environment. The importance of the circadian system is given by the necessity of the existence of a strict phase relationship, both among organical rhythms and between internal rhythms and the external cycle, for the best human performance. Status of normality (health) is characterized by that synchronization (3, 4, 5, 7, 10).

In mammalians, the main circadian system structures are located at the suprachiasmatic nuclei of the hypothalamus, whose morphology and physiology have been studied only recently (5, 9, 10, 11, 12, 13, 5, 9, 14, 15). Other synchronizers are the periodical access to food, magnetic fields and specially in humans, socialization (6, 9, 16, 17, 18, 19).

The circadian system main endogenous syncronizer (or "internal Zeitgeber") is the pineal hormone melatonin. This gland supplies a circulating signal proportional to the darkness length, that acting on the suprachiasmatic nuclei, synchronizes the circadian system (11, 12, 13, 20, 21, 22, 23, 24, 25).

One of the most common aggression of the circadian clock is the desynchronization by transmeridian flights through several time zones, that produces a sudden disorder between the "Zeitgebers" of the new geographical place and the traveller's circadian system ("jet-lag"), who needs some days to adapt himself to the new situation, unless he stays in an environment that is totally isolated from outside and with lights on and off in the way of his usual residence (7, 10. 22, 26, 27, 28, 29). The most common disorders include alteration of sleep, gastrointestinal discomfort, decrease of attention and allertness, and general drowsiness. These alterations occur chronically, at different levels, in air lines' crew members, suffering from stress, fatigue and difficulty in concentration ability (26, 30, 31, 32).

It is possible to establish the hypothesis that the desynchronization is a common aspect of the verifiable neurovegetative alterations observed in air line crew

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members, and that the productivity in these subjects would increase significantly with a chronobiological therapy (27, 28, 33).

Given that the alterations of the circadian system can be the origin for lower productivity, higher incidence of emotional alterations, and a decrease of the living quality of the air crew and to some extend also to decrease in flight safety, it is interesting to get further insights the modifications observed in the biological rhythms and when and how they occur, as a necessary step for its potential management (17, 19, 22, 23, 32).

It must be stressed, however, that the rhythmical behaviour of subjects submitted to situations as those above described is still not completely understood, not even it is accurately known the circadian rhythm evolver depending on the time of permanence in labour routine of transmeridian flights. This information is essential to precise which factors contribute to stabilize the circadian rhythms alterations that are observed in air line crew members.

MATERIAL AND METHODS

Subjects of the study were volunteer pilots of IBERIA Airlines of Spain. The airplaine was a Boeing 747 Jumbo Jet flying westbound (Madrid- Mexico city-Madrid, n = 12 pilots) or eastbound (Madrid- Tokyo-Madrid, n = 21 pilots). Non flying persons (n = 10) were used as controls. Subjects were divided into two groups.

According to age: Under 50 years and pilots older than 50 years. The study was extended over six days: It started 36 to 30 h. before the flight, continued the day of the departure, the first and second day at destination, the day of the return flight, and 24h. after this.

Non-invasive procedures were used to monitor the chronobiological variables in the crew members, without affecting their normal working activity (34). Cardiac frequency, motor activity (35, 36, 37, 38, 39), and skin temperature were registered at 5 minutes intervals over the whole period using a Minilogger ML 2000 from Mini-Mitter (USA) with the appropiate sensors (39). Twenty four hours after returning from the flights. Minologgers were taken from the pilots and data transfered to a P. C. with an appropriate interphase, and processed using the EXCEL programm. TAU programm was also used for the conversion to actograms.
Determination of blood pressure was carried out during the flight by a non-invasive digital system, the Finapres from OHMEDA USA (35), every 2 hours during 6 minutes.

To evaluate the state of anxiety, tiredness and performance of attentional perceptive tasks, the STAI, a Figure test and a Perceptive-spacial test were used (40, 41 42). The three tests were carried out previously and at the end of the flights (forward and return), during the stopover days at destination, and finally 24 h. after returning to Madrid. Non parametric Mann -Whitney test and Wilcoxon were used to evaluate results.

Urinary samples for 6-sulphatoxy melatonin (6 S M) determinations were collected in 6 hourly periods over the six days. Samples were kept in dry ice and carried on containers over the whole experiment.

Flights were performed between June and December 1996, two investigators were asigned to each flight, taking care during all the time of carring out the different physiological test, collecting urinary samples and controlling the correct cumplimentation of the psycholmetrical tests. The investigators were doctors of the depts. of physiology from the medical schools of Madrid and Buenos Aires and did the flight together with the crew, were lodged at the destination in the same hotel, carefully supervising the collection of samples and the timetable for the tests.

Radioimmunoassay of 6 sulphatoxy melatonin (6 S M). The reagents used were from Stockgrand, Surrey UK. The urinary samples were diluted 1:250, ^{125} I-6 S Mel was used as tracer and dextran -coated charcoal for separation of bound/free fractions. The standard curve had a sensitivity of 1 pg and a coefficient of variation of 8%.

Data obtained were analyzed using the COSINOR approach for temporal series and the ANOVA system for hormonal measurements with Students's test.

RESULTS

Locomotor activity was the most reliable parameter exhibiting a robust rhythm at baseline (Acrophase : 95.5 $\pm$ 17.65 counts), with maxima during the day (15.53 $\pm$ 0.81h), in clear correlation with temperature and heart rate rhythms. During westbound flights, a 6 h phase delay in activity acrophase was achieved (21.64 $\pm$ 0.38) in both groups. Acrophases were back to normal within two days of the flight back to Madrid (14.96 $\pm$ 0.38, 16.34 $\pm$ 1.40 for pilots older and younger than 50 years respectively). A significant decrease in amplitude was found in pilots older than 50 years after flights to Tokyo

(90.17 ± 12.81 vs 55.13 ± 9.77 counts), which was further decreased after the returning flight (35.27 ± 6.86 counts). Pilots under 50 years old only exhibited a non significant decrease in the amplitude of the activity rhythm. Both groups had significantly ($p < 0.0001$) advanced their rhythms by 9.73 ± 0.74 in older pilots and 8.43 ± 0,58 in younger ones by the second day in Tokyo. Visual inspections of the actograms for the three variables showed a larger fragmentation of the rhythms in the eastbound flights.

Control subjects showed a clear cut rhythm in melatonin excretion with acrophase at 07:55. Signifficant differences between day and night excretion were detected ($p< 0.01$). After the flight to Mexico, melatonin did not show significant changes in acrophase and kept significant day/night diferences ($p< 0.05$). A readjustement was initiated in the second day in Mexico, showing a delay in the peak of maximal excretion of melatonin. Returning flight from Mexico was coincident with the peak of highest melatonin excretion (Fig. 1 and 2). Pilots flying to Tokyo showed a rapid disruption of rhythm of melatonin with acrophase at 05:30 and absence of diurnal variations (Fig. 3 and 4). All the pilots older than 50 years exhibited lower excretion values of melatonin than younger ones and the rhythms were also less prone to change.

The results of the psychological tests showed that the level of anxiety was quite low in all the pilots, but even lower in pilots younger than 50 than in those older, specially in crews fliying to Mexico ($p< 0.05$). In this group, those older than 50 years showed a marked decrease of anxiety in the first stopover day (from 10.2 to 5.6, $p< 0.05$), while younger pilots remained around 12.0 The level of anxiety increased about 10% in all the pilots during the second stopover day. In the flights to Tokyo, all pilots had a peak of anxiety at the end of the returning flight (increase of 40%, $p< 0.05$).
In both, eastbound and westbound flights, pilots showed a peak of tiredness at the end of every flight, being significant at the end of the returning flights. Travelling to Mexico implied a better recovery from the fatigue than travelling to Tokyo, in which the return flight was performed without a complete recovery.All the pilots presented less improvement in the execution of attentional-perceptive tasks than controls.

DISCUSSION

The robust rhythm observed in motor activity showed a clear 6 h. shift when flying to Mexico, when pilots adapted themselves to the new environmental light/dark cycle, after a very long "day" during the flight. The rhythm was again synchronized with Madrid after the return flight. However, in the flight to Tokyo, the rhythms observed during the stopover were completely disorganized with erratic periods of activity and rest as shown by other authors (31, 43, 44). This leads also to the incomplete recovery of the post flight tiredness (43). Cardiac frecuency and skin temperature followed to some extent the patterns observed in activity, (data not shown) thus corroborating the more marked influence of eastbound flights on rhythm disturbances (30, 45).

When comparing the urinary excretion of 6 S M in the control population, with a marked Madrid adapted pattern of excretion (3, 31, 37), with pilots flying eastwards, two different situations appear when considering two different groups. Pilots older than 50 years showed an excretory pattern "fixed" to Madrid and thus desynchronized with Mexico. Only in the 2nd day in destiny a shift in the pattern can be observed, indicating the initiation of the adaptation to Mexico. This effect disappeared after the return flight. These data speak in favour of a reduced capability of adaptation to the new environmental situations (3, 5, 9, 30, 37, 46, 47). Younger pilots show already under "basal" situation, an alteration of the excretion rhythm of 6 S M, possibly due to previous entrainment to other destinations.This leads to a desynchronized pattern all over the flight revealing a better capability of adaptation that is perhaps negative for their well being (2, 3, 31).
The very high melatonin excretion during the return flight indicated an increased tendency to sleep (13) that could be perhaps overcomed by using light as strategic weapon to reduce this effect (21, 22, 27, 33).

When analysing eastbound flights, 6 S M excretion showed a different pattern probably induced by the fact that the subjective night takes place under solar light, thus inducing a marked phase shift (2, 9, 15, 48). The disorganization of the rhythm is associated with sleep disturbances (43, 44) and also to an inconvenient return flight during the biological night (25, 29,48). Probably it would be advisable to implement some resynchronizing measurements to induce an advancement of melatonin secretion and thus absence of this hormone when the pilots are confronted
with the approach and landing manoevers requiring the highest alertness (2, 20, 22, 27, 28, 32, 33).

The permanent situation of disadjustment suffered by air line crew members, leads to a decrease in performance, being this situation counteracted by increasing the number of crew members to maintain a sufficient operational capability and to avoid risks (19,21,28).

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Urinary melatonin excretion .Pilots under 50. Flights to **Mexico**

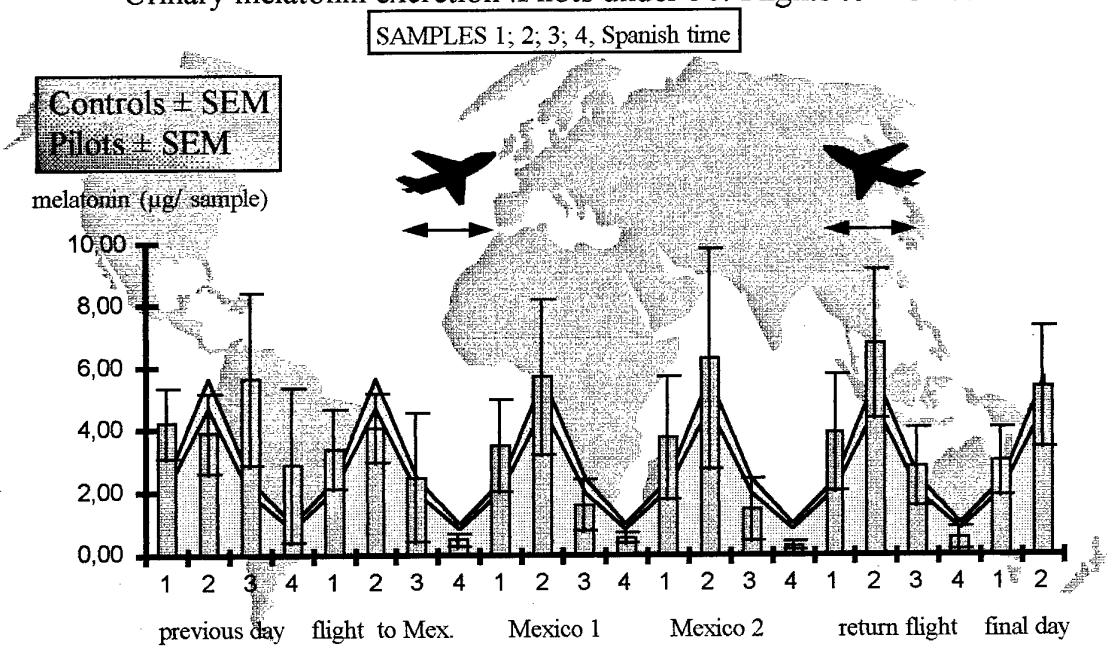


Fig. 1

Urinary melatonin excretion .Pilots under 50. Flights to **Tokyo**

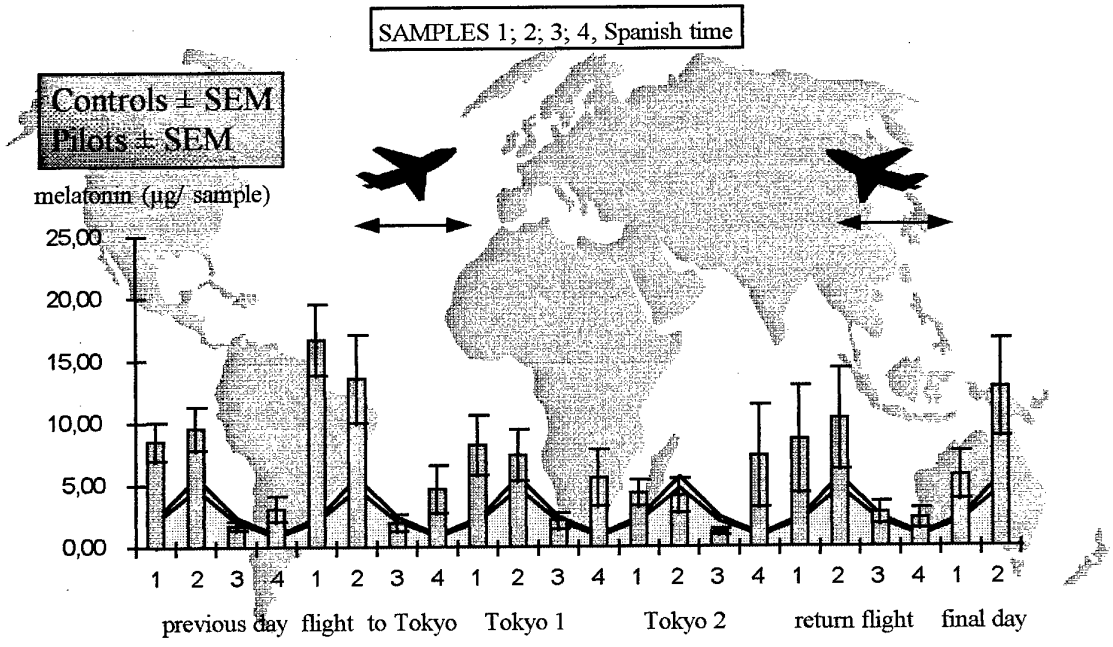


Fig. 2

Urinary melatonin excretion .Pilots older than 50. Flights to **Mexico**

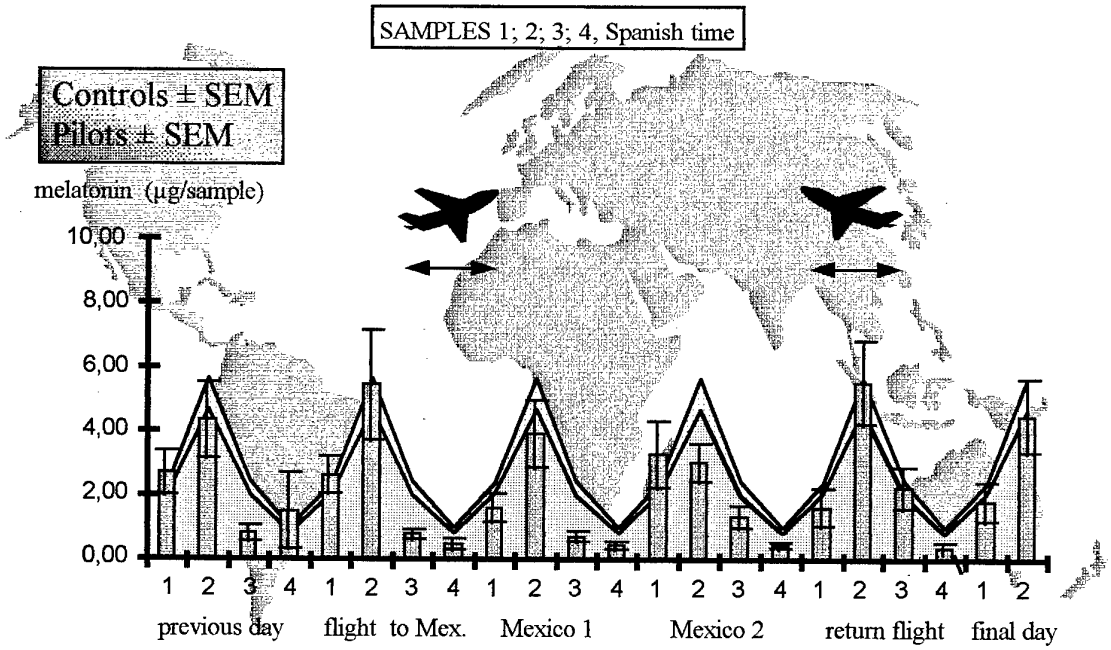


Fig. 3

Urinary melatonin excretion .Pilots older than 50. Flights to **Tokyo**

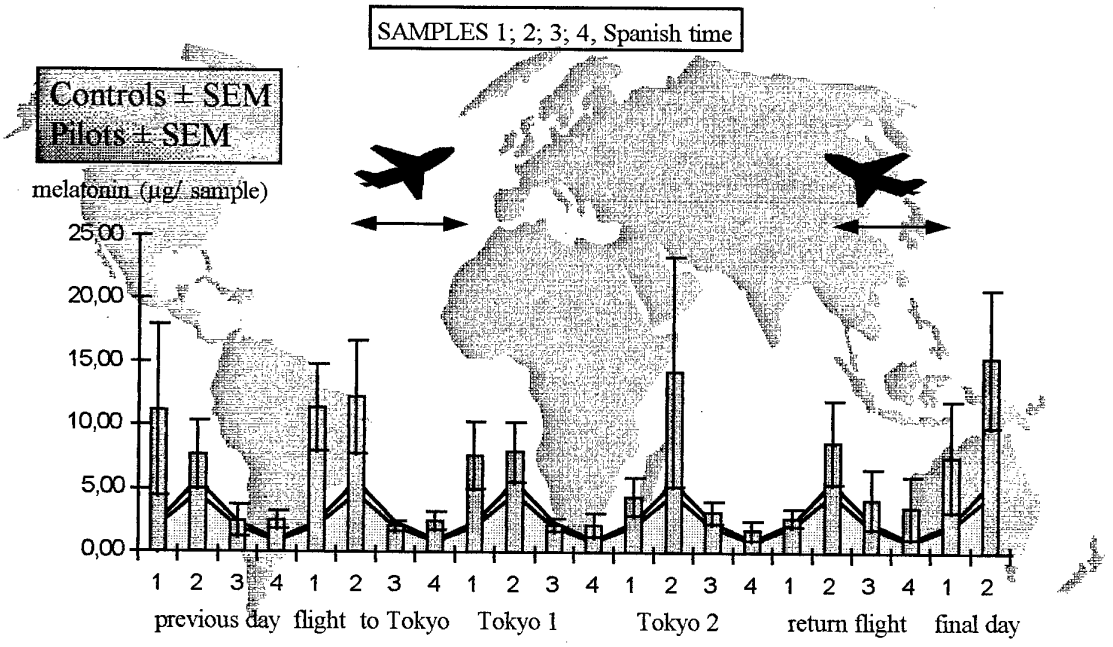


Fig. 4

Aviator's Grounding Time after Melatonin Administration during Rapid Deployment Missions

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Introduction

The determination of drug-induced grounding time for aviation personnel can be derived from the drug's half-life, the assessment of hangover effects, and the evidence that sleep, alertness, and cognitive functions are normal some time after administration. Melatonin's half-life has been reported at approximately 60 minutes (Lane, Moss, 1985; Waldhauser, Weiszenhacher, Frisch, Zeitlhuber, Waldhauser, and Wurtman, 1984; Waldhauser, Saletu, and Trinchard, 1990). Its side effects, particularly in the case of low doses no greater than 1 mg, generally are limited to drowsiness during the first 2 h after administration. This would imply that grounding time would be minimal for regimens employing 1mg or less. However, the use of melatonin in rapid military deployments depends upon the development of regimens which can induce large advances or delays of circadian rhythms in relatively short periods of time (1-2 days).

Evidence that melatonin regimens can induce large shifts of endogenous circadian rhythms in single administrations recently was reported by Deacon and Arendt (1995). In a paper published in the journal of Brain Research, a relatively large dose of melatonin, 5 mg, administered at 17:00 (pill form) was shown to induce approximately a 1.5 h advance in the phase of the endogenous melatonin rhythm. These observations suggest that melatonin doses of 5 mg or more may result in larger advances in the phase of circadian rhythms and possibly result in faster sleep/wake cycle resynchronization times than those induced by 1 mg doses. The faster resynchronization time would be operationally useful for military personnel during deployments across time zones if melatonin's effects on performance do not require long grounding times.

Evidence of degradation of cognitive performance as a function of melatonin concentration has been reported frequently in studies designed to reveal melatonin induced side effects. An inverse relationship between dose and cognitive ability has emerged from studies in which exogenous melatonin is administered and cognitive performance is assessed for several hours thereafter. Supraphysiological levels of melatonin generally are associated with performance degradation. Dollins et al (1993) studied the effects of melatonin doses of 10, 20, 40, and 80 mg on performance in an auditory vigilance task. The task consisted of the presentation of an auditory stimulus of 500 Hz and 70 decibels sound pressure level, every 2 seconds. The tones presented were of two durations, long and short. The subject's task was to press a key when a short tone was heard. Melatonin was administered at 11:45 and subjects were tested at 12:00 and 14:00. Average correct responses were reduced at 12:00 and 14:00 relative to placebo as the concentration of melatonin in serum reached peak levels. Supraphysiological levels were observed throughout 5 hours after administration (11:45). In contrast to other doses, the 10 mg dose exhibited the lowest supraphysiological profile falling to levels comparable to nocturnal physiological levels by 16:00. Fatigue levels remained above normal throughout the testing period.

Since 1993, we have been developing melatonin regimens for use during rapid deployments. In many instances, Army aviation personnel must travel in military cargo planes between 6-15 h during rapid deployments, and must be ready to work upon arrival to their destination. Thus, for melatonin regimens to be operationally effective in similar situations, they must result in shifts of circadian rhythms within 24 h, without requiring

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grounding times that exceed the time used to transport troops from the origination to the destination time zone. We recently examined the potential use of regimens prescribing the administration of a 10 mg dose. At this point, our major concern is the accurate assessment of side effects that may adversely impact health, performance, and safety. In 2 studies we used a paradigm in which a 10 mg melatonin pill was administered prior to the daily sleep period, and performance in cognitive tasks was tested for several hours after awakening.

In this article we will discuss the persistence of supraphysiological levels of melatonin throughout the day after the administration of a 10 mg dose of melatonin. Changes in performance associated with the resulting concentrations, and the potential impact of the time of day of the melatonin dose administration will be discussed within the context of grounding time for aviation personnel .

Methods

Subjects

Both studies were double-blind and placebo controlled. All volunteers were female since our experimental objectives also included the study of melatonin effects on menstrual rhythms, prolactin release, the timing of the luteinizing hormone surge, and mood. Twenty volunteers were recruited in each study. Prior to induction in the study, volunteers were medically screened for pre-existing conditions such as autoimmune disorders, pregnancy, disorders of the reproductive system, menstrual cycle irregularities, mood disorders, depression, and psychosis. After the medical screening, volunteers were allowed to participate after all questions pertaining to the study were clarified and the informed consent signed. This research was carried out under FDA IND 41171, active since March 1993.

Procedures

In contrast to the experimental paradigm used by Dollins et al, 1993, in which cognitive performance was tested shortly after administration, we allowed 7.5-8.0 h of sleep after each melatonin or placebo dose and tested subjects using vigilance tasks shortly after awakening. In this report, data from a 4-choice vigilance task will be presented as a function of melatonin concentrations to describe the possible effects of supraphysiological melatonin levels on alertness.

Vigilance performance. In each trial of the vigilance test, a series of visual stimuli were presented at one of four adjacent spatial locations on a computer screen. Subjects were instructed to strike one of four adjacent keys on a computer keyboard, each corresponding to spatial locations on the screen, indicating the correct location of each stimuli (Figure 1). Incorrect responses were recorded throughout 20 minute sessions.

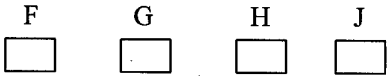


Figure 1. Illustration depicts the 4 spatial locations and the keys used to indicate each location. In the actual test the keys are omitted from the display.

Study 1. In this study, melatonin (10 mg) or placebo was administered at 23:00 h for 7 days. Subjects slept from 23:00 h-06:30 h and were tested throughout the day from 06:30-18:30 h. Urine specimens were collected throughout the day and assayed for 6-sulphatoxy melatonin levels using RIA (radioimmunoassay) kits obtained from Stockgrand Ltd.

Study 2. In study 2, melatonin (10 mg) or placebo was administered at 13:00 for 5 consecutive days. Subjects slept from 16:30-00:30 and were tested after awakening from 01:30-15:30. They received bright light exposure from 01:30-sunrise, and after sunrise, daylight exposure until 13:30. This schedule mimicked a light-dark cycle approximately 6 time zones east from Fort Rucker, AL. In this case, saliva and blood specimens were collected throughout the day and assayed for melatonin levels using RIA kits obtained from American Laboratory Products Company.

Results

Study 1

Changes in melatonin concentrations during the regimen. The following data correspond to the melatonin regimen used in study 1, namely 10 mg administered at 23:00 h for 7 days. Figure 2 shows 6-sulphatoxy melatonin concentrations in urine specimens throughout the day for placebo subjects. Notice that daytime levels between 12:30-21:30 h fell well below 5 ng/ml. Compare the patterns of 6-sulphatoxy melatonin concentrations depicted in Figures 2 and 3. In Figure 3, individual 6-sulphatoxy melatonin concentration profiles for volunteers receiving melatonin (10 mg) at 23:00 h are plotted as a function of time of day. Notice that daytime levels between 12:30-22:30 h remain elevated above 10 ng/ml.

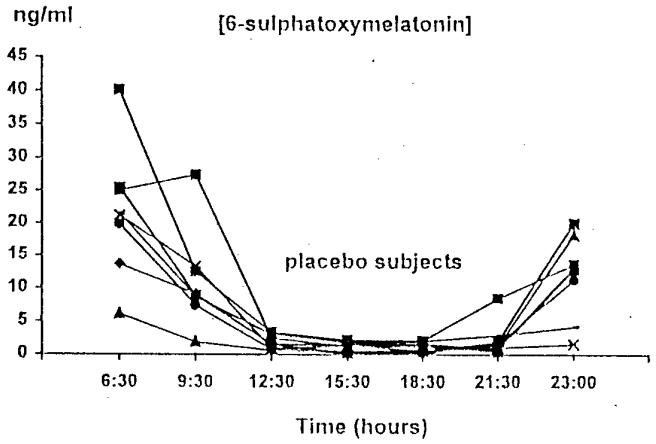


Figure 2. This illustration depicts 6-sulphatoxy melatonin concentrations (ng/ml) in urine specimens throughout the day for placebo subjects. Notice that daytime levels between 12:30 h -21:30 h fell well below 5 ng/ml. Dose administration took place at 23:00 h. The nocturnal increase in melatonin production was reflected in the first void samples (06:30 h), while the evening rise in melatonin production was indicated by the rise in 6-sulphatoxy melatonin levels after 21:30 h.

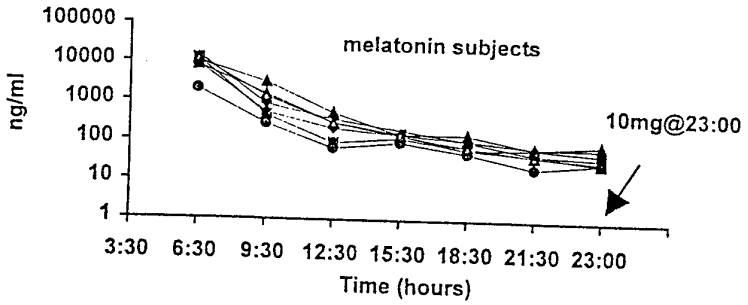


Figure 3. Six-sulphatoxy melatonin concentration profiles for 8 volunteers receiving melatonin (10 mg @23:00). Concentrations are expressed in logarithmic scale. Daytime levels between 12:30-22:30 remain elevated above 10 ng/ml.

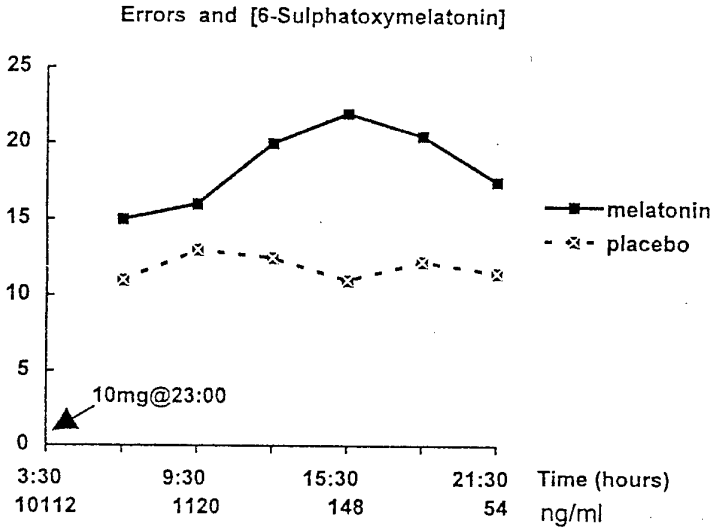


Figure 4. This illustration depicts errors in the four choice task for both melatonin and placebo subjects as a function of time shown on the horizontal axis. Note that 6-sulphatoxy melatonin concentrations for the melatonin group are written below the time of day.

Vigilance errors as a function of melatonin concentrations. Throughout the regimen, melatonin subjects exhibited their highest 6-sulphatoxy melatonin levels upon awakening (06:30) and 3 h later at 09:30 (see Figure 3). Thereafter metabolite concentrations fell below 300 ng/ml (12:30) and reached levels comparable to normal nocturnal concentrations at 21:30.

Melatonin treated participants exhibited significantly greater errors (MANOVA, $F[4,52] = 4.2757$, $p = .0019$) than the placebo group, particularly at 12:30 h (Tukey HSD, $p = .00014$), 15:30 (Tukey HSD, $p = .00012$), 18:30 (Tukey HSD, $p = .00012$), and 21:30 (Tukey HSD, $p = .0007$). Note in Figure 4 that the separation between the melatonin and the placebo group did not begin until the 12:30 h test session when average 6-sulphatoxy melatonin concentrations fell below 300 ng/ml. Thereafter, the placebo group consistently exhibited less errors.

Study 2

Changes in melatonin concentrations during the regimen. The following data correspond to the melatonin regimen used in study 2, namely 10 mg administered at 13:00 h for 5 days. Figure 5 depicts melatonin concentrations in saliva specimens throughout the day for the melatonin group during a 24 h period prior to the beginning of the melatonin regimen. Daytime melatonin concentrations in saliva between 07:30-21:30 remained well below 5 pg/ml, while concentrations during the sleep period, 23:00-07:00 h increased above 5 pg/ml and often exceeded 10 pg/ml. In Figure 6, individual melatonin concentration profiles during the implementation of the regimen (10 mg at 13:00 h) are plotted as a function of time of day. Daytime levels between 13:30-22:30 h remained well above the physiological levels depicted in Figure 5. During the regimen, placebo and melatonin treated volunteers slept between 16:30-00:30 h and were exposed to bright artificial light (above 3000 lux) beginning at 01:30 h and to daylight from sunrise to 13:30 h . This light regimen would result in the acute suppression of endogenous melatonin production after awakening. However, in the melatonin group, concentrations between 00:30 h and 06:30 h remained elevated at levels comparable to the endogenous nocturnal rise during the pre-regimen observations(see Figures 5 and 6).

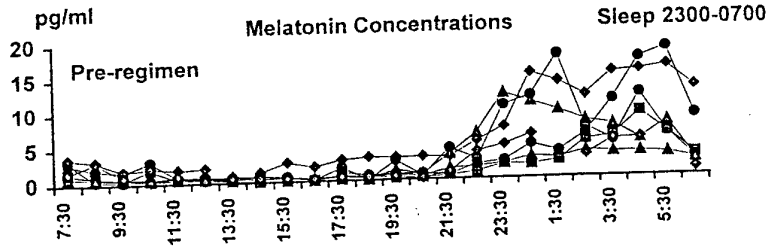


Figure 5. Melatonin concentrations in saliva analyzed from samples obtained from subjects in the melatonin group prior to the beginning of the melatonin regimen used in study 2.

Vigilance errors as a function of melatonin concentrations. Figure 7 shows that during the melatonin regimen, the melatonin group exhibited significantly greater errors (MANOVA, F [4,68] = 2.56, p= .0446) than the placebo group, particularly after dose administration during the 13:30 and 15:00 test sessions (Tukey HSD, p = .0002 and p=.0002, respectively) when melatonin concentrations ranged between 901 and 1,288 pg/ml (see Figure 5 and 6). These observations are in agreement with the results by Dollins et al., 1993, in which high melatonin concentrations post-dose were associated with sleepiness and performance degradation.

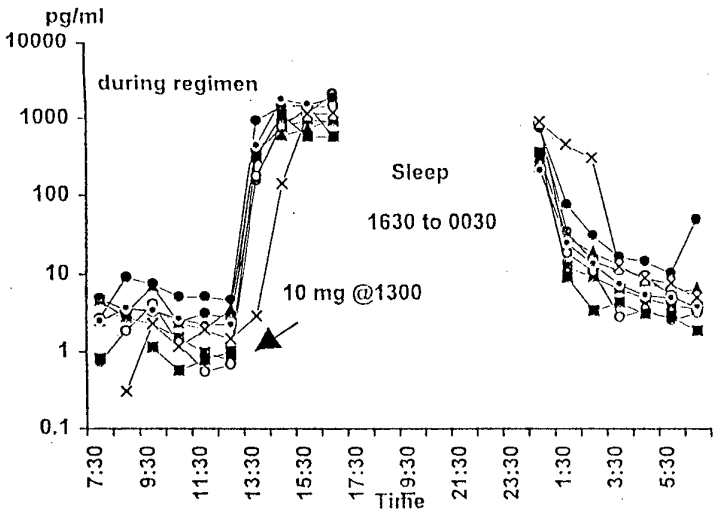


Figure 6. Melatonin concentrations in saliva analyzed from samples obtained from 8 subjects in the melatonin group during the melatonin regimen used in study 2, namely 10 mg administered at 13:00 h for 5 days.

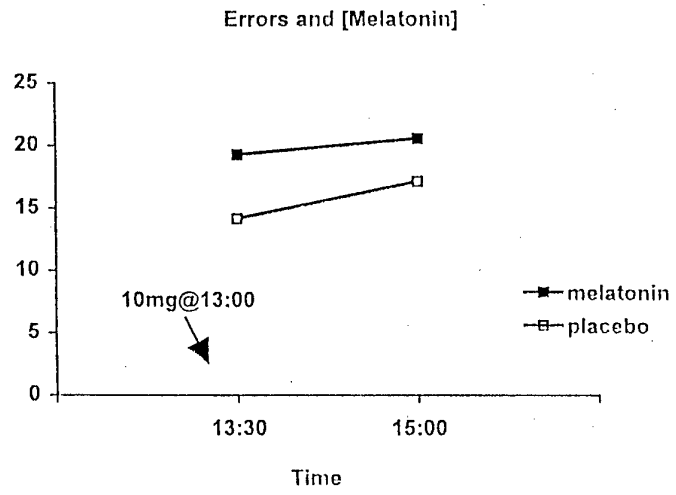


Figure 7. Errors in the four choice task as a function of time of day during the implementation of the melatonin regimen in study 2, 10 mg administered at 13:00 h for 5 days.

After 8 hours of sleep from 16:30-00:30 h, participants were tested at 01:30 h, 03:30 h, and 06:10 h. Upon awakening, the melatonin treated participants made significantly more errors in the vigilance test than the placebo group (Tukey HSD, $p = .0045$). However, this pattern did not persist during subsequent test sessions at 03:30 h and 06:10 h (Tukey HSD, $p = .427$ and $p = .99$, respectively). Figure 8 illustrates that in general, participants in the melatonin group exhibit a consistent pattern of performance throughout the 3 test sessions. During this period of time melatonin concentrations are elevated at levels comparable to nocturnal physiological levels (see Figures 5 and 6).

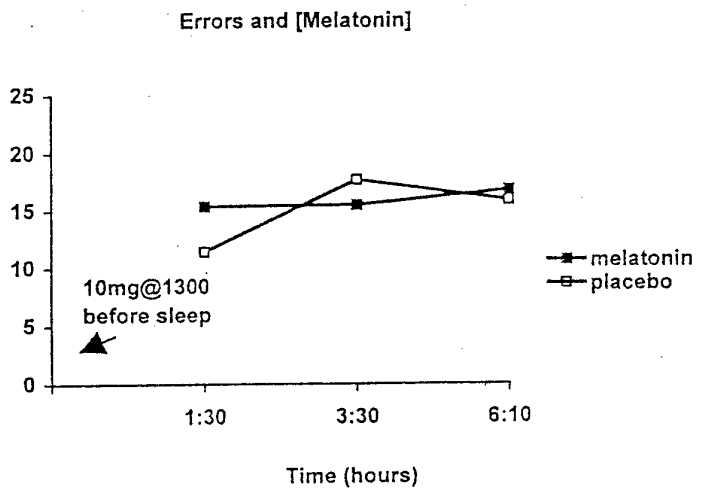


Figure 8. Errors in the four choice vigilance task after normal sleep plotted as a function of time of test session. Both groups slept from 16:30-00:30 and tested at 01:30, 03:30, and 06:10.

Discussion

Results from study 1 agree with the concept that supraphysiological levels of melatonin are associated with cognitive performance degradation (Dollins et al, 1993). Six-sulphatoxy melatonin concentrations were elevated well above physiological levels for most of the day, and did not return to normal throughout the regimen. If grounding time would be derived from these data, it would certainly be advisable to recommend grounding personnel between 16-24 hours after administration of a single 10 mg dose at 23:00 h to allow endogenous melatonin levels to return to normal. A regimen prescribing 7 consecutive doses of 10 mg would be impractical because aviators would be grounded during each day of the regimen. However, the vigilance data leave considerable doubts that melatonin concentration and performance followed a linear and inverse relationship since supraphysiological levels of 6-sulphatoxy melatonin (1,120 ng/ml) detected 3 hours after awakening (09:30 h) were not associated with significant differences in errors between the melatonin and placebo groups (see Figure 3 and 4). In fact, the melatonin group exhibited a consistent increase in errors after 12:30 h, beginning 6 hours after awakening from the night's sleep period (see Figure 4).

In study 2, in which melatonin was administered at 13:00 h, concentrations in saliva remained elevated throughout most of the day (see Figures 5 and 6). However, after approximately 8 h of sleep and 12.5 hours post-dose, there were no significant differences in errors detected between melatonin and placebo treated participants.

In contrast to the results of study 1, the 13:00 h melatonin regimen resulted in the most clear pattern of performance degradation in the hours immediately after administration (at 13:30 and 15:30 h), but not after normal sleep (see Figures 7 and 8). In general, melatonin concentrations did not return to physiological levels until 24 h post-dose. However, the impact on vigilance performance appears to be negligible after sleep (see figure 8). It is likely that in the case of melatonin regimens in which administration is prescribed in the afternoon hours, grounding time may not exceed the duration of travel time required for long range deployments.

These data also indicate that the relationship between supraphysiological levels of melatonin and performance may not be inverse and linear and that it may depend on time of day of dose administration as well as time of testing. Both studies suggest that the determination of grounding time requires the assessment of performance in paradigms which allow normal sleep to occur, and that in the case of melatonin, half-life alone may not be a good indicator of grounding time.

Finally, we recognise that these conclusions are derived from data obtained in 2 separate studies using a between-subjects design and using different methods of assessing melatonin concentrations (urine 6-sulphatoxy melatonin and saliva melatonin). Our next step will be to contrast the 13:00 h and the 23:00 h regimens using a within-subjects experimental design with both female and male volunteers.

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ZOLPIDEM, VIGILANCE ET CAPACITES PSYCHOMOTRICES DE PERSONNELS AU SOL ET DE PILOTES

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RESUME

Lors d'opérations soutenues, les équipages présentent souvent une fatigue liée à des périodes de repos insuffisantes quantitativement ou qualitativement. Ces privations de sommeil sont multifactorielles: charge de travail, désynchronisation en cas de déploiements avec franchissement de plusieurs fuseaux horaires ou missions de nuit répétées voire exclusives, conditions environnementales de sommeil inadéquates (bruit, températures extrêmes), excitation liée aux opérations, au stress du combat. L'utilisation d'hypnotiques est un des moyens qui permet d'optimiser le repos des équipages. L'hypnotique idéal pour cet usage devrait pouvoir induire rapidement un sommeil, de qualité équivalente à celle du sommeil physiologique, d'une durée d'environ 5 heures, et ne pas avoir d'effets résiduels au réveil, même sur des tâches complexes comme le pilotage.
Nous avons évalué le zolpidem, hypnotique de la famille des imidazopyridines, non benzodiazepine, de demi-vie courte (2.4 h) chez 12 personnels au sol de l'armée de l'air (groupe 1) et 12 pilotes de l'Aéronavale (groupe 2). Dans cette étude croisée en double aveugle, les sujets recevaient au couché, lors de 3 sessions, soit 10 mg de zolpidem, soit 1 mg de flunitrazepam, hypnotique benzodiazepine dont la demi-vie est de 19 h, soit un placebo. Les premiers tests étaient effectués à 06h30, les pilotes se couchant à 01h00, et les non pilotes à 22h00. Le sommeil, l'humeur et la vigilance étaient évalués subjectivement par les échelles visuelles analogiques de Bond et Lader, les sujets du groupe 1 subissant en plus des tests psychomoteurs de type tracking instable et des enregistrements électroencéphalographiques 10, 12, 14 et 16 h après la prise du traitement. Les sujets du groupe 2 effectuaient un vol simulé, 7 h après l'administration du traitement, sur un simulateur de Super Etendard, chasseur bombardier monoplace de l'Aéronavale. Les résultats de cette étude sont détaillés dans l'article en référence. Ils montrent un effet favorable significatif dans les deux groupes sur la qualité subjective du sommeil avec les deux hypnotiques comparés au placebo. La qualité de l'éveil est dégradée dans le groupe 1 avec le flunitrazepam comparé au placebo et au zolpidem dont les scores sont identiques. La forme physique au réveil est rapportée significativement meilleure avec le zolpidem par rapport à l'autre hypnotique. Les performances psychomotrices ne sont pas dégradées sous zolpidem comparé au placebo, même dans le groupe 2 qui accomplissait le vol simulé 7 h après la prise du traitement. L'analyse spectrale électroencéphalographique sous zolpidem était superposable à celle sous placebo; le flunitrazepam était responsable de signes de sédation avec notamment un déplacement significatif du pic maximal vers des fréquences plus basses (5 à 7 Hz contre 8 à 9 Hz sous placebo et zolpidem). L'absence d'effets résiduels du zolpidem sur la vigilance et l'humeur des sujets au réveil, le maintien des performances dans les deux groupes de sujets (y compris le vol simulé), sont donc corrélés avec les résultats EEG. Cet hypnotique présente donc un profil pharmacodynamique cohérent avec ses qualités pharmacocinétiques et sa spécificité d'action, et donc potentiellement intéressant en opérations soutenues.

ref: Sicard BA, Trocherie S, Moreau J, Vieillefond H, Court LA. Evaluation of zolpidem on alertness and psychomotor abilities among aviation ground personnel and pilots. Aviat. Space Environ. Med. 1993; 64:371-7.

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

Discussion #4

CALDWELL, US: We recently did a zolpidem study where we used a prophylactic nap prior to a sleep deprivation period. The drug was given at 8:30 pm and then subjects slept between 9:00 pm and 11:00 pm. Then we woke them up and tested them for the remainder of the next day. We found no significant difference between zolpidem and placebo in any of the large number of tests that we used for evaluation immediately upon awakening. We also did the repeated test for sustained wakefulness. The first one was done at 2:30 am. Again, we did not find significant differences between zolpidem and placebo, although we certainly could tell the difference between the two napping conditions and the no-nap condition. We did the study to find out whether or not we could help aviators go to sleep if they just had a short-duration sleep period. The zolpidem was very effective for promoting sleep and did not seem to produce unwanted side effects. Our results are consistent with what you found (in reference to Paper #19).

LANDOLT, CA: Prof Brown, you started your talk by saying that there are two components; there is a hormonal component and a circadian rhythm component. Does that imply that there are two separate brain mechanisms, one for sleep inducing and the other for phase shifting? If so, are the drugs that we are giving having an effect on one of these components and not the other, or are they working on both (in reference to Paper #14)?

BROWN, CA: There clearly are two different brain mechanisms, one for sleepiness, which is built up when you are sleep deprived, and the other is the circadian rhythm in sleep. Melatonin may well act on both because it promotes sleep directly; if you give it in the middle of the day at a time when you get no phase shift it will promote sleep. So it seems to induce sleep and that may well be by a totally different brain mechanism than the phase shifting effect of melatonin. Drugs like zolpidem, of course, don't seem to have any effect on the circadian mechanism; they have to do with the sleep mechanism. Whether the dose of melatonin used would interact with the phase shifting or with the sleep promoting is another matter. To this point, nobody has been able to demonstrate this. Even a dose of 0.3 mg melatonin produces some sleepiness if you test reaction time and so on. It also has some phase shifting effect so it probably acts on totally different brain centers.

COMPERATORE, US: I would like to address the question of dose. Deacon and Arendt (Brain Res., 1995) showed clearly that a larger dose of melatonin results in a corresponding larger phase shift. Certainly, large doses of melatonin affect alertness and they induce sleep. Therefore, with larger doses of melatonin, up to a point, one can reset the sleep/wake cycle quicker. In our study that Prof Brown referred to, we used 10 mg because we wanted to maximize the hypnotic and chronobiotic effects of melatonin. We don't claim that the 10-mg dose is the best one; we use it because it is probably the upper bound of the dosage levels that we would consider.

BROWN, CA: I certainly agree with what has been said but I'd like to point out one thing and that is that the phase shifting effect of melatonin follows the phase response curve. If you give melatonin in the evening, you get a phase advance of rhythms; if you give it in the morning you get a phase delay of rhythms; if you give it mid-afternoon there is a dead time where there is no phase shift in rhythms. At any of those times you can get the sleep inducing effect so these are different mechanisms.

ALONSO-RODRIGUEZ, SP: I have heard that women are more sensitive to the effects of melatonin. Does anybody have a response to that and, if so, would a lower dose be recommended for women than men for preventing jet lag?

STEFFEN, CH: We compared women and men in our limited trials but we didn't find a clear cut difference. I think also, for the simplicity of advice, that we should not go for differing doses between men and women because the situation is already complicated enough.

TRESGUERRES, SP: I would like to make a further comment. The endogenous excretion of melatonin is altered by age. People older than 50 years normally have quite reduced excretions of melatonin and this has been implicated as a factor causing insomnia. In some countries, melatonin is administered to people over 60 years old as a sleep inducer. Perhaps melatonin needs to be considered not as a normal hormone, but as a signal telling the rest of the body that it is night time and the body should sleep. In some people older that 60 years having very small excretions of melatonin during the night, the body does not realize that there is a need for sleep. Then the situation occurs that these people, who do not sleep during the night, continuously fall asleep during the day. Sometimes, for these people, the administration of 3 mg melatonin during the night helps to restore the normal wake/rest cycle. Melatonin is a special hormone that needs to be considered from a very special point of view. It has been said that melatonin is an inhibitor of the reproductive function in animals having seasonal reproduction during parts of the year when the nights are long. Then when Spring comes and melatonin excretion is reduced since the nights are shorter, the reproductive system is activated in these animals. The opposite occurs in animals that have a longer pregnancy period; for example, in deer, in which the reproductive system is activated when Winter arrives. This happens when the melatonin levels are increasing. We still need to learn more about the physiology of melatonin and that is the reason that many of us are still very interested in this particular hormone.

SICARD, FR: In melatonin treatment of jet lag, several questions need to be answered. What is the optimal dose and timing of melatonin administration, should there be evening or morning departures - which bears on the issue of sleep deprivation versus jet lag - and how useful is melatonin for rapid adaptation?

BROWN, CA: I have a question related to the previous session where we heard about dextroamphetamine, modafinil and caffeine. I don't know of any studies looking at the effects of those agents on melatonin. It would be very interesting to know if they do influence it and if that's part of the mechanism on how they act.

LAGARDE, FR: I know of a study that showed that caffeine has an effect on the excretion of melatonin.

OPERATIONAL DETERMINANTS OF MEDICAL PLANNING

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Summary

Aeromedical evacuation is but one stage of medical treatment for surviving casualties of a military operation. Planning for aeromedical evacuation must take account of the overall medical estimate. This paper describes the factors that medical staffs have to take into account during the planning stage of a military operation and draws attention to some of the lessons learned from recent operations.

Introduction

The most important point is that medical staffs must be involved in operational planning from the very earliest stages. If they are not, there are the risks that non-medical operational planning staffs will make unwarrantable assumptions about host nation or allied medical support, plan for the wrong quantity or quality of medical support or arrange for it to arrive in an inappropriate time scale.

Factors affecting operational medical planning include developments in governments' foreign policies, concepts of operations, medical doctrine, military and medical technology and lessons learned from previous operations.

Obviously, aeromedical evacuation planning is affected by governments' willingness to become involved in Military Operations Other than War (MOOTW). A potential enemy may interpret the deployment of a robust medical presence as a signal of willingness to take casualties and thus of resolve and firmness of purpose.

Operational Concepts

Medical planning is greatly affected by emerging operational concepts. NATO nations are much less likely than they were to become engaged in independent military operations. Operations with allies, or combined operations, will have an effect on medical planning. One nation may be willing to take a lead role in one aspect of medical support. One recent example is the part played by Germany in providing Role 3 medical support in the Multi-National Division (South West) area of operations in the former Yugoslavia. Similarly, because most nations cannot afford duplication of assets, single Service operations have given way to joint operations. In the UK, it is accepted policy that the Army will provide Role 3 support in most land operations for the other 2 Services.

Developments in Military Technology

Modern weapons can be targeted with greater accuracy, thus generating more casualties. Modern weapons are also much more efficient at killing and wounding than older ones. The wounding potential of a projectile is proportional to the cube of the velocity, the cross-sectional area and the mass. Modern guns make use of the relationship by increasing muzzle velocity and by making the bullet tumble or mushroom on impact. Moreover, many weapons are designed to be non-lethal.[1] Such weapons create more work for the medical services than for the chaplaincy services. For example, rifles and fragmentation weapons kill

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only 20-25% of the casualties they cause.[2] Biological and chemical weapons have the potential to cause both great mortality and morbidity. Such weapons are tempting for smaller states and terrorist organisations because they are effective, cheap and easy to produce. Effective intelligence is required so that training and prophylaxis can be given and appropriate protective equipment procured and distributed.

This tendency to increased casualty rates is balanced by improvements in individual and collective protection. However, such technology may actually increase wounding rates at the expense of death rates. Casualty rates may also be reduced by the more modern dispersed battlefield, by manoeuvre warfare and by adequate intelligence or warning of an attack.

One major determinant of medical planning is the analysis of casualty rates. Each successive conflict allows refinement of expected casualty rates.[3] However, it is important that the casualty rates for a particular operation are agreed with the operators, if only to preclude a post-operation accusation of over-egging the medical support.

Developments in Medical Technology

It is almost axiomatic that changes in medical technology have an impact on medical planning. No recent example has had the impact of the introduction of antibiotics. However, there is the risk that modern doctors practising in peacetime may regard the newest gadget as indispensable and insist on its inclusion in the armamentarium. For example, 5 years ago field units did not possess CAT scanners; now there are strong arguments for them to be available in the field. However, there are disadvantages. Field equipment must be transportable and robust. CAT scanners may be inappropriate for use by a light, airmobile field surgical unit.

Another example is the use of keyhole surgery. The time taken to carry out keyhole, as opposed to conventional, surgery may be incompatible with dealing with mass casualties. Anaesthetic apparatus and surgical instruments must be simple, robust and standardised. Similarly, surgical training should be simple, robust and standardised. There is little place for the superspecialist on the battlefield.

There may therefore be a conflict between military requirements and with modern expectations and demands. The media will play a large part in this. They will be there, in large numbers, filing reports directly to home.[4] They will undoubtedly manipulate public perception of the adequacy of medical care. What may be acceptable for mass casualties in war will not be acceptable for MOOTW, for example peacekeeping. For example, the bid to obtain containerised operating theatres for British IFOR forces in the former Yugoslavia was greatly aided by Parliamentary comment on the acceptability of operating in tents.

In the future, the wider availability of satellite communication may change the composition of field units. For example, telemedicine will allow supervision of surgical operations from a distant base or the remote viewing of X-rays, thus avoiding the deployment of a senior surgeon or radiologist. However, we should not become dependent on such technology because the bandwidth demands are high and because of the risk of interference with the electromagnetic spectrum in wartime.

Developments in Medical Doctrine

Changes in operating medical doctrine can also affect medical planning. For example, recent considerations on the

"golden hour" and the "6 hour rule" will affect the placing of Role 1 and Role 2 medical support. This should lead to the salvaging of casualties who previously would not have been expected to live and will, in turn, impact on the aeromedical evacuation requirements.

The intended location of care will impose restrictions on medical planners. For example, surgery within theatre (SWIT) will lead to the evacuation of more stable casualties; but surgery without theatre (SWOT), that is stabilisation of casualties with aggressive resuscitation and then evacuating them for definitive surgery at the home base, will require more highly trained aeromedical escorts and more specialist in-flight equipment.[5]

Finally, the role played by the hospital service and the Voluntary Aid Societies (VAS) at the home base will help to decide what medical facilities have to be sent to the theatre of operations. In the UK, any inability of military medical forces to cope will be covered by the National Health Service (NHS). In addition the NHS and VAS will play a large part in the arrival and transfer procedures of British war casualties.

Lessons Learned from Previous Operations

The lessons that medical planners in the UK have learned in recent years are hardly new:

1. There is the vital importance of including environmental health personnel on the initial reconnaissance. This requires the understanding and the co-operation of the operators.

2. Formed units perform better than ad hoc units. It is best practice to keep units together for training and deployment than to cadreise them and reinforce to war establishment for deployment or to cobble together a unit from scratch.

3. A rigorously applied system of medical standards is essential to ensure that only those personnel who are fit to deploy are deployed.

4. The task must be clearly defined, otherwise the operation will suffer from "mission creep". This is particularly important in MOOTW.

5. The medical supply system must be efficient and reactive.

6. Personnel need to be kept adequately briefed.

7. The military system should take care of the welfare of the deployed personnel as well as their families at home.

8. Unless a reliable, robust, simple, contemporaneous medical records system is available that can be rationalised with operational records, the military will be increasingly vulnerable to post-operation legal action.

9. Think "JOINT". Put inter-Service rivalries aside. Most of all maintain the common courtesies.

10. Finally, observe Healey's First Law of Holes.[6]

"That men do not learn very much from the lessons of history is the most important of all the lessons that history has to teach."[7] Unless action is taken to change procedures and practice, lessons learned become merely problems identified.

Medical Planning

With all these factors in mind, the steps taken by British medical planners, together with the single Service operational commands, in developing an operational plan are as follows:

1. Assess the operational scenario. Take account of scientific and technical intelligence and general military intelligence, including any NBC threat. Assess prevalent diseases, vectors, and host nation and allied medical capabilities.

2. Ensure an environmental health presence, and if possible a medical presence as well, on the reconnaissance.

3. Assess expected Disease and Non-Battle Injury (DNBI) Rates and develop appropriate expected casualty rates **with the operators**.

4. Determine the operational orbat.

5. Apply the appropriate operational medical doctrine.

6. Determine casevac and aeromedical evacuation requirements.

7. Determine the medical orbat and assess the need for pre-deployment training.

8. Assess operational concurrency and the need for reserves.

9. Determine the need for roulement.

10. Maintain contact with Other Government Departments.

Conclusions

A variety of factors affect operational medical planning. These range from operational concepts and the impact of technology to emerging medical doctrine. Medical planning has to be kept in the context of the overall operational plan and the medical planners must be an integral part of the operational planning organisation. Aeromedical planning, in turn, must reflect the overall medical plan and the operational plan. The British Army has a saying, "Failing to plan is planning to fail".

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[1] Coupland RM. "Non-lethal" weapons: precipitating a new arms race. *Brit Med J*, 1997; **315**: 72.

[2] Coupland RM. Epidemiological approach to the surgical management of the casualties of war. *Brit Med J*, 1994; **308**: 1693-7.

[3] Kuhn GWS. Ground forces casualty rate patterns: uses in casualty estimation and simulation evaluation. Proc 60th Military Operations Research Society Symposium, June 1992. 101, South Whiting St, Suite 202, Alexandria VA 22304.

[4] Lehrer T. "So long Mom", in *"That Was the Year That Was"*, 1965: Reprise Records.

"While you swelter,
Down there in your shelter,
You can see me,
There on your TV..."

[5] STANAG 3204, draft Nov 96.

[6] Denis Healey, when Secretary of State for Defence (1964-9) enunciated his First Law of Holes as follows, "When in one, stop digging".

[7] Huxley A. Case of Voluntary Ignorance. *Collected Essays*, 1959.

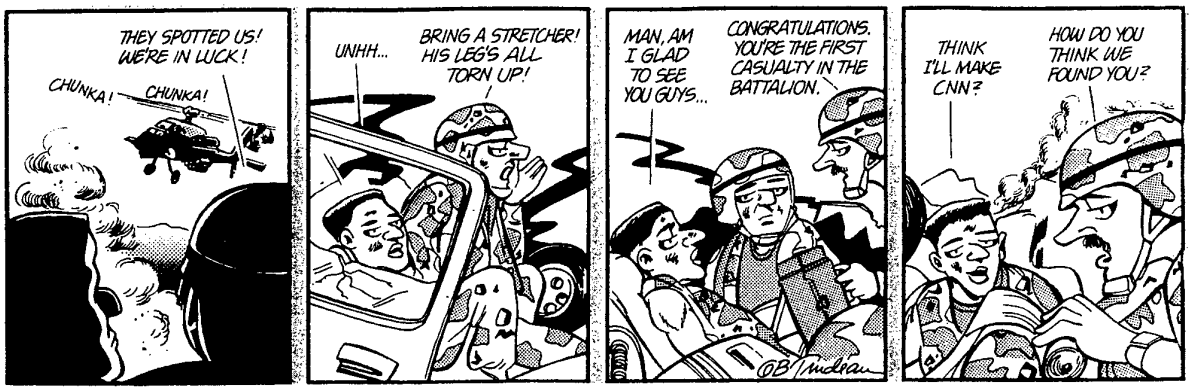


Figure 1. DOONESBURY © 1991 G.B. Trudeau. Reprinted with permission of UNIVERSAL PRESS SYNDICATE. All rights reserved.

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Casualty Care for 2010 and Beyond



Lt Col Richard A. Hersack
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Cold War

- Bipolar - one major global threat
- Held smaller regional threats in check
- Massive military build-up
- Prepositioned large forces overseas
- Primary military strategy
  - Deterrence
  - Strong determined response
  - Mainly defensive

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

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World Situation Today

- Monopolar - one world superpower
- Numerous smaller regional threats
  - Not held in check
  - Attempt to exert greater regional influence
  - Ethnic, religious, politically based disputes
  - Situations develop rapidly
  - Little warning time

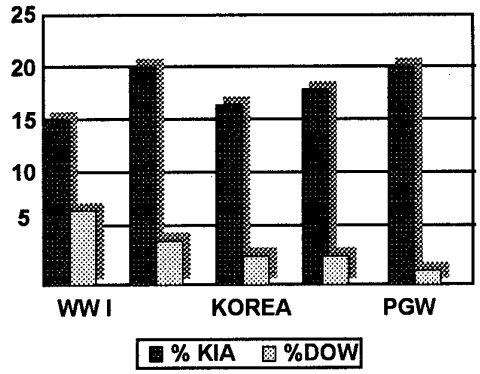
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Guides for Reengineering

- Analysis of Patient Statistics
  - Casualty statistics
  - Impact of DNBI's
- National Policy
  - Change in world situation / National strategy
  - Increasing military role / Operations tempo
  - Shrinking defense budget
- Operational Constraints
  - Tailor medical support to the scenario
  - Consider limited lift capabilities
  - Cover the initial build-up phase
  - Medical coverage from first day until final pull-out
  - Must follow the lead of the "Line"

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Casualties Who Die



- % DOW * decreased dramatically
- % KIA unchanged this century
- 1/3 survived at least 10 minutes

*DOW (Died of Wounds) = Died After Reaching Care of Physician

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Casualty Statistics

1000 Casualties

200 KIA

800 Survivors

100 Fatal
- 70 CNS
- 30 Multiple

100 Exsanguinate
- May live 10 minutes
- 60 delayed death
- Direct pressure

28 DOW

772 Survivors

Bellamy RF. The Causes of Death in Conventional Land Warfare: Implications for Combat Casualty Research. Military Medicine; 1984, 149:55-62

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Historical Data

- Far Forward Surgery used since W.W.II
  - U.S. (Pacific, African, and European Theaters)
  - British (Falkland Islands Campaign)
  - Israelis (ongoing)
- Does decrease morbidity and mortality
- Evacuation does not increase risk
- Early evacuation may improve

*Dolev E. Early Evacuation of Patients from the Battlefield After Laprotomy: Experiences in Vietnam, Israel, and the Falklands. Military Medicine, 1987;15

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Impact of DNBI's

- Disease Non-Battle Injury casualties
- 80% of loss of force strength
- Prevention is key
- Must educate line commanders
  - Are essential to sound preventive practices
  - Enforced discipline reduces DNBI's
  - Reducing DNBI's preserves fighting force
    - Overwhelming force decreases combat casualties
  - Sound tactics reduce combat casualties
  - Personal protective gear - e.g. body armor
  - Modern weapons technology

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Civilian Influence on Military Policy

- Domestic versus defense spending
- Domestic spending winning out
  - Returning to militia mentality
  - No definitive threat obvious to policy makers
- Dramatic reduction in military end strength
  - 2,000,000 during Cold War
  - 1,400,000 currently and shrinking
- Civilian opinion expanding military role
  - Increasing operations tempo
  - OOTW's - Peacekeeping, Humanitarian, Drug Interdiction, etc.
  - Part of Lake Doctrine - "Engage and Enlarge"

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New Emerging Roles

- The new paradigm
  - "While we have historically focused on warfighting, our military profession is increasingly changing its focus to a complex array of military operations other than war."
    General John M. Shalikashvili (AFM, July 1996)
- Military medicine as an instrument of national power
  - "Medics are the tip of my spear."
    General George A. Joulwan, Supreme Allied Commander, Europe
  - Warfighters support military medicine in humanitarian relief operations
  - Application of "Engage and Enlarge" (Lake Doctrine)

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Summary of Effect of Policy Changes

- Changing threats to vital national interests
  - regional and less predictable
- National Strategy
  - Engage and Enlarge vs. Containment
- Expanding military roles / operational tempo
  - Peacekeeping, humanitarian relief, etc.
- National military strategy
  - Rapid deployment of expeditionary forces
- Budget debate
  - decreasing defense dollars
- JV 2010
  - Attempt to position military for future

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Joint Vision 2010

- General John Shalikashvili - CJCS
  - Increasing operations tempo
  - Expanding role for the military
  - Decreasing budget and infrastructure
- Preparing the military for the future
  - Capability-based versus Threat-based planning
  - America's core strengths
    - Quality people
    - Advanced technology
  - Utilize service unique capabilities
  - Flexible, mobile, multi-role joint forces
  - Achieve full spectrum dominance over opponents across range of military operations

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Joint Vision 2010

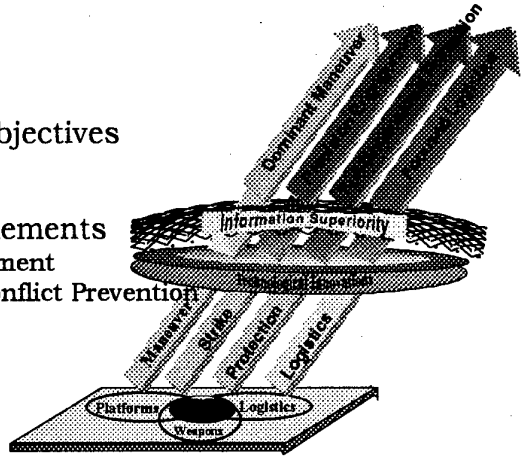
- Four Pillars
  - Dominant Maneuver
  - Precision Engagement
  - Focused Logistics
  - Full Dimensional Protection
- Six Critical Elements
  - People
  - Leadership
  - Doctrine
  - Education and training
  - Organizational structure
  - Materiel

"Persuasive in Peace. Decisive in War. Preeminent in any Conflict"

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JV 2010 Emerging Operational Concepts

- Two Overriding Objectives
  - Promote Stability
  - Thwart aggression
- Three Strategic Elements
  - Peacetime Engagement
  - Deterrence and Conflict Prevention
  - Fight and Win
- Strategic Concept
  - Power Projection
  - Forward Presence



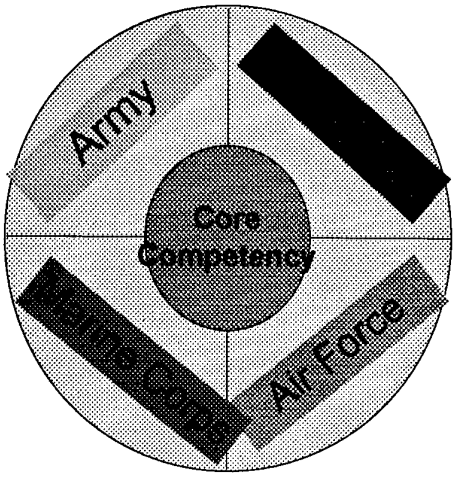
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Service Specific Components

- Service specific operational constraints
- Service specific capabilities
- United around joint core competency

"Interoperability" not "Interchangeability"



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Operational Constraints

- Tailor medical support to operational scenario
  - Not all operations warrant a full size field hospital
    - Limited scope and size of forces
    - Limited duration of scenario
  - Need to depart from "Cold War one size fits all" thinking
- Limited forward lift available
- Must cover the build-up phase

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Three Priorities for Medical Readiness

- Provide "essential" care forward
  - Switch from "definitive" care forward
  - Emphasis on casualty prevention
- Critical care capable evacuation system
- Modularize deployable medical units
  - Follow the lead of the "Line"
  - Light-weight, rapidly deployable, flexible
  - Taylor medical support for each scenario
  - Capabilities-based vs. Threat-based planning
  - Medical coverage from first to last day

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Essential versus Definitive Care Forward

- Reduces the Human Logistic Tail
  - MHSS initiative
- Decreases medical supply requirements
- Decreases overall medical footprint
- Decreases medical lift requirements
  - During initial deployment
  - For sustaining capability
  - Allows more available lift for war materiel
  - Allows forward usable medical capability early
- Emphasizes early evacuation
  - Reduces forward casualty support requirements
  - New 7/15 Evac Policy

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Current Patient Evac System

- Designed for stable patients
  - In convalescent phase
  - Require minimal in-flight care
  - Sick patients require medical attendant
- Enroute care personnel may not be current in critical care medicine
- Forward field hospitals cannot afford to lose medical personnel as attendants

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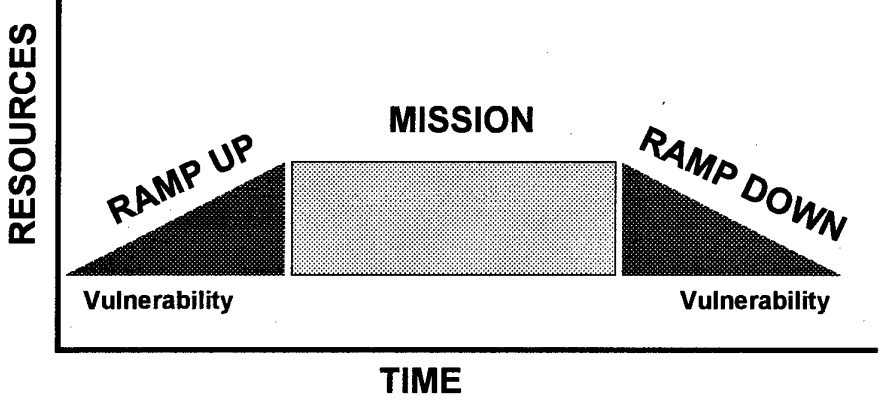
Evacuation System of the Future

- Must prepare patient for evacuation
  - From C-Day
  - "Shock-treated" includes surgical intervention
  - Preserve vital functions
- Must continue care during evacuation
  - Critical care in the air capability
- "Man-portable" capability
  - No pallets
  - Arrives in AOR on C-Day

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Medical Deployment

Why Modularize?



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The Period of Vulnerability

- Initial "ramp up" phase
- Combatants at risk on first day
- Need medical coverage
- Minimal medical capability forward
- Little or no patient holding capability
  - Limited number of beds forward

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Deploying Medical Assets Early

- Limited airlift
  - Losing C-141's and C-5's
  - Limited number C-17's
- Current hospitals huge
  - "Cold War" design and concept
  - Designed for definitive care forward
  - Large holding capacity (many beds)
  - May take weeks to deploy

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Deliberate Planning Process

- How Warfighting CINC's plan for possible contingencies
- Planning process takes several months
- Emphasizes moving equipment and personnel into place rapidly for early "functional" capability
- Medical is part of logistical plan annex
  - Concentrates on moving people and pallets
  - Should move equipment and people to provide early usable capability
    - Follow the line's example (e.g. fighter deployments)
    - Usable capability within hours of arrival

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Modularity Answers the "Dynamic" Problem

- Enables rapid deployability
- Minimizes initial lift requirements
  - More lift for war fighting capability
- Allows "functional" capability deployed early
  - Provides essential care forward on C-Day
- Flexible response
  - Variety of scenarios
  - Based on size and duration of scenarios
  - Allows a tailored medical response

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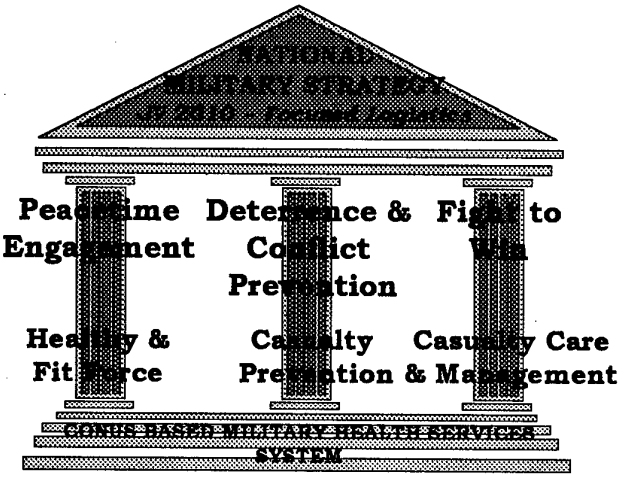
Joint Health Services Support Vision

- Health support key to achieving JV 2010
  - Health and fitness are force multipliers
- Improve capabilities by promoting physical fitness
- Enhance mission effectiveness by prevention of illness and injuries
- Minimize environmental impact by military operations
- Reduce human logistic tail
  - Reduce exposure of troops deployed forward
  - Rapid evacuation of serious casualties requiring significant medical capability

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JV 2010 -- JHSS LINKAGE

Three Pillars



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JHSS Casualty Care Concept

- Reflects national military strategy, JV 2010 and MHSS Vision
- Project essential care forward
- Stabilize by preserving vital functions
- Evacuate early to definitive care
- Maintain care enroute

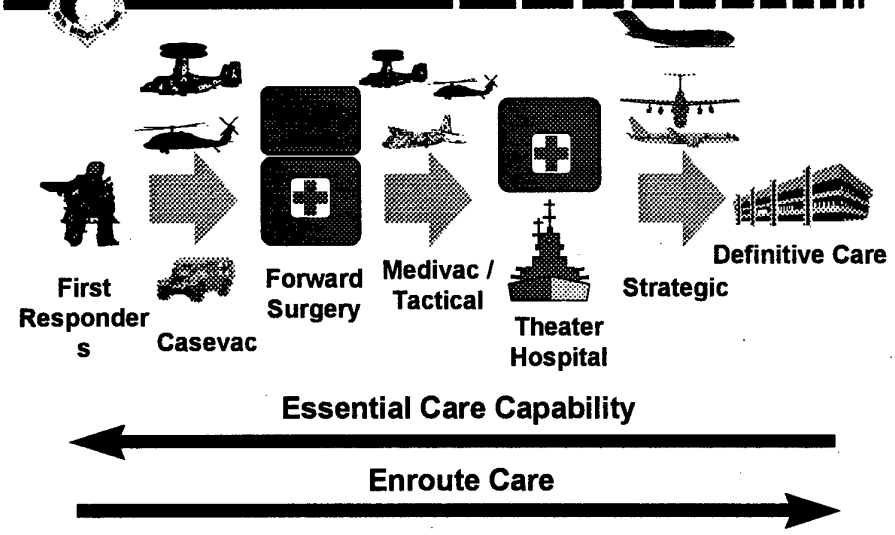
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JHSS Casualty Care Components

- First Responders
- Forward Resuscitative Surgery
- Theater Hospital
- Continual Enroute Care
- Technology
- Logistics
- Preventive Medicine - Healthy Force

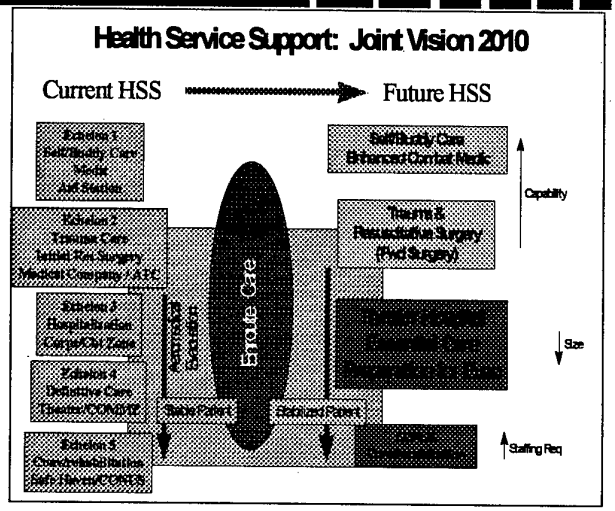
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Aiming for 2010 (JHSS)



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JHSS Operational Concepts: Differences From NATO 4E Concept



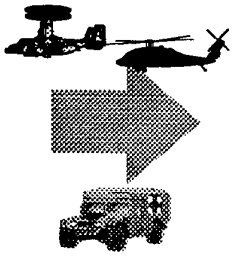
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First Responder Phase



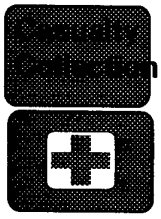
First Responders

Initiate Field ATLS:
- Airway
- Breathing
- Hemorrhage control
- Fluid resuscitation
- Limb stabilization
- Initiate within 10 min.



Casevac

Maintain life / limb saving interventions:
- ABC's
- mainly technical
- minimal monitoring
- space / lift limitations
- duration <1-2 hrs.



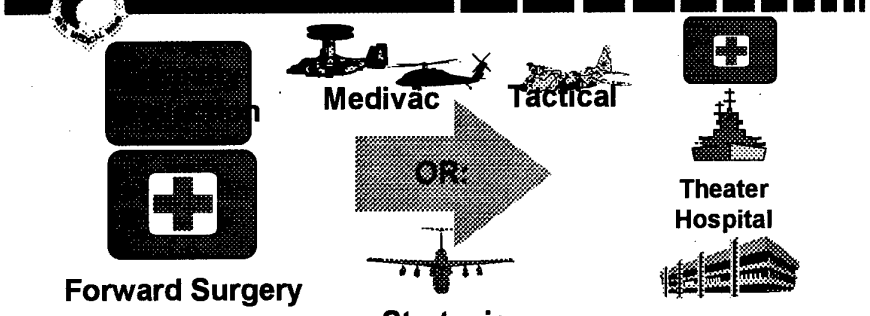
Forward Surgery

Medical personnel triage all casualties

(10-15% get operations)

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Forward Surgery Phase



~10-15% receive operations

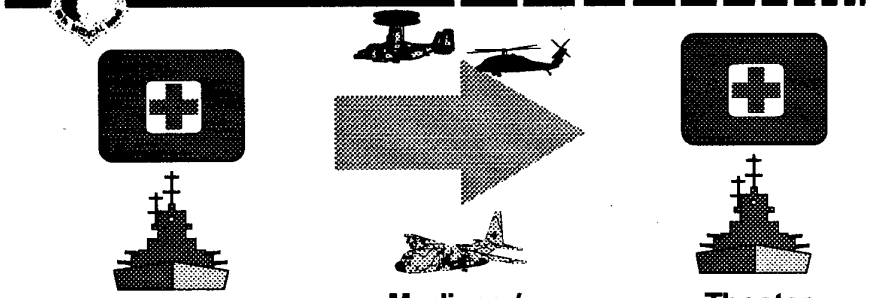
Maintain ABC's +
Post-operative care
- Space/ lift limitations
- duration limited to operational range (~2-8 hrs.)

All casualties receive surgical intervention within 12 hours of injur

(Varies based on airfield, mode of transportation, travel time, operational constraint

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Theater Hospital Phase

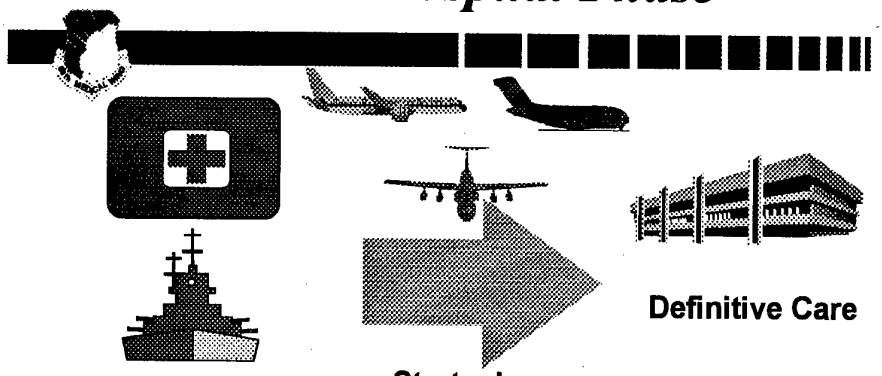


Maintain ABC's +
Postoperative ICU Care +
Medical ICU Care
- Increased duration of flight
- Space and lift capability variable
- Limited lift availability

OR:

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Theater Hospital Phase



Theater Hospital

Strategic

Definitive Care

Maintain ABC's +
Postoperative ICU Care +
Medical ICU Care
- Increased duration of flight
- Increased space and lift capability
- Limited lift availability
- Duration several hours

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Enroute Care

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Continual Care Concept

- Continuum of care
  - From first intervention
  - To definitive care
- Scope
  - First responder
  - Forward surgery
  - Flow through hospital

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Enroute Care - Major Goals

- Emphasize proper patient preparation prior to evacuation
- Ensure evacuation system has clinical skills to move sick patients (sustain care enroute)
- Preserve deployed field medical assets

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Proposed Definitions



- Casevac
  clearing the battlefield
- Medivac
  rotary wing / ground
- Tac Evac
  fixed wing in theater
- Strat Evac
  fixed wing out of theater

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Major Issues

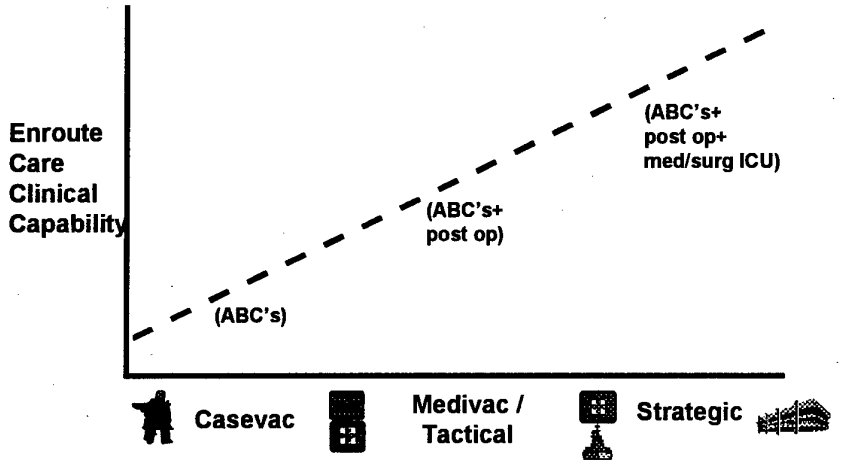


- Modes of Transportation
- Prerequisite treatment / Intervention
- Sustain / Advance care en route
- Personnel
- Equipment
- Command and Control
- Communication

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Enroute Care Clinical Requirements

(by Phase of Care)



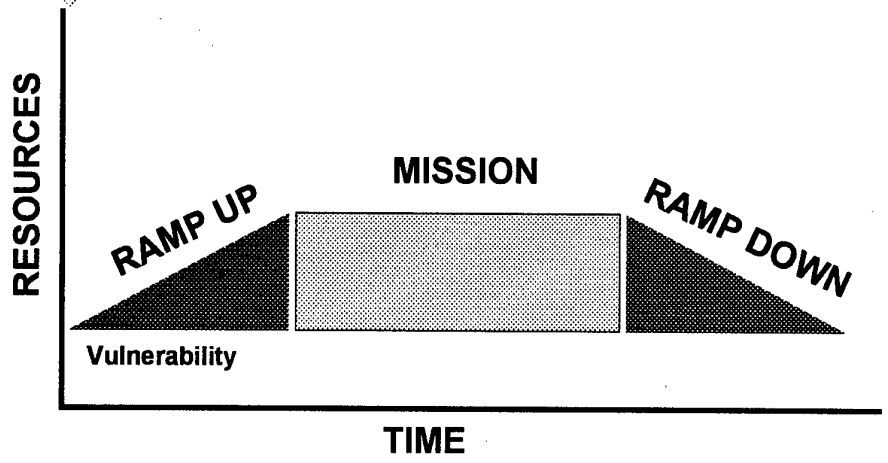
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Clinical Requirements Determine:

- **Personnel**
- **Training**
  - **Clinical**
  - **Operational**
  - **Sustainment**
- **Equipment**
- **Technology**

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Medical Deployment



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JHSS Concept / Time Phase Deployments

1. Essential "stabilizing" care forward
2. Stabilize by preserving vital functions
3. Early evacuation to definitive care
   Minimal holding capability forward
4. Maintain care enroute
5. Must begin coverage on first day (C-Day)
6. Require minimal additional airlift
   Ideally deploy with combat units
7. Medical presence throughout deployment

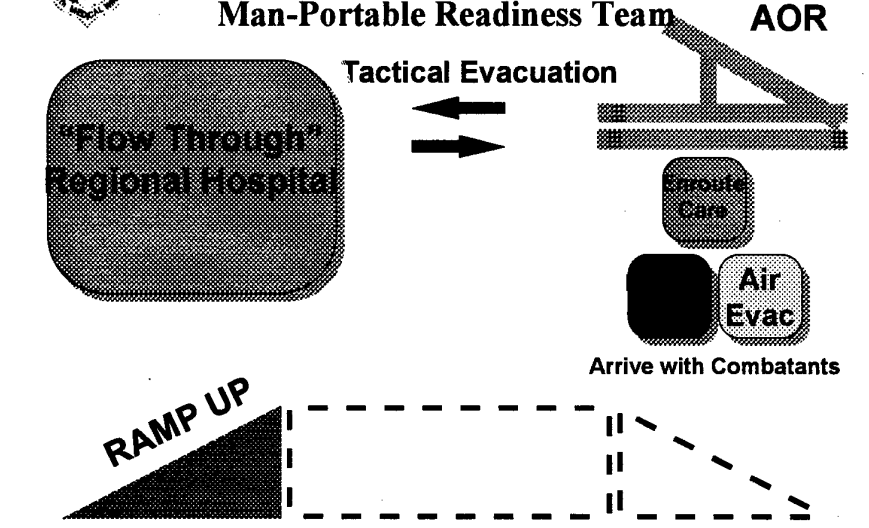
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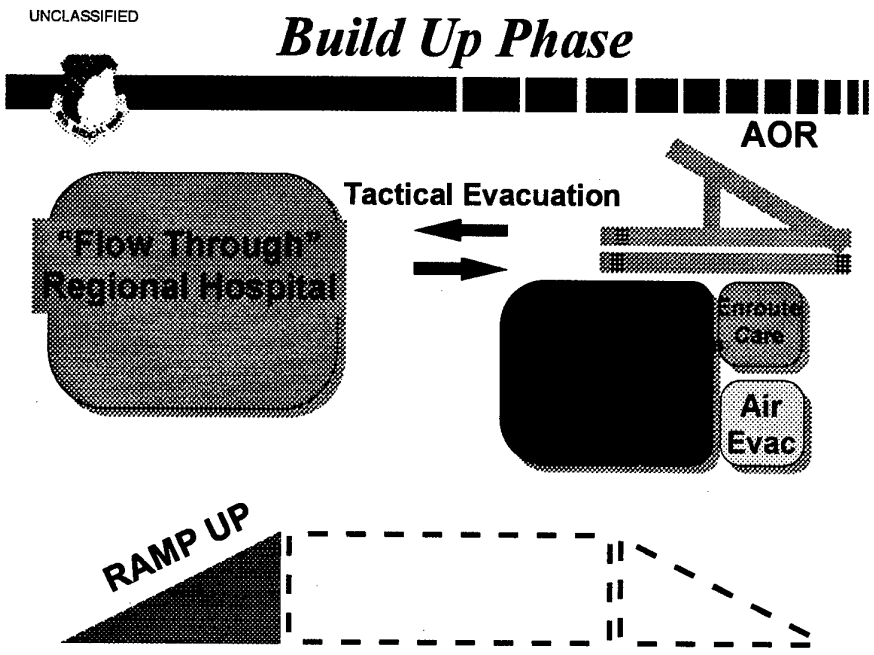
The Modular Solution

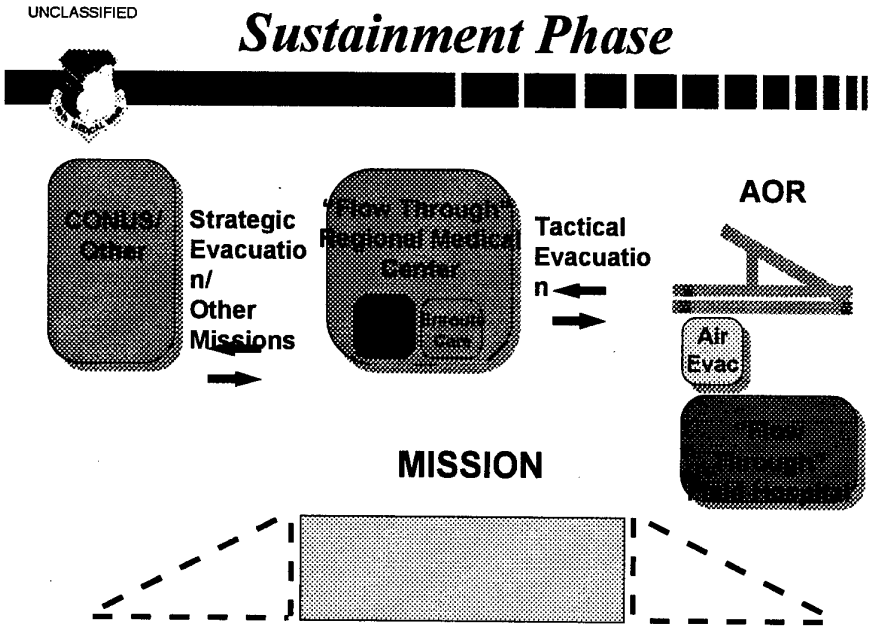
- Modularize hospitals
- Deploy essential stabilizing care
- Tailor medical support to scenario
- Initial elements man portable
- Use minimal additional airlift
  - Initial elements use same airlift carrying combatants
  - Follow-on modular units with minimal lift requirements

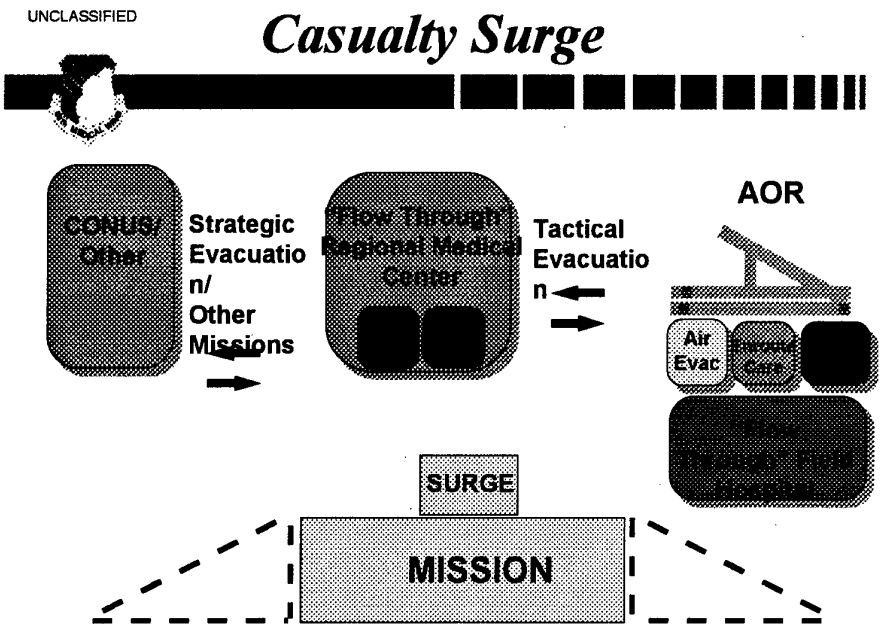
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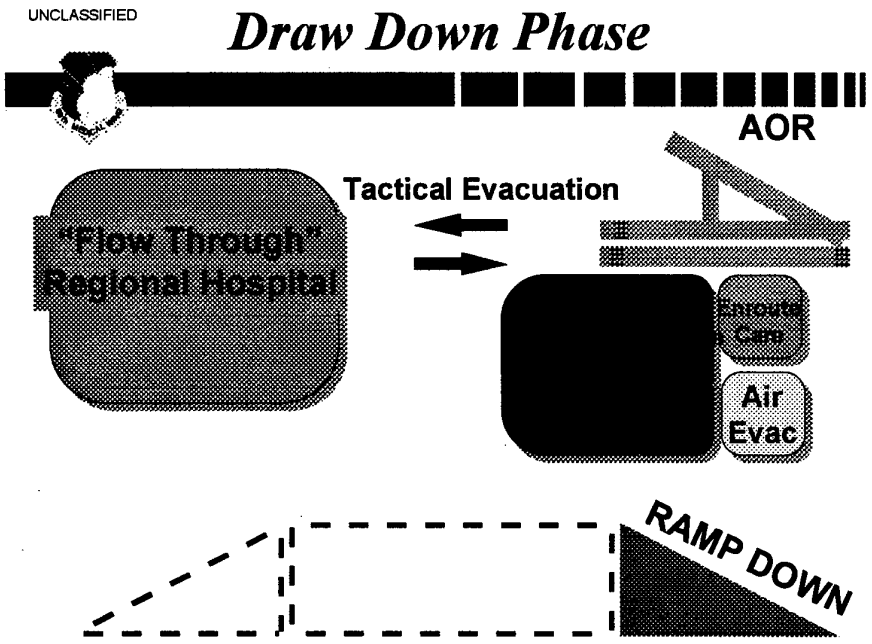
Initial Response -

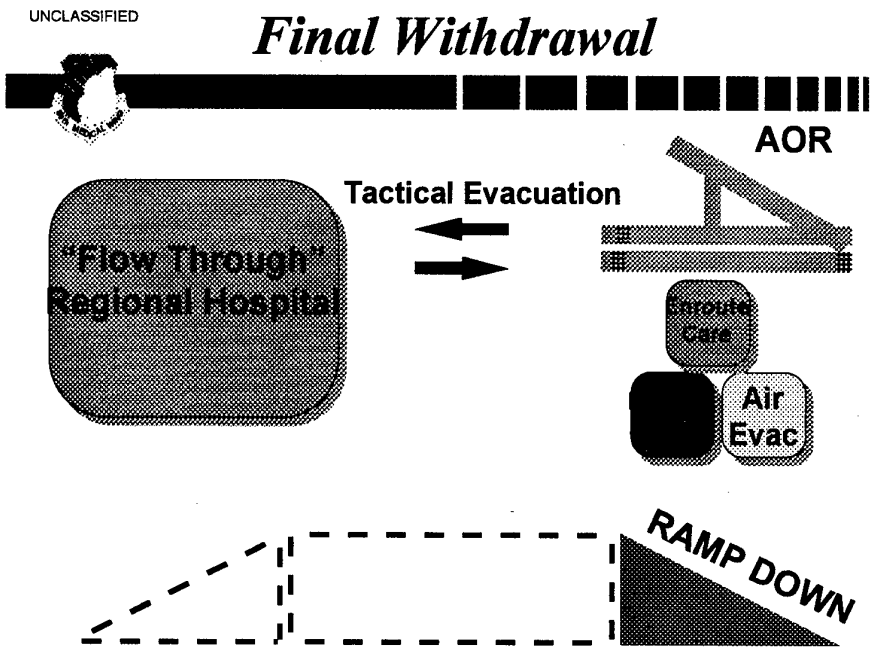


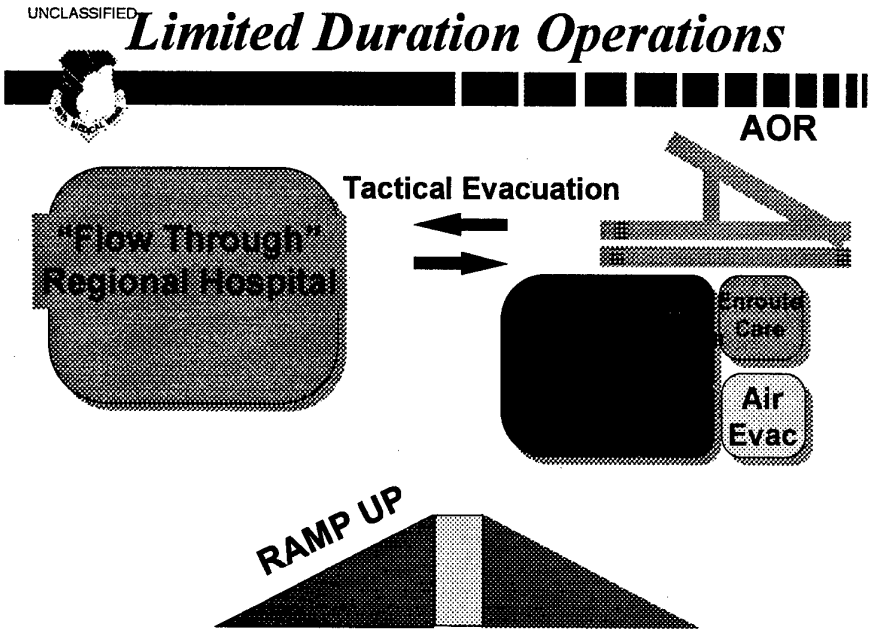

UNCLASSIFIED
Build Up Phase
AOR
Tactical Evacuation
"Flow Through" Regional Hospital
Enroute Care
Air Evac
RAMP UP


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Sustainment Phase
CONUS/ Other
Strategic Evacuation/ Other Missions
"Flow Through" Regional Medical Center
Tactical Evacuation
AOR
Air Evac
MISSION


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Casualty Surge
CONUS/ Other
Strategic Evacuation/ Other Missions
"Flow Through" Regional Medical Center
Tactical Evacuation
AOR
Air Evac
SURGE
MISSION

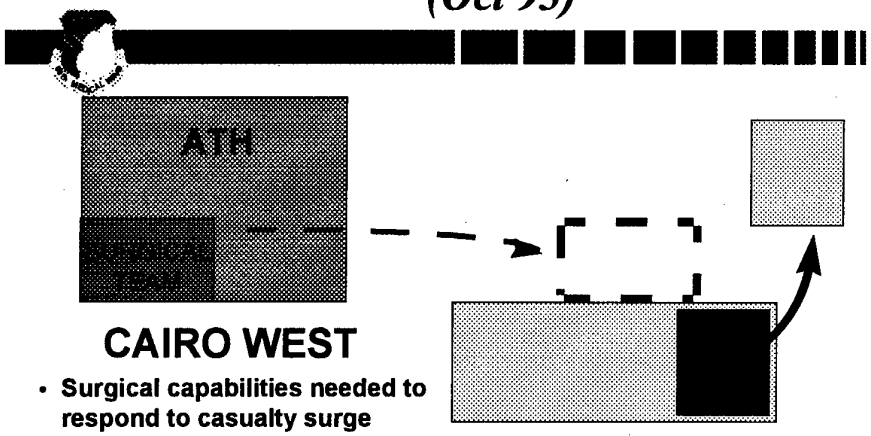

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Draw Down Phase
AOR
Tactical Evacuation
"Flow Through" Regional Hospital
Enroute Care
Air Evac
RAMP DOWN


UNCLASSIFIED
Final Withdrawal
AOR
Tactical Evacuation
"Flow Through"
Regional Hospital
Enroute Care
Air Evac
RAMP DOWN


UNCLASSIFIED
Limited Duration Operations
AOR
Tactical Evacuation
"Flow Through"
Regional Hospital
Enroute Care
Air Evac
RAMP UP

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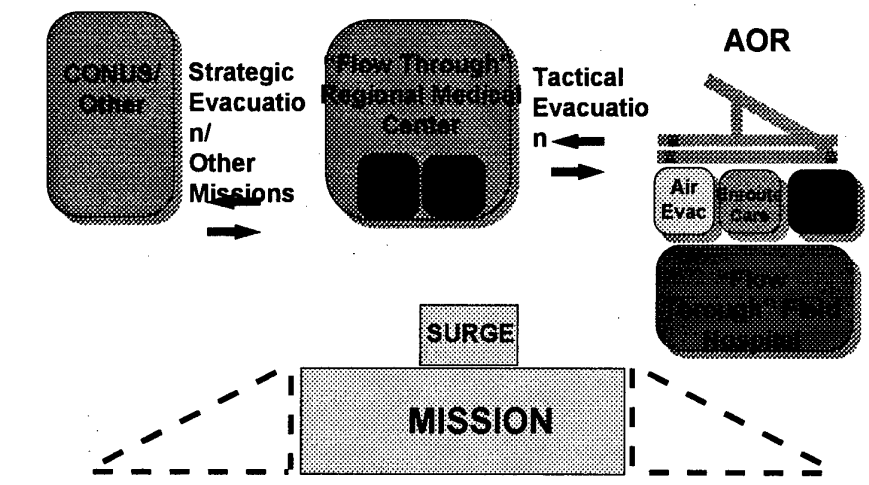
Why Enroute Care? -- Mogadishu (Oct 93)



- Surgical capabilities needed to respond to casualty surge
- Forward strength reduced due to patient evacuation
- No capability for timely reinforcement

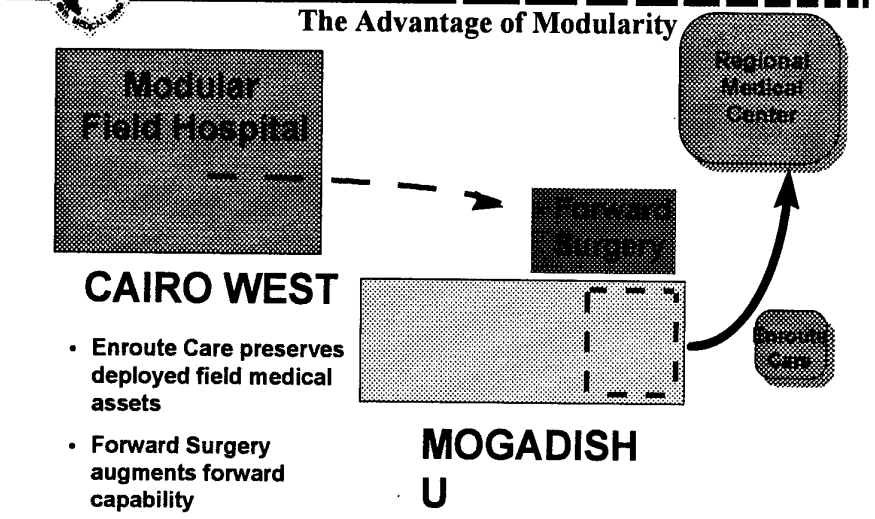
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Casualty Surge



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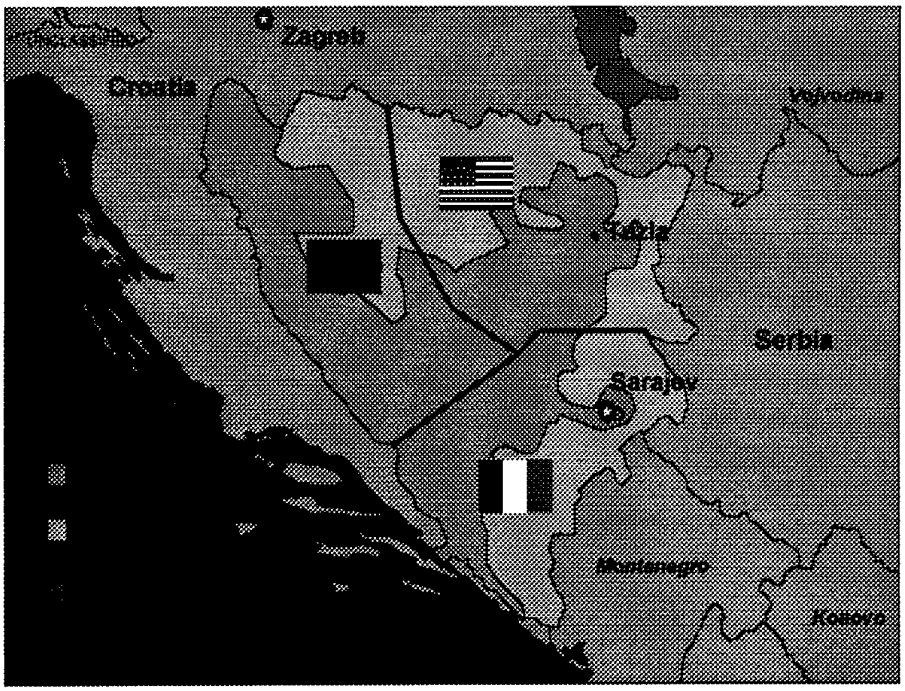
With Enroute Care / Forward Surgery Support

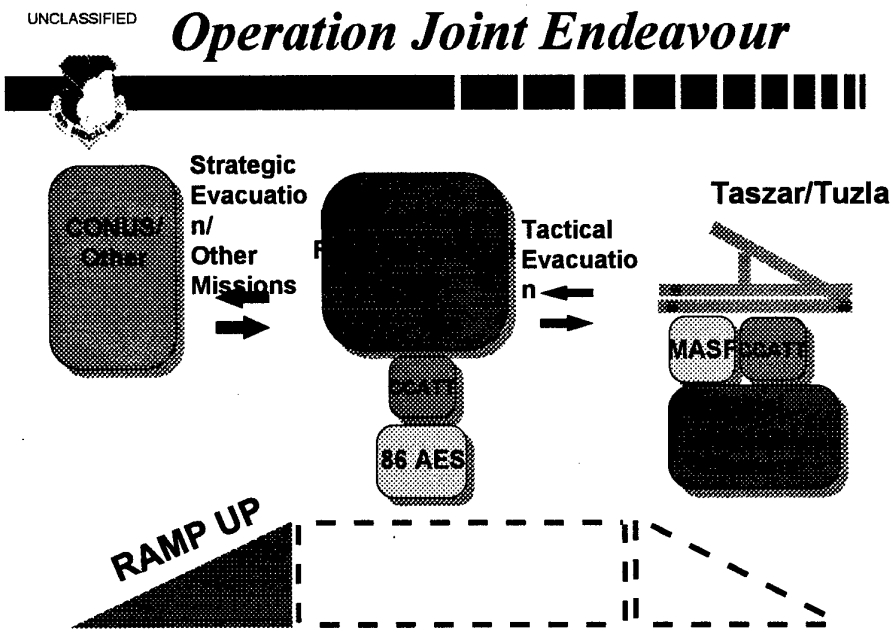


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Examples of JHSS In Action

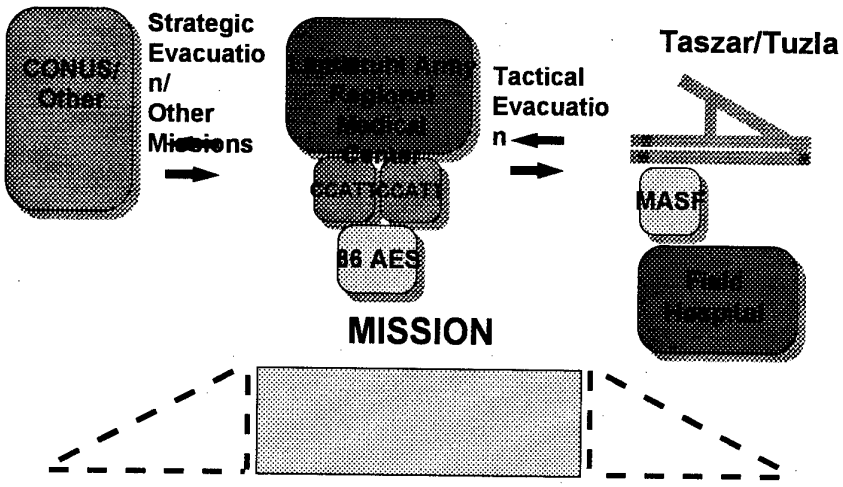
We Are Doing JHSS Today!

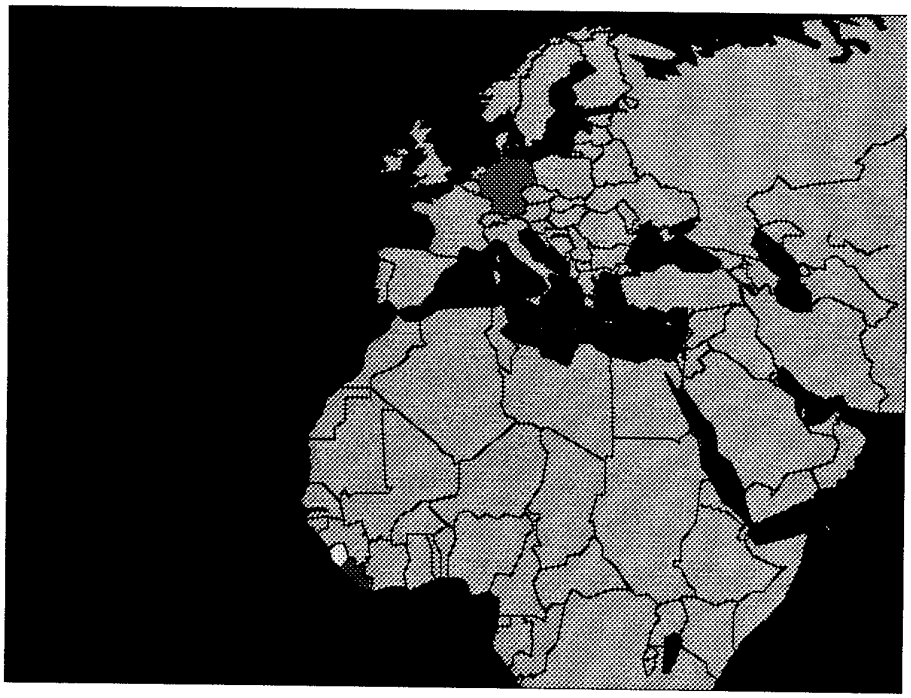

Zagreb
Croatia
Vojvodina
Tuzla
Serbia
Sarajevo
Montenegro
Kosovo

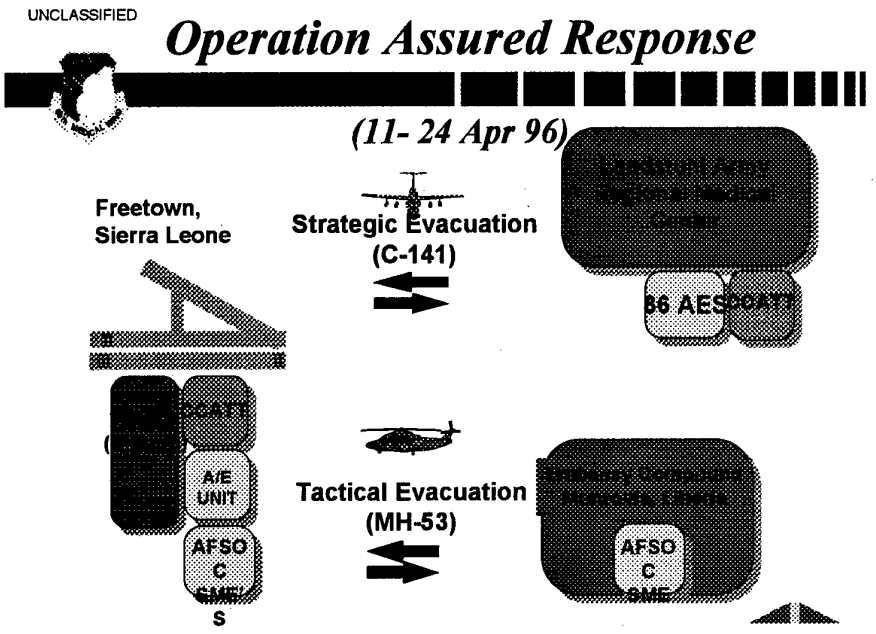

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Operation Joint Endeavour
CONUS/ Other
Strategic Evacuation/ Other Missions
Tactical Evacuation
Taszar/Tuzla
MASF
86 AES
RAMP UP

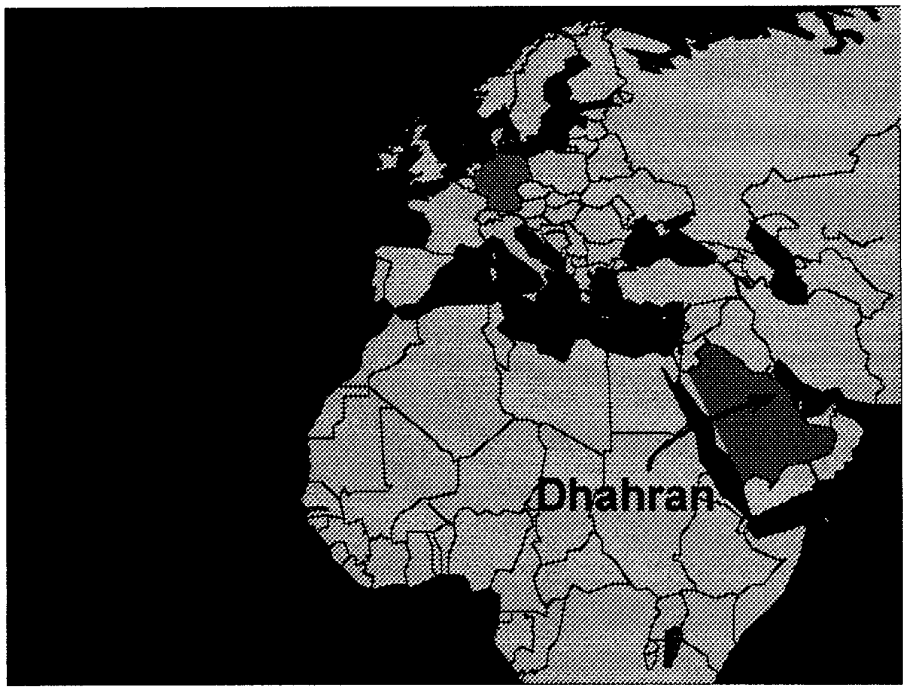
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OJE - Sustainment Phase





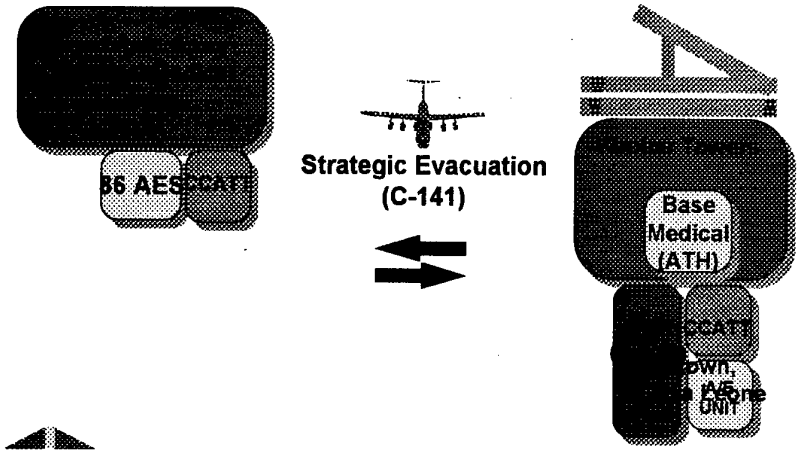

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Operation Assured Response
(11- 24 Apr 96)
Freetown,
Sierra Leone
Strategic Evacuation
(C-141)
86 AES
CATT
A/E
UNIT
AFSO
C
Tactical Evacuation
(MH-53)
AFSO
C


Dhahran

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Dhahran Terrorist Attack

(June 1996)



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Other Examples

- Oklahoma City Bombing - Apr 1995
- Operation RESTORE DEMOCRACY (Haiti) - Fall 1994
- Ecuador Plane Crash -- Dec 1996
- Canadian Soldier shot in Haiti -- May 1997
- Guam Plane Crash -- July 1997
- Two to Three CCATT Missions per Week at Wilford Hall -- Ongoing

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JHSS and Coalition Medical Operations

- **Col. A. Hawley. Trauma Management on the Battlefield: A Modern Approach. Journal of the Royal Army Med. Corps, Oct 1996; 142: 120-125.**
  - **Nature of battle precludes rapid evacuation; "Surgical facility has to be brought to the casualty".**
  - **Describes a "triad"**
    - **Advanced Resuscitation (Battlefield ATLS).**
    - **Far Forward, Mobile Surgery for Hemorrhage Control**
    - **Field intensive care with critical care capable evacuation**
  - **Reflects same components as JHSS**
  - **Provides basis for interchangeable medical**

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Guides for Reengineering

- Analysis of Patient Statistics
  - Casualty statistics
  - Impact of DNBI's
- National Policy
  - Change in world situation / National strategy
  - Increasing military role / Operations tempo
  - Shrinking defense budget
- Operational Constraints
  - Tailor medical support to the scenario
  - Consider limited lift capabilities
  - Cover the initial build-up phase
  - Medical coverage from first day until final pull-out
  - Must follow the lead of the "Line"

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Three Priorities for Medical Readiness

- Provide "essential" care forward
  - Switch from "definitive" care forward
  - Emphasis on casualty prevention
- Critical care capable evacuation system
- Modularize deployable medical units
  - Follow the lead of the "Line"
  - Light-weight, rapidly deployable, flexible
  - Taylor medical support for each scenario
  - Capabilities-based vs. Threat-based planning
  - Medical coverage from first to last day

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Aiming for 2010 (JHSS)

Go lightweight!
Go mobile!
Go modular!
Go Forward!
High-capability!
"Man Portability" is the key

EXPERIENCES OF THE CRITICAL CARE AIR TRANSPORT TEAMS (CCATT) DURING OPERATION JOINT ENDEAVOR

Rick Hersack, LtCol, USAF, MC
Dennis Lawlor, Maj, USAF, MC
P.K. Carlton, Jr, MajGen, USAF, MC
William Beninati, Maj, USAF, MC
Thomas Grissom, Maj, USAF, MC
Carlos Morales, LtCol, USAF, MC
Stephen Derdak, LtCol, USAF, MC
J. Cristopher Farmer, LtCol, USAF, MC
59th Medical Wing
Wilford Hall Medical Center
2200 Bergquist Drive, Suite 1
Lackland Air Force Base, TX 78236-5300, USA

SUMMARY

For the past year, Critical Care Air .Transport Teams (CCATT's) from Keesler Medical Center, Keesler AFB, Mississippi and Wilford Hall Medical Center, Lackland AFB, Texas have been deployed to support Operation JOINT ENDEAVOUR (OJE), the NATO peace effort in Bosnia. This is the largest operation involving the use of the CCATT's to date. A CCATT consists of a physician specializing in intensive care medicine, a critical care nurse, and a cardiopulmonary technician. The CCATT uses transport monitors, ventilators, portable blood analyzers and other medical equipment commonly used in our medical centers' intensive care units. The CCATT augments the standard aeromedical evacuation aircrew so that critically ill or injured patients may be evacuated from forward areas to definitive care hospitals. Otherwise, field hospitals in forward areas would have to provide care for these patients until they were stable enough to travel unaccompanied, creating huge logistical demands, or provide a physician to accompany the patient during evacuation, leaving forward field hospitals understaffed. Providing increased clinical capabilities aboard patient evacuation flights is not new. Several other nations' military medical services have extensive experience using enroute care providers to manage critically ill or injured patients during evacuation. During one year of the OJE deployment, the CCATT's moved 44 patients in 42 missions. Of these patients, 22 required mechanical ventilation during the flight. Eight missions were transatlantic flights to return patients to treatment facilities in the United States. CCATT's also redeployed to support the evacuation of foreign nationals from Liberia and rescue operations after the Khobar Towers Bombing in Dhahran. With the end of the "Cold War", a shift in military medical planning now calls for a reduced medical presence in areas of conflict and a subsequent increased reliance on patient movements out of theater for definitive medical and surgical care. The CCATT concept is an effective solution that fills the need for long range critical care air evacuation and easily integrates into the current aeromedical evacuation system.

INTRODUCTION

Casualty management today is marked by relatively dramatic changes from casualty management twenty to thirty years ago (Ref 1). There is limited air lift available. Combat forces today are smaller although more heavily equipped for more intensive battles. The time for build up of both combat as well as medical forces is limited as battles and engagements occur with relatively little warning. Because of the diverse locations and widely geographically spread areas of involvement, in-theater beds will be limited, especially in the first few days of combat. This is due to a multitude of reasons which include the disappearance of most permanent fixture overseas hospitals which can no longer be funded. Because of the multiple numbers of potential sites of battle, prepositioned medical assets are difficult to be placed in appropriate locations worldwide. Frequently, the nearest definitive care hospital may be in the continental US (CONUS). To increase survivability of casualties and also because of the higher intensity and larger number of critically injured patients with today's battles, we must be able to ***stabilize*** and evacuate critically ill casualties as soon as possible. This has led to the concept of continual en-route care so that from the initial intervention to definitive care there will be some surgical capability as well as en route critical care available. This concept is not a new one. It has been espoused for civilian trauma care (Ref 2) and by other military air evacuation services (Ref 3). Our current air evacuation system was originally designed for stable patients. Patients were required

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

to be in their convalescent stage, and require relatively minimal in flight care. More critically ill patients would have required medical attendants which would usually have been provided from the fixed base facility that was sending the patient. This system worked well for large numbers of patients that required relatively low level amounts of care. For these reasons, air evacuation personnel usually were not required to be current in critical care experience and this system was difficult on small field hospitals which frequently had to temporarily lose critical medical personnel for significantly long periods of time as medical attendants to accompany their sicker patients into the system. One solution to fix the ability to transport critically ill patients and not weaken field hospitals by taking medical personnel was a critical care air transport team. This system would upgrade the critical care capability of the air evacuation system and provide a critical care medicine capability wherever the air evacuation system goes. It would augment the air evacuation personnel and not replace them. It would allow evacuation of ***stabilized*** patients as early as combat day or C day. By augmenting air evacuation personnel, field hospitals would not have to give up their medical personnel and they would be preserved and remain in the field where they belong. These CCAT teams needed to be small, rapidly deployable, be relatively self sufficient and provide their own supplies and critical care capability. To maintain their critical care skills, preferably they should be medical center-based so they would have an ongoing daily experience with the critically ill patient. The personnel that would man the CCAT teams would be a critical care physician which in tertiary care hospitals is a pulmonary or critical care physician, an anesthesiologist, a critical care trained surgeon or a board certified emergency room physician. A critical care nurse should also augment the team and this can be a medical, surgical or emergency room nurse. Additionally, because of the difficulties with respiratory circuit configuration in multiple different kinds of aircraft, an experienced respiratory therapy technician is essential to the team. The CCAT team concept was developed several years before Operation Joint Endeavor (OJE); however, OJE provided the first opportunity for an extensive real world test.

DEPLOYMENT PHASE OF CCATT

Three OJE CCAT teams were deployed; two from Wilford Hall Medical Center, one from Keesler AFB Mississippi. One team went to Ramstein Air Force Base, Germany and one team went to Taszar, Hungary. The last team was deployed to Tuzla Airbase in Bosnia- Herzegovina. The plan was to rotate the CCATTs monthly for them to get experience at all three locations. OJE served as a prototype regarding the appropriate method of deploying the CCAT team in a major operation. During the ramp up phase there was a CCAT team in physical proximity to the mobile air staging facility (MASF) at both Taszar and Tuzla which would provide tactical evacuation back to Landstuhl Army Regional Medical Center where a reserve CCAT team was prepared to rotate in as the down range CCAT team brought critically ill casualties out. Also, the CCAT team at Landstuhl; if necessary, could provide strategic air evacuation for critically ill casualties to go back to CONUS sites. During the sustainment phase, since there was initially a relatively low number of casualties down range, two CCAT teams were placed back at Landstuhl but were ready to deploy at approximately one hour's notice to go down range to either Tuzla or Taszar to provide air evacuation from the mobile air staging facility of either Taszar or Tuzla back to Landstuhl. Also, based on the clinical need of the patient, could provide strategic air evacuation back to CONUS. The goals of this mission were to support the medical needs of the patients in OJE. Additionally, goals were to define the role of the CCAT teams and how to utilize them best during air evacuation missions in contingencies, and develop command and control relationships with field hospitals and regional medical centers. Also, it would help to define their long term role in-theater. These initial CCAT teams were also to provide for a smooth transition for later replacement teams. Regarding command and control issues; the initial method of implementation was to interrelate with the 86th Air Evacuation Squadron from Ramstein AB, Germany since they had extensive air evacuation experience. The CCAT team would augment the air evacuation units and provide critical care capability on the flight with the air evacuation crews providing the air medical safety role on the flights. The point of initiating a request for the CCAT teams would be either by the air evacuation liaison team (AELT) or the air evacuation combat control (AECC) officers. Decisions to use the CCATT would preferably be made jointly by the combat control as well as the downrange officer in command (OIC) of the MASF who could either coordinate with the air evacuation squadron flight surgeons or in consultation directly with the CCATT physicians back at the 86th Air Evacuation Squadron.

PATIENT MOVEMENT BY CCATT IN OJE

To summarize, the patient movement during OJE by the CCAT teams included a total of 44 patients moved from December of 1995 to December of 1996. This constituted a small minority of approximately 10% of the overall patient missions during OJE and slightly less than 5% of all patients by the air evacuation system. The majority of CCATT missions were tactical missions of less than four hours duration. All 44 patient moves were greater than 2 hours air transport time, and a total of 12 were greater than 8 hours air transport time. The missions greater than 8 hours were strategic missions going back to CONUS. As a measure of the intensity or severity of illness, approximately 22 of the patients required mechanical ventilation for respiratory failure. Four of the patients had chest tubes and required either a Heimlich valve or pleuravac drainage. Eight of the patients

utilized in-flight point of care testing (POCT) for evaluation of serum chemistries or arterial blood gases. Five patients were on an intravenous continuous paralysis sedation medical regimen. Fourteen were on some form of intravenous vasopressor or vasodilator therapy and fourteen patients required invasive hemodynamic monitoring with either arterial and/or Swan-Ganz catheters. There were no in-transit deaths in air evacuating critically ill patients by the CCAT teams during OJE.

LONGEST CCATT MISSION

To illustrate the capabilities of the CCATT one of the longest non-stop OJE CCATT patient moves was for a nineteen year old patient that was electrocuted in the Czech Republic. He had 40% body surface area burns (BSA), and 25% BSA burns were full thickness. He also had a closed head injury with a skull fracture and a cerebral spinal fluid leak. He had a right pneumothorax requiring chest tube drainage and was intubated requiring mechanical ventilation. He also had possible anoxic brain injury from a brief period of asystole immediately after his electrocution injury. He was briefly treated in a local civilian hospital and air evacuated via Army helicopter to Landstuhl Army Regional Medical Center (LARMC). He was then air evacuated via C-141 from Ramstein Air Force Base, Germany to the Brooke Army Burn Center in San Antonio, Texas. His flight was a 14 hour flight that required a mid-Atlantic mid-air refueling.

CCATT MISSION WITH COMPREHENSIVE MONITORING

The second illustrative CCATT mission is one utilizing the most comprehensive monitoring of the patient moves for OJE by the CCAT teams. This was a fifty-six year old American tourist who had severe coronary artery disease and severe left ventricular dysfunction. She developed unstable angina with flash pulmonary edema upon arrival on a vacation in Wurzberg, Germany. Because the patient had Medicare eligibility, no German hospital was willing to offer coronary artery bypass surgery. The only option for the patient was to be transferred back to the United States or be treated with medical therapy only. Medical management alone was felt to be inappropriate for the severity of coronary disease the patient had. She was initially air evacuated by helicopter to LARMC and stabilized with intubation, mechanical ventilation , intravenous sedation, nitroglycerin, heparin and morphine and invasive monitoring with arterial and Swan-Ganz catheters. She was subsequently air evacuated with mechanical ventilation, intravenous sedation, nitroglycerin, heparin, morphine and continuous monitoring with arterial and Swan-Ganz catheters to Fairfax, Virginia. In Fairfax she subsequently underwent an uneventful coronary artery bypass surgery.

LESSONS LEARNED

Important command and control lessons learned during CCATT's participation in OJE is CCAT teams are an air evacuation asset. CCAT teams are under the command and control of the air evacuation units and may work to augment other units critical care medicine capabilities. A CCATT physician may act as a critical care medicine consultant to the air evacuation system as well. The CCAT teams do not replace air evacuation medical teams. In addition to controlling the use of the CCAT teams, the air evacuation system must provide support for the CCAT teams. The air evacuation medical teams continue to be responsible for the safety of the flight and the overall mission completion.

Deployment lessons noted during the ramp up/ramp down phases were that logistics worked best when the CCAT team was deployed with the air evacuation teams. That means being deployed forward to provide an intensive care unit capability down range. Once the field medical unit becomes operational, the CCATT is redundant to the intensive care medical capability that is inherent in most deployed field medical units. During the sustainment phase, after the field medical unit is operational the CCATT can be redeployed to a central regional medical center to be available via the host air evacuation unit for a wider range of missions. By working in a regional medical center, the CCAT team members also can be maintaining their critical care skills by working in the medical center.

Patient care lessons noted during participation in OJE were multiple. The capability to analyze blood in flight by point of care testing (POCT) could be an important adjunct; but was only important for longer missions, usually of greater than 2 or 3 hours duration. It was infrequent for short flights that point of care testing really had a role as most patients had an opportunity to have most blood analysis done prior to entering the transportation phase, and the flight itself was relatively short. Although infrequent, when they did occur, we found aircraft-to-aircraft transfers of complex critically-ill patients can be extremely slow and tedious. Important lessons that were learned to simplify such transfers are: 1) it is important to clarify precisely the patient needs between the two care teams so that appropriate equipment is out and ready; 2) the more complex the patient with multiple intravenous lines, arterial lines, nasogastric tubes, foley catheters, chest tubes connected to pleuravacs, and ventilator tubing, the more important to make these sets of tubing on the patient very orderly so that as equipment is disconnected and reconnected, the tubing does not become tangled and become difficult to be separated from equipment; 3) if possible like equipment between care teams should be exchanged instead of being taken down from the patient and then new equipment from the new team of the same type reestablished which is a timely process; 4) if possible only finish the essential intravenous and

mechanical ventilator configurations during ground time as many adjustments and final configuration changes can be made after airborne which allows for a shorter ground time transfer. The future of patient movement items or PMI may simplify these transfers in the future. Pieces of medical equipment, in that concept, should stay with the patient during transfer from team to team.

To reiterate, complex care situations require more pre-planning to make for smooth team-to-team transitions. The most difficult patients to transport are those with the highest ventilatory needs as any brief disconnect can immediately become a life-threatening event.

CONCLUSIONS

Conclusions learned from Operation Joint Endeavor: long range critical care air evacuation is needed to fill the gap in the current military environment of a small footprint forward of medical assets. Long range critical care air evacuation is fundamentally different than regional air ambulance services. Regional air ambulances operate with the goal "arrive alive" moving the patient from the field to a close tertiary facility. Long range critical care air evacuation must serve as a ***continuum*** of critical care during the lengthy transit times. This requires a higher skill and capability intrinsic to the care team to deal with a multitude of care and contingency requirements. The CCATT concept integrates into the current air evacuation system to fill the need for long range air evacuation of the critically ill patient. In real world contingency operations such as Operation Joint Endeavor, the CCAT teams provide the necessary skill and inherent capability to expand the range of potential patients that can be safely evacuated on a multitude of airframes. In keeping the team equipment needs small, balancing between providing most types of supplies needed for airway and shock resuscitation yet maintaining stock only for a defined, short period of time (about 24 hours), the team and its equipment can be easily utilized on most aircraft that can carry patients.

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Evolving Doctrine in the Theater Aeromedical Evacuation System (TAES): Operation JOINT ENDEAVOR/GUARD and Beyond

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SUMMARY

With an increase in contingency operations in the NATO theater of operations, the Theater Aeromedical Evacuation System (TAES) needs to be flexible to meet the ever-changing demands of both combat operations and military operations other than war. Recent evolution in United States medical evacuation policies have made it necessary for the TAES to also change the way it does business. This paper discusses the composition of the TAES, recent additions to the TAES, trends in US medical policies, and implementation of the TAES during Operation JOINT ENDEAVOR/GUARD.

TAES COMPOSITION

The TAES consists of a number of different functional elements created to provide the smooth transition of patient movement from a forward user service to the rear for more definitive care. The ultimate goal is to increase the survivability of the injured soldier. In particular, the TAES accomplishes this through the use of scheduled, alert and opportune aircraft. By "opportune" we mean an aircraft already bringing cargo in theater. These aircraft would then be used to "back haul" casualties out of theater.

Currently, the 43d Aeromedical Evacuation Squadron (AES) is tasked with five elements of the TAES: Aeromedical Evacuation Advance Echelon Team (ADVON), Aeromedical Evacuation Coordination Center (AECC), Aeromedical Evacuation Liaison Team (AELT), Mobile Aeromedical Staging Facility (MASF) and Aeromedical Evacuation Support Cell (AESC). Each will be discussed to provide information on personnel and functions.

Aeromedical Evacuation Advance Echelon Team

The ADVON team is the lead element for the TAES. Their responsibility is to establish a liaison with all user services involved for sites and logistical support. Working with theater medical treatment facilities, they establish procedures for aeromedical evacuation and, if necessary, are able to perform as stand alone element for short periods of time until the Aeromedical Evacuation Coordination Center is established. It is composed of the following specialties:

Medical Service Corps	2
Flight Nurse	1
Aeromedical Evacuation Technician	1
Computer Systems Technician	1
Medical Administration	1
Logistics	1
Radio Operator	1

Aeromedical Evacuation Coordination Center

The AECC is the command and control element of the TAES. The AECC may have multiple AELTs, AECMs and MASFs under its command. Additionally, it is the radio net manager for the aeromedical evacuation (AE) theater of operations. Nineteen personnel make up this package with the following specialties:

Medical Service Corps	4
Flight Nurse	4
Radio Operators	3
Administration	8

Some of the functions performed by the AECC are coordinating airlift, validating patient requirements, aircrew management, ensuring adequate logistical support and coordinating all AE missions.

Aeromedical Evacuation Liaison Team

The AELT is the "front door" to the tactical AE system. Usually co-located with the user service, they provide initial clinical consultation and radio communication to the AECC and the MASF. They relay patient requirements both in number and specific care needs to the AECC. This input initiates the generation of an AE mission. The flight nurse acting as the flight clinical coordinator provides training on patient preflight considerations and acts as a consultant to medical and nursing staff regarding physiology of flight concerns. The 43 AES is unique in that it has the only airborne qualified AELT in the active duty force today. They may, as required, jump in with Army forward medical units. The AELT consists of:

Medical Service Corps	2
Flight Nurse	1
Radio Operators	3

Mobile Aeromedical Staging Facility

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The MASF provides preflight processing and nursing care the day of the AE mission. It can be positioned as far forward as a C-130 aircraft can land. Located approximately 100 feet from the taxiway, this facility can process up to 50 litter patients at one time with the capability of processing 200 litter patients per day. Casualties are generally held between two to six hours awaiting a mission. Time allotted is used for final processing and briefing of patients. Staffing at the MASF also allows for generating up to two AE crews in cases of emergencies. The personnel package for the MASF includes:

Medical Service Corps	1
Flight Nurses	9
Aeromedical Evacuation Technician	23
Medical Administration	3
Radio Operators	3

Aeromedical Evacuation Support Cell

The AESC provides medical material, administration and maintenance support to all elements of the TAES. Vehicle, radio and aerospace ground equipment (AGE) maintainers are all represented in this element. This is the element that keeps all the other elements maintained and sustained. The AESC consists of the following:

Medical Administration	1
Logistics	1
Radio Maintenance	1
Vehicle Maintenance	1
AGE Maintenance	1

Aeromedical Evacuation Crew Members

The primary role of the AECM is to provide in-flight nursing care to AE patients. In preparation for this the AECMs configure the aircraft to meet patient need and load specifications. Rapid configuration is essential for quick turnaround of opportune aircraft. The standard AE crew consists of:

Flight Nurse	2
Aeromedical Evacuation Technician	3

NEW ADDITION

Critical Care Air Transport Team (CCATT)

While not directly part of the MASF personnel package, the CCATT may be assigned with the MASF to provide care for the most critically ill/injured once at the MASF and during their subsequent mission. Theater requirements may also place the CCATT at an airhead where aircraft and AE crews are positioned to provide broader theater coverage. They enhance care by providing continuous observation and stabilization/advanced care during transport to the next level of care. They are particularly valuable as they provide the close observation and advanced care necessary for the stabilized patient when the sheer number of patients could preclude the AE crew from close monitoring. The CCATT is comprised of:

Intensivist Physician	1
Critical Care Nurse	1
Respiratory Therapist	1

TRENDS IN US MEDICAL POLICIES

Of late, the trend towards smaller contingency operations has necessitated a smaller forward medical footprint. In the past, there were a large number of inpatient beds in theater for casualty recovery and rehabilitation. As less specialties are available downrange, there is a greater necessity for AE. As a result, there will be a need to transport "stabilized" versus "stable" patients. Stabilized is defined as receiving initial care to include treating for shock, airway maintenance, splinting of fractures.

In addition, there is now a policy of "evacuate and replace" which means if a patient cannot be returned to duty in a short period of time, they are evacuated and replaced rather than treated in theater. This will increase AE volume as these patients are removed from theater.

Telemedicine or the ability to send patient information through electronic transmissions is a new and experimental initiative. With telemedicine, a casualty could be tracked throughout the entire medical system including in the air. As designed, AE crew members, with the aid of a laptop computer, could contact destination physicians with updates or for new orders without having to go through the pilot.

OPERATION JOINT ENDEAVOR/GUARD

The 43 AES initially deployed to the Bosnian theater of operations in December of 1995 and have maintained a presence in the operation ever since. The bulk of our mission was performed from December of 1995 to April of 1997 with a MASF, AELT, portions of the AECC, AESC and multiple AECMs. During that period the aeromedical evacuation flight safely evacuated over 870 patients on 138 missions. Twenty-nine percent of those missions were prioritized as urgent or priority. Those missions required the patient to be evacuated in less than 24 hours. The quickest "turnaround" time was just over 90 minutes from notification of an urgent patient to take off. This particular mission demonstrated the value of being able to use opportune airlift. The last mission out of Tuzla for the day was held and the aircraft configured while awaiting patient arrival. Using this aircraft not only saved time but also the expense of having to generate an alert aircraft from Ramstein Air Base, Germany.

The patients evacuated had a wide variety of illnesses and injuries. We were fortunate indeed that the operation had very few casualties. The most frequent single diagnosis was pregnancy. Orthopedic injuries had the greatest number for a diagnostic group. As for the urgent

missions, they ranged from myocardial infarctions to severe burns, to gunshot wounds to Hanta virus. All were successfully evacuated to Germany.

The TAES for this operation was pared and tailored to meet peacekeeping requirements. The MASF package was only about half of what the normal package would be. A single tent on the edge of the taxiway was the only tent allowed. The MASF can be up to six large tents (including billeting). As the operation wore on, the MASF became even smaller until the primary aircrews were taken out of Tuzla and moved to Ramstein Air Base, Germany. The number of missions per month decreased as did the number of urgent and priority patients.

The CCATT was stationed at Ramstein Air Base, Germany, not in Tuzla. This had both positive and negative effects. Due to the slow pace, being stationed out of Germany allowed for flexibility in tasking. One CCATT could respond to Tuzla or Tazar, Hungary, as required. The only drawback was that once alerted, it was a minimum of four to six hours before the CCATT could be in Tuzla. This made it difficult to use opportune aircraft already on the ground in Tuzla. In this particular case it was not a problem as the flight nursing staff available were critical care trained and experienced which allowed them to transport a critical patient without any decrease in the quality of care. These cases were few and far between and the CCATT was used for the majority of urgent missions without delay in patient transport.

ALLIED COOPERATION

Allied cooperation was in full force in Tuzla. The MASF had the opportunity to assist several countries including Russia, Sweden, Bosnia and Jordan in the staging and/or evacuation of some of their patients. Also, joint classes such as the advanced cardiac life support course were offered with multinational participation.

CONCLUSION

The TAES is a flexible system for movement of patients from forward to rear echelons for more definitive care. With a wide continuum of conflicts and peacekeeping operations now the norm, the TAES will need to consistently adapt as well as pare and tailor itself to meet the needs of its user services. A smaller medical footprint and a policy of evacuate and replace will increase the demand for tactical AE. A shift to transporting stabilized rather than stable patients will drive the need for the utilization of the CCATT as well as increase the need for advanced nursing care training for the AE crew. Flexibility will continue to be the key to the success of tactical aeromedical evacuation.

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The Mobile Field Surgical Team (MFST): A Surgical Team for Combat Casualty Care in the Information Age

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Overview

The current military medical system is designed to support 20th century combat: the forces involved in the conflict were large, powerful, and ponderous. Medical planning for conflicts such as these included several assumptions about the conditions involved:

- Discrete build-up phase - medical units would have time to assemble their assigned personnel and materials, and would be permitted to set up these facilities *before* use of the facilities would be required.
- Large number of casualties
- Definitive care in theater - lines of battle were fairly stable; thus injured personnel would be treated in-theater until they reached a convalescent phase. At that point they would be returned to duty or evacuated from the theater.
- Traditional evacuation system - the Air Evacuation system would serve to transport patients who had been injured, but had essentially no ongoing requirements for medical care.

The assets that were developed to meet the medical needs of these conflicts (the Air Transportable Hospital (ATH), Combat Support Hospital (CSH), and Fleet Hospital) are very capable and offer a variety of medically oriented services. They are essentially full-service hospitals packaged in a format that can be moved by air or sea. As full-service hospitals, they are quite large and heavy, and they require a significant amount of time and space to set up.

The ATH (for example) is intended to be deployed in a modular or "building block" fashion, but this is implemented by bringing primary care capability into the theater first. Thus a full 50-bed ATH is necessary before trauma surgery or even an appendectomy can be performed. This set of equipment is packaged on 52 pallets, requiring airlift of seven C-141 aircraft.

21st Century Vision

Strategic planners in the US believe that the next era of conflict will be very different. They believe that information technology will allow more accurate, more rapid, and further reaching application of force where necessary. They expect to apply smaller and more potent assets to strike "strategic centers of gravity" which may well be located over the horizon from friendly forces. The expected engagement scenarios include Major Regional Conflict (MRC), Military Operation Other Than War (MOOTW), and Humanitarian Assistance.

The rapidly mobile nature of engagement, and the unpredictable timing and geography, place new demands on the military medical system. Medical planners can no longer rely on prolonged preparation time prior to employment. Because of an increased demand on airlift by the "line" side medical assets must choose to deploy only the necessary capability, and must package this capability in the smallest possible space.

On the other hand, the demands on the medical system are somewhat relieved by a smaller expected number of casualties, and by a revival of the concept of essential care only in theater. There is also a renewed recognition that outcome depends significantly on the amount of time required for a casualty to reach surgical care. This is an extension of the understanding in civilian practice that salvage surgical procedures (distinguished from definitive surgery) can be life saving; this concept is sometimes referred to as "Forward Resuscitative Surgery."

The Mobile Field Surgical Team (MFST)

The MFST is conceived as the smallest possible unit for provision of surgical care to combat casualties. The team has been pared down to a minimum in terms of personnel and equipment, retaining the "high value" resources that allow the team to provide advanced resuscitation and salvage surgical therapy for combat casualties. The very small weight and size of the team makes it possible to respond rapidly and to impose a minimum requirement on transportation and logistics resources.

The team is composed of five personnel, with surgical gear that is strictly man-portable. The surgical gear is carried in backpacks, and the team has a generator to supply power for it's instruments. Total equipment weight (including personal gear) is approximately 600 pounds. The five personnel are:

- General Surgeon
- Orthopedic Surgeon
- Anesthesiologist/CRNA
- Emergency Medicine Physician
- OR Specialist

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

The team's equipment and personnel are selected to provide initial trauma care and resuscitative trauma surgery. Specific capabilities for early trauma care and stabilization include:

- airway management, fluid resuscitation, and other ATLS skills
- control of hemorrhage in any body cavity or from extremity wounds
- control of intra-abdominal contamination (bowel closure)
- stabilization of fractures
- major wound debridement

Employment of the MFST

The composition and size of the MFST place it on the smallest and most mobile end of the spectrum of units available to provide trauma surgical care. The team may be thought of as a "building block" that may be the first on the scene or may "plug into" medical units already on site. The small size of the team and minimal logistical support required allow the team to comfortably attach to nearly any type of host medical unit ranging from a Casualty Collection Point to a Regional hospital: in every case the personnel and equipment carried by the team will raise the level of combat casualty care available. Again, the rapid mobility and minimal airlift requirement allow the team to reach the area of need and to institute care of casualties before any other unit with surgical capability could.

The MFST has exercised the doctrine of forward resuscitative surgery at the Joint Readiness Training Center in Louisiana. During a simulated combat exercise, the MFST reduced the Died of Wounds rate from 30% (commonplace at JRTC) to 12%, by moving closer to the site of wounding.

The MFST concept has also been tested in a real-world humanitarian mission to Ecuador in October of 1996, after a cargo aircraft crashed into the city of Manta in that country. Three MFST's and three CCATT's (Critical Care Transport Teams) deployed on short notice to South America, where they assisted in both critical care and surgical therapy of the injured civilians.

Mission Summary

We understand this small surgical team to be a single piece of a "building-block hospital." A team such as this one can be used to provide early surgical care in whatever situation it is required, and can be matched up with other mobile medical units as dictated by the situation.

Examples of specific missions appropriate for the MFST are:

- Triage/therapy/salvage surgery at airhead
- Surgical care of critically injured patients within the Air Evac system
- Surge augmentation of an existing deployed facility
- Ramp up/down phases of classic deployments
- Civilian disasters - augmentation of existing resources
- Mobile forward surgery
- Special operations support

Discussion #5

COMPERATORE, US: I have a three part question for anyone in the audience to consider. First, during surgical operations, what kind of duty days did you experience? Second, how long did you sustain long duty days during surgical operations be it emergency evacuation, rapid deployment, or others. Third, have you developed any strategies as a result of your experiences in surgical operations that you have been able to implement during sustained long duty days?

MILLER, US: Fortunately, our latest operations did not have high casualties. We practice surgical operations in field exercises during search capability assessments using live bodies, and, in particular, for appraising mass casualty evacuations. We do this not only because we are practicing casualty care, but also because we are providing the manual labour to actually put litters onto the aircraft. This becomes very physically demanding if you have 50 casualties and are running back and forth carrying litters to an aircraft that is 100 yards away. The hardest thing to do is to get your personnel to sleep under such conditions. Everyone wants to take part in the action and that's when you get into problems. As a Commander you want to maintain their rotations, not interfere, if possible, yet be assured that they are fresh for the next rotation. Because the exercise only lasts for a short time, there may also be a tendency on the part of everyone to say: "Well, I can stick it out for a week or so." However, in a real world situation, this could last for months and then it becomes a problem.

FARMER, US: As we are bringing the critical-care aeromedical transport-team (CCATT) concept forward, one of the questions that has arisen relates to how many of these teams do you need. In fact, one of the variables that we have had to look at is surgical operations itself. It is always difficult to decide where you draw the line regarding length of duty hours, and to what level do you staff. For these purposes, we have used an estimated standard crew duty day of 16 hours and have built our planning factors around that. The anticipation would be that in a surgical operation situation, it will go well beyond that and, in fact, we don't have a defined policy. The only example I can cite would be the Khubar Towers terrorist bombing that occurred near Dhahran Air Base, Saudi Arabia in 1996, where crew were on duty treating the wounded for somewhere between 48 and 72 hours before the initial transition.

GIBSON, UK: We must remember that the Army units that we are supporting are not capable of fighting continuously for long periods of time. They will have a surge of activities, then fall back and be replaced. The medical crew surge lags a bit, so when Army units are in the rest-and-recuperation phase, medical crews are still working hard and dealing with the backlog of casualties. The planning figures that our last Director General of Army Medical Services used were that, normally, surgeons would be expected to work 12 hour shifts; in a surgical case for a maximum of two days, they may be expected to work an 18 hour shift.

SICARD, FR: In the former Republic of Yugoslavia at a French field hospital based in Mostar, we used a new self-contained operating and intensive care room that comes in moving boxes with its own power plant. It is much more convenient and more rapidly deployable than the standard tent hospital.

GIBSON, UK: The British bought two of these as Tri-Service assets but our Army is using them at the moment. We found them to be sufficient for operations other than war but

for mass casualties we had to rely on the old tent system with lots of beds.

SAVASAN, TU: I would like to ask Maj Pilcher how far his Mobile Field Surgical Team (MFST) can be deployed, how long it takes to be deployed and the nature of the cases that the team can handle (in reference to Paper #26)?

PILCHER, US: In terms of distance, the MFST is intended to serve worldwide needs. The teams that currently exist are based at Wilford Hall Medical Center in San Antonio; there are five teams, one of these is ready to depart within two hours notice, a second one within four hours notice and two more within 12 hours notice. Then, you need to add flight time to determine the total time required for deployment. Regarding your question about which cases the teams can handle, firstly, let me say that we would not be able to handle complex back fractures. I think that we would attempt to stabilize these patients in terms of the fracture and then transfer them further. However, we can perform thoracotomies, laparotomies, extremity fixations and, potentially, even craniotomies if that were necessary.

BURTON, US: The US Air Force (USAF) is involved in developing an air expeditionary force (AEF) capability that includes the transportation of up to 1000 personnel in some aircraft. Will a medical component be part of the AEF capability?

PILCHER, US: Yes, we've been in contact with the AEF planners and their initial plans included a primary care capability. After some further discussions with them, it's been recognized that it would be useful, even for Forces not under direct threat, to have some higher level capability available. Those plans are in progress.

GRAHAM-CUMMING, UK: I think a big issue is that one cannot assume that aeromedical equipment that has been cleared by the USAF for use in USAF aircraft can then be used by the Royal Air Force and in Royal Air Force aircraft. Someone recently pointed out that aeromedical equipment that had been safely cleared by the USAF for fixed wing flight burst into flames during a radio transmission in a helicopter. So there is enormous difficulty just clearing USAF equipment for transfer from one American aeroplane to another. To actually hope to use a French ventilator on an American patient in a British aircraft is probably impossible.

Title: **"The Provision of Intensive Care Medicine in Austere Field Locations"**

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Introduction: The single most difficult challenge providing intensive care in an austere field location is overcoming logistical hurdles. However, the recent commercial development of small lightweight portable advanced medical devices has greatly expanded the potential of sophisticated intensive care medicine in such locations. In contrast to the Viet Nam era, where cardiac monitors and mechanical ventilators were not only extremely uncommon, but were unreasonably large, we now have choices among many remarkably capable machines that are small and lightweight. These include mechanical ventilators, cardiac respiratory and invasive monitor, and precision infusion pumps. Many of these devices are highly sophisticated and can provide a technical level of care equivalent to that of an intensive care unit in a fixed medical facility. During this talk the following elements were discussed:

1. A review of necessary field elements to provide quality intensive care.
2. A discussion of unique logistical requirements imposed by an austere environment.
3. A discussion of unique clinical consequences of this environment.

Discussion:

The Portable ICU:

General Considerations: When considering the general equipment requirements for the development of a portable intensive care unit the following universal considerations are important. First of all, all medical devices should be small and lightweight and should be clearly portable, as opposed to luggable. For a military field environment this equates to getting the equipment on the same litter as the patient. All medical devices should have an extended battery life with a minimum useable time of at least four to six hours. This is especially important given the unpredictable nature when medical transport is involved. For example, it is common to arrive at a location expecting your next level of transportation to be in place, but in fact, to find that you must wait (and that further battery capabilities are required).

All medical devices should have prominent visual alarms. An austere field environment is commonly characterized by high ambient noise levels so that a dependence on auditory alarms can easily lead to medical mishaps. All medical devices should be durable, that is water and dust resistant. Again, because of the inherent transport nature required for these patients, all medical devices should be certified for aeromedical usage. Certification includes an assessment of electromagnetic interference with navigational instruments as well as an ability to withstand a high vibration environment. Finally, in general these devices should avoid proprietary peripheral interfaces. For example, many small transport ventilators now in use include a proprietary tubing circuit as opposed to a standard 22 mm diameter set up. If the care of these patients is past from one critical care team to another an additional confusion may occur related to the transfer to other medical devices with differing machine patient interfaces. This is additionally true, as another example, for many IV infusion pumps.

Mechanical Ventilation. The prototypical transport mechanical ventilator is oxygen powered and electrically controlled. In general these machines are time and/or pressure triggered, volume limited, and time cycled. Because many of these machines are oxygen powered and therefore lack an internal compressor as well as an air oxygen blender, they can consume excessive amounts of oxygen. As suggested above, nonstandard proprietary tubing circuit setups can also be problematic.

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The ideal transport mechanical ventilator for a field environment is small and lightweight, uses a standard 22 mm internal diameter tubing circuit, has an internal compressor and blender, has easily seen alarms and knobs that utilize standard conventions, has a long battery life, is durable, and is electromagnetically well shielded. This run-on sentence encapsulates all of the necessary and desirable features of a field mechanical ventilator. While this may seem to describe wishful thinking, in fact machines are now coming on to the commercial market (in the less than 15 pound category) that meet all of the above described specifications.

The Cardiac Monitor. A filed utilizable transport cardiac monitor should include ECG monitoring with multiple leads, noninvasive blood pressure monitoring, pulse oximetry, and as a nice to have feature capnography. Audible alarms are especially problematic for these devices. They should have a high threshold for filtering artifactually generated monitor noise from either patient movement or excessive vibration. Challenges that remain to be solved for these monitors, especially since visual alarms are required, include a central monitoring station capability, a reliable arrhythmia and abnormal vital signs notification capability, nurse and physician charting, and a clear link to telemedicine.

Intravenous Drug Delivery System. As described above, the proliferation of proprietary cartridges and IV tubing sets can make the movement and care of a field critical care patient very frustrating. Most IV pumps in use are either cartridge or piston driven or of a syringe pump version. Issues of importance with this include size and portability, battery performance, and again electromagnetic interference. Commercially available machines are now available that can simultaneously infuse IV fluids, blood and enteral tube feedings, all from the same cartridge and tubing circuit. The watchword for an austere environment is standardization.

Oxygen Source. During the last 50 years of medical support for military conflicts and wars, adequate availability of oxygen and the logistical requirements this imposes, has been essentially the largest materiel problem to be solved. In this regard, it is essential that we seek medical devices that are very frugal with their oxygen utilization. We are additionally looking at a variety of machines that include oxygen generation capabilities from ambient air. Unfortunately, at this time, many of these remain quite large and bulky, or their oxygen flow generation rates are not sufficient to reliably drive a mechanical ventilator.

In general, most transport mechanical ventilators require a reliable 40 psi oxygen source for proper utilization. This oxygen must not include any contaminants and must be logistically well placed. Most of this oxygen comes in two forms, either gaseous storage or liquid oxygen storage. Both have advantages and disadvantages. Liquid oxygen is smaller and more compact, and for Air Force purposes is typically more available than gaseous oxygen. However, in a high-temperature environment, liquid oxygen containers must be frequently refilled. In contrast, gaseous oxygen, while more stable is provided in containers which are larger, bulkier, and heavier. Transport of these gaseous oxygen canisters in a hypobaric environment is also potentially dangerous.

Laboratory Devices. As the level of sophistication increases for the transport and care of these patients, interval assessment of laboratory status becomes critical. These devices must be small and portable and should easily accompany the patient. They should be insensitive to environment changes and should be easily calibrated They should usable by a bedside care provider, and should not require laboratory personnel. Fortunately, at this time a variety of point-of-care laboratory devices that fulfill these requirements are now available. Many of these include arterial blood gases as well as simple chemistries and other studies such as hemoglobin and hematocrit. In the near future, these will additionally include magnesium, ionized calcium, and phosphorus capabilities as well.

Other Medical Devices. In order to provide quality critical care in an austere environment other clinical considerations must also be met. These include the availability of a powered, portable suction apparatus, a defibrillator, an ability to humidify inspired gases, and a reliable mechanism to warm hypothermic patients. Hypothermia greatly compounds morbidity and mortality for traumatized critically ill patients.

Other requirements for austere critical care include sufficient intravenous fluids including crystalloid and colloid solutions, vasoactive medications, advanced resuscitation cardiac drugs, antibiotics, sedative hypnotic and analgesic agents, muscle relaxant drugs, anti-seizure medications and other common formulary agents such as $D_{50}W$, thiamine, narcotic reversal agents, etc.

Logistical Challenges:

Planning Factors. In order to safely care for patients such as these in an austere environment as well as transport them to definitive care a variety of planning factors need to be considered:

1. Anticipated casualty loads drives the number of providers required, the number of medical devices required, and the consumable medical supplies.
2. Weight and cube issues. In order to be forward deployed these should be relatively portable with the largest mass considerations being IV fluids and oxygen.
3. Personnel utilization. The pace of these types of deployment can be quite hectic and issues of crew duty and crew cycle times need to be additionally considered.
4. Communications. As has been discussed, it is assumed that these patients will be transported from a forward location to a definitive care site. Appropriate coordination and communication to successfully complete this transport is vital. Inpatients with multisystem medical diseases, the volume of analytical and clinical data that need to be communicated on each individual patient can be immense. Communications is especially important for these patients.

The ultimate goal is to define a seamless continuum of care from the point of injury to definitive treatment. We can anticipate difficulties to arise at the interface points. Again, the emphasize communication of specific patient needs is especially important. In addition, coordination of transport vehicles, differences in available treatment modalities, equipment and compatabilities and medical device requirements must be considered as well. Finally, interoperability of team members is vitally important in this environment. As an example, a critical care nurse must facile with trouble shooting of ventilator and conversely a respiratory therapist must be able to start a peripheral intravenous line.

Clinical Issues:

There are three universal rules of patient transport and care of critically ill patients in a field environment. These include:

1. Remember the A-B-C's, when bad things happen in this environment it is almost always airway or breathing (oxygenation) related.
2. Things deteriorate at light speed, if you have not previously practiced a variety of clinical scenarios, then it is difficult to assign tasks and successfully resuscitate a patient in this environment "on the fly."
3. Never leave a secure clinical environment until you are certain you have everything you may need.
4. Travel light.

Given the above, when caring for or moving the mechanically ventilated patient in an austere environment, it is important to estimate and/or calculate the supplemental oxygen needed prior to leaving a secure environment. This can be simply done using a patient's known minute ventilation while on the mechanical ventilator and ensuring that you do not proceed to an austere environment unless you are carrying at least one and a half to two times that amount of oxygen. Furthermore, it is important to know the battery life of the medical devices prior to entering this environment. Be sure to consider additional consumption based on increased use (example, cycling the noninvasive blood pressure device). It is extremely important to have a backup plan in case something breaks enroute such as the mechanical ventilator. Are you going to carry an additional ventilator or would you simple bag the patient until a secure environment is obtained? Finally, it is important to use checklists wherever possible to ensure all potential problems are considered before entering an environment that does not lend itself well to "heat of the moment" decisions.

Hemodynamic Support and Resuscitation. In this section we will briefly delve into the treatment and transport of "shock treated" casualties. Clearly "shock treated" is in the eyes of the beholder. For some this may mean establishing sufficient IV access, while for others this means their hemodynamic resuscitations has been completed. Understand that even hospitalized patients may require further resuscitation. Finally, be vigilant for the development of new problems in these patients such as other surgical emergencies as in rebleeding or compartment syndromes or the like. Ensure maximum patient accessibility in this environment. If you are going to transport a patient do not load them below the knee level or higher than the chest level, think of trying to emergently intubate a lost airway in either of those two extreme positions.

If aeromedical resuscitation is required, understand that the hypobaric environment exacerbates resuscitation requirements. It is important to ensure hemodynamic assessment is adequate and in this regard profusion status is assessed by the usual methods. This includes heart rate, blood pressure, urine output, capillary refill, and pulse oximetry observing the morphology of weight form as well as respiratory variation. It is important for all treatment

teams to adhere to a established trauma life support algorithms or other clearly defined "A-B-C" type approaches.

In many patients hemodynamic monitoring is desirable. For the majority, this is limited to placement of arterial lines in patients with blood pressure instability or severe respiratory failure requiring serial arterial blood gas determinations. Pulmonary artery catherization is rarely needed in this patient population. All invasive lines should be well secured and sewn down.

Before initiating transport, vital signs should be "relatively stable." Again, "relatively stable" is an ambiguous term and requires further delineation. In general, this means that all traumatic injuries have been identified and that transport time does not impose an unacceptable delay until surgery and that non-surgical treatment for these major traumatic injuries is at least "in progress." For patients with nontraumatic causes of shock, therapy should also be " in progress." These etiologies in this environment potentially include sepsis, cardiac failure, and allergic reactions.

Respiratory Failure. In many regards this is clearly the "all or nothing bet" of austere critical care provision. Mistakes or lapses in judgment as they relate to the respiratory system will most quickly lead to patient demise. In other words, the pulmonary respiratory system is **the** most dependent on external medical device support. It is also the system most at risk for complications such as barotrauma. Finally, it is the system that is most easily affected by an aeromedical/hypobaric environment.

If transport of these patients is required then a variety of criteria need to be met before this process is undertaken. First of all, if you cannot adequately oxygenate and ventilate this patient on the ground then you will on exacerbate the situation by placing the patient in a hypobaric environment. Adequate oxygenation is defined as an oxygen saturation greater than 92% by pulse oximetry, a minute ventilation equal to or less than 15-20 liters per minute, and a PCO_2 less than 55-60 tor, and/or a pH greater than 7.25-7.30. Furthermore, the mechanical ventilator must not require excessive pressures to deliver tidal volume. This is defined as a peak airway pressure equal to or less than 45-50 cm of water, pulmonary calculated compliance greater than 25, and/or an I:E ratio equal to or greater than 1:1. If the above parameters are not met, then the patient is at high risk for respiratory deterioration enroute while in the airplane.

Most current transport ventilators are nothing more than modified oxygen regulators that depend on the psi from the oxygen source in order to generate a title volume. As mentioned earlier in this paper, newer machines are incorporating small, low volume displacement, high rpm internal compressors and blenders.

In order to use these mechanical ventilators in a hypobaric environment, the clinician must be cognizant of the effects of altitude on ground level calibration of these medical devices. Problem areas include measured versus actual delivered oxygen concentration, delivered gas volumes, lung distending pressures, endotracheal tube cuff volumes, and accurate assessment of positive and expiratory pressure (PEEP). As a general rule of thumb, these transports cannot be successfully accomplished without the on scene presence of a respiratory therapist. The respiratory system is simply too unstable to endure many mistakes without rapid recognition of ventilator problems.

Other important clinical adjuncts for patient transport with respiratory failure include humidification which is generally accomplished using a heat and moisture exchanger as opposed to a humidifier. A colorimetric carbon dioxide detector may also be useful as well as portable bronchoscopy.

Other Organ System Support Requirements. Acute brain injury can be easily exacerbated in an austere environment. Two general clinical rules of management include:

1. Avoid maneuvers that may exacerbate elevated intracranial pressure. These include loading patients head to the front during take-off and reversing their position for landing as well as a liberal use of sedatives and muscle relaxants to minimize oxygen consumption.
2. Ensure adequate volume resuscitation for these patients. It has been previously accepted dogma that relative dehydration limits the effects of brain swelling with acute brain injury. We now know that this is clearly flawed and that the inpoint for volume resuscitation should be uvolemia. Furthermore, given that these patients come from a field environment, most are already relatively dehydrated.

Management of elevated intracranial pressure in a field environment is generally limited to the use of Manitol as an osmotic dehydrating agent and selected use of hyperventilation only in order to temporize. Seizure prophylaxis should be liberally undertaken for all patients with significant head trauma. In this environment it is defined as a loss consciousness

which exceeds 5-10 minutes in duration. Drugs of choice for this include benzodiazepines, phenytoin and a variety of barbituates. Finally as a general rule of thumb, inpatients with elevated intracranial pressure avoid activities which may cause nasopharyngeal stimulation such as placement of nasogastric tubes or nasotracheal intubation. These maneuvers may precipitate herniation.

Summary:

Recent advances in portability of advanced medical devices have exponentially increased our abilities to provide far forward and enroute intensive care medicine. This is a rapidly evolving and changing area. In contrast to a mere decade ago, our ability to provide sophisticated field critical care has dramatically increased as has the risk for complications and mishaps. In summary, we can provide far forward sophisticated intensive care, but this must remain in the hands of skilled clinicians as the margin for error is truly paper thin.

POINT-OF-CARE TESTING: CAN IT BE ADAPTED FOR THE FIELD ENVIRONMENT?

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SUMMARY

Technologic advances have made laboratory testing feasible at the bedside. Point-of-care testing (POCT) allows medical providers to assess a wide range of clinical conditions in a rapid fashion at the site of patient interaction. While POCT has begun to impact on the delivery of care in the hospital setting, its potential for use in remote, field environments or during aeromedical evacuation is just being realized. In the civilian setting, discussion of POCT focuses on regulatory guidance, cost effectiveness, and reimbursement. Little attention has been paid in the literature to expanding the use of these capabilities beyond the traditional hospital boundaries. In this paper, we will briefly review the development of POCT and the associated technology. In addition, we will discuss the potential role of POCT in the field using current technology. Finally, we will review the available literature on use of POCT in the field.

INTRODUCTION

When providing direct patient care in nontraditional settings, there occasionally arises the need to ascertain physiologic measurements which are difficult to obtain outside of the hospital environment. Rapid analysis of laboratory tests can be essential in the management of our patients, particularly the critically ill and injured. The availability of selected analytes such as glucose, electrolytes, hematocrit, blood gases, and pH can significantly affect the direction of treatment, prognosis, and triage decisions. The lack of this information can lead to the assumption of a "worst case" which will then drive triage and treatment decisions that may adversely impact the delivery of care to other patients and the need for evacuation.

The development of devices incorporating microchemistry, miniaturization, and microcomputerization has led us to a point where many of these desired tests can be performed real-time at the point of patient interaction. This capability is referred to as point-of-care testing (POCT). It would seem a simple answer to a complex clinical problem, but even in the traditional clinical setting, POCT is surrounded by controversy. Issues of regulation, quality management, and cost effectiveness often interfere with the establishment of a POCT system. In the field setting, there are even more questions regarding durability, reliability, and ease of use.

In this paper, we will review the development of POCT along with its associated technology. Using this information we will examine some of the currently available systems and their applicability for use in the field or during aeromedical evacuation. Finally, we will review the limited literature on POCT in the field to assess the overall utility of this technology for application in the, more often than not, hostile field environment.

POCT DEVELOPMENT

There has always been a desire on the part of clinicians to have immediate access to all of the variables which impact on our patient's diagnosis, treatment, and prognosis. Technologic advances continue to provide us with greater opportunities to have that information at our fingertips. Point-of-care testing has been available for many years. The monitoring of blood glucose concentrations through the use of reagent strips and subsequent techniques has been available since the 1970's (Ref 1). The Vietnam conflict with the resulting movement of large numbers of casualties led to early attempts to provide portable, miniaturized electrolyte analyzers (Fig 2). Concerns about the need to provide rapid evaluation of hematocrit and electrolytes in burn patients being moved through the aeromedical system was the prime motivating factor in these development efforts (Ref 2).

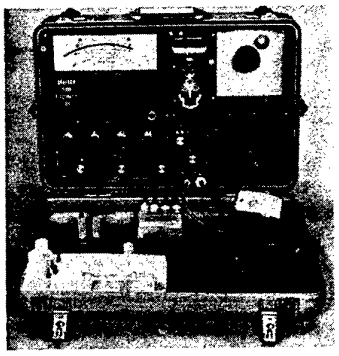


FIGURE 1. Complete analytic system with case open and with miniature centrifuge mounted on its charger base (Aerospace Med 1970;41:880).

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The real drive to bring POCT into a useful role was tied to the requirements of liver transplantation (Ref 3). In these cases, rapid changes in ionized calcium demanded an almost immediate knowledge of its level to direct appropriate therapy. This need exceeded even the capabilities of most "stat" laboratories and led to the introduction of whole blood biosensors directly into the operating room. The addition of bedside potassium and hemostasis testing following almost immediately.

This shift away from the traditional laboratory paradigm was quick to take hold in other areas. No longer did discrete specimens have to be collected, transported, centrifuged, analyzed, recorded, and transmitted back to the originator. The use of whole blood samples in portable, often hand held, instruments simplified the process to the point that relatively little training was required to produce consistent accurate results. The development of critical test clusters now provides valuable indicators of vital functions right at the bedside. As of 1995, approximately 83% of U.S. hospitals had handheld POCT programs (Ref 4) and that number is probably 100% today. The addition of *in vivo* and *ex vivo* instruments to POCT has even further expanded our already plentiful capabilities.

POCT TECHNOLOGY

Conventional methods of diagnostic testing present several problems when dealing with critically ill or injured patients. Unnecessary process steps, prolonged turnaround times, and delayed results which are no longer relevant to the current patient condition contribute to delays in therapy. The improvements made in sensor technology over the last two decades now allow us to implement a patient-focused testing system. A chemical sensor consists of three basic elements: a sensing unit where recognition of the analyte occurs, a relay section that transmits the signal produced to the sensing unit, and a measurement instrument that interprets the signal and calculates its value (Ref 5). These new chemical biosensors can be broken down into two major categories: electrochemical or optical.

Electrochemical Sensors

Electrochemical sensors are able to measure blood gases, pH, electrolytes, and metabolites. These sensors produce a potential or current in response to their reaction with the analyte of interest. Ion-selective electrodes measure the free ion of interest in whole blood. They do so by use of ion-selective membrane coverings which extract or bind the ion creating a charge separation or electrical potential in proportion to the concentration. Electrodes of this type can be used to measure bicarbonate, sodium, potassium, ionized calcium, chloride, magnesium, pH, and the partial pressure of carbon dioxide (pCO_2).

Amperometric sensors produce current through oxidation or reduction of the analyte. They contain two electrodes which, when a voltage is applied, allow for oxidation or reduction of the analyte. The resulting current is proportional to the analyte concentration. The Clark electrode for the measurement of the partial pressure of oxygen (pO_2) is a classic example of an amperometric sensor.

Other varieties of electrochemical sensors are electrical conductance and enzymatic-coupled sensors. Most bedside POCT devices which measure hematocrit do so by use of an electrical conductance sensor. These sensors rely on measurements of impedance to electrical current which is related to the erythrocyte concentration. Since erythrocytes are essentially nonconducting compared with plasma, increasing hematocrit decreases the current flow in the circuit. Enzymatic-coupled sensors rely on an interaction between an enzyme in the sensor matrix and the analyte to produce an amperometric or potentiometric response which is then measured. Most glucose analyzers use the enzyme glucose oxidase to produce a reactant which is then measured amperometrically.

Most devices on the market are capable of multiple analyte measurements using a combination of these sensors to provide all of the data from a single, small, whole blood sample (Fig 2). These sensors are usually arranged along a flow through channel that allows for contact with the sample and calibration or flush solution as needed (Fig 3). In those devices not using disposable cartridges, the channel is then flushed and the waste discarded.

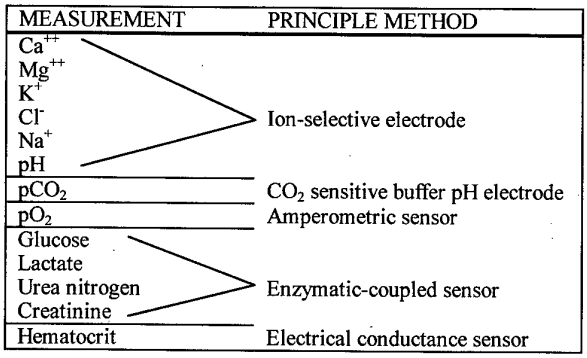


FIGURE 2. Potential analytes and methods of measurement in a single POCT device.

Optical Sensors

Optical sensors were originally developed to measure blood gases and pH using a light signal and indicator dye to measure the specific analyte of interest. The dye is separated from the blood sample by a permeable membrane to prevent clot formation and protein buildup. The sensor can use either absorbent or fluorescent modification of the light signal to determine the concentration of the analyte. This is similar to the process used in many oxygen saturation devices.

In Vitro Instruments

In vitro POCT devices are the most common form used at the bedside. The blood sample is drawn from the patient and then

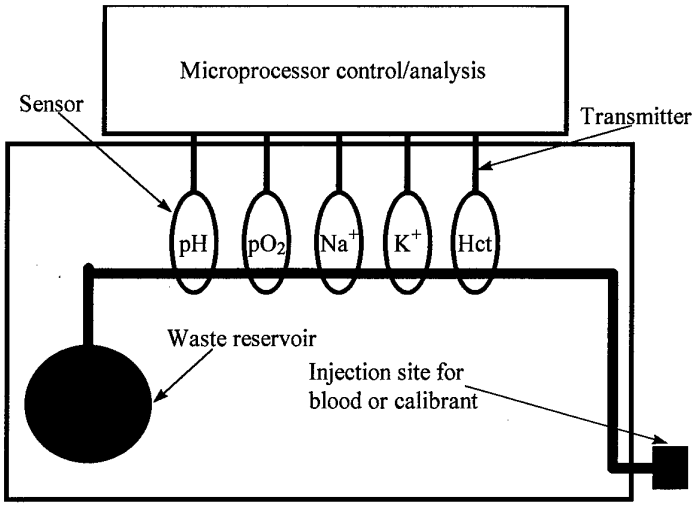


FIGURE 3. Schematic representation of a multiparameter POCT device. Note multiple sensors in-line with blood injection port to allow for simultaneous measurement of all parameters.

injected into the POCT instrument. While this does not provide true "real-time" measurements, it does allow for rapid (seconds to minutes) determination of desired variables. Most of these devices originated as single parameter instruments (Ref 6), however, most now do multiple parameters with a single sample. Two of these devices, the i-STAT Portable Clinical Analyzer (i-STAT Corp., Princeton, NJ) and the IRMA (Immediate Response Mobile Analysis) System (Diametrics, Inc., St. Paul, MN), have been evaluated extensively for their utility as portable, handheld analyzers.

To evaluate the accuracy of the i-STAT (Fig 3), it was used in an emergency department by staff without previous laboratory training (Ref 7). Samples from 574 patients were analyzed and compared with standard laboratory measurements. There was excellent correlation with urea nitrogen, glucose, and potassium. The correlations for hematocrit, sodium, and chloride were less satisfactory. A more recent study, however, found acceptable correlation in the emergency department and the stat laboratory for all analytes (Ref 8).

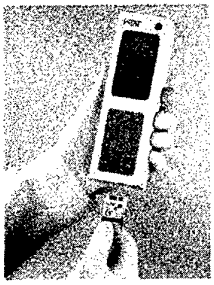


FIGURE 4. Handheld i-STAT Portable Clinical Analyzer with cartridge ready for insertion.

The IRMA has also been evaluated in the hospital setting (Fig 5). Zaloga et al analyzed 239 split blood samples in critical care patients in an intensive care unit (Ref 9). They found correlation coefficients between 0.96 to 0.99 for pO_2, pCO_2, and pH with a decrease in the turnaround time. Similarly, Wahr and colleagues reported similar results using the IRMA to assess blood gases and pH during cardiopulmonary bypass surgery (Ref 10).

A number of other devices exist and a recent review summarizes the features of each (Ref 11).

In Vivo and *Ex Vivo* Instruments

A more novel approach to the use of POCT involves *in vivo* and *ex vivo* testing devices. This includes familiar technology such as mixed venous oxygen saturation monitoring by use of pulmonary artery catheters. More novel and developing concepts such as continuous arterial blood gas monitoring through the placement of sensors directly into the artery are beginning to appear (Ref 12). Excessive expense and fragility of the systems (Fig 6) has limited their overall use and acceptance.

A more practical approach is *ex vivo* monitoring. This is accomplished by positioning the sensors outside of the body and allowing blood to travel from an invasive line to the sensor site before returning to the circulation. This is similar to the use of blood gas sensors placed in-line on a cardiopulmonary bypass machine. The measurements can be done continuously or on an "as needed" basis. Currently, there are no devices of this type in widespread use.

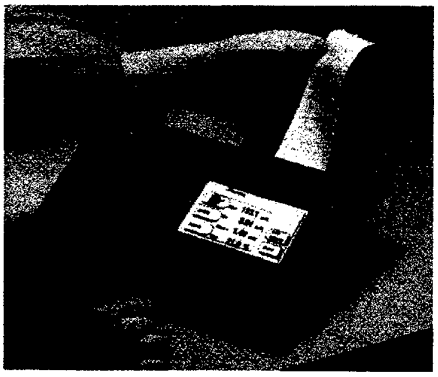


FIGURE 5. Immediate Response Mobile Analysis (IRMA) System with sample attached to injection port.

POCT IN THE FIELD

When looking at the technology currently available to perform POCT, it would appear that these devices should be extremely useful in the management of patients at remote locations. There are, however, challenges to providing this capability in the field. The environmental considerations are one of the greatest threats for the use of POCT in remote or hostile environments. Not far behind is the issue of ensuring the repeated accuracy of the equipment.

Both the IRMA and i-STAT have operating temperature ranges that can easily be exceeded in field conditions. The IRMA will operate from 15 to 30°C while the i-STAT has recently been upgraded to 16 to 30°C. These temperature ranges also apply to the cartridges. In our experience, this is one of the more common operating errors encountered when using the IRMA outside of the hospital. When working in a cold environment, like the inside of a C-130 at altitude, it becomes necessary to carry the disposable cartridges for both systems inside a flight suit in order to ensure that they remain within the temperature operating range. Both devices are capable or working in a low humidity environment down to 0%, however, their upper limit is around 65% according to the manufacturer's recommendations. Barometric pressure should not be a problem under most operating conditions. The IRMA is reported to function from 350 to 900 mm Hg (59-86 kP). An onboard barometer calibrates the system for the current barometric pressure prior to each use. The i-STAT has recently completed testing at the Armstrong Laboratory, Brooks AFB, TX where there were no reported problems when using both electronic and liquid controls in a hypobaric environment. This testing resulted in an "Approved" rating for its use aboard selected U.S. Air Force aircraft used for aeromedical evacuation. The IRMA has not completed testing at this time

Evaluating the repeated accuracy of these devices is an important part of using the equipment. The process of quality checking involves the method whereby the analyst tests the equipment through a standardized routine to document the accuracy of the measurements. Common laboratory practice



FIGURE 6. Intra-arterial probe for continuous arterial blood gas monitoring (Paratrend 7, Diametrics, Inc., St. Paul, MN). Fragility of the probe which is placed through an arterial cannula is a known problem.

frequently requires multiple test samples of known quantity to be run on the system in order to ensure accuracy. This time consuming process has been greatly simplified with POCT devices. In fact many of the current systems do not require the use of any reagent based calibration samples. Electronic calibration is performed using a calibrated cartridge and accomplished in seconds to minutes. A second method of calibration involves the placement of a calibration gel or liquid on each disposable cartridge such that a calibration is performed before each sample. The calibration gel or fluid is then replaced by the actual sample during the testing phase. Some systems such as the i-STAT and the IRMA use a combination of these methods with an option to perform independent liquid calibration. This combination of calibrations should be easy to perform even under field conditions and will allow for the smooth operation of the devices.

Discussions about the clinical utility of POCT in a nontraditional environment revolve around not only its usefulness in decision making, but also its impact on therapeutic turnaround time and outcomes. Whatever role POCT has in improving the care our patients receive when we are far from the traditional hospital should be based on sound evidence-based medical decisions. When deciding about the usefulness of POCT derived data, we are not looking at a turnaround time based on minutes, but on hours or even days if it is not available. Clinical decisions such as the need or urgency of aeromedical evacuation from a remote location may be better guided if hard evidence, rather than the "worst case" scenario, is available for review. The availability of a simple blood test, using POCT principles, to rule out an acute myocardial infarction (such as a test for troponin-I) can be combined with the exam and electrocardiogram to risk stratify the patient with atypical chest pain. Ultimately, POCT is only useful if you have the capacity to use the information for establishing diagnosis, instituting treatment, or performing triage. If, after careful review, POCT appears to offer benefits for use in the field, then the cost factor needs to be considered.

Point-of-care testing is not inexpensive. A single multiparameter device can run over $5000 with a cost of $3-9 for each cartridge. The addition of a short half-life for the cartridges can add significantly to the overall cost of maintaining this capability. This must be weighed against the information gained when POCT is used and implemented properly.

The literature looking at the implementation of POCT in the field is very limited. There are only two studies which have

taken this type of analytical capability out of the hospital and into the field setting. Both of these studies examined the utility of the i-STAT in this role. One concentrated on its use in an ambulance service and the other in a helicopter rescue unit.

Tortella et al examined the consistency of measurements obtained when in the field (Ref 13). In this study, all samples were collected in the back of a moving ambulance and run on two i-STAT units while en route. An additional specimen was saved for later testing in the emergency department on the same units and an additional i-STAT analyzer. The samples showed excellent consistency between those obtained and run "on the move" and those run in the emergency department. Of note, the authors reported having problems with operation of the units in the field due to cold temperatures and they had to design a special insulated bag to protect the analyzers.

In the second study, Herr and colleagues reported on their experiences using the i-STAT during helicopter transport of 81 patients (Ref 14). Samples were simultaneously run through the analyzer and stored for later analysis at the main laboratory. Of the 332 samples run at both sites, only 1.8% did not correlate. No therapeutic decisions were made based on those measurements which did not show good correlation. In this study, POCT led to the administration of insulin in two diabetics and the administration of glucose to another. Since these helicopter flights also had the capability to administer blood products, the discovery of a low hematocrit leading to transfusion was the most common treatment received on the basis of POCT (16 patients or 19.8% of all patients). Overall, 24.7% of all patients received some form of treatment based on the results of POCT testing. Of note, the problems with temperature reported in this study were similar to those reported in the preceding one, underlining the significance of environmental factors in the performance of these units.

CONCLUSIONS

Currently, POCT is a reality in our hospitals and its use is going to continue to expand in the future. Under controlled environmental conditions, POCT can be used in the field. Most notably, problems with the extremes of temperature are going to require innovative solutions in order to get the most from these devices. Additional improvements may correct these shortfalls since it is a recognized limitation for expanding its use outside the hospital.

If POCT can help guide the management and triage of our most critically ill patients as they flow through the military medical system, it will quickly establish itself as a new paradigm. For the U.S. military medical community, if we are going to provide essential care forward with early evacuation of the "stabilized" patient, POCT will be immensely useful in maintaining a continuum of en route care that currently does not exist in its full capacity.

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Use of Point of Care (POC) Laboratory Devices by Critical Care Air Transport Teams (CCATT) of the United States Air Force

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SUMMARY

Point of Care (POC) laboratory devices have recently been utilized in medical centers to provide rapid results at the bedside of critically ill patients. The locations most commonly targeted are the Intensive Care Unit, the Operating Room, the Recovery Room and the Emergency Room. The impetus to use these devices is to provide immediate, accurate results of several critical laboratory values, especially those values that can change quickly. Instruments that can measure pCO_2, pO_2, pH, hemoglobin, hematocrit, sodium, potassium, chloride, glucose, urea, and ionized calcium and provide results in several minutes are already available. Technological requirements for a POC device include being small (less than 10 pounds), use small quantities of blood, can use AC or DC current, and require a minimum of effort to calibrate.

Extended air evacuation of critically ill patients with continuous flight times of longer than 1 or 2 hours with only vital sign monitoring, pulse oximetry and/or capnography limit the ability of the physician to recognize and respond to rapid physiologic changes. We recognized the potential utility of these portable POC devices to provide additional in-flight bedside information on critically ill patients. This abstract describes the experience of the USAF CCAT teams with the IRMA, Immediate Response Mobile Analysis, System (Diametrics, Inc., St. Paul, MN) in transcontinental and transoceanic transports (continuous flight times of 4 to 12 hours) of critically ill patients during participation in Operation Joint Endeavor (OJE). The summary of our experience, as well as illustrative individual patient transports will be discussed. Advances in POC technology such as the ability to measure troponin-I in the rapid diagnosis of myocardial injury are adding to the tools available to the clinician in remote locations. The effect of the aeromedical environment on performance of current POC devices will be reviewed with potential remedies to limit the adverse impact of aeromedical environmental conditions on device performance. In addition to the IRMA POC device, performance characteristics of the i-STAT Portable Clinical Analyzer (i-STAT Corp., Princeton, NJ) POC device will be reviewed.

INTRODUCTION

Recent technological advances in Point of Care testing (POCT) have included major innovations in miniaturization to allow a much higher degree of transportability of laboratory testing devices. Two units recently approved by the FDA for use in fixed care facilities are the i-STAT and the IRMA POC testing devices. The i-STAT unit is 2 inches by 8 inches by 2.5 inches and only weighs 18.3 ounces. The IRMA unit is 5 inches by 9.5 inches by 11.5 inches and weighs 5 lb. 5 ounces. These devices provide excellent data management capabilities and storage of test results. Quality control programs are simplified with a combination of aqueous calibrating solution and built-in electronic quality control. Battery life is practical with a useful life of two to three hours. These new devices have a broader menu of parameters that are available and extremely relevant for the critically ill patient. Parameters that are currently available for analysis vary with manufacture device design. Available parameters are usually done in sets of panels that are configured on disposable cartridges. Available parameters include multiple chemistries such as glucose, potassium, sodium, chloride, blood urea nitrogen and ionized calcium. Arterial blood gases are available which include pH, pCO_2 and pO_2. Hematocrit and hemoglobin are also available. The application of POCT was originally targeted for the tertiary medical facility for bedside testing in the intensive care units, operating rooms, recovery rooms, and emergency rooms. The technology was mainly driven by the need for reducing the time to obtain bedside results. Potential

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cost savings were a secondary consideration. The utilization of POCT for pre-hospital areas is really only a follow-on development. However, POCT provided an information capability that previously was not available to those locations. Pre-hospital areas include ground ambulances, regional air ambulances, extended air evacuation and austere or remote environments. The rationale for use in extended air evacuation was as extended air evacuation was being used for critically ill patients, the rapidly evolving conditions of complex critically ill patients would require more comprehensive monitoring to maintain quality care. POCT would augment conventional monitoring modalities such as vital signs of heart rate, respiratory rate, temperature, blood pressure and urine output. POCT also would supplement non-invasive monitors such as electrocardiograms, pulse oximetry, capnography or end tidal CO_2 ($ETCO_2$) monitoring.

CCATT EXPERIENCE WITH POCT IN OJE

Experience with POCT in OJE was notable in that of a total of 44 patients that were transferred during OJE by CCAT teams, only 8 had in-flight POCT utilized. Of those 8, all were on mechanical ventilation for respiratory failure and most of these were for flights greater than 8 hours. The majority of experience with POCT by the CCAT teams in OJE was with the IRMA device. The parameters measured en route 75% of the time were done to evaluate the adequacy of mechanical ventilation by arterial blood gas testing. Notably, during OJE the Propaq model 104 monitor was used. This monitor model does not have $ETCO_2$ monitoring capability. The latest Propaq model, the 106EL, does have $ETCO_2$ monitoring capability and is now being used by the CCAT teams. However, this has not significantly reduced POCT for arterial blood gas assessment during long flights with mechanically-ventilated patients. Another 25% of testing was done to evaluate electrolytes during fluid resuscitation to follow sodium and potassium levels. Hematocrit and blood urea nitrogen parameters were not available at the time of OJE for the IRMA device. In approximately one third to one half of patients who had POCT utilized, the results prompted a change in therapy (i.e. adjustment of minute ventilation, potassium supplementation, etc.)

NON-OJE CCATT EXPERIENCE WITH POCT

A more recent illustrative case of utilization of POCT which was outside of Operation Joint Endeavor occurred during the air evacuation of survivors of the Korean Airliner crash in Guam in August of 1997. Four patients were air evacuated from Guam via a C-141 aircraft to Brooke Army Burn Center in San Antonio, Texas. The patients ages ranged from 11 to 39 years of age. They had severe burns averaging between 35% and 70% of body surface area (BSA). This was a long mission of nearly 21 hours; approximately 10 hours flight time from Guam to Hawaii, 3 hours refueling and aircraft maintenance on the ground in Hawaii where the patients remained in the aircraft with the CCAT team, followed by the final leg of 8 more hours of flight time from Hawaii to San Antonio, Texas. POCT helped guide the care of the rapidly evolving patients by allowing close monitoring of sodium and potassium levels when each patient received on average greater than 5 liters of intravenous fluid during this mission. Arterial blood gas testing was used to confirm increasing hypercapnia noted on the $ETCO_2$ monitor. The increasing hypercapnia mandated an increase to higher levels of minute ventilation to maintain pCO_2. The etiology of the worsening hypercapnia was felt to be a combination of increasing hypermetabolism due to the extensive burns as well as increasing problems with mucus plugging on several of the patients.

ENVIRONMENTAL CONSTRAINTS

Important issues affecting use of POCT in both austere environments as well as air evacuations are some of the environmental constraints of these devices. Operating temperatures for the IRMA device are 15 to 30 degrees Celsius or 59 to 86 degrees Fahrenheit. For the i-STAT device essentially the same 15 to 30 degrees Celsius and 59 to 86 degrees Fahrenheit range. These temperature ranges clearly limit the use of these POCT devices in either extremely cold or hot environments. In cool areas, prior to use, the cartridges for either device should be placed in the breast pocket of a flight crew member to keep the disposable cartridges warm and ready for use. An important potential environmental limitation is barometric pressure and its affect on POC device results obtained in a hypobaric environment. Notably, the IRMA device can operate from sea level to a cabin altitude of approximately 16,000 feet because of its built in barometer compensation. The i-STAT does not have an intrinsic barometer compensation.

FUTURE DEVELOPMENTS

Potential future developments in POCT technology will include an increasing array of available parameters. Markers for myocardial injury are becoming available as either troponin-I or creatinine kinase MB bands included on a separate cartridge. Coagulation testing is being developed as another parameter to provide for monitoring with both the IRMA and i-STAT devices to guide anticoagulation therapy mainly, but also as a limited panel for bleeding disorder assessment. Another potential parameter under development relevant for the critically ill patient is a test for lactic acid levels.

CONCLUSION

In conclusion POCT compliments both austere ground environment and enroute care capabilities. Short legs of

patient movement, usually less than 2 to 3 hours, rarely require POCT. However, in extended air evacuation of the critically ill patient for periods longer than two hours, POCT provides a real asset that augments the vital sign monitoring of these patients. Shorter missions may potentially use POCT if the time and resources for assessing patients prior to patient movement are not provided. In that situation, POCT may be useful to evaluate a patient either at the staging facility or enroute, depending on the urgency of the air evacuation. It is important to consider environmental constraints to not utilize erroneous data on which clinical decisions may be made. An important caveat noted during testing of the IRMA device at Armstrong Laboratories, Brook AFB, TX was that after a rapid decompression, a number of the cartridges were found to leak. This concern may apply to either POC device. If by circumstance, a rapid decompression occurs, cartridges that were transported during that flight should not be used and should be discarded. Guidelines in choosing a POC device that differentiates the two devices are: 1) If you need a printer frequently, a built-in printer may be preferable which would favor using the IRMA device; 2) If you desire a built-in barometer, in other words, if it is used mainly for air evacuation, choose a device with inherent barometric pressure adjustment which would also be the IRMA device; 3) If your highest priority is small size and portability, the i-STAT device is significantly smaller than any other device available. Remember to evaluate the environmental constraints of where you are mainly going to be working. If the temperature environment would make the POCT device inoperative most of the time, POCT probably has little to offer. However, if you can work within the environmental limitations of these devices, they can add a testing capability previously unavailable in such a small package. Space and weight constraints rarely exclude current POCT devices from even the most highly mobile and austere medical teams.

LIFE SUPPORT FOR TRAUMA AND TRANSPORT (LSTAT™): A NATO LITTER-BASED CRITICAL CARE TRANSPORT PLATFORM

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Summary

A significant portion of the military field medical footprint is currently consumed by post surgical patients, which according to current doctrine, must be stable before evacuation.[1] This requirement results in a significant logistical burden for our ground forces. At present, we do not have adequate monitoring or therapeutic capabilities during ground or air transport to a definitive care treatment facility. In response to this need, we initiated a research and development activity to design and build a NATO-stretcher-based mini-intensive care unit that incorporates resuscitative and life-sustaining capabilities for field surgery and *en route* care. The LSTAT™ has 3 basic components: (i) the base unit, (ii) a NATO stretcher, and (iii) a canopy that covers the entire patient. The LSTAT™ base contains medical diagnostic and therapeutic components while medical parameters, system performance data and user interactions are continuously monitored and logged by an on-board CPU. Provision is made for storage of up to 36 hours of physiologic and system performance data which can be uploaded to a local or remote host computer. When necessary, this data can also be communicated to the receiving hospital during evacuation for review by physicians to aid in their medical preparations for treatment. This facility provides a new life support capability for transport of marginally stable or unstable patients which integrates with existing NATO evacuation platforms.

List of Symbols

ABP	Arterial Blood Pressure
CO_2	Carbon Dioxide
CVP	Central Venous Pressure
DARPA	Defense Advanced Research Project Agency
ECG	Electrocardiogram
Hb	Hemoglobin
HR	Heart Rate
ICP	Intracranial Pressure
ICU	Intensive Care Unit
IV	Intravenous
LAN	Local Area Network
LSTAT™	Life Support for Trauma and Transport
MTF	Medical Treatment Facility
NIBP	Non-Invasive Blood Pressure
O_2	Oxygen
RR	Respiratory Rate
TV	Tidal Volume
WRAIR	Walter Reed Army Institute of Research

Introduction

Clearing the battlefield quickly and efficiently while providing the patient the best possible care is a priority mission of the US tri-service, military medical community. At the same time, reduction in the size of the medical footprint and enhancement of the mobility of our MTFs is also a high priority. Expedient movement of the critical care patient population would contribute significantly to the attainment of these goals. Although a small fraction of the total casualty population, these patients require a disproportionately large number of man-hours and logistical support in the field.

Current US military evacuation procedures require that a patient be held in a field MTF until ready to return to duty or until stable enough to be evacuated[1]. For the critical patient, this can be several days or more before he can withstand the added stresses of ground or air evacuation with the attendant high ambient noise and vibration, and in the case of rotor-wing air evacuation, low atmospheric pressure conditions. Although there is little reason to believe that the high acoustical noise or vibration are, in themselves, medical hazards, they would, and do, significantly degrade the attendant care-giver's diagnostic and therapeutic capabilities *en route*. Heart and lung sounds are difficult if not impossible to detect above road or aircraft noise and even simple palpation of peripheral pulses can be very challenging in high vibration environments. These conditions create a significant hazard for the patient since a medical crisis

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may escape detection*en route*. The LSTAT™ project was initiated to address this portable critical care transport requirement.

In April of 1993, a meeting of Army researchers and health care providers was convened at DARPA to discuss the concept of a critical care life support platform which was then called the "Trauma Pod". The principle operational objectives were to design and build an *en route* life support capability which was to be compact, man portable and useful throughout the entire evacuation chain. This required it to be compatible with both ground and air evacuation vehicles in all U.S.military services. Operationally it was also to serve as a pre-surgical, intra-operative and post-operative critical care life support capability for field surgical facilities. The design of this facility was to provide a developmental foundation for implementation of emerging new diagnostic and therapeutic technologies.

Operational Objectives:

- Improve field mobility
- Provide evacuation capability for transport of unstable patients for earlier evacuation
- Decrease patient holding requirements by allowing earlier evacuation
- Provide critical care capability throughout all levels of evacuation chain without moving patient
- Enable effective therapeutic intervention during transport
- Over-fly middle echelons of care
- Optimize use of care-giver 's time by automating patient record keeping and therapeutic device adjustments
- Stretch limited resources with "smart" resuscitation algorithms

Guidance from the Army's Directorate of Combat Doctrine and Developments at Ft. Sam Houston, defined the following requirements for a life support transport system.

LSTAT™ Requirements:

Minimal:

- Integral suction and ventilatory capabilities
- "Hands off" defibrillation system
- Integrated parenteral infusion system
- Compatibility with external O_2 delivery systems
- Physiological monitoring (non-invasive & invasive)
- BP, ECG,HR, Core temp, O_2 saturation
- Protection from Biological & Chemical agents
- Battery power support for at least 30 minutes

Optional:

- Self contained environmental control system
- Construct from materials allowing decontamination without removing or harming the patient
- Protection from chemical agent intrusion
- Allow patient treatment without compromising protection from chemical agent intrusion

LSTAT™ Design Principles

- Constrain external dimensions to NATO stretcher envelope
- Adhere to standard NATO attachment points
- Avoid diminishing vehicle patient transport capacity
- Avoid need for vehicle retro-fits
- Accomodate Army/Air Force ground and air evacuation vehicles
- Use servo-controlled automation to leverage care-giver's time (ventilation, O_2, and fluid delivery)
- Accomodate future telemedicine and sensor requirements

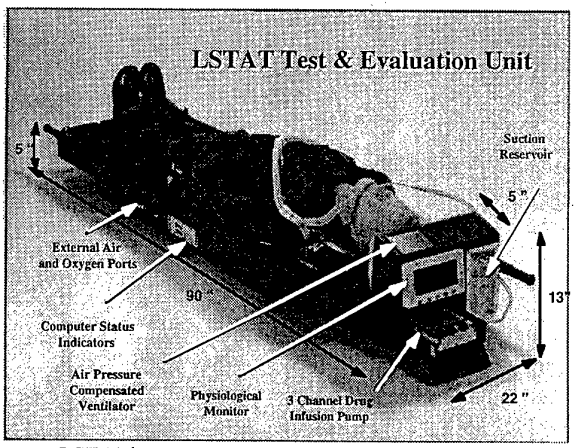


Fig. 1. LSTAT™ Design Test & Evaluation Unit shown here was built by Northrop Grumman Corporation, Pico Rivera, CA. Dimensions are given in inches.

LSTAT™ System Description

Physiologic Monitoring

Cardiovascular

- Non-invasive blood pressure
- 2-invasive pressures (e.g. CVP, ABP, ICP)
- Temperature (e.g. core, skin)
- ECG
- HbO_2 Saturation (pulse oximetry)
- Heart rate

Respiratory

- Airway Flow
- Airway Pressure
- Expired CO_2
- Respiratory rate
- Tidal volume
- Dynamic and static lung compliance

Blood chemistries

- Hand-held blood chemistry analyzer (e.g. blood gases, electrolytes)

Therapeutics

- Air Pressure compensated ventilator with buiilt in compressor
- Automated External Defibrillator
- 3-channel IV drug infusion pump (1L/hr/channel)
- Resuscitation infusion pump (6 L/hr)
- Oxygen cylinder (490L) with oxygen blending
- Continuous and Intermittent Suction

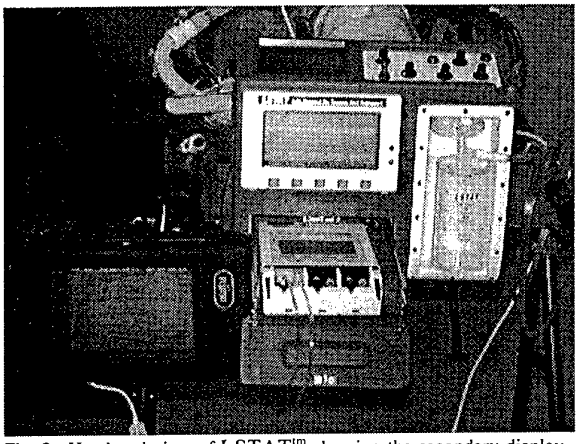


Fig. 2. Head-end view of LSTAT™ showing the secondary display, ventilator display and controls, physiological monitor, 3-channel drug infusion pump and the suction cannister. LSTAT™ is shown here supported on current field litter stands.

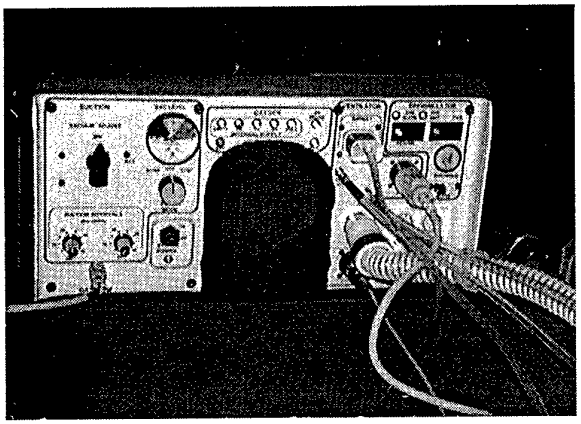


Fig. 3 View of the patient side of head fairing showing (left panel, top to bottom), vacuum gauge , vacuum level adjustment, continuous/intermittent suction mode selection switch, main power switch, intermittent suction duration and interval controls and Ethernet communication port: (center panel) oxygen tank status LEDs; (right panel) automatic external defibrillator power and controls, airway pressure and flow, mainstream carbon dioxide sensor connections, ventilator breathing circuit and expiratory valve connections, ECG, 2 invasive pressure transducers, temperature sensor, NIBP cuff and pulse oximeter connections.

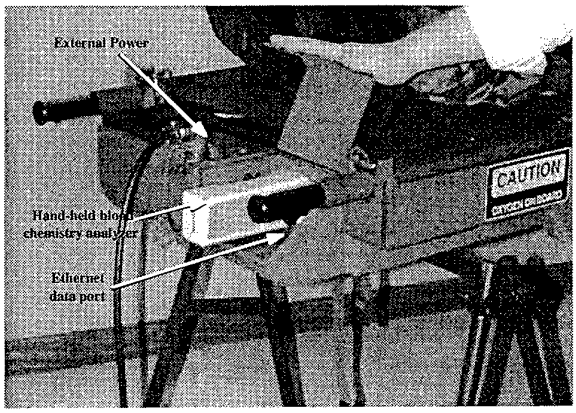


Fig. 4. Foot end of LSTAT™ showing the external power connection, a hand-held biochemistry analyzer and a second Ethernet data communications port. (Not seen is the internal oxygen tank shut off valve, trickle charge selector switch and subsystem fuse bank.)

System Monitoring

3-axis accelerometry
Tilt sensing
Compartment, battery and component temperatures
Barometric Pressure
Humidity
Power utilization power bus voltage
Battery charge level and recharge rate

System parameters are monitored to enable trouble-shooting of environmentally induced system failures and to provide the potential for elimination of data artifacts induced by high vibration or high impact events. Knowledge of the history of the environmental exposure of the units will also allow tailoring of maintenance schedules.

Data Collection, Display and Telemetry

2-Ethernet data communication ports
Secondary touch-screen computer display
Physiologic and Sytem Data logging

The two Ethernet data ports are available to support a secondary display in either a tethered or wireless mode to provide a display alternative in situations where the head end displays are not readily visible. These ports may alsobe used to interface with Ethernet-compatable ambulance radios to allow real time or patient trending data to be forwarded to a receiving hospital where a consulting care-giver can review it and anticipate incoming patient care requirements or can mentor the local care-giver on patient care issues *en route*. These data communication ports allow the LSTAT™ platforms to be networked together or may integrate with existing LANs. The data logging capability automates the patient record keeping task and will yield a comprehensive data collecting capability during *en route* care never before available.

Environmental Isolation

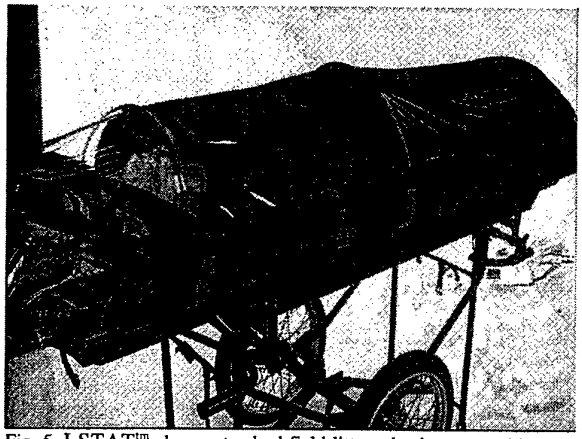


Fig. 5. LSTAT™ shown standard field litter wheel system with canopy deployed for over-pressured environmental protection.

The LSTAT™ has 3 basic components: (i) the base unit, (ii) a NATO stretcher, and (iii) a canopy that covers the entire patient. The LSTAT™ base contains a ventilator, oxygen source, suction, capnograph, environmental control, onboard computer, batteries, and a physiologic monitoring system.

The physiologic monitoring system of the LSTAT™ platform acquires and archives ECG, 2 invasive pressures, pulse oximetry, expired CO_2, airway pressure and flow waveforms. All discrete measured and derived variables such as heart rate, respiratory rate, temperature, NIBP etc. are also logged and available for trending.

The LSTAT™ conforms with all NATO air and ground evacuation vehicles, is adaptable to aircraft, ground vehicle and domestic and foreign power requirements and can be battery powered to run autonomously for up to 1 hours without the environmental control unit and with all subsytems running at 100% duty cycle.

Advance Development Features

Algorithms are being developed to (i) servo control the ventilator based on the arterial oxygen saturation and end tidal CO_2 to properly ventilate a patient and (ii) drive a servo controlled intravenous fluid resuscitation pump based on blood pressure. Closed loop ventilator algorithms using feedback from capnography and pulse oximetry are being developed to provide appropriate ventilation under conditions where trained personnel are not available to properly manage a critically injured soldier. This control system automatically adjusts ventilatory parameters based on input from airway pressure, airway flow, expired carbon dioxide and arterial oxygen saturation sensors. Oxygen delivery into the ventilatory circuit is controlled by the arterial oxygen saturation level which is determined by pulse oximetry methods. This system will conserve the limited oxygen supply while optimizing oxygen delivery to the patient. The utilization of capnography (expired carbon dioxide levels) will facilitate the appropriate setting of ventilatory parameters as well as serving as a validation tool for endotracheal tube placement. Closed loop fluid resuscitation algorithms which couple non-invasive continuous blood pressure measurements to the output of a high volume resuscitation pump have been developed to provide fluid resuscitation aimed at optimizing tissue perfusion while minimizing usage of resuscitation fluid resources. The algorithm has been designed to provide the appropriate volume of fluid in a timely fashion while avoiding over or under fluid resuscitation. The closed loop control of both the fluid and ventilation is an element which is directed at diminishing the adjustment requirements of the care-giver whose capabilities become overwhelmed in mass casualty care and transport situations. This servo-control feature can be over-ridden and controlled manually at any time at the care-giver's discretion.

Conclusion:

The LSTAT™ is a stretcher-based mini-intensive care unit that incorporates resuscitative and life-sustaining capabilities into a universally adaptive platform for trauma management and unattended patient support. It allows the transport of medically unstable patients and fits into existing NATO evacuation platforms. The LSTAT™ has been constructed to provide continuous care from the battlefield through transport to a surgical unit, and on to a fixed facility. With the canopy in place, the LSTAT™ serves as a protected, temperature controlled pre-operative "waiting room" as well as a post-operative intensive care unit.

The LSTAT™ platform not only has military application but also has excellent potential application for critical care in natural disaster settings where access to medical care may be difficult. In addition, the LSTAT™ platform may serve as an ICU hospital bed which would greatly facilitate movement of ICU patients to other hospital areas such as X-ray, or MRI facilities.

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AN INTEGRATED MEDICAL MONITOR FOR AEROMEDICAL USE

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PREFACE

A Canadian Forces requirement exists for a portable, integrated system for monitoring the vital signs of patients in the field, under adverse, unconventional conditions. A short history is included summarizing various projects which have led to the current design. A vital signs monitor (VITSEM) capable of monitoring heart rate, body temperature, blood pressure and blood oxygenation in the field, is described in this report. The versatility of the design is that the hardware has been kept to a minimum and the emphasis of the design has been placed on the software, which can be easily reprogrammed to reflect changing priorities with respect to which signs are to be monitored.

The device has been studied in various scenarios and has performed well. Using laboratory-generated signals and formal test equipment, in controlled environments, excellent results were achieved. The device has been used external to a modified chemical warfare casualty bag, to monitor the heart rate, temperature, and blood pressure of a person in a controlled field trial. A study has just been completed which compares the blood pressure values of many individuals, taken with the VITSEM and a standard mercury sphygmomanometer and stethoscope. The performance of the device has also been evaluated successfully in a cold chamber set to -20°C. In a role more common to an aeromedical scenario, a helicopter used in casualty evacuation has been identified as a worst case condition for exposure of the device to ambient noise. Preliminary trials have been successful in monitoring the heart rate, body temperature and blood pressure in this scenario also.

In conclusion, a VITSEM 200 has been made available for a brief demonstration. A volunteer's heart rate, body temperature, blood pressure and blood oxygenation will be monitored towards the end of the presentation, and meeting participants will be invited to view the monitor up close.

ABSTRACT

As early as 1973, the Canadian Forces Medical System realized that medical monitoring of a casualty in the field, in the presence of an NBC threat, is very difficult. More recently, during the Gulf War, this deficiency was again addressed. A Canadian Forces (CF) requirement was written for a portable, integrated system for monitoring the vital signs of patients in the field, under adverse, unconventional conditions. Design considerations of such a device included that it be rugged, battery operated, easy to use, and yet be accurate enough to be useful as a monitoring tool. A project began, within the Canadian research and development branch, to identify existing technologies, to perform a feasibility study of developing the technology internally, and then to develop a vital signs monitor, if economical to do so. A CF version of a vital signs monitor was developed, and the technology was transferred to industry.

The device, VITSEM 200 produced by CME Telemetrix, is described, and available for demonstration. The VITSEM 200 can be used to monitor heart rate, body temperature, and blood oximetry continuously, and blood pressure when required. It measures 14.7 x 9.3 x 5.4 cm and weighs approximately 390 g. A version of the device (less the blood oximetry capability) has been evaluated successfully in a simulated NBC environment, and in a helicopter - deemed to be two of the most demanding adverse scenarios.

The VITSEM 200 is currently being acquired by the Department of National Defence in sufficient quantities for user evaluations. If the user evaluations are successful, it is anticipated that the VITSEM 200 will become a new and valuable tool within all the medical elements of the CF.

SUBJECT MATTER KEYWORDS

Vital signs, monitor, portable, heart rate, body temperature, blood pressure, blood oximetry, and trials.

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1.0 INTRODUCTION

As early as 1973, as a consequence of a large Canadian medical field trial, it was found that performing triage on patients wearing protective ensembles was very difficult. Obtaining vital information, such as pulse rate and blood pressure, using standard issue instruments, could not be done without creating breaches in the casualty's protection. As a result of this capability deficiency, several devices have been developed [1,2,3] which monitor the heart rate of casualties in adverse environments, such as within casualty bags, without breaching the casualty's protection. Since one of the early design criteria was to measure signs without first compromising the casualty's protection, the first heart rate monitors (HRM) employed microphones to pick up and filter heart sounds through multi-layers of clothing. Concurrently, a blood pressure clamp (sphygmoclamp) was developed [4], which could adapt the cuff of any existing blood pressure monitoring device to an arm, from the outside of a casualty bag. Using the electronic stethoscope capability built into the HRM, also from outside the protection, blood pressures (auscultation method) were measured. This did, however, necessitate the use of three devices (blood pressure monitor, HRM, and sphygmoclamp) to measure one vital sign. Ultimately, because the reliability of the heart rate readings of the HRM was lower than anticipated, it was not accepted.

It was not until the outbreak of hostilities in the Persian Gulf that the requirement for vital signs monitoring was reviewed. As a result, several compromises were made to the existing philosophy of monitoring vital signs. The two most important changes were, that the essential vital signs to be monitored were heart rate and body temperature (as opposed to heart rate and blood pressure), and that skin contact was allowed. The latter condition came from an extension from a current stated philosophy. The philosophy states that "injured personnel in a chemical warfare (CW) environment, require decontamination, treatment, protection from further contamination, and external monitoring of their vital signs in a casualty bag and/or inside a helicopter". Decontamination infers clothing removal, and presents an opportunity for the placement of medical transducers.

The vital signs monitor to this point has been driven by an NBC requirement. Most devices that exist in the market today would have to be modified in some respect in order to make them compatible with special Canadian Forces clothing and equipment. Because the possibility of medical monitoring integration with several current and near future projects exists, where modifications and redevelopment may be required frequently, a feasibility study was launched to determine the possibility of in-house vital signs monitor development. It was determined that the in-house development of a device for monitoring heart rate, body temperature and blood pressure, reliably and continuously, was feasible [5,6,7]. More recently, the Canadian Air Force has become aware of this project, and has suggested that if this device were to also monitor pulse oximetry, that such a device would also meet an Air Force aeromedical requirement. This paper describes the final development of a portable microcontroller-based vital signs monitor (VITSEM) for monitoring blood pressure as required, integrated with the capability of monitoring heart rate, body temperature and pulse oximetry, continuously on casualties, even within a casualty bag in a helicopter.

2.0 DESIGN CRITERIA

During the development of the vital signs monitor, the following general factors were considered as design guidelines:

a. rugged construction yet compact and light;
b. long shelf life (minimum 10 years);
c. be used by a medical assistant without extended training periods;
d. must fit all male/female adults and be as non-invasive as practical;
e. powered by batteries with an endurance of at least twelve hours;
f. alarm functions must be audible (capable of being switched off), visual, and power loss sensitive;
g. monitored parameters should be displayed digitally and be readable in dark or other adverse conditions;
h. the power source must be isolated, eliminating the possibility of injuring the patient;
j. employ reliable components;
k. since this device will have wide application, many units will be required, therefore cost must be as low as possible; and
m. environmental operating parameters consist of the following:
    i. storage and operating temperature range -40°C to +50°C,
    ii. humidity operating range 0-95% R.H.,
    iii. not effected by electromagnetic forces normally associated with aircraft or other machinery,
    iv. stable in pressure reductions of up to 10,000 ft (523 mm Hg),
    v. water resistant (waterproof desirable),
    vi. unaffected by the usual chemicals and toxins that could be used in CB warfare, and
    vii. the operation or connections of the monitor must not compromise the protection of a patient in a chemical and/or biological environment.

The vital signs monitor must be capable of measuring heart rates, body temperatures, blood pressure and pulse oximetry. Heart rates should range from 15-240 $\pm$ 1 BPM (beats/minute).

Alarms are required, and should be adjustable. Averaged heart rate values are preferred in order to assess trends better. The body temperature will not change rapidly, and thus, an instantaneous display is sufficient. The range to be measured is from 25-40 ± 0.2 °C. Temperature alarm settings should also be adjustable. In the event of transporting a hypothermic patient, it must be possible to reset the alarm, or turn it off. The range of blood pressures to be measured with the device should be 50-200 mm Hg, and the values, once acquired, should be displayed such that both systolic and diastolic pressures could be read simultaneously. Audible and visual alarms for blood pressures are not required. Pulse oximetry is required to monitor blood oxygenation levels of from 0 to 100% (± 2% from 70-100%), with an alarm when measured levels are too low. If possible, the design of the device should also be flexible enough to adapt to changing priorities, i.e. be modified easily to measure other vital signs as deemed necessary in future scenarios.

3.0 DESCRIPTION OF THE HARDWARE

3.1 General

Because the vital signs monitor required by the CF should be capable of monitoring various vital signs (currently heart rate, body temperature, blood pressure, and pulse oximetry), a programmable and expandable monitoring device which can be reprogrammed to meet changing medical requirements as required, is implied. This philosophy and many of the design targets lend themselves to a microcontroller technology to meet the objectives of this project. The programmability of the microcontroller not only allows for future expansion and/or modification of the capabilities of the device, but also drastically reduces the total component count, maintaining a portable and robust design. The microcontroller acquires and analyses the sensor signals, formats the measurements for the display, activates various alarms and performs various calibrations and diagnostic tests. The display receives the formatted data from the microcontroller and provides a readout of the vital signs and other information as required. The display currently being used is 16 characters wide by 2 lines (enough space to display SaO_2 saturation, pulse rate, heart rate, body temperature, systolic and diastolic pressures, simultaneously), and is backlit on demand.

3.2 Heart Rate and Body Temperature Measurement

To monitor heart rate accurately, reliably, and simply, measurement and conversion of ECG-like R-R wave intervals was chosen. Access to the bare chest during decontamination would provide the opportunity for attaching two ECG electrodes (HP adult disposable electrodes model 14445A) above and below the heart. R-waves are converted to pulses and presented to the microcontroller, which converts the pulse train to a heart rate.

To monitor body temperature, measurement and conversion of the output of a rectal thermometer, or thermister (Yellow Springs Instrument Co. Inc. Model 401 91A7207, or Baxter Healthcare Corp. 400 Series Rectal/Esophageal Probe) was chosen as the simplest (most reliable) and most commonly accepted method. Such a transducer could also be appropriately positioned during decontamination. A microcontroller-controlled switch applies current to the thermister only when a reading is taken, eliminating the possibility of self-heating. The voltage across the thermister is measured, and the resistance-temperature relationship of the thermister is used to calculate the temperature.

3.3 Blood Pressure Measurement

The oscillographic method of obtaining blood pressure was chosen, because it yields the most accurate determination of arterial pressures, is already widely used and accepted, is simple in design by using the cuff as the only transducer, and has the advantage of being adapted to various non-standard locations on the body. Compared with the method described in the introduction (Sphygmoclamp, etc.), using oscillography reduces the number of devices required for taking the blood pressure from three to one.

When considering the means of inflating and deflating the cuff, the semi-automatic method was selected over the automatic or manual methods. The semi-automatic method requires the operator to inflate the cuff manually, eliminating the need for a power-hungry, noisy, and expensive pump (automatic method). The pre-set pressure relief valve allows the cuff to deflate automatically, at a uniform, generally accepted rate (~ 2-4 mmHg/second). During the deflation phase, cuff pressure measurements are made. This valve overcomes the subjectivity of the bleed rate inherent in the manual method.

Basic signal conditioning was used to convert the raw output of a pressure transducer connected to the cuff, into signals compatible with the microcontroller.

3.4 Blood Oximetry

The hardware for the blood oximetry portion of the vital signs monitor is a circuit supplied by the manufacturer of the blood oximetry capability (OEM from NONIN). The fingertip sensor is attached to an extension of the circuit board, the output of which is fed directly to the micrcontroller.

3.5 Packaging and Power Supply

The vital signs monitor (VITSEM), Figure 1, measures 14.7 x 9.3 x 5.4 cm, weighs approximately 400 g, and is packaged in ABS (acrylonitrile butadiene styrene) plastic i.e. exhibits high impact strength and flame retardency. The upper and lower halves are separated by a recessed polyurethane gasket for water and dust protection. The display is located on the face of the case, along with three push-button switches (on/off, reset/backlight and set alarms) and one indicator light (red = alarm). All the components on the face are sealed via a plastic mask, which also indicates, via units of measure, where each of the vital signs are displayed. Water resistant connectors are located on the upper long side of the case. The two lead connector is for the ECG electrodes, the mini-plug connector is for the rectal probe, the hose connector is for one end of the blood pressure cuff, and the 9-pin connector is for the blood oximetry sensor.

The electronics inside the case are all powered by three 'AA' sized batteries. The size and number were determined by the requirement of 12 hours continuous use, with intermittent display backlighting. When the device is first turned on, the display is lit for approximately 1 min, the battery condition is displayed, and then the backlighting automatically turns off. After this time, backlighting is achieved by pressing the reset switch. This was done in an effort to conserve power.

4.0 DESCRIPTION OF THE SOFTWARE

4.1 General

The software for measuring and displaying heart rate and body temperature [5] was developed separately from that measuring blood pressure [6] and later combined [7]. The current VITSEM combined that program with new code which determines blood oxygenation, such that all four signs could be measured and displayed simultaneously.

4.2 Heart Rate and Body Temperature Software Development

The microcontroller receives a pulse for every heart beat sensed by the conditioning circuit. This fact was used to write a program that calculates the time between each pulse and converts this value into a heart rate. The general method selected to determine the heart rate was to average the duration of 6 pulses and then determine how many pulses would be received in one minute. An additional program was then developed to acquire the thermister voltage and convert it into a temperature.

4.3 Blood Pressure Software Development

As the cuff pressure decreases from a suprasystolic to a subdiastolic pressure, pulses of increasing, then decreasing amplitude are superimposed on the decreasing cuff pressure signal. The pressure where the greatest increase in pulse amplitude occurs corresponds to the systolic pressure, and the pressure where the greatest decrease in pulse amplitude occurs (after the maximum oscillations) is the diastolic pressure [8]. The mean arterial pressure corresponds to the lowest cuff pressure at which the maximum oscillations occur. A software method of digitally sampling pressure pulses, using a two dimensional filter for determining pulse validity, and establishing systolic and diastolic blood pressure via a 7-point averaging technique, was developed and is considered unique.

4.4 Blood Oximetry

The relationship between the output voltage of the printed circuit board and the percent blood oxygenation was given by the manufacturer (NONIN), and additional code was added to the microcontroller to measure and interpret this signal at appropriate intervals, and display the results.

5.0 TRIALS

5.1 General

It would be useful at this point to describe two different models of the vital signs monitors, used in the following trials. Although this paper describes the production version (model 2) of the vital signs monitor, some test results are reported for the development model. Model 1 is defined as the development model, which measures heart rate, body temperature, and blood pressure. Model 2 is defined as a production model, which measures heart rate, body temperature, blood pressure, and pulse oximetry. The two models contain essentially the same program for the vital signs common to both, with minor differences relating to the fact that the two models contain different micrcontrollers.

5.2 Laboratory Trials of Model 1

During the development of the vital signs monitor, many tests were done on the device at various stages of its development to confirm proper function. These have been reported previously [5,6,7] and are not repeated here.

5.3 Helicopter Trials of Model 1

In the final stages of the development of the blood pressure monitoring capability, it was decided to evaluate the performance of Model 1 aboard a CF twin Huey helicopter. Three sorties were flown, each of approximately one hour duration, where heart rates, body temperatures and blood pressures were measured on the ground with rotor spinning, hovering, and in flight simulating a casualty evacuation.

5.4 Other Trials of Model 1

On 6 October 1995, five vital signs monitors were tested on five simulated casualties, at four different stages of a casualty evacuation at a training base (CFB Borden). ECG electrodes were attached, a temperature probe was placed under the axilla, and a blood pressure cuff was wrapped around the arm immediately following clothing removal, before entering collective protection. Measurements were made after the sensors were applied, then again inside the collective protector, then outside the collective protector in a modified casualty bag, and finally inside a wheeled ambulance as it drove around in a circle across country.

In the spring of 1996, six units were taken into a temperature controlled room, set to -20°C. Blood pressures were taken of one individual, once with each device. This procedure was repeated 1, 6, and 12 h later.

5.5 Laboratory Trials of Model 2

The pulse rate was verified using a DNI Nevada Inc. 214B ECG simulator. Pulses from 30 to 240 beats per minute were generated on the simulator, and measured by the VITSEM 200.

The temperature of a water bath was measured by a Fluke 52 and by three random VITSEM 200 units. Since the relationship between the resistance of a YSI 400 series temperature probe and temperature is known, various resistors were used to replace the YSI 400 temperature probe during another series of tests, to determine how accurately the VITSEM calculated the conversions.

The pulse oximeter is an OEM (original equipment manufacturer) module with 510k approval. To verify that the pulse oximeter functions properly with the VITSEM 200, a phantom finger oximeter testing system supplied by the manufacturer, was used.

The blood pressure was measured using a Pro Med NIBP simulator. The simulator was not used to calibrate VITSEM 200 monitors, however, it was used to approximate valid readings. The NIBP simulator was also used to verify the blood pressure portion of each instrument because it was able to reproduce its output signal repeatedly. At each simulator setting, each of three VITSEM units took three readings, and the results were averaged.

5.6 Other Trials of Model 2

Seventy-seven individuals (fifty-eight males and nineteen females) aged 37 ± 10.3 yr., 175 ± 8.3 cm tall, weighing 79 ± 14.5 kg, with a resting pulse rate of 70 ± 11.6 bpm, and having an arm circumference of 30 ± 3.4 cm, had their blood pressures measured from one to three times with the VITSEM 200, and compared that value with one measured using an apparatus using the standard auscultation method The total number of measurements taken with each method was 280; 140 systolic measurements and 140 diastolic measurements.

The Model 2 version of the vital signs monitor was also tested in a cold chamber at -20°C. The unit was placed into the room with the leads hanging out of the room through a hole in the wall. Pulse oximetry and body temperature were measured once the monitor was in its place, and then repeated at 1, 6, and 24 h.

6.0 RESULTS AND DISCUSSION

Throughout this development stage, constant attention was focused on maintaining a low component count to lend ruggedness and compactness to the design. Readily available, high precision components were chosen for ease of maintenance and resupply, and low cost. Low power consumption, long shelf life, and environmental (temperature, humidity, pressure) operating characteristics, were also considered in component and design selection. The resultant device is described above.

The goals with respect to measurement ranges of the vital signs of interest have been met or exceeded. Heart rates of 15 to 240 BPM, temperatures of 25 to 40°C, and pulse oximetry of 0 to 100% have been met, and the blood pressure requirement of 50 to 200 mmHg has been exceeded i.e. 16 to 255 mmHg.

During the helicopter trials of model 1, it was discovered that the heart rate and body temperatures were acquired and displayed without any problems. The determination of blood pressure, however, proved to be very difficult because of the high interference of the low frequency vibrations in the cockpit. Proper filtering was not achieved until the third sortie, when digital signal processing and filtering was invoked. Sharper filter frequency cut-offs resulted in more reliable blood pressure readings. Ten blood pressure determinations were attempted, and readings in the expected range were determined on 8 out of 10 tries.

In order to meet the requirement of being able to take measurements of a casualty within a casualty bag without causing any potential breach of the casualty's protection, a modification to the casualty bag was developed. The bag was modified with the addition of an interface between the casualty and monitor, at about the waist area of the bag, towards the zipper/Velcro side. This would allow for easy hook-up of sensors and cables to the internal portion of the interface before closing the bag. The casualty bag modification has been tested on one individual in the lab, and no problems were encountered. Field trials were conducted at CFB Borden with model 1, to evaluate the vital signs monitor and the modifications to the casualty bag. Problems were encountered reading blood pressures in moving ambulances. During the debriefing of trial participants, it was discovered that the units had been supplied with manual deflating valves, and all agreed that deflation rates chosen in a moving ambulance were always too high. This would reduce the number of pressure pulses used to determine the blood pressures and many more errors would be the result. It was believed that had auto deflating valves been used, the erroneous readings would have been reduced. Alarms are both audible and visible and it was suggested that the audible alarm should shut off after a set period. The authors even now are not sure whether this is bad or good. The request for easier access to batteries has been remedied in the model 2 version of the device..

The cold room trials of the model 1 version of the vital signs monitors, resulted in no surprises. All monitors worked at -20°C for 12 h, however, the performance of the displays was very sluggish, and have been improved in the model 2 version. Some minor difficulties were encountered with the switches and connectors at the lower temperatures, and some product improvement has also been done on these components to reduce cold weather sluggishness.

Various lab tests were performed on the VITSEM (model 2) to confirm its reliability and accuracy. Results of the tests heart rate are shown in Table 1. Except for the rates of 199 bpm acquired when a rate of 200 bpm was presented, all readings of heart rate were exact.

Pulse Rate	Unit 1 0159	Unit 2 0192	Unit 3 0198
30	30	30	30
60	60	60	60
80	80	80	80
100	100	100	100
120	120	120	120
140	140	140	140
160	160	160	160
180	180	180	180
200	199	199	199
220	220	220	220
240	240	240	240

Table 1: ECG generator compared to VITSEM 200 results.

Two tests were done to validate the temperature measuring portion of the device. The first simply used the VITSEM to measure the temperature of water, and compare the readings to an accurate, calibrated temperature measuring device. Those results are shown in Table 2. High precision resistors were also placed across the temperature sensing inputs, to simulate a known temperature. Those results are shown in Table 3. Both tables 2 and 3 indicate that the temperatures measured with the VITSEM are consistently within 0.2°C of other precision instruments.

Temperature Fluke	Unit 1 0159	Unit 2 0192	Unit 3 0198
33.0°C	33.1°C	33.1°C	33.2°C
37.6°C	37.8°C	37.8°C	37.8°C
39.6°C	39.8°C	39.8°C	39.7°C
40.6°C	40.8°C	40.7°C	40.8°C

Table 2: Temperature of water measured by a Fluke 52 and VITSEM 200

Temperature by Resistance	Unit 1 0159	Unit 2 0192	Unit 3 0198
30.0 °C	30.0 °C	30.0 °C	30.0 °C
33.0 °C	33.0 °C	33.0 °C	33.0 °C
35.0 °C	35.0 °C	35.0 °C	35.0 °C
37.0 °C	37.0 °C	36.9 °C	37.0 °C
37.95 °C	38.0 °C	37.9°C	38.0 °C
39.9 °C	40.0 °C	39.9 °C	40 °C
42.0 °C	42.0 °C	42.0 °C	42.0 °C

Table 3: Probe resistance compared to temperature displayed.

A phantom finger was used to test the pulse oximetry portion of the VITSEM. Three blood oxygenation levels were measured with the three different VITSEMs, and reported in Table 4. Within the range of 80 - 97%, the three units were always within 2%.

Finger Phantom	Unit 1 SN 0159	Unit 2 SN 0192	Unit 3 SN 0192
97 % SpO2	98 % SpO2	97 % SpO2	98 % SpO2
90 % SpO2	92 % SpO2	89 % SpO2	91 % SpO2
80 % SpO2	79 % SpO2	78 % SpO2	82 % SpO2

Table 4: Finger Phantom SpO2 values found by VITSEM 200

The VITSEM was also tested with a blood pressure simulator to confirm its ability to consistently and reliably measure various systoles and diastoles. The results are shown in Table 5. Although the VITSEM clearly shows when a blood pressure is high or low, and is consistently within 9 mmHg when measuring systole, and within 7 mmHg when measuring diastole, the readings can vary by as much as 20% at the lower values.

NIBP output Hart rate 80 bpm	Unit 1 0159 Mean of 3 samples.	Unit 2 0192 Mean of 3 samples.	Unit 3 0198 Mean of 3 samples.
60 / 30	64 / 36	64 / 34	66 / 37
80 / 50	86 / 56	83 / 54	86 / 56
100 / 65	105 / 70	100 / 68	104 / 69
120 / 80	127 / 86	125 / 86	129 / 85
150 / 100	158 / 105	153 / 106	152 / 107
200 / 150	195 / 154	193 / 153	194 / 153

Table 5: Blood Pressure simulator output compared to VITSEM 200 results.

Seventy-seven people (58 males and 19 females) had their blood pressures taken with the VITSEM 200 and a sphygmomanometer (ausculatation method). These tests were done at two establishments. For consistency in each establishment, the standard auscultation method was performed by the same person at that establishment. Some persons were measured once, and others were measured 3 times. A total of 280 comparisons were made, 140 systolic and 140 diastolic. When comparing systolic readings, the average difference was -0.15 ± 8.08 mmHg (the minimum difference was -22 mmHg, and the maximum difference was 25 mmHg), and the average difference of diastolic readings was 0.35 ± 6.67 mmHg (minimum difference of -20 mmHg, and maximum difference of 16 mmHg). During the course of these measurements, the VITSEM gave an error reading on 23 occasions. Approximately half of those readings were on personnel with larger than typical arms. It is believed that some, possibly half, of the erroneous readings may have been avoided with a larger sized cuff.

The VITSEM was placed in a cold room set to -20°C. Temperature and pulse oximetry sensors were connected to the unit, and the display was read every 0.5 h. The unit functioned properly at 3.5 h, but not at 4.0 h. The display on the VITSEM 200 is larger than the development model, but in spite of the larger characters, was still faint and difficult to read after about 1 h. It is believed, that by going to 'AA' sized batteries from the 'C' sized batteries in the development unit, is the main contributor to the reduced operating times within the cold.

7.0 CONCLUSIONS AND RECOMMENDATIONS

A vital signs monitor capable of monitoring heart rate, body temperature, blood pressure, and pulse oximetry in the field under adverse, unconventional conditions, is described. The design, minimising hardware and emphasising software, has taken into account the need for future change or expansion (most of the work done with software) and to easily adapt to the changing needs of the medical services. The device works well in response to laboratory-generated signals, and is producing good results with measurements in the field. In the case of blood pressure measurements, a clinical trial which would compare the measurements against an approved direct method, is required to establish the reliability of the blood pressure algorithm in hypo- and hypertensive patients..

Several noisy environments in which this device might be used, have been identified, e.g. helicopters and ambulances used in casualty evacuation. Thus far, problems have been encountered in taking blood pressure readings in these noisy environments, but when some care is taken during the procedure, readings were acquired more often than not.

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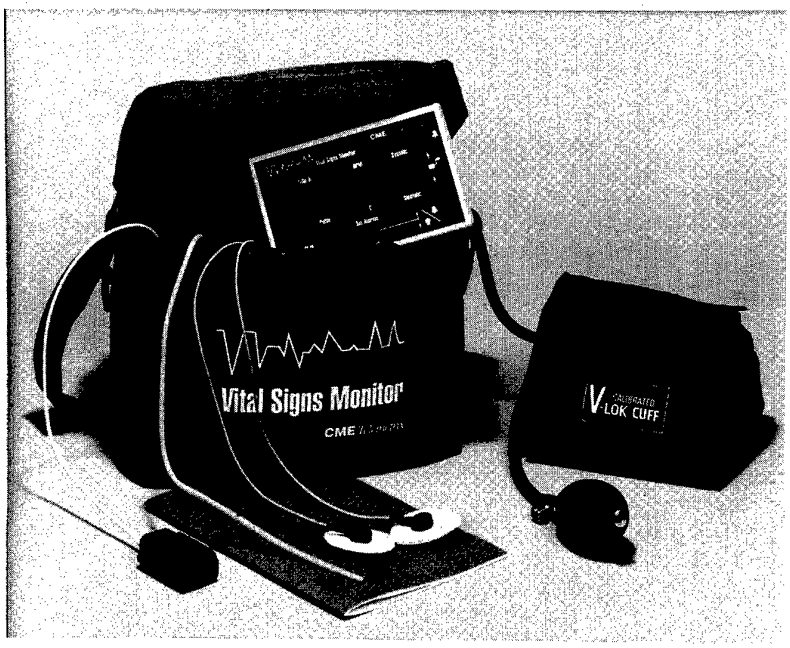
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Figure 1. A photograph of the VITSEM 200, including all its peripherals.



SPINAL CORD INJURY TRANSPORT SYSTEM

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SUMMARY

The United States Air Force Air Mobility Command (AMC) is tasked to provide the aeromedical evacuation of casualties in routine and contingency operations. To carry out this mission, AMC needs a medical support system suitable for transporting patients with spinal cord injuries and all types of extremity and cervical traction requirements. This piece of equipment would be a Spinal Cord Injury Transport System (SCITS). The current method for transporting these patients is on the Stryker Turning Frame with a Collins Traction Device, for cervical traction. The system has been in use for over 20 years and is no longer logistically supported and must be replaced. The replacement system should provide a quality of care comparable to that available in fixed (ground) medical treatment facilities; i.e., a system that provides traction and kinetic therapy through incremental side-to-side rotation. Although SCITS will primarily be used for the previously mentioned patients, it would be beneficial and used for a variety of other patient conditions such as multiple trauma, burns, chest wounds, pulmonary complications, and post operative, depending on availability.

NEW PROGRAM

In 1992, AMC Surgeon General drafted a mission need statement to respond to a medical deficiency noted in the transport of spinal cord injury and trauma patients. AMC directed the Human Systems Center to develop a replacement system for the Stryker turning frame which is no longer is logistically supported. A formal acquisition program was developed at the Human Systems Program Office (SPO). SCITS is a joint service patient movement item and the SPO works closely with the Defense Medical Standardization Board. The SCITS integrated product team is dedicated to developing an improved spinal cord injury and trauma transport system that provides quality care comparable to that available in medical facilities.

CURRENT STANDARD OF CARE

The Stryker turning frame has been the method of choice for transport of spinal cord injury patients. We are able to position the patient either prone or supine, very limited and uncomfortable for the patient. The Collins traction device provides the patient with cervical traction in two pound increments up to sixty pounds. The Stryker Turning Frame is no longer manufactured, replacement parts must be custom manufactured, are costly, and require a long lead time to procure. The Collins traction Device is also no longer manufactured, spare parts for the device are not available from any source. Consequently we need a new piece of equipment to move the patient as soon after injury as possible.

SPINAL CORD INJURY TRANSPORT SYSTEM (SCITS)

The SCITS will provide a mechanism for safe movement of the spinal cord injury patients, from time of injury to final destination hospital via aeromedical airlift. The system performance capabilities required of the SCITS include the following:

a. Support Surface: firm, padded surface, rigid enough to allow administration of cardiopulmonary resuscitation, and shall have adjustable restraint devices that minimize patient movement during transport and side-to-side rotation.
b. Side-to-Side Rotation: shall provide incremental, side-to-side surface rotation, that is effective in preventing pulmonary, cardiovascular and skin breakdown complications.

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c. Trendelenburg/Reverse Trendelenburg: shall provide the capability to elevate and lower the patient's head or feet 15 degrees
d. Integrated Traction: shall be designed to maintain constant force traction while the surface rotates side-to-side, with the amount of traction in 5 pound increments from 0-65 pounds. Cervical, upper and lower extremity traction shall be provided and will be acceleration independent.
e. Accessibility to Patient: medical personnel shall have the capability to easily perform routine and emergency nursing care. The surface shall provide access to the occipital, thoracic, and rectal areas to perform patient care without removing the patient from the surface or compromising the stability and alignment of the spine.
f. Radiolucent Surface: shall be designed to allow X-rays to be taken of the entire vertebral column, chest, and lower abdomen of the patient without removing them from the surface.
g. Integration into Aircraft/Vehicles: shall fit into Air Force and Army aeromedical evacuation aircraft. Shall also fit into both Department of Defense and civilian rear loading ambulances and ambuses.
h. Accessories: shall provide accessories capable of being stored within the SCITS, that are necessary to prevent foot drop, relieve pressure on the brachial nerve plexus and ulnar nerve at the elbow, that accommodate a standard orthopedic plastic bed pan, urinary drainage tube, chest drainage tube and an intravenous pole.
i. Federal Aviation Administration (FAA): Certification shall conform to FAA safety regulations for carry-on medical devices.
j. Food and Drug Administration (FDA) Approval: shall be certified to comply with the requirements on the FDA for medical devices.
k. Human Factors (user friendly): shall be ergonomically designed to assist aeromedical crews in the treatment and transportation of spinal cord injury and multiple trauma patients.

ROUTINE AND CONTINGENCY OPERATIONS

The SCITS will serve as a forward deployed patient movement item for use during routine medical situations and in contingency operations. SCITS employment in routine aeromedical evacuation operations, would be to transport military members with unstable spinal injuries to facilities capable of providing the required treatment. In this scenario, the patient would be placed on SCITS in a controlled hospital environment. Traction would be incorporated as the patient is placed on the SCITS and would remain in place until the patient reached their final destination and definitive treatment such as spinal fusion can be accomplished. This transport phase will be relatively quick.

During a contingency the idea is for safe transport of the spinal cord injury patient from the Combat Zone to the Communication Zone and on to the continental United States. The patient would be placed on the SCITS in the austere environment of the field hospital in the third echelon. The patient can then expect to move from one echelon of care to another by ground or air transportation, and may take up to 15 days to reach the final destination medical treatment facility. SCITS must be able to accommodate the patient transport periods established by the movement protocols. Due to the requirement to employ SCITS in the field environment it should be understood that any transport of the SCITS will involve a combination of rolling and lifting to move the unit and patient from a treatment area to ground transportation, and then ground transportation from the treatment facility to the landing zone or flight line where the patient is again lifted and carried on the SCITS to the aircraft and secured in a litter stanchion to prevent inflight movement of the unit. Throughout movement phases - traction, lateral rotation, and Trendelenburg/Reverse Trendelenburg capabilities will be required.

CONCLUSION

The development of a Spinal Cord Injury Transport System will do much to improve the medical treatment provided injured personnel during aeromedical evacuation.

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ADVANCED HYBRID OXYGEN SYSTEM-MEDICAL

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SUMMARY
In 1993, a human system need request was submitted by Air Mobility Command to the Human Systems Center Plans and Program Office. This document tasked the aeromedical systems division to determine the feasibility of a hybrid oxygen system that could support the flight crew, patients and passengers on board an aircraft. What is currently available for flight crew is a variety of oxygen systems. There are liquid oxygen (LOX) systems, gaseous oxygen and onboard oxygen generating systems. The Patient Therapeutic LOX system is currently used for the patient therapeutic oxygen and passenger supplemental oxygen onboard some aeromedical evacuation aircraft. The limitations of existing onboard oxygen generating systems are they are not capable of generating or storing sufficient oxygen to meet patient and passenger needs.

REAL LIFE
During past deployments to such areas as Somalia, a resources problem had developed with regard to obtaining liquid oxygen for the Portable Therapeutic LOX (PT LOX). The PT LOX had to be flown about 1200 miles to be filled and then returned for operational use. The AHOS-M is a much needed device which will avoid future LOX supply problems and ensure a supply of medical grade oxygen which will be generated at the site.

PORTABLE THERAPEUTIC LOX (PT LOX)
The PT LOX is utilized in the field medical treatment environments and on some aeromedical evacuation aircraft. This equipment has become a logistical nightmare. It requires frequent maintenance, because the current PT LOX Dewars, vents liquid oxygen at a rate of approximately one liter per day and as a result requires frequent refilling even if it isn't used. The hazards of storing and maintaining the appropriate liquid for the gas and pressure in the unit have become very labor intensive for the field maintainers to service. The constant filling and scarcity of liquid oxygen source in deployed locations makes the unit very difficult to logistically support. Additionally, the PT LOX units are shipped as opportunity cargo, not given dedicated missions and therefore are at the mercy of scheduled cargo missions or as additional cargo on aeromedical evacuation missions.

ADVANCED HYBRID OXYGEN SYSTEM-MEDICAL (AHOS-M)
The AHOS-M will provide both ground and aeromedical operations with a portable unit, that is capable of generating medical grade oxygen on demand. There is an initial time of ten minutes for the AHOS-M to generate gaseous oxygen, and then an additional thirty minutes to generate LOX. AHOS-M will provide greater flexibility in supporting world wide contingencies and Operations Other Than War. It will decrease the logistic support requirement by being self contained, not dependent on liquid oxygen carts or plants for aeromedical evacuation aircraft and ground medical treatment facilities.

AHOS-M is a two part electrically powered system; the Molecular Sieve Oxygen Generating System side generates gaseous oxygen using, as the name implies, a molecular sieve system. The cryogenics side takes the gaseous oxygen and cools it to liquid oxygen using state of the art cryogenic technology. The system stores that oxygen in two 10 liter LOX Dewars, for a total of 20 liters of liquid oxygen. Each liter of LOX is equivalent to 860 liters of gaseous oxygen. It is because of this large volume reduction, we store the oxygen as a liquid. AHOS-M will generate 33 liters per minute (lpm) of gaseous oxygen, peak usage can be as high as 125 lpm if the Dewars are full. The purity of the oxygen generated is a minimum 99.0%.

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AHOS-M is currently in the lab attempting to resolve the following issues:

a. too big, 27 cubic feet
b. too heavy, weighs 500 pounds
c. requires more power than most aircraft can supply, 3 phase 220 VAC

To be fielded the AHOS-M needs to be less than 20 cubic feet, weigh less than 400 pounds and have an electrical power requirement of less than 220 VAC, 400HZ, 34 amps.

CONCLUSION

AHOS-M will provide therapeutic grade oxygen generation for aeromedical evacuation and ground medical operations. It increases the oxygen delivery and storage capacity, improves reliability and maintainability. The existence of AHOS-M will ensure medical grade oxygen is available whenever the need arises at field locations or in the air without having to rely on long supply tails.

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Technology Transition Plan for Advanced Hybrid Oxygen System-Medical, PE 63231F, Oxygen Systems, Armstrong Laboratory, 29 Jul 96.

MECHANICAL VENTILATOR PERFORMANCE DURING AEROMEDICAL EVACUATION

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SUMMARY

Current United States military medical planning calls for a decreased medical presence in areas of conflict with increased reliance on patient movements out of theater for more definitive medical and surgical care. As a result, the aeromedical evacuation system will be moving patients with critical conditions and injuries faster and further than during past contingencies. This will include the movement of an increasing number of patients requiring mechanical ventilatory support. Advances in ventilator technology have led to the introduction of smaller and more capable transport ventilators. Some of these ventilators use built in air compression devices which remove the necessity of carrying an external compressor. In addition, manufacturers have incorporated newer modes of ventilation to improve patient tolerance of mechanical ventilation and provide the user with more flexibility in patient management. We report the evaluation results of two relatively new transport ventilators for use during aeromedical evacuation. We also review available information on other ventilators which have been used for air transport of the critically ill or injured patient.

LIST OF SYMBOLS

F_iO_2	fraction of inspired oxygen
I:E ratio	inspiratory to expiratory ratio
MV	minute ventilation
P_{aw}	peak inspiratory airway pressure
P_{BA}	barometric pressure
TV	tidal volume
V_{max}	peak inspiratory flow

INTRODUCTION

With the evolving world environment faced by NATO members as we move through the 1990's, some changes in medical doctrine are beginning to appear. Lt Col Hawley, RAMC, recently outlined the requirements for providing medical support to the modern battlefield as the British Army moves away from "an essentially attritional battle against...the Warsaw Pact" to "manoeuvre warfare" with "speed, tempo, and violence...unlike anything" in past experience (Ref 1). The changes in medical doctrine he suggests match almost perfectly with the United States Joint Health Services Support Operations Concept presented in detail elsewhere in these proceedings. Instead of a medical support focus which concentrates on a major land battle in Europe, we are now looking at multiple regional and low-intensity conflicts throughout the world. Limitations in response time, a potential decrease in airlift capability, and a manpower drawdown all combine to limit our future ability to move in large, comprehensive medical support elements with definitive care capabilities for many of these short duration, limited conflicts. Current military medical emphasis for these types of actions now highlights the provision of "essential care" far forward with the establishment of a seamless en route care capability for the critically injured or ill patient as they move through the evacuation system.

The delivery of "essential care" in forward areas carries with it the burden of moving recently stabilized casualties to a facility in order to provide a higher level of support where the patient can have more extensive surgical evaluation and treatment of injuries. As stated by Lt Col Hawley, "Once surgical resuscitation has been performed then the casualty's condition will need adequate intensive care." The movement of these "salvageable but very sick" patients will require evacuation by a "fully trained medical staff" (Ref 1). It can be anticipated that recent postoperative patients who have undergone resuscitative surgery will frequently require either airway or mechanical ventilatory support. For many of these patients, the availability and use of a transport ventilator will be essential to the delivery of continuous, supportive en route care.

From a technological standpoint, the capabilities and range of operation of transport ventilators have shown significant improvement during the last decade. Advances in miniaturization and computerization have led to the introduction of smaller and more versatile transport ventilators. Some of these ventilators now incorporate built in air compression devices or air entrainment systems which

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removes the requirement to carry an external compressor if a variable F_iO_2 is necessary. In addition, manufacturers include newer modes of ventilation to improve patient tolerance of mechanical ventilatory support and to provide the user with more flexibility in patient management. This includes the provision of demand modes of ventilation which allow the patient to breathe spontaneously without excessive effort.

Our purpose in this work was to evaluate performance of two relatively new transport ventilators, the Univent (Model 750, Impact Instrumentation, Inc.) and Univent Eagle (Model 754, Impact Instrumentation, Inc.), for use during aeromedical evacuation. The Univent is currently in use by the Critical Care Air Transport Teams of the 59th Medical Wing and other U. S. military medical units. The Univent Eagle is a newer model with expanded capabilities, including a built-in air compressor and automatic compensation for changes in P_{BA}, which we evaluated as a potential replacement for the Univent. All work was completed at Wilford Hall Medical Center, Lackland AFB, TX.

METHODS

Following approval by the Institutional Review Board, we evaluated the Univent, Model 750, and Univent Eagle, Model 754 (Impact Instrumentation, Inc.) using an Adult Test Lung connected to a laptop computer running PneuView data acquisition software (Michigan Instruments). The test lung and ventilator to be tested were placed inside a decompression chamber with the data cable and ventilator high pressure oxygen supply line running into the chamber via airtight seals. We used a small decompression chamber capable of sustained drops in P_{BA} representing a simulated altitude of 40,000 ft (12,222 m) for all parts of this study.

The test lung was configured with normal parameters including a total compliance of 0.08 L/cm H_2O and an airway resistance of 5 cm H_2O/L/sec. The ventilator settings were a TV of 0.8 L, rate of 10, and an I:E ratio of 1:3 with an F_iO_2 of 1.0. Software was set to record TV, rate, P_{aw}, V_{max}, and MV.

Data was collected at the baseline altitude of 600 ft (183 m) with repeat collection every 2000 ft (611 m) up to 16,000 ft (4889 m). The data was averaged for a one minute period at each interval following recalibration of the data acquisition algorithm. The data acquisition software required entry of the new effective P_{BA} with every change in altitude and this was accomplished using the digital readout available from the decompression chamber.

To evaluate the capabilities of the Univent Eagle's built-in air compressor under hypobaric conditions, the maximum output of the compressor was evaluated from 600-15,000 ft (183-4583 m). The evaluation was performed using an F_iO_2 of 0.21 without a high pressure oxygen source connected to the ventilator. The maximum output was determined by setting the tidal volume at 1 L with an T_{insp} of 0.3 and adjusting the rate until there was no further increase in MV. The ventilator was then placed in the decompression chamber and tested in a similar fashion to the other experimental runs with the exception that measurements were made at 5000 ft (1528 m) increments.

Data are presented graphically.

RESULTS

Both ventilators performed well without significant problems. The Univent, Model 750 demonstrated a marked increase in TV with successive increases in altitude (Fig 1). There was a 107% increase in the delivered tidal volume at 16,000 ft (4889 m) compared to 16% for the Univent Eagle. The V_{max} increased from 41 to 84 L/min in the Univent, Model 750 in association with the increase in delivered TV (Fig 2). The marked increase in V_{max} seen in the Univent Eagle at 12,000 ft was due to a recording error. The impact of the increase in TV on P_{aw} is shown in Figure 3. There was no significant change in rate or inspiratory time during any of the studies for either ventilator.

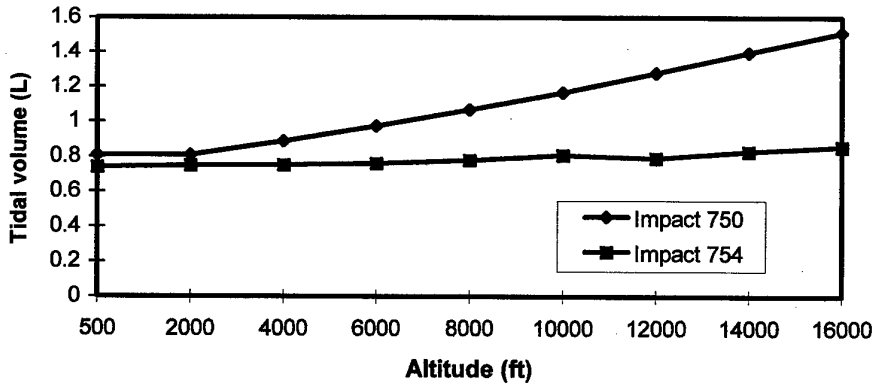


FIGURE 1. Change in tidal volume (TV, L) with changing altitude (ft) for the Univent 750 and 754 ventilators.

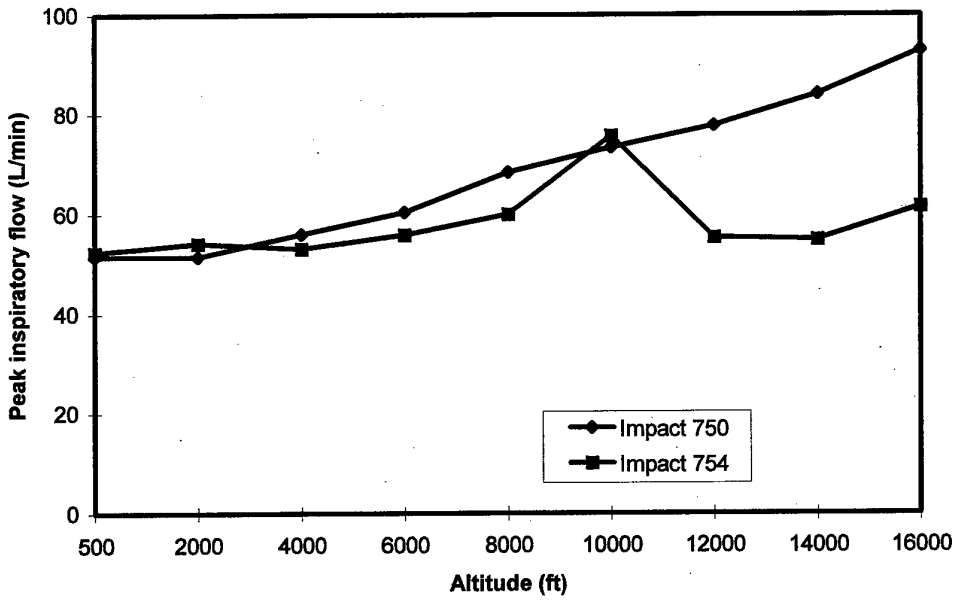


FIGURE 2. Change in peak inspiratory flow (V_{max}, L/min) with changing altitude (ft) for the Univent 750 and 754 ventilators.

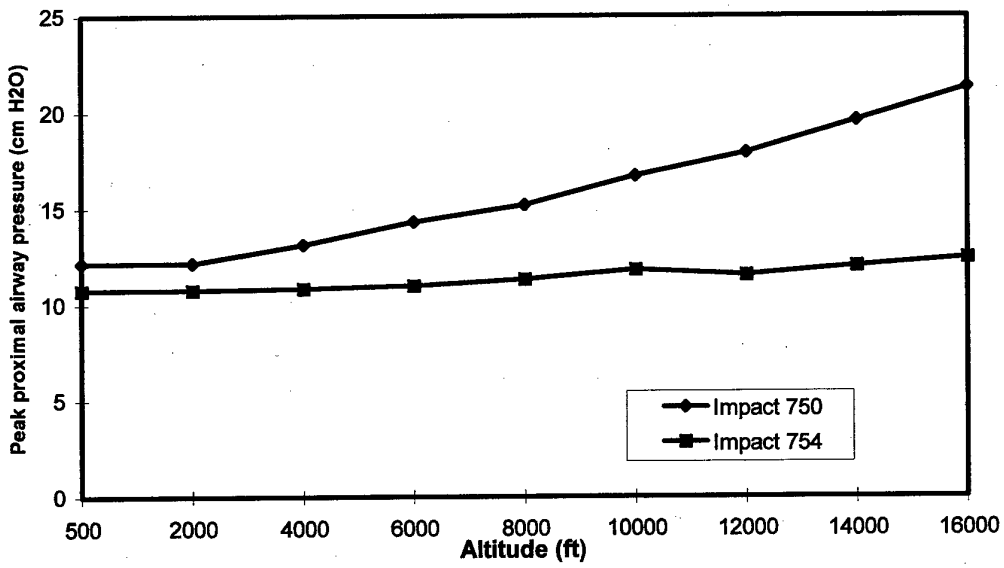


FIGURE 3. Change in peak proximal airway pressure (P_{aw}, cm H_2O) with changing altitude (ft) for the Univent 750 and 754 ventilators.

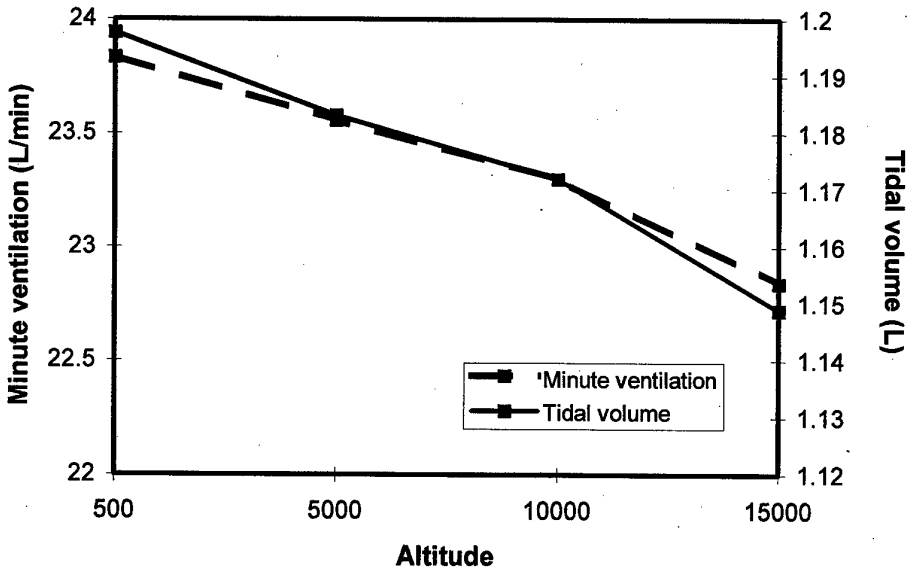


FIGURE 4. Maximum minute ventilation (MV, L/min) and corresponding tidal volume (TV, L) produced by the Univent Eagle, Model 754 with changing altitude (ft).

The air compressor in the Univent Eagle performed well up to 15,000 ft (4583 m) with a small drop in the MV from 23.8 to 22.8 L/min or 4% at the peak altitude (Fig 4).

DISCUSSION

The need to develop special transport ventilators for the movement of military casualties was recognized during the United States involvement in Vietnam (Ref 2). A review of "resuscitators and respirators" in 1966 sought to establish the definitions, characteristics, classifications, and necessary criteria for an ideal system (Ref 3). Many of these desirable criteria still hold true today and are outlined in a review by Branson and McGough (Ref 4). The characteristics of the ideal transport ventilator include:

1). Variable tidal volume (for example, 100-1500 ml)
2). Variable ventilator rate (2-30 breaths/min)
3). Variable minute ventilation (4-20 L/min)
4). Intermittent mandatory ventilation (IMV) and controlled mechanical ventilation (CMV)
5). Low and high pressure alarms
6). Continuous positive airway pressure (1-20 cm H_2O)
7). Demand-flow valve (for example, 100 L/min peak flow rate on demand)
8). Monitoring of airway pressure

When addressing the special requirements for transport by air, the ideal ventilator should also deliver a continuous MV, without alteration in TV or rate, across a wide range of P_{BA}.

The newer transport ventilators in use and under development incorporate all of these features and more. Desirable additions such as built-in air compressors or other mechanisms to allow for the delivery of a variable F_iO_2 are also available on many of the current models.

Even with the improvements in transport ventilator capabilities and associated equipment and personnel issues, the question remains whether or not there will be a need to move large numbers of ventilator dependent patients through the military medical system. During the Vietnam era, there was a huge medical system in place with large theater hospitals scattered throughout the area of operations. A moderately injured soldier could take up to 18 days to return to the United States after "8 flights-44 on-off loadings-and 6 surgical operations" (Ref 5). This lengthy movement phase was necessitated by the need to move "stable" patients as compared to "stabilized" patients. Thus, only a small percentage of casualties were transferred on mechanical ventilatory support when they could receive their care in a large, comprehensive facility overseas.

That type of extensive field support capability may not be present in future conflicts as outlined in the United States Joint Health Services Support Concept. In future actions, airlift and operational limitations may severely limit the medical presence in the area of operations. This pushes the aeromedical evacuation system into providing a critical care capable air transport system. This is not an entirely new idea. As early as 1970, McCann et al recognized that the aeromedical evacuation system functioned primarily as an

"austere air ambulance" which required updating to move it towards "current concepts of a mobile treatment facility" (Ref 5). The "new" ideas now being implemented to provide essential and en route care in order to decrease overall theater medical support requirements were clearly espoused in McCann's article and his assessment of the AES potential is still valid.

The concept of moving surgically stabilized patients is also not a new or unique approach. Sharar and colleagues reported on the use of air transport to move civilian trauma patients from outlying hospitals to a regional trauma center following emergent operative stabilization (Ref 6). In their series, 17 of 19 patients with Injury Severity Scores of 44 (range, 20-66) required mechanical ventilatory support en route. The movement of critically ill patients is not limited to those with trauma. Reporting on preparation of critically ill patients for interhospital transfer, Runcie et al found that 74% required the institution or maintenance of mechanical ventilation for their movement (Ref 7). The experiences of the Royal Air Force also show that 37% of their world-wide transports involve the use of mechanical ventilation (Ref 8). Recent patient movements by the Critical Care Air Transport Teams of the U.S. Air Force in support of Operation Joint Endeavor also show a similar number of patients requiring mechanical ventilatory support (see related section in this Proceedings). Thus, if we adopt a policy of forward essential care with a continuum of en route care, there will likely be a significant number of patients in a major regional conflict who will require mechanical ventilatory support.

When mechanical ventilatory support is required, how will altitude and the other flight stressors impact ventilator performance? The potential for a decreased (or increased) P_{BA} to affect transport ventilator function has long been recognized (Ref 9). In 1969 Kirby and colleagues reported on the function of the Bird Mark VIII Respirator at altitudes up to 34,000 ft equivalent (P_{BA} of 188 mm Hg) in dogs (Ref 10). They noted a decrease in ventilator rate and an increase in TV. The drop in the ventilator rate was attributed to alterations in the performance of the expiratory timer cartridge which became over pressurized with the decrease in P_{BA}. The increase in tidal volume was only moderate and the overall MV was relatively unchanged.

More recently, Thomas and Brimacombe evaluated a modern transport ventilator, the Dräger Oxylog, under hypobaric conditions (Ref 11). This ventilator is a time-cycled, volume-constant ventilator with pneumatic logic controls. Like the Bird Mark VIII Respirator, the Dräger Oxylog showed a moderate increase in TV from 700 to 1442 ml at 30,000 ft with a decrease in ventilator rate from 12 to a little over 8 breaths/min. The overall effect was an increase in MV of 13 and 45% at 6676 and 30,000 ft respectively. Neither of these ventilators is microprocessor controlled and the interplay of pneumatic controls limits the impact of altitude on the delivered TV.

The Univent, Model 750 and Univent Eagle, Model 754 are electronically controlled, time cycled, pressure limited transport ventilators. The observed increase in tidal volume of the Univent, Model 750 comes close to that predicted by the application of Boyle's Law. Since the delivered TV comes from a pressurized gas source at 45-55 psi, a certain "mass" of gas is delivered in the microprocessor controlled time interval which expands by a factor of two at an altitude equivalent of 18,000 ft. This problem, however, is readily avoided in the field by disconnecting the patient from the ventilator and performing a recalibration of the ventilator after significant changes in cabin altitude. Since the calibration process takes almost 60 seconds to perform, certain patients may require manual ventilation during this procedure.

The Univent Eagle avoids this potential problem by the inclusion of an internal barometer. Changes in P_{BA} are continuously fed to the onboard microprocessor. In the microprocessor, the current pressure is compared to those located in a lookup table. At 5000 ft intervals the microprocessor automatically adjusts the flow rate to compensate for the change in P_{BA} based on the correction factors in the lookup table (personal communication, Les Sherman, Impact Instrumentation, Inc.). These calibration factors are set at 5000 ft intervals up to 25,000 ft. This explains the nonlinear appearance of the TV data obtained from the Univent Eagle (Fig 1). Beyond the preset range, the ventilator can be expected to show an increase in tidal volume similar to that seen in the Univent, Model 750. In the event of decompression at a high altitude, the increase in peak airway pressures should be blunted by the preset peak pressure limits. When these limits are exceeded, the ventilator stops the delivery of gas to decrease the risk of barotrauma. Both ventilators have this pressure limited feature.

In addition to the automatic compensation for changes in barometric pressure, the Univent Eagle incorporates a built-in air compressor to allow for an F_iO_2 of 0.21 to 1.0. The air compressor output is minimally affected up to 15,000 ft and should perform well in the aeromedical evacuation role. Additional testing of these and other ventilators has been accomplished at the Armstrong Laboratories by the Aeromedical Research Group, Crew Systems Directorate which provides final recommendations and clearance for all aeromedically related equipment to be used on USAF aircraft.

While studies in the medical literature about the function of transport ventilators under hypobaric conditions are limited, there are a number of technical reports on mechanical ventilators tested for use in aeromedical evacuation. These reports are available from the Systems Research Branch, Armstrong Laboratory, Brooks AFB, TX. At that location, evaluation of ventilator performance under the classic stresses of flight is performed before flight certification is granted. Comprehensive testing with vibration, acceleration, environmental, altitude, and rapid decompression studies (MIL-STD-810D) along with evaluations of electromagnetic interference potential leads to a final recommendation regarding airborne feasibility. Table 1 lists some of the ventilators, both transport and conventional, which have been studied over the last 30 years and their current recommendation for aeromedical evacuation use on USAF aircraft designated for that function. This is an abbreviated

TABLE 1.

Ventilator	Manufacturer	Recommendation*	Year Tested
Babybird Infant Ventilator, Model 5900	3M/Medical Products Division	Acceptable	1979
Bear 2 Adult Volume Ventilator	Bear Medical Systems, Inc.	Unacceptable	1984
Bear 33 Volume Ventilator	Bear Medical Systems, Inc.	Conditional	1989
Bear Model Infant Cub Ventilator	Bear Medical Systems, Inc.	Unacceptable	1983
Bennett Ventilator Model MA-1	Bennett Respiration Products	Unacceptable	1972
Bio-Med Devices P-7 Adult Ventilator, SN 0298204	Bio-Med Devices, Inc.	Unacceptable	1986
Bio-Med Infant Ventilator, Model MVP-10	Bio-Med Devices, Inc.	Conditional	1990
Bird Mark 7A	3M/Medical Products Division	Acceptable	1987
Bird Mark 10 Ventilator	3M/Medical Products Division	Acceptable	1967
Bird Mark 14 Ventilator	3M/Medical Products Division	Acceptable	1975
Bird Ventilator Unit, IMV Bird, Neonate Urgency Bird	Bird Corporation	Unacceptable	1977
Bourns BP200 Infant Pressure Ventilator	Bourns Life Systems	Unacceptable	1979
Flynn Series III Ventilator with oxygen powered aspirator	Marion Health and Safety, Inc.	Acceptable	1976
Impact Uni-Vent 750 Ventilator	Impact Instrumentation, Inc.	Acceptable	1995
Life Care PLV 102 Ventilator	Lifecare	Conditional	1992
Military Transport Respirator, Model TXP	Bird Space Technology	Conditional	1989
Monaghan 225 Volume Ventilator	Monaghan, Division of Sandoz	Unacceptable	1976
Penlon Transport Ventilator	Bear Medical Systems, Inc.	Unacceptable	1986
Siemens-Elema 900B Servo Ventilator	Siemens Corporation	Unacceptable	1979

* The terms used to denote the recommendation refer only to acceptability for use on designated USAF military aircraft used for aeromedical evacuation without implication about acceptability for use in other situations. These terms will soon be replaced by "Approved", "Conditionally Approved", and "Not Approved".

list and is intended to serve as initial reference only. More specific information can be obtained by visiting the Aeromedical Research Status Guide site produced by the Systems Research Branch on the World Wide Web at: http://www.alcft.brooks.af.mil/HTMLPOOL/Vent.htm. Some additionally useful areas included in the Guide deal with oxygen, airway, and monitoring equipment. The Guide is currently under revision and should be updated in the near future.

Special mention should be made of the TXP ventilator (Percussionaire Corporation, Sandpoint, Idaho). This ventilator is a portable, pressure-limited, time cycled device which is used by the burn flight team from the Army Burn Center located at Brooke Army Medical Center, San Antonio, TX. This unit weighs only 1.5 lbs (0.68 kg) and can provide respiratory rates between 6 and 250 breaths/min with TV between 5 and 1500 ml. The F_iO_2 is preset at 0.6 with support of spontaneous breathing above the respiratory rate with minimal resistance. One of the unique features of this ventilator is that it is powered entirely by oxygen and requires no electrical power. In a recent review of its use for the movement of burn patients, the authors report on a series of 146 patient transfers for a total of 86,889 miles (Ref 12). The excellent performance of this ventilator recommends it for use during aeromedical transports although it is currently only approved for in-flight use by the U.S. Air Force in a one-to-one clinical relationship where constant qualified medical surveillance is provided (Ref 13).

A number of other ventilators exist world-wide which have been modified to function as transport ventilators or which have been specifically designed for this purpose (Refs 4, 14).

Not all of these ventilators have undergone the rigorous testing imposed by the U.S. Air Force before being allowed on aeromedical evacuation aircraft. Criteria exist, however, which can help the user focus on the equipment considerations and potential problems unique to this environment before items are put to work during air transports (Ref 15). Simple studies such as the ones described in this paper, can also help to answer questions about the performance potential of new equipment before it is put into practice.

SUMMARY

The current shift in U.S. military medical planning will bring forward the requirement to move critically ill and injured patients early in the course of their treatment. With fewer medical and surgical options available in theater, many of these critical casualties will require mechanical ventilatory support during potentially lengthy evacuation missions. The current generation of transport ventilators including the Univent Eagle, Model 754 are well suited for this purpose. The Univent, Model 750 is also adequate if recalibration is done with each change in altitude. Failure to perform this function with changes in altitude can lead to the delivery of tidal volumes significantly greater than predicted, and in the patient with poor pulmonary reserve, this may be detrimental. Acquisition of new ventilators needs to take into account the special requirements for use in the aeromedical evacuation system and should include functional testing similar to that presented in this paper.

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THE USE OF ULTRASOUND IN MILITARY TRAUMATOLOGY

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Summary
In the last decade ultrasound (US) has become a very important diagnostic tool in many areas of medicine, including traumatology. US is a reliable method to detect blood in the peritoneum.
When a modern system and a skilled examiner are available the invasive diagnostic abdominal tap has become obsolete. Also hematothorax and hemopericard are easily diagnosed with US and diagnostic or evacuating puncture can safely be performed under US guidance.
US can also evaluate organ damage, in particular of pheripheral anatomical structures. It may guide interventional procedures and is very helpfull in the detection of foreign bodies, not visible on conventional radiographs.
For these reasons 21 portable US systems were purchased by the Netherlands armed forces in 1993, intended for use - next to X-ray equipment - in field hospitals with operating room facilities. Practical experience with the US systems was obtained during two years of "peacekeeping" activities in former Yugoslavia.
Due to modern technology a further reduction in size with development of one hand hold systems with good imaging qualities will soon be realised. This allows US examination of injured patients on the battlefields. In case of many victims and limited capacities US may play an important role in triage.

History.
The use of ultrasound (US) to identify invisible objects is not an invention of mankind. In 1794 the Italian scientist Spazzaloni suggested that flying bats, who in the dark can avoid obstacles and localise their prey, made use of US and he was right. In the development of US imaging to identify invisible objects military institutions played a big role.
After the Titanic disaster (1912) increasing research was performed to detect underwater obstacles. So in World War I experiments with high frequency ultrasound were performed by the French Navy to detect submarines and in World War II the successful SONAR (SOund Navigation And Ranging) system to detect under water obstacles was developed by United States Navy Institutions.
The basic principle is a short emission of ultrasound by activation of a crystal which is received again after being reflected by an object. The time past in between is a measure for the distance of the reflecting object and the amount of reflected US-waves gives some rough information about size and structure of it.
The same principle is used for ultrasound imaging of internal body structures, which are reflecting the US waves emitted the crystals in the transducer on the outside.
In 1952 Douglas Howry (Colorado, USA) constructed with use of surplus Sonar equipment of the Navy an imaging system, which could visualise a piece of liver with a nail, a piece of plastic and piece wood pricked in it. Remarkable was the fact that the pieces of plastic and wood were visible as well as the nail, while on a conventional X-ray only the nail could be visualised. This experience suggests already the potential of US in identifying foreign bodies.
The first examinations of patients were performed in a tank with the patient up to his neck immersed in water and an underwater rotating transducer. This construction was for example shown in the "gun turret scanner" (1954), constructed with materials from a B29 bomber aeroplane.
The water was needed as intermedium because the ultrasound waves can not pass a fluid-air barrier was soon replaced by a jelly substance and in the early seventies the first commercial scanners came on the market. They were huge and expensive with poor (B-scan) images.
In the late seventies the strong reduction of the acquisition time, for needed one picture allowed a 'real time-imaging', which promoted diagnostic ultrasound imaging to a dynamic examination with a quick increasing clinical value in areas as gynaecology/obstetrics, cardiology and internal medicine.
The quick development of computer technology allowed the construction of today's light weight, compact US equipment and even portable systems, of which the monitor-screen is the main part in size and weight.

Role of US in modern traumatology.
The application of US to detect blood in the peritoneal cavity following blunt abdominal trauma has become a common practice in the last decade. US equipment is easily transportable and the non invasive examination can rapidly be performed and does not impede other diagnostic and therapeutic procedures.
In experienced hands US is a highly accurate method for evaluation of the abdomen in the blunt trauma patient (2), which makes the diagnostic peritoneal lavage an obsolete technique.
Main places where blood can be identified are Morrison's pouch between liver and right kidney, (the lowest place in upper abdomen in the patient laying on the back, subphrenic areas, right paracolic gutter and the area above and behind the urinary bladder in the lower abdomen (Cavum of Douglas).
Abdominal fluid (blood) in the hemodynamically instable patient means emergency surgical treatment, in particular in case of increase of the amount of intraperitoneal fluid on repeat examination.
The main pitfall is the rather uncommon presentation of clotting or fresh clotted blood as a reflecting material, which is often indistinguishable of hepatic, splenic or renal parenchyma. In these cases the skill of the examiner is most important to make the right diagnosis.

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In case of thoracic trauma the diagnosis of hematothorax and hemopericard is also easily made by US with a higher reliability than on conventional x-ray. In the unstable patient US guided evacuating puncture of blood or fluid collection in the pleural or pericardial cavity can be live saving. Furthermore, in the unstable patient with normal findings on US surgical treatment is not indicated but in that situation US should be repeated after a while.
In the stable patient application of US is important for detection and evaluation of organ damage, although Computed Tomography -when available- is mostly preferable for evaluation of abdominal organ damage (3).
When it is impossible to utilise one of the usual places for a central venous access US can be helpful to guide the puncture of a vessel which is otherwise not accessible e.g. the upper femoral vein. This vein is located just behind the artery, but can safely be punctured from a side under US guidance.
The peripheral structures of the body (thoracic and abdominal wall and extremities including the surfaces of bones) can be well visualised with modern US with a good near field transducer for evaluation of traumatic damage, even better than on Computed Tomography can perform.
Muscle and tendon ruptures, haematomas, damage of neurovascular bundles, periferal fractures of bone (also fractures of the cartilage parts of the ribs, invisible on conventional radiographs are mostly easily diagnosed with US.
Also foreign bodies, not visable on conventional X-ray (e.g. lead free glass, pieces of wood and plastic shrapnell) (4) are mostly easily demonstrated on US.

US in the Netherlands Armed Forces.
In the light of the high diagnostic value of US imaging in traumatology in 1993 21 portable US systems were purchased by the Netherlands Armed Forces together with some middle class systems. The systems were intended for use, next to x-ray equipment, in any fieldhospital with operatingroom facilities, also in the smallest ones.
Soon practical experience was got during two years "peacekeeping" activities in the former Yoegoslavian republic. Practical use of US was realised in the daily healthcare for the military men but an even more frequent application was the examination of diseased local civilians in the context of humanitarian medical care.
There were only a few casualties in wich US was used to evaluate the blunt trauma abdomes and for exact localisation of shrapnell, which allowed simple removal by the surgeon.
In the opinion of our expeditionary surgeons the use of diagnostic US systems, in case of modern equipment and skilled examiners, was at least as valuable as availability of conventional x-ray.

New developments.
In the last decade diagnostic US systems are considerably reduced in size with substantial increase in quality of imaging. Due to modern chiptechnology this development will problably even be accelerated in the near future.
A main challange is the replacement of the heaviest and biggest part of the system, the classic glass screen, by a flat, light-weight screen with adequate imaging quality. Illustration is the development of a US system by a leading ultrasound manufacturer in the USA, light and small enough to hold in one's hand (5).
This project should be realisized within two years and is granted by the USA Department of Defense for half of the costs of USA $ 12 miljons.
Philosophy behind is the intention to better utilize the 'golden' hour, in wich medical care to the victim of violence is most effective. The small US system should be brought to the injured patient on location of severe accidents, disaster and battlefield to evaluate the site and severity of the injuries and guide effective (first) aid.
In particular in case of many victims and limited capacities US could be very helpful in triage of the patients. It is evident that other manufacturers soon will follow or already started similar developments.
So, it is not needed to be a fortuneteller to predict that in the near futher many trauma-teams will be equipment with small, portable ultrasound systems and that US examination of victims on location of the violence will become a common procedure.

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This article will also be published elsewhere

Discussion #6

SALISBURY, CA: Major Lawlor, I noted that you were only considering gaseous oxygen and liquid oxygen (LOX). We've had some success in using OBOGS, i.e., on-board oxygen generating systems, using molecular sieve technology. It has been ground-based tested so far, but I do think it's a potential technology that will cross over from the aeromedical to the clinical world. It can solve a lot of your logistical problems, because basically you can't do the rest of your work unless you have power, and if you have power you can use the OBOGS (in reference to Paper #28).

KILPATRICK, US: Major Lawlor, you spoke of the two-to-three-hour battery life for the point-of-care laboratory devices. When you are on longer range missions, can you get two to three hours of actual battery use? How long a mission can you sustain with one battery given that kind of battery life?

LAWLOR, US: The actual time it takes to run a sample is approximately 5 - 10 minutes. So, usually, the device is powered on when running the sample; then it is turned off. So it is not necessary to use the battery for the entire mission. Most of the time, samples are not being analyzed continuously throughout the mission; they run periodically to make an assessment and, then, perhaps later again in the mission. The actual cycle time for having the device on is relatively short.

KILPATRICK, US: So you can run probably 20 samples before you run out of battery power.

LAWLOR, US: To date, we've never had to run that many samples at one time.

GRAHAM-CUMMING, UK: Dr Pearce, how heavy is the LSTAT (in reference to Paper #30)?

PEARCE, US: The current unit weighs 130 pounds. The goal to get it down to 100 pounds after the second stage of prototype development. The weight of the LSTAT is an issue. The strategy that is driving the weight is the fact that this particular unit is an attempt to be all things to all people. Also, the US Food and Drug Administration (FDA) design principles that we used put a constraint on how we developed the unit. If we reduce the design engineering restrictions that we have imposed, we could drop the weight considerably.

GRAHAM-CUMMING, UK: In consideration of a number of environmental factors including flight envelopes requiring 6 ½ Gz and accelerations during landing up to 4 Gz, what dynamic testing have you done?

PEARCE, US: We have a Tri-Service program that is in progress right now and have four prototype units that are designed to 'shake out' those kinds of problems. We've been through vibration testing at Northrop Grumman. We are starting environmental testing at Brooks AFB, and Patuxent River Naval Air Station is handling the electromagnetic interference (EMI) testing. We have a problem in the US Army getting equipment air-certified for our rotary-wing environments. One of the reasons for this is that the EMI requirements are

much more stricter than they are in the US Air Force. That is necessary because the distances from the cabin to the avionics are very much shorter in rotary wing aircraft, so we have to be very compulsive about shielding all of the equipment. Our design enables us to house all of the equipment inside the base unit, which can be sealed effectively in one box. EMI shielding techniques employed in the B2 bomber achieved up to 70 decibels of noise improvement. By applying these techniques, we think we will be able to make this work also in the rotary-wing environment.

WALLACE, UK: The system that you have described is very much a closed-loop system. What modifications, if any, have you made to systems like the Propaq and the ventilator to give you the sort of functionality that you need? As a second question, what sort of logistic support will the LSTAT require? I'm thinking in terms of the Australian Mobile Intensive-care Rescue Facility (MIRF); I'm sure Wg Cdr Dines is aware of that, which is, at first sight, a simpler unit. I wonder what sort of infrastructure the LSTAT will carry?

PEARCE, US: In response to your first question, there have been modifications to Propaq. Inputs have been moved from the side to the back of the unit and we had meetings with the FDA about what they require to make those kinds of modifications to the equipment. The response was that we needed to show that there was equivalent performance before and after that reconfiguration. That is being done now. With regard to your second question, it does look like a MIRF equivalent to some degree. We looked at the MIRF which became available around 1993, near the same time that we were conceptualizing the LSTAT. We consciously made the decision to diverge from the individual component approach, which is the approach that the Australian unit takes, for several reasons. One has to do with this issue of EMI shielding and its use in rotary-wing aircraft. We have only had seven medical devices approved on our aircraft so we needed a better situation for the EMI shielding. The other issue was the integration of all the components, both software and hardware integration. We decided that packaging it in this manner gave us more flexibility. Moreover, the data acquisition telecommunications capabilities that are not on the MIRF are included in the LSTAT. We considered it a next generation product in medical evacuation.

SICARD, FR: I am also concerned about the weight. I wonder whether you did any tests with the patient on the LSTAT, and then tried to put your device in some aircraft cargo bay? I ask this question because some helicopters or light-weight aircraft are quite difficult to get into, so I wonder how easy it is to manipulate the LSTAT and set it into the cargo bay?

PEARCE, US: In the US Army, we have done some loading tests on the UH-60 (Black Hawk) helicopter by loading a patient onto the helicopter. We've also looked at the Bell 412 helicopter in the civilian Emergency Medical Service community. It has a little different loading problem. The interiors of civilian aircraft are not configured with the same conventional requirements that we have in NATO. Civilian-configured helicopters are more of a challenge than

the military has in its ground and air evacuations because military aircraft are designed to accommodate the NATO litter stretcher. However, there is a problem with NATO litter stretcher compliance and NATO litter variability. Although it is supposed to be a NATO standard stretcher that we used, we did encounter a great degree of variability in the manufacturers' compliance to that standard. There are many of these litters in the field that don't fit all that well because of lack of compliance. That is an issue.

DINES, AU: With respect to the MIRF, my understanding is that it weighs about 50 kg. It was used in Australia's operation in Rwanda about two years ago. It was well accepted by the medical team using it. However, there was a consistency in the feedback obtained from the medics that it was a very heavy, difficult unit to operate.

MILLER, US: How modularized is the LSTAT? We can have all of these nice pieces of equipment but, when one is looking for space and weight, there is a point when one has to say: "I really don't need all this; I only need part of it". Is the LSTAT one unit that cannot be separated in that once one item is broken the system becomes non-functional? How exactly does it work?

PEARCE, US: We went about this with the philosophy that this was going to be a critical care requirement, that we would focus on what are the medical needs of a critical patient. The only controversial element has been whether or not the defibrillator should be put on the aircraft. I think the statistics are that 1 in 1000 transports require defibrillation. We don't do in-flight defibrillation in the US Army anyway because of the EMI problems. We could drop that requirement and carry a unit that stays with the air or ground ambulance. That would help to reduce the weight. The other components have not been controversial in terms of what one needs for critical care transport.

MILLER, US: Yes, I think that will work, especially as it concerns the defibrillator. I know for fixed-wing aircraft in the US Air Force there is a defibrillator on-board which can be utilized as necessary. Any equipment that can be kept off the aircraft would be the best approach.

LAWLOR, US: Maj Mason, do you have a prototype of your spinal cord system, the SCITS (in reference to Paper #32)?

MASON, US: The request for proposals is being sent out to different contractors. We have several companies that have expressed an interest and we are fairly confident that there will be some competition for developing the SCITS prototype.

MILLER, US: For the oxygen system, the AHOS-M, is this an item that will be on board the aircraft, or will it be used to fill other devices (in reference to Paper #33)?

MASON, US: Currently, it's being considered for use on board the aircraft. This system is at the laboratory stage and hasn't formally entered the acquisition program of the Human Systems Program Office. We haven't established how many we would need, when we would purchase them, or how we would use them operationally.

MILLER, US: Presumably, you would have this system running somewhere, first in storage to accumulate some oxygen before you actually get on the flight, and that down range it would only be operating on generator power. It sounds like a power consumer, so do we even have generators that would be able to support this system down range?

MASON, US: There is a considerable amount of work still to be done with the AHOS-M: how it would be used operationally, where it would be placed, how far forward it would be, on which aircraft, etc.

BURTON, US: It is a technical breakthrough, the ability to filter oxygen out of air. When you do that you end up with some argon and to filter off the argon itself and end up with 100% oxygen is a remarkable feat. Then to cryogenically take it down to liquid oxygen is even more remarkable. What you have heard about concerns a first prototype; it is just a matter of time before it becomes operational (in reference to Paper #33).

LYON, US: I have a comment followed by a question for both Dr Pearce and Maj Mason. We have spoken about several commercial-off-the-shelf (COTS) items; e.g., for point-of-care testing and ventilators. The limitation of these COTS items is often their operational limitations. We have also discussed the LSTAT, the SCITS and the AHOS-M. Here we're concerned about acquisition programs, and developmental items. Of course, the risk for developmental items is the schedule, cost and performance. You don't know when you'll get the item, how much it will cost, and if it will finally work or be FDA approved. It would always be wise to thoroughly look at what's available in COTS items before proceeding with an acquisition program. Are there COTS aeroevac integrated stretchers available, or COTS spinal-injury transport systems? Could Dr Pearce and Maj Mason comment on what is COTS available in those two areas.

MASON, US: As far as the SCITS is concerned, companies have come forward with quite a few ideas for integrating COTS items into the stretcher. Sometimes it is a challenge to ruggedize some of the COTS equipment, but that can usually be overcome.

LYON, US: Are the proposals that you are receiving identifying modified COTS equipment or will they utilize COTS equipment per se?

MASON, US: We haven't received any proposals but when we speak with the companies, we ask them about what is already available and can it be integrated to take into account all of the different performance capabilities that the user wants. We don't want companies to come up with anything new that would drive up the cost.

Trauma Surgery for Contingency Operations: Test Based Improvements

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Introduction/Overview

This paper describes work undertaken at Wilford Hall Medical Center for testing and quantification of practice changes planned to facilitate the concept of "forward resuscitative surgery." This paper will begin by discussing the rationale for and composition of the Mobile Field Surgical Team (MFST). It will then proceed to discuss the challenges that arose in the formation of the team and it's concepts of operation, with a description of several areas in which we have performed objective testing of the proposed new practices. I will describe our evaluation of the following areas:

- instrument disinfection technique that does not use an autoclave
- live surgery using a pared-down equipment package
- trauma surgery without visible light
- possible application of thermal imaging to commonplace medical care

MFST Concepts

Improving outcomes for our injured soldiers in future conflicts will require the appropriate surgical care to be applied as soon as possible after the injury occurs. This must be accomplished despite several factors that make such a task more challenging:

- Conflict in the future is likely to occur with little warning, and it is likely to take place "over the horizon" from the permanently based medical facilities.
- Because of the rapid rate at which information age combat progresses, a surgical team should be ready to operate soon after reaching the desired location.
- As the field of conflict shifts, it is likely that the surgical team will need to move frequently as well.
- The "line" side of the military will hesitate to give up their airlift capacity for purposes other than transport of "beans and bullets."

Currently available assets (such as the US Air Force Air Transportable Hospital, or ATH) are very capable but are too large and cumbersome to be able to provide the mobility required. For example, an ATH cannot even provide capability for an appendectomy without moving it's full set (52 pallets, 7 C-141 aircraft).

The MFST is designed with significantly less capability than an ATH, but in a package that is small enough move around without overburdening the airlift assets. The early application of surgical care to trauma victims is important, even if the surgical care is not definitive. In other words, the MFST will plan to do resuscitative surgical procedures on patients who would not otherwise survive to reach the next echelon of care. Resuscitative surgery may thus leave the casualty with a requirement for another operation, but their stability for Air Evacuation should be significantly improved.

MFST composition

Personnel

- General Surgeon
- Orthopedic Surgeon
- Emergency Medicine Physician
- Anesthesiologist/CRNA
- OR specialist

Equipment

- Surgical Equipment - 5 backpacks
- Generator
- 2 folding litters
- Personal gear

Total equipment weight: approx. 600 pounds

Field Disinfection techniques

In search of a way to clean instruments that would not necessitate carrying an autoclave, we chose to study A-33. This is a quaternary ammonium compound with excellent bactericidal activity, though only moderate activity against viruses and spores.

In this experiment, fresh human feces were obtained from healthy volunteers on the day of experiments. The stool was vigorously mixed with 2 liters of sterile saline and dispensed into a container large enough to immerse the 10 surgical instruments to be contaminated. All work was then conducted under a laminar flow hood by personnel wearing gloves and gowns. The ten surgical instruments were placed into the stool mixture for a minimum of 5 minutes and cultured one at a time. After initial culturing, instruments were next placed in a container of A-33 solution prepared according to the manufacturer's instructions using non-sterile potable water. Instruments were then individually scrubbed with a brush from MFST supplies. Particular attention was paid to cleaning teeth and other areas of instruments where fecal material might collect. After scrubbing, instruments were placed back into the same A-33 solution until all the instruments were cleaned. Each instrument was then rinsed individually with 100 ml of non-sterile potable water. After rinsing, instruments were placed in an second identically prepared solution of A-33. After soaking for 15 minutes in the second A-33 solution,

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instruments were removed and wiped dry with sterile 4" x 8" gauze sponges. Instruments were then returned to the stool suspension, and the contamination and disinfection cycle was repeated for a total of 10 cycles to simulate the 10 surgical cases in the MFST concept of operations.

Each instrument was cultured three times during the experiments: after initial stool contamination, after the last(10th) disinfection, and after an 11th recontamination to reassess stool suspension bacterial counts. To neutralize residual disinfectant which might inhibit bacterial growth, Dey/Engel (D/E) broth was prepared prior to the experiments and dispensed in 1.0 ml aliquots into sterile capped tubes. Sterile swabs were moistened with D/E broth and used to sample designated instruments areas felt to be most likely to be difficult to disinfect, such as joints. Swabs were then placed in test tubes and vigorously agitated to dislodge microorganisms. Samples of the D/E broth were then removed in a sterile manner and cultured as follows: for aerobic cultures, 0.1 ml was spread on a blood agar plate; for anaerobic cultures, 0.1 ml was spread on an anaerobic blood agar plate. Plates were incubated at 35 ° +/-2° C and examined for evidence of growth at 48 hours and again after 5 days. Colonies on plates were counted and gram stained. Swab cultures of the second A-33 solution were also obtained after the last disinfection.

The initial counts of bacteria after contamination ranged from 6.4×10^5 bacterial to 1.3×10^7 bacterial/ml. Seven out of 10 instruments had no bacterial growth after 10 cycles of stool contamination and disinfection with A-33 alone. Three instruments grew low numbers of bacteria (3, 17, 3 bacteria/ml for instruments labeled C, E, and H respectively) after final disinfection. The final bacterial counts after the instruments were recontaminated in the stool suspension ranged from 2.0×10^6 to 2.1×10^7 bacteria/ml.

Salvage Surgery Skills Lab

Ten Yorkshire swine, each weighing 70 to 90 kg were pre-anesthetized. Anesthesia was induced with 2.5% isoflurane using the flow over vaporizer (Ohmeda Universal PAC, Madison, WI) and maintained with spontaneous breathing of room air. The animals were transported to tents at a field site after initial intubation at the Clinical Investigations facility. After aseptic preparation with Betadine, sterile drapes were applied. Evaluating surgeons then surgically induced multiple injuries to which the operating surgeon was blinded. Ten multisystem trauma cases were specifically designed to evaluate MFST equipment and concepts in the surgical care of thoracic, abdominal, vascular and head trauma, as well as major fractures. The ten animals underwent sequential damage control procedures using only equipment and supplies contained in MFST backpacks. During the 16 hours of the surgical lab, the outside temperature ranged from 42 to 54 degrees Fahrenheit, with 4 of the procedures being performed at night. Animals were supported for 30 to 60 minutes postoperatively in the field setting, and then euthanized. Equipment and damage control procedures were evaluated by the participating team members. In all, the team members were pleased with the functionality of the backpacks.

Damage control procedures were performed on the ten animals in 15 hours and 45 minutes. The first animal died near the end of the first case secondary to hypothermia. Twenty-two operative procedures were performed during the 10 cases. The intravenous fluid supply was adequate.

Salvage Surgery in a Light-Limited Environment

The evaluation of night vision equipment and surgeons' performance in a light-limited environment was accomplished following initial training in the use of night vision goggles (NVG's), and consisted of salvage surgery with NVG's utilizing the porcine model. Two generations of NVG's were used in the evaluation; AN/AVS 6 and AN/AVS 9 (ITT, Roanoke, VA). The AN/ALS 6 and AN/AVS 9 goggles provide Snellen visual acuities of 20/40 to 20/70, and 20/20 to 20/40, respectively. The experiment tested the ability to operate with very limited light and NVG's alone and then the use of the two goggle types with infrared (IR) illumination. The injuries were similar to those treated in the salvage surgery skills lab. Operative times and the gross ability to complete required procedures in the light-limited environment were recorded, and were compared with results of the initial salvage surgery skills lab.

Thermal Imaging and the Detection of Bowel Ischemia

Four pigs were pre-anesthetized. Laparotomy was performed on each animal and a 25 cm segment of mid-jejunum was isolated and tagged with silk sutures. Arcade and collateral vessels were ligated at the marking sutures to allow perfusion of the segment through a single mesenteric vessel pair. The two mesenteric arteries to the isolated segment were then ligated. A Generation 2 thermal imaging system (Army Night Vision Labs, Ft. Belvoir, VA) was used to detect a marked temperature change between the marking sutures 10-25 seconds after vessel ligation. Five minutes after ligation the extent of bowel ischemia was estimated using the following six methods; unaided visual inspection in normal light, visual inspection with NVG's and IR illumination, palpation of mesenteric arterial pulse, doppler ultrasound of antimesenteric surface of jejunum, fluorescein injection with Wood's lamp examination and evaluation using a thermal imaging device with and without cool fluid contrast (room temperature). Measurements of the junction of viable and non-viable tissue were made from the marking sutures with each technique. After two hours of warm ischemia under general anesthesia, a generous section of mid jejunum was harvested. The jejunum was pinned to maintain length and sent for permanent section in a glutaraldehyde solution. The jejunum was longitudinally sectioned and measurements were made between the reference ties and the microscopic demarcation line of necrosis.

Light was judged inadequate to perform major salvage surgery without IR illumination.

Conclusions

Optimization of outcomes for casualties in 21st century conflict will require surgical capability that is more mobile than before. Development of such mobile surgical capability include the application of testing and simulation wherever possible.

Temporary Arterial Shunts for Management of Major Extremity Arterial Injury: A Field Expedient Bridge to Definitive Surgical Reconstruction

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(The views expressed herein are those of the authors and do not reflect the official policy of the Department of Defense or other departments of the United States Government.)

SUMMARY

Shunts were successfully placed and patency maintained for 24 hours in all 8 animals. Shunt malposition with subsequent thrombosis requiring thrombectomy and repositioning occurred in one pig during the 4th hour of the experiment; this was successfully corrected and the shunt remained patent throughout the remainder of the experiment. Flow data from two animals was not able to be analyzed—one developed malignant hyperthermia which caused a hyperdynamic state, skewing the data; and the second had incomplete flow data due to equipment malfunction. This graph depicts the flow data comparing the control and shunted limbs. (Fig. 3) Although the flow through the shunted limbs was significantly lower than that of the non-shunted ones ($p = 0.0015$), the shunted limbs remained warm and well-perfused without any clinical evidence of ischemia. Flow rates did not differ significantly over time in either the shunted or control limbs.

INTRODUCTION

Although extremity arterial injuries comprise only a small portion of battlefield casualties, they can be a major source of morbidity and limb loss. Irreversible ischemia may occur within six hours. Forward surgical teams can treat patients within minutes of wounding but are ill-equipped to deal with major vascular injuries, given the complexity of repair and the time involved. Their goal is to stop major hemorrhage, treat shock, and stabilize casualties for transport to higher echelon facilities. Definitive repair of vascular injuries may need to be delayed in order to treat the maximum number of patients in the minimum amount of time. Further delays may also be forced due to tactical considerations. A simple method to temporarily restore arterial flow and maintain perfusion pending definitive care would improve limb salvage rates.

Intravascular shunts have been used to restore and maintain arterial flow during the repair of complex injuries, especially those involving extensive bony or soft tissue destruction.[1,2,3,4] Such injuries are common in battlefield wounds. The use of temporary arterial shunts to permit transfer has been described[5], but this practice has never become a standard treatment. It is not known how long shunts will remain patent when placed for extremity arterial injury. We propose that the insertion of shunts at forward surgical units would serve as an expedient bridge between primary surgical intervention and definitive repair. We designed a porcine model to investigate shunt patency, limb ischemia, and possible systemic effects during the shunted period. Additionally, we performed arterial size measurements in order to make recommendations for shunt sizes to be stocked and utilized by the forward surgical teams.

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

ANIMAL STUDY

Materials and Methods

Eight female pigs were utilized during the study. The animals were anesthetized, intubated, and maintained under inhalational agent anesthesia with neuromuscular blockade. Crystalloids were given at a rate of 10 mg/kg/hr and adjusted to maintain an adequate blood pressure and urine output. Vital signs, oxygen saturation, fluid intake and output were continuously monitored. Bilateral femoral artery cutdowns were performed and ultrasonic flow probes for continuous monitoring of femoral artery flow were placed. At laparotomy, the right common iliac artery was identified, divided, and a 4 mm x 5 mm Sundt external shunt was inserted to restore flow to the hindlimb. Shunt patency was documented with a continuous wave Doppler probe. This artery was chosen as its size approximates the human superficial femoral artery. The contralateral limb served as a normal control. Flows in both femoral arteries were monitored continuously. Balloon catheter thrombectomy and shunt irrigation were performed as necessary to maintain patency. The average femoral artery flow rates were calculated for 2 hour intervals. Analysis of variance for repeated measures was performed to determine whether flow rates were different in the shunted and control femoral arteries and whether there was any change in flow rates over time.

This slide depicts the experimental set-up. (Fig. 1)

This slide depicts the shunt inserted into the artery. (Fig 2)

ARTERIAL SIZE MEASUREMENTS

Materials and Methods

B-mode ultrasonography was performed on 15 healthy, male human volunteers in order to determine the luminal diameters of the peripheral arteries. Bilateral examinations were performed at 12 separate sites for a total of 360 size determinations.

Results

Data were derived from 30 arteries at each anatomic site. The data are shown in this table (Table 1).

DISCUSSION

Vascular injury in military operations and combat

Injuries to the major arteries of the extremities have long been recognized as limb-threatening, often leading to amputation. Vascular repair techniques were introduced early this century; however, their widespread use during armed conflict was not adopted until the Vietnam War. Tuffier stressed ligation of injured vessels as the treatment of choice during World War I.[6] This practice continued during World War II when Debakey and Simeone analyzed 2471 arterial injuries and reported suture repair in only 81 cases.[7] The 35.8% amputation rate for arterial repair was much lower than the 48.9% rate reported for primary ligation. The authors recognized that the average delay between injury and operation of more than 12 hours was detrimental to the overall results. Other problems cited were lack of training in vascular techniques and the extensive nature of associated wounds which mandated life saving procedures taking precedence over limb saving ones.

Vascular techniques had improved by the time of the Korean conflict, but had were not universally adopted. Hughes reported an 88.9% limb salvage rate for surviving patients upon whom he performed arterial repairs.[8] Reduced time from injury to repair played an important role in these results, as did recognition of compartment syndromes and the need for fasciotomies in selected cases. However, most surgeons continued to practice ligation as their primary treatment, and Hughes' results were much better than overall results theater-wide. In Vietnam, Rich and colleagues reported an overall limb salvage rate of 86.5%.[9] Repair of arterial injuries was the norm and only 15 patients out of 1000 cases were treated with primary ligation. Rapid transportation, better surgical training, and new techniques, including the use of the Fogarty embolectomy catheter and external fixation of associated fractures, contributed to these improved results.

Further insight into vascular trauma can be gained from the paramilitary and terrorist activities in Northern Ireland. In his report on a decade of such trauma, Barros D'Sa documented an impressively low 5.1% lower limb amputation rate.[10] 95% of patients were admitted to the hospital within 30 minutes of their injury and over 80% had revascularization within 4 hours. In addition to rapid intervention, patch angioplasty arterial repair and the use of temporary shunts to maintain flow during treatment of associated fractures and soft tissue injuries were felt to have contributed to these results.

Resource requirements for traditional management of major arterial injury

The traditional management of major arterial injuries requires an intensive use of time, personnel, and other resources. Properly trained surgeons and specialized instrumentation are necessary. Operative time may be prolonged. Given the alternative of spending several hours treating one complicated vascular injury, or being able to rapidly perform "damage control surgery" on several casualties, surgeons at forward echelon facilities may be able render only the minimally required intervention to the vascular injured patient. This may ultimately lead to increased morbidity, even limb loss.

Advantages to use of shunts

The use of shunts by front-line surgical units could be advantageous and would require little additional training. The only special instrumentation required would be a hand-held Doppler to monitor shunt function. Shunts could be rapidly inserted during initial resuscitative surgery and would maintain perfusion during transport to definitive care. This early and rapid intervention would allow for "damage control" in vascular injuries, avoiding potential morbidity and limb loss.

Prior experience with shunts for trauma management

The time between injury and restoration of flow is critical in vascular injuries. Arterial perfusion needs to be restored within 6 to 8 hours to maximize limb salvage rates. In 1949, Miller and Welch created experimental ischemic lesions in dogs to better quantify the relationship between ischemic time and limb loss.[11] They found that 90% of the limbs survived with 6 or less hours of ischemia, 50% survived with 12 to 18 hours, and only 20% survived with 24 to 30 hours.

In 1971, Eger and colleagues first reported the use of temporary shunts, which had previously been used only for carotid artery surgery, in vascular trauma.[1] They used simple polyethylene tubing which was inserted as soon as possible in the operating theater. This restored distal flow and allowed time for thorough debridement of devitalized tissue and fracture fixation. In their series of 36 patients, the average time from injury to repair was 10 hours, yet their amputation rate was only 8%. Majeski and Gauto reported using a commercially available Javid shunt for complicated arterial repairs in 1979[2], and Nunley et al described the routine use of other commercially available shunts in both veins and arteries for upper extremity reimplantation and revascularization in 1981.[3]

In 1982, Johansen et al defined criteria for "complex vascular injuries" and advocated the routine use of shunts in their management.[4] These criteria were prolonged ischemia, profound or prolonged shock, associated fractures, associated massive soft tissue damage, or other concurrent life-threatening injuries which had a higher surgical priority. They identified 10 patients in whom indwelling shunts were used for up to 6 hours without anticoagulation before restoration of arterial continuity. There was one death in the group, and limb salvage was achieved in 7 of the 9 survivors.

Very little is known about the use of temporary shunts for arterial injuries during transfer. One case has been reported which described the insertion of a shunt in a superficial femoral artery injury for a 950 mile air evacuation from Alaska to Washington.[5] Anticoagulation was not used. This shunt remained patent for over 16 hours and arterial repair was successfully performed. Unfortunately, a compartment syndrome developed during the transfer which led to necrosis of previously undamaged calf muscles and, ultimately, amputation.

Experimentally, shunts have previously been shown to remain patent for 12 hours after insertion. In a study involving a sheep model, 5 of 7 shunts inserted into the femoral artery of a normal limb and 5 of 6 placed in a limb rendered ischemic for 6 hours prior to insertion remained patent.[12] Shunt failures were early and attributed to intimal damage at the time of insertion. This study used a heparin-bonded shunt which our data indicate is not necessary. We achieved patency for 24 hours using a non-heparin-bonded shunt. Our only shunt thrombosis was also due to a technical problem, and the shunt remained patent for the remainder of the experiment after this was corrected.

Commercially available vascular shunts

There are several types of shunts available commercially. These have chiefly been developed for use during carotid artery surgery. All are constructed from plastic materials, polyurethane or silicone elastomer, to allow for flexibility and to provide non-thrombogenic surfaces. Based on our arterial size measurement data, we chose to use a 4 mm x 5 mm external Sundt-type shunt which is tapered and reinforced. (Fig. 4) This shunt is flexible and easy to work with, and its size is ideal for most peripheral arterial applications. A smaller 3.5 mm x 4.5 mm shunt could be used for upper extremity shunting and other smaller arteries.

RECOMMENDATIONS

We recommend the use of temporary shunts for the early management of selected arterial injuries. Patients arriving at forward surgical units with a complex vascular injuries could be safely stabilized for transport to better equipped facilities using this technique. Surgical packs for forward teams should be stocked with 4 mm x 5 mm and 3.5 mm x 4.5 mm external Sundt-type shunts. Sterilized polyurethane intravenous tubing could be used as an alternative, field expedient substitute.

Shunt placement for vascular injuries should be a part of training in "damage control" or "salvage" surgery which general and orthopedic surgeons assigned to forward surgical teams currently receive. Basic instruction should include: simple, non-invasive methods to detect the presence of a vascular injury; techniques for inserting and securing shunts; performance of thrombectomies of both shunts and native vessels; and vascular anatomy and exposure. The importance of adequate resuscitation in addition to stopping hemorrhage is of vital importance in vascular injuries and must continue to be stressed.

Aeromedical personnel should also receive training for their role in the treatment and transport of patients with vascular injuries. First, a basic understanding of the fundamental issues in the management of arterial injuries is necessary—vascular anatomy, mechanisms and signs of arterial injury, the importance of adequate and ongoing resuscitation during transport, and an appreciation that anticoagulation is not necessary and may be detrimental. Additionally, they must learn how to monitor the shunted limb for developing signs of ischemia which might indicate shunt malfunction or the development of a compartment syndrome. The techniques of pulse examination, detection of arterial flow with a continuous-wave hand-held Doppler probe, and measurement of compartment pressures are easily mastered and applied. Finally, their education should include diagnosis and management of complications such as on-going bleeding or compartment syndrome.

Need for further work

Further work is needed for this use of shunts. The effect of hypovolemic shock on shunt patency has not been addressed and we are currently investigating this. Similar efficacy in humans has yet to be demonstrated and will be difficult to demonstrate without actual combat situations. Other issues include: the role and effect of resuscitation fluid composition and amount, including hemoglobin substitutes; the use of fibrin sealant to assist in hemostasis and its possible prothrombotic effects; and the possible effects of reperfusion injury when definitive repair is finally performed after a long period of relative ischemia due to diminished flow in the shunted limb. We feel these issues can be resolved and that the use of temporary arterial shunts will enhance the management of extremity arterial injuries in combat.

FIGURES

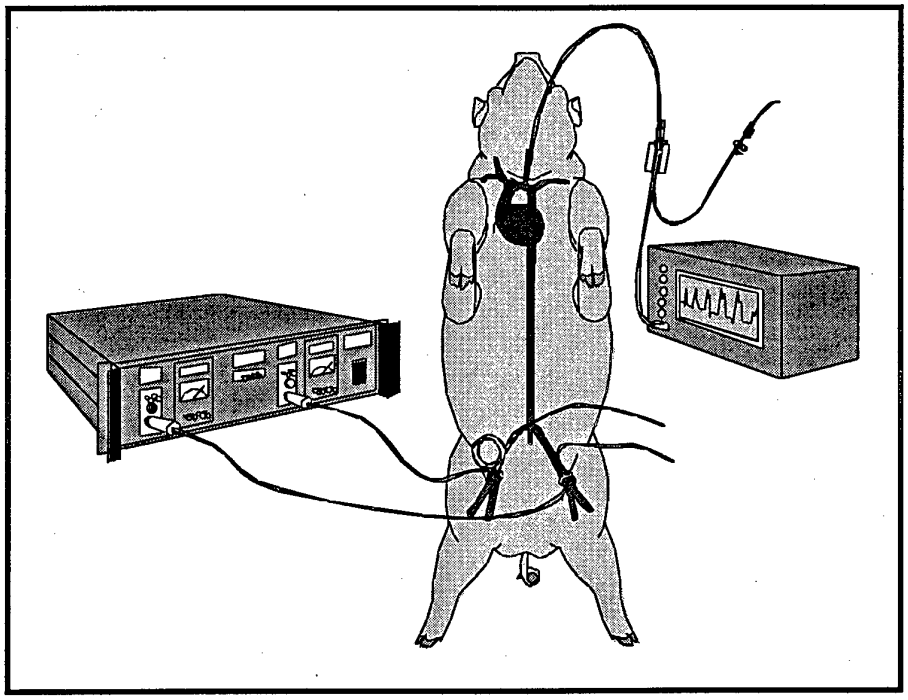


Fig. 1 - Pig model setup

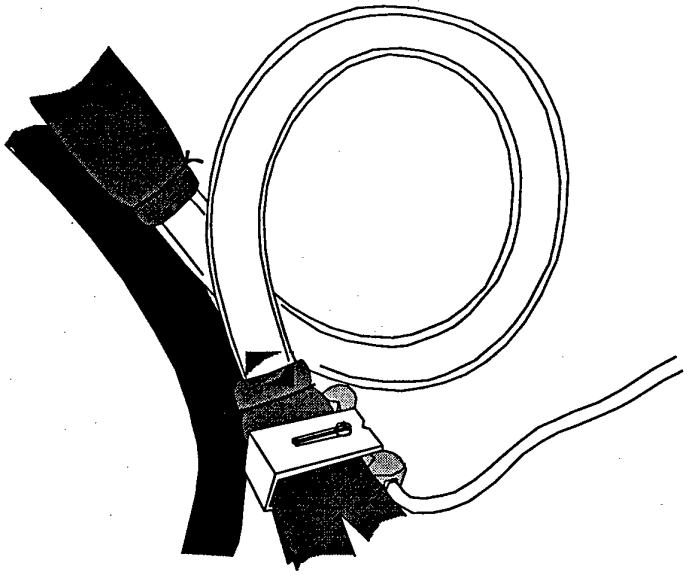


Fig. 2 - Shunt insertion close-up

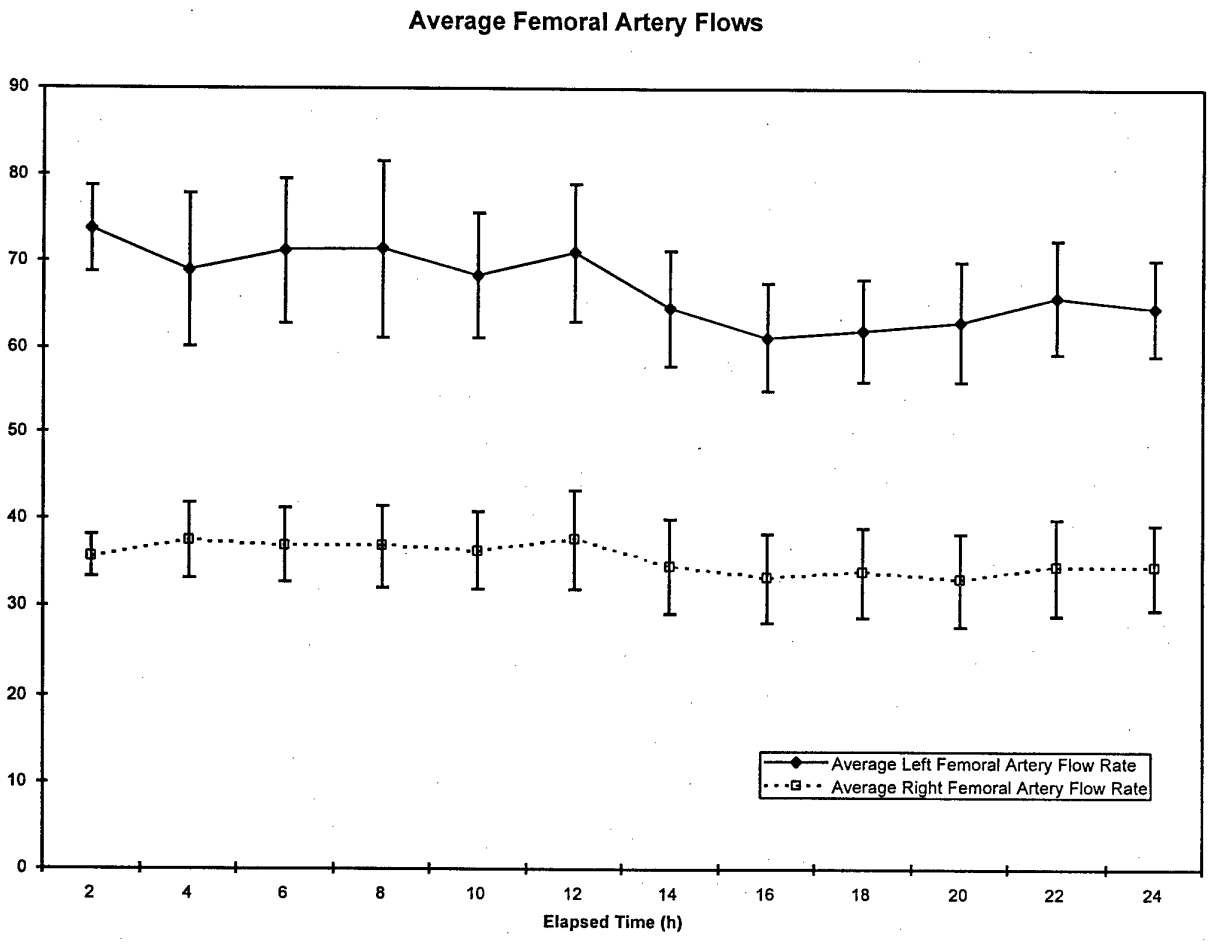


Fig. 3 - Graph: limb blood flow

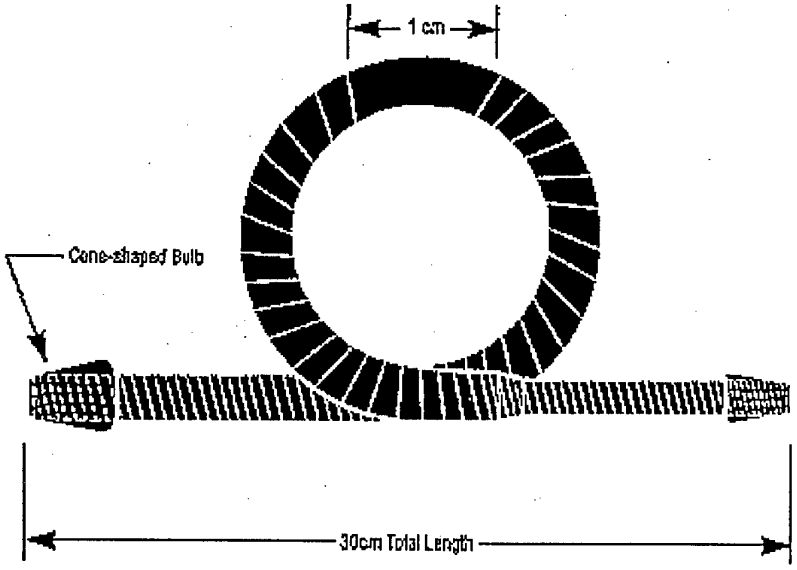


Fig. 4 - Sundt Shunt

TABLE

Vessel Examined	Arterial Luminal Diameter (mm ± SD)
Internal Carotid	0.61 ± 0.10
Common Carotid	0.75 ± 0.09
Axillary (infraclavicular)	0.70 ± 0.11
Proximal Brachial	0.48 ± 0.06
Mid-Brachial	0.43 ± 0.06
Proximal Radial	0.32 ± 0.06
Proximal Ulnar	0.26 ± 0.04
Distal External Iliac	0.91 ± 0.14
Common Femoral	0.94 ± 0.12
Proximal Superficial Femoral	0.72 ± 0.13
Mid-Superficial Femoral	0.74 ± 0.09
Popliteal	0.65 ± 0.11

Table 1. - Ultrasound measurement of arterial dimension

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BLOOD SUBSTITUTES IN CONTINGENCY OPERATIONS

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INTRODUCTION

For many years there has been a concerted effort by both industry and the military to develop blood substitutes. Such products are expected to be well-suited for use in emergency/trauma settings where the timely provision of fully cross-matched blood for resuscitation and/or transfusion may be difficult and prohibitively expensive.

The use of cell free hemoglobin solutions as a safe and effective adjunct or alternative to red blood cell transfusion has long intrigued and challenged medical practitioners dealing with the various aspects of trauma, elective and emergency surgery, and other branches of medicine. Interest in this field has been heightened by concerns of the safety of blood and blood products, particularly in terms of possible contamination with infectious agents. There are still concerns about transmission of blood-borne diseases during the "window period" when infectious agents may be present, but antibodies are not yet detectable in blood using current methods[1]. In addition, the incidence of immune suppression[2], the occasional accidental mismatching of blood and recipient, and the extent of both major and minor reactions associated with blood transfusion continue to cause concern[3].

To address these concerns, a product that substitutes for red cells would have the following characteristics:

i. it must be free of serious toxicity in any of the organ systems of the body;

ii. it should be universally compatible with all blood types to obviate the need for typing and cross-matching the donor blood and the recipient, i.e. the hemoglobin must be essentially free of antibodies and cell membrane fragments which contain the blood group antigens;

iii. it must reduce the risk of transmitting pathogens, i.e. the manufacturing process must contain multiple steps which consistently destroy infectious agents;

iv. it should have an extended shelf life, preferably at ambient temperature so that the product can be transported without refrigeration;

v. it should bind and release oxygen in a manner similar to that of normal whole blood so that oxygen can be effectively released to tissues.

HEMOGLOBIN PREPARATIONS

Earlier studies in human subjects used hemoglobin preparations significantly contaminated with red blood cell membrane fragments, other blood-derived proteins and endotoxin. Administration of these solutions caused hypertension, renal toxicity and coagulation abnormalities. [4] Other problems included the rapid renal excretion of $\alpha\beta$ dimers derived from the spontaneous dissociation of native tetrameric ($\alpha_2\beta_2$) hemoglobin outside of the red blood cell, and the markedly increased affinity to oxygen of such hemoglobin rendering it unsuitable for efficient oxygen transport to tissues under physiological oxygen tensions.

Most of these concerns have been addressed in the present generation of oxygen-carrying solutions. Both infectious contaminants and essentially all non-hemoglobin proteins are effectively eliminated by pasteurization and purification of the hemoglobin solutions. Currently there are several hemoglobin based oxygen carriers (HBOCs) under clinical development. These are of either human or bovine origin, or are made using recombinant DNA technology. The hemoglobin from which they are prepared has been modified chemically to prevent its spontaneous dissociation into the dimer, and to maintain the oxygen affinity (P_{50}) in the physiologically useful range, and prolong their circulation time. These products are listed in Table 1.

TABLE 1.

Product	Hb Source	Modification/ Cross-linker	Molecular Weight Range kDa	Status
Hemosol	human	o-raffinose (β-β)	64-~512	Phase II (Surgery)[5]
Baxter	human	fumaryl (α-α)	64	Phase III (Trauma and Surgery)[6]
Northfield	human	glutaraldehyde and pyridoxal phosphate	128-~512	Phase III (Surgery)[7]
Apex	human	polyoxyethylene	64-~512	Phase I/II (Septic Shock)[8]
Somatogen	recombinant	α-α linkage	64	Phase II (Surgery)[9]
Enzon	bovine	polyethylene glycol	>64	Phase Ib (Cancer)[10]
Biopure	bovine	glutaraldehyde	64-~640	Phase II (Surgery)[11] Veterinary Use

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

PRODUCTION

Hemolink™, the trademark of the Hemosol product, is prepared from either outdated or fresh red blood cells which are washed, lysed by gentle osmotic shock and filtered to remove platelets and large membrane fragments providing stroma-free hemoglobin. Since this hemoglobin still contains impurities such as erythrocyte enzymes, other forms of hemoglobin, and membrane surface fragments bearing blood group antigens, endotoxin and phospholipids, further purification is needed. After the mixture is pasteurized for at least 10 hours, an essentially pure hemoglobin product is obtained. This process also provides assurance that any contaminating bacteria or viruses are destroyed. A self-displacement chromatography process using both anion and cation chromatography yields highly purified hemoglobin A_o. This is then reacted with o-raffinose, a hexa-aldehyde obtained by oxidation of the trisaccharide, raffinose. Oxidized raffinose stabilizes the tetrameric structure of hemoglobin by forming a covalent bond between the two β chains specifically between the two lysines and an N-terminal valine within the DPG binding site. As well, intermolecular cross-linking results in the formation of polymers of crosslinked hemoglobin having a molecular weight up to 500kDa. Molecular weight distribution analysis shows the presence of approximately 35% cross-linked hemoglobin tetramer and 65% crosslinked hemoglobin polymer.

PRECLINICAL STUDIES

Preclinical studies conducted in several animal species have demonstrated that Hemolink™ is both safe and effective. There is no evidence of renal damage or other end organ toxicity at doses up to and including a 90% exchange transfusion. Hemolink™ has a mild to moderate pressor activity, increasing mean arterial blood pressure by 10-15%, which could be advantageous in treating hemorrhagic shock. Other HBOC products have been shown to increase mean arterial pressure by as little as 5%[7] to as much as 30-40%[6] above baseline. Hemodynamic studies have shown that Hemolink™ maintains both normal cardiac output and perfusion of organs. Indeed, in models of hemorrhagic shock, Hemolink™ has been shown to be an effective resuscitation fluid. In rats and dogs, submitted to severe hemorrhage with shock, Hemolink™ effectively restored blood pressure, cardiac output, and heart rate to normal values. There was no evidence of pulmonary hypertension in these models, unlike that reported by some workers[12] for swine. These studies demonstrate that Hemolink™ has great potential for resuscitation in humans where hemorrhagic shock is a factor.

Studies in models of both normal and compromised renal function have shown that Hemolink™ administration did not impair renal function. Isolated kidneys, when perfused with Hemolink™ maintained normal functionality suggesting the possibility of its utility in preserving this organ, possibly for prolonged periods.

CLINICAL STUDIES

A Phase I clinical trial was undertaken in human volunteers to confirm the safety of Hemolink™ administration. This was a dose escalation study in which 42 volunteers were randomized to receive either Hemolink™ or the control vehicle, Ringer's lactate solution. The initial dose of Hemolink™ administered was small, but was quickly escalated to levels of clinical relevance, i.e. up to a dose of 42g of hemoglobin, once safety of the product was demonstrated. This represents a dose of hemoglobin approximating that in a unit of whole blood. The observed and measured side effects were few and not serious. An approximately 15% increase in mean arterial blood pressure was observed that could be quite beneficial in surgical or trauma settings where hypotension is common. There was a compensatory decrease in heart rate. Renal and respiratory function were not affected. Serum electrolytes, creatinine and creatinine clearance remained stable and within the normal range throughout the study. Patients receiving higher doses, i.e. > 30g, reported abdominal pain, gas and flatulence, and some difficulty swallowing. These effects were transitory and easily treated with medication. Similar gastrointestinal effects have been reported with other HBOC's. Blood coagulation was not affected by Hemolink™. Platelet counts, prothrombin times, activated partial thromboplastin times, and fibrinogen degradation products remained unaffected.

Hemolink™ levels in plasma followed a single exponential decay, similar to data obtained in preclinical animal studies. The plasma half-life increased with dose, to a maximum of about 18-20 hours. These studies indicate that Hemolink™ is safe for administration to humans, and suggest that it will be effective for use in emergency and surgical applications.

Phase II trials are currently being conducted to demonstrate the safety of Hemolink™ when administered to individuals in a highly-controlled and well-monitored anesthesia/surgical setting where blood loss occurs. For safety studies, this model is preferable to a trauma setting where the situation is, by definition, not under full control. Based on the knowledge of product safety gained from such elective surgery trials, studies will be undertaken to demonstrate the efficacy of Hemolink™ in a trauma setting. The current Phase II trial is also a dose escalation study using Hemolink™ at up to 100 g of hemoglobin protein (1000 mL).

PRODUCT APPLICATIONS

No single protein can substitute for the multiple functions of blood, consequently, the term "blood substitute" is a mis-nomer. HBOC's are oxygen carriers, but they also have

oncotic and colloidal properties, which suggest many potential uses for these compounds. It was initially envisioned that these products could by used away from a hospital setting in trauma and emergency medicine where they would be available for immediate use without the need for cross-matching. They are currently finding utility in the more controlled elective surgical setting as a direct replacement for blood loss or as part of a hemodilution protocol. Their vasoactivity and oxygen-carrying capability permit greater hemodilution without concerns about inducing tissue ischemia. The term for these products coined at the Dutch Red Cross is "emergency blood", one that describes these uses very well.

Other potential uses of the HBOC's relate to their physical as well as pharmacological properties. For example, due to their acellular nature, these compounds may be appropriate for oxygen delivery to tissues with compromised blood flow, such as the heart during acute myocardial infarction and the brain during an occlusive stroke. They are also expected to help wound healing in patients with peripheral vascular disease. In addition, by increasing oxygen delivery to malignant tumors, the sensitivity of these tissues to chemo- and radio-therapy could be enhanced. Because of its inherent vasoactivity, an HBOC can be used to restore blood pressure in patients with septic shock, thereby preventing the vicious circle of deterioration characterizing this condition. Potentially an HBOC could also provide a super-bioavailable source of heme and iron to stimulate the synthesis of new red blood cells. HBOCs could then be used to treat anemia, including that associated with certain chronic diseases. Finally, HBOC's might be used for the preservation of organs harvested for transplantation, thereby extending the period of viability of organs such as the heart, liver, and small intestine. This could permit more efficient matching of donor and recipient and allow organs to be transported over greater distances. Ultimately, the benefit expected is improved effectiveness of the transplantation programs.

The properties of HBOC's suggest many potential uses for these blood substitutes. This brief description in no way exhausts the potential avenues for HBOC use, but only outlines some of the broad categories where studies are currently being conducted. The reader is directed to more thorough reviews of this field such as those of Dietz *et al* [13] and those included in the recent book by Dr. Winslow[14].

CONCLUSION

The era of clinically useful blood substitutes is upon us, as demonstrated by the numerous Phase I, II, and III trials currently being conducted around the world. However imperfect these initial HBOC products may seem, their safety has been established and proof of their efficacy seems clear. In the period between their formulation and the present, many of the properties of these products have been defined. In the future we can anticipate improved product formulations that will significantly extend their clinical applications.

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Discussion #7

UNKNOWN SPEAKER: Maj Pilcher, is the A-33 solution non-toxic to humans (in reference to Paper #36)?

PILCHER, US: The material is fairly non-toxic to human tissue, and in low concentrations, can be used as an ophthalmic rinse. We think the amount that we have on our instruments would not affect human tissue adversely, even when operating in sensitive areas. One part of the experiment that I did not discuss is that after we had completed the entire 10 cycles of contamination and disinfection, we recontaminated the instruments with the same stool culture slurry and recultured them with exactly the same high levels of contamination that had been present before to ensure that we had not killed the culture with over-contamination of the A-33 solution.

KILPATRICK, US: One of our medical teams in Chad was using relatively inexpensive instruments but different solutions - not A-33 - in an exercise. Through the course of the exercise, the instruments themselves were beginning to become etched and damaged by the disinfectant solution. Have you had any damage to the instruments from using the A-33 solution?

PILCHER, US: We didn't see any of that in our experiments and, actually, the same set of instruments went through the ten cycles about three times.

MOLOFF, US : How much I.V. fluid do you carry?

PILCHER, US: It's all hypertonic and we carry 20 500cc bags of Hespan (hydroxyethyl starch) and 20 500cc bags of 3% saline. We feel that we are much more effective when we are associated with any kind of neighbouring medical unit whether that be a battalion aid station or a hospital, so I.V. fluid is something we would ask for in resupply.

UNKNOWN SPEAKER/QUESTION:

PILCHER, US: We depend on host unit support for the potable water. This team only carries its surgical capability; it doesn't carry food, tents, or transportation items. We have learned to fit in with minimal stress on the local system because we are small. We will not bring everything that we need. We will ask for some help from our host unit.

UNKNOWN SPEAKER/QUESTION:

PILCHER, US: The members of the team are comprised of people who do the civilian standard type of trauma care on a day to day basis. We proposed that a team like this be employed in situations where other medical assets are simply not available. The triage criterion for operation by this team is that the injured person will not survive to the next level of care that is available. We have not attempted to get FDA approval because we are not trying to meet their standard.

UNKNOWN SPEAKER/QUESTION:
Question on night vision goggles

PILCHER, US: Night vision goggles are very challenging; my neck hurt a lot the day after the surgery. I wore them for about 2 ½ hours straight. Certainly that factor helps to degrade the ability to do accurate surgery. The latest generation of goggles is about the same size and weight as those in the preceding generations. They're balanced because the battery pack sits on the back; nevertheless, the goggles are quite heavy.

KILPATRICK, US: Dr Light, you haven't mentioned infection rate and, obviously, in an experimental porcine model where you are only looking at 24 hours of trauma, you will not be able to evaluate the risk of limb infection that is related to putting in this shunt. It would seem that the problem of infection would be one of the biggest risks of this technique. What can you say about that (in reference to Paper #38)?

LIGHT, US: You would intuitively think that the risk of infection would be high, and we have no firm data to say that it wouldn't. However, we know from the general trauma experience that when you leave a wound open you may get a superficial colonization, but that doesn't necessarily mean that it will become infected. This is especially the case if you can go back later and take care of it as is done at the definitive care area. The ischemia, which is the key portion of why something would get infected, would be resolved. We would probably do a bypass through a plane that is not involved in the open wound, and we would excise and remove all of the devitalized and dead tissue.

GIBSON, UK: I have one question about the aeromedical evacuation of such patients. From your data, you would suspect that the perfusion in the affected limb would be much less than in the contralateral side. Since tissue ischemia depends on oxygen carriage to the tissues, and you've cut back on half the transport of oxygen by the perfusion, would you recommend that such patients be given supplementary oxygen in flight?

LIGHT, US: We would certainly recommend that these patients be placed on supplemental oxygen in flight. Our patients are under general anesthesia and, if I remember correctly, are receiving 25% to 30% inspired oxygen throughout the experiment. We were able to show that the delivery of oxygen to the traumatized limb was not impaired compared to the other limb. When we looked at the amount of oxygen delivered and the venous oxygen return, and then calculated the oxygen consumption, we found that both limbs had equivalent oxygen consumption.

WILLIAMS, US: In conjunction with the question about tissue hypoxia, a lot of these patients are also going to be suffering from acute blood loss. Since this is done in a forward setting where you don't have blood products administered as part of the aeromedical evacuation, have you considered what the effect of haemorrhage is going to have on the tissue hypoxia.

LIGHT, US: We know that in a shock model, where we took 40% of the pig's blood volume away and then gave half of it back, we still maintained the animal in a relative degree of shock. The shunts stayed open but we did resuscitate the pig to a degree. From the failure that we had in one pig, we feel that if the animal is not resuscitated adequately the shunts may not stay open. It's imperative not only for the forward surgical team that they begin the resuscitation, but also that the aeromedical personnel continue this procedure as the patient is transported towards the definitive care area.

WILLIAMS, US: I think that when you are aeromedically transporting one of these individuals, after this kind of a shunt procedure, that oxygen with a mask would be imperative. This is necessary because you are going to be dealing with low ambient pressure as well as having a patient that is in a state of shock, perhaps hypovolemic, and suffers from a reduced haemoglobin that hasn't been replaced as a result of some blood loss.

LIGHT, US: Some of these patients may even be intubated, so they will obviously be on oxygen.

WILLIAMS, US: In high velocity missile injuries, I know that the damage can extend far beyond the actual wound itself. If you had missile injuries and these were just proximal to major vessels like an iliac vessel or an aorta, and then you had to transport that individual for a period of time, is there a risk of developing an occlusion in that vessel? Is there ever such a thing as a prophylactic shunt.

LIGHT, US: There is certainly a risk of developing an injury if you have what we call intimal damage from the proximity injury. We would advocate that the forward surgical unit be an MFST team. We would recommend that they carry with them a hand-held Doppler system, or something to that effect, so that they can diagnose whether there is any sign of a vascular injury. We know that if you have a normal pulse, and if you have a normal arterial pressure from the injured limb to the non-injured limb, then the chance of having a significant injury is very low. Obviously, if the patient has an ischemic limb or if there is much difference in the blood pressure between the two limbs, then that would direct the surgical team to look for the site of injury and, perhaps, put a shunt in when resuscitative surgery is performed.

LAWLOR, US: Dr Magnin, how long does the product last before it breaks down and what kind of things do you do to try and stabilize it for long periods of time (in reference to Paper #39)?

MAGNIN, CA: There are two answers required for that question: one relates to how long does it last when it's put into the bag, and the other one relates to how long does it last when it's put into people. The product can be stored in bags, in certain forms, for two years and more. There appears to be some evidence now that the product can be stored at room temperature for that same period of time, which would obviously make life much easier for the military. The product circulating half-time in people is dose dependent but it does appear to be on the order of 24 hours. It can get you over an emergency situation and, as in the case of our rats, if you are stabilized you may not need a transfusion. In other cases, it may just postpone the situation until there is time to do it properly.

KILPATRICK, US: So it's cleared in 24 hours.

MAGNIN, CA: The half-life is, so if you put in a litre, i.e., 100 g of product into the body, you will have 50 g left at 24 hours and 25 g after 48 hours.

PEARCE, US: I'm sure you are familiar with some endurance athletes that will do red blood cell packing before an event to increase their oxygen carrying capacity. I'm sure you are not building this product for that market, but it occurs to me that they might provide a useful source of data if some were willing to volunteer. That's part A of the question. Part B is that other endurance athletes are using glycerin products to increase their water carrying capacity so that they don't have to drink a lot during an event. I am wondering if you have given any consideration into including glycerin in your product for hydration purposes, especially when we are talking about how difficult it is to get I.V. solutions out into the field.

MAGNIN, CA: The short answer is no. We have taken this product through the regulatory agencies and I doubt that they would approve such a trial involving glycerin for hydration purposes. I wouldn't even ask them.

SEED, US: The doses that you used to test for safety were 0.6 g/kg. That compares with a normal human haemoglobin of 10 g/kg so you're close to the normal I.V. amount to increment 5 - 10% haemoglobin concentration.

Have you looked at larger amounts that would be relevant to an aggressive transfusion situation?

MAGNIN, CA: This is what we are doing in the Phase II trials. The reason you do not do it in the Phase I trials is that you are looking at healthy individuals. You are giving them a product that they don't need and we felt that there is a limit that we could ask the regulators to go to and that was 10% of the blood volume. In a situation such as surgery where you are losing a certain amount of blood you can give more and, of course, that includes a trauma situation. The products being tested by one of our competitors calls for as much as 500 g, 100% blood volume replacement in a trauma situation. We are not sure how much product actually stayed in a patient. Another competitor is working around the 100-g level. One of the problems is obtaining the numbers of patients required, because the more blood that they need the rarer it is to find such a patient in a civilian hospital who fits the clinical trial criteria.

UNKNOWN SPEAKER/QUESTION: Question on multiple dosing and immunogenicity

MAGNIN, CA: Multiple dosing in human beings at this stage of the trial is not done but, when looking at rats, we see no evidence of immunogenicity. The product can be given daily for a 14-day period without any evidence of distress on the part of the animal. The product does appear to be safe; any antibodies that have been able to form to it have been directed only against the haemoglobin and not at any epitopes created by the modification of the haemoglobin.

KILPATRICK, US: To those of us who are physicians, this sounds like it represents great potential, but we certainly would have many questions about things like immunogenicity, as yet undetected impact on other organ systems, microvascular impact and so on. While we are excited about it, we will certainly be watching with concern that we ferret out all the potential problems related to the product.

MAGNIN, CA: I agree. These will be looked at in our future clinical trial programs.

A Worldwide Epidemiological Survey on the Infrastructure for Prevention of Communicable Diseases in the Military

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Introduction

Infectious diseases represent a heavy burden for mankind. In 1995 infectious diseases were responsible for more than 17 million (33%) of nearly 52 million deaths worldwide **(1)**. Among these infectious diseases, 65% were those characterized by person-to-person transmission, such as the sexually and air-borne transmitted diseases; followed by food, water and soil-borne (22%), insect-borne (13%) and animal-borne (0.3%) diseases. They include, in order of importance, acute respiratory infections (4.4 million deaths/year), followed by diarrhoeal diseases (3.1 million deaths/year), tuberculosis (3.1 million deaths/year) malaria (2.1 million deaths/year), hepatitis B (1.1 million deaths/year), HIV/AIDS (>1 million deaths/year), measles (>1 million deaths/year), neonatal tetanus (500.000 deaths/year), whooping cough (355.000 deaths/year) and lastly roundworm and hookworm (165.000 deaths/year) **(1)**.

During the past twenty years it has been shown repeatedly that emerging and reemerging infectious diseases and related public health problems are a challenge which has not been successfully met. For example twenty years ago Legionnaires' disease and Ebola virus were first identified, while at the same time gonococcal resistance to penicillin and chloroquine-resistant malaria were becoming widely dispersed in Southeastern Asia. Though HIV infection was still unknown twenty years ago, retrospective analysis shows that it was already present in Africa in 1976, with a seroprevalence of less than 1%. At the same time, however; smallpox still was eradicated, clearly demonstrating the dynamic state of infectious diseases.

Now, twenty years later, Legionnaires' disease and HIV infection are known to be worldwide and continue to spread, and Ebola haemorrhagic fever has occurred periodically, with human outbreaks in Zaire, Sudan and Gabon; and animal outbreaks in Côte d'Ivoire, Italy and the United States of America. By 1996 gonococcal resistance to penicillin and chloroquine-resistant malaria had spread worldwide, while their resistance to other antimicrobial agents had also developed and spread. Current examples of other emerging and reemerging infectious diseases are the spread of diphtheria in Eastern European countries in the early 1990s, of pulmonary Hantavirus in USA in 1993, of cholera which reemerged in Latin America in 1991 after decades of absence, and the appearance of a new subtype of Vibrio cholerae, O139, in India and Myanmar in 1993 **(2)**.

The causes of the present situation in infectious diseases are several, including urbanization (about 45% of the world's total population live in urban settlements, with inadequate provision for water, sanitation and garbage collection), increase in travel and trade (the number of total air-travellers exceeded 1,200 million in 1994) and the breakdown of public health practices in both, developing and industrialized countries, the latter linked to the erroneous idea in the 1960s and early 1970s that infectious diseases no longer represented a danger for public health **(1)**.

Military personnel are at special risk for infectious diseases. Military community life favours the spread of air-borne, food-borne and water-borne infectious diseases. Military operations and resulting injuries facilitate transmission of blood-borne infections, while long periods away from home, family and/or stable sexual relationship favours the spread of the sexually transmitted diseases (STDs). STDs are in fact 2-5 fold higher in military than in civilian population in peacetime, and up to 100 fold higher in times of war **(3)**. In addition, deployment overseas, with different climates, insect vectors and endemic microrganisms increases the risk of diseases.

Given this background, it is extremely important to develop effective measures to fight infectious diseases. The strategic response of the World Health Organization (WHO) to the current situation of infectious diseases has been focussed on global and national surveillance, alert and control of infectious diseases. At a series of meetings conducted by WHO in 1994 and 1995, four goals intended to guide the worldwide response to emerging, reemerging and other communicable diseases and public health problems were defined as follows:

Goal I: To strenghten the global surveillance of communicable diseases;
Goal II: To strenghten the national and international infrastructure necessary to recognize, report, and respond to emerging communicable diseases;
Goal III: To strenghten national and international capacity for the prevention and control of communicable diseases;
Goal IV: To support and promote research in communicable disease control.

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These goals are similar to those adopted by the United States of America (4-5), Canada, Thailand and other countries worldwide. Inadequacies in national surveillance programmes were dramatically demonstrated during the recent outbreaks of plague in India (1994) and of Ebola in Zaire (1995), where a more effective and prompt detection and diagnostic capacity would possibly have limited the dimensions of outbreaks.

To implement global surveillance and alert, WHO builds on existing networks, such as the WHO Collaborating Centres, specialized national laboratories and institutions with expertise in infectious disease diagnosis and epidemiology. WHO is strengthening its collaborating centre system by encouraging governments to provide the resources necessary to ensure that collaborating centres are up to date, facilitating exchange of information and reagents among its centres, increasing the number of centres in developing countries and ensuring that all centres are linked electronically and are regularly exchanging information with WHO and among themselves.

A second global monitoring system is based on the WHO network for monitoring and containing antimicrobial resistance. WHO is currently developing a network of laboratory centres in developing countries to perform national antimicrobial resistance testing using standard quality-controlled procedures, participate in the WHO proficiency testing programme and regularly report their results nationally and to WHO. Through this network WHO assists countries in using test results for sound national drug policies and uses the information internationally to demonstrate the problem and advocate for research and development on antibiotics. A bank of well-characterized resistant strains of microrganisms being established for research and development.

A third system is the International Health Regulation (IHR), currently the only international public health legislation which requires mandatory reporting of infectious diseases: cholera, plague and yellow fever. To transform the IHR into a working global alert system, the WHO is revising the IHR to focus on the reporting of clinical syndromes of potential worldwide importance for which standard and internationally accepted responses by countries will be promoted. Syndromic reporting will be followed by etiologic reporting once the diagnosis is known at which time modifications in the response may be made. Accompanying the revision is the development of clear and concise guidelines, which describe appropriate and inappropriate responses once a syndrome is reported.

WHO proposes involving military facilities in these systems and a military liaison officer to assess the feasibility of such military involvement is currently based at WHO (R. D'Amelio). Justification for liaison with military laboratories in these monitoring and alert systems is that 1) the military is at special risk for infectious diseases; 2) military laboratories in some developing countries are better equipped than civilian laboratories.

The WHO military liaison officer began collaboration in April 1995, with the goal of creating a network of global surveillance in the military, parallel and complementary to those of WHO. The creation of the network began with a survey among WHO Member States to identify countries committed to collaboration through a military laboratory capable of diagnosing common infectious and/or notifying infectious diseases in a national reporting system. This was followed by a second survey among military laboratories willing to collaborate in which their diagnostic and reporting practices were assessed. The third stage will be training workshops in developing countries, and the establishment of electronic links for exchange of information.

The survey

Until now, out of 107 countries to which an adhesion to the project has been requested, 76 have replied, involving 25/34 (73%) from Africa, 14/28 (50%) from Asia, 9/17 (53%) from the Americas, 26/26 (100%) from Europe, Australia and New Zealand **(Table I)**. A military laboratory able to diagnose endemic infectious diseases and to recognize the presence of unusual ones is present in 19/25 (76%) African countries, in 17/26 (68%) European countries, in 5/9 (55%) American countries, in 12/14 (86%) Asian countries and it is absent in Oceania **(Table I)**. A military notification system for infectious diseases is present in 19/25 (76%) African countries, in 24/26 (92%) European countries, in 7/9 (78%) American countries, in 11/14 (79%) Asian countries and in 1/2 Oceanian countries **(Table I)**.

Table I. **Presence of a military laboratory and/or of a military notification system for infectious diseases.**

Continent	(%) countries replied	(%) with Military Lab	(%) with Military Notification System
Africa	25/34 (73)	19/25 (76)	19/25 (76)
Americas	9/17 (53)	5/9 (55)	7/9 (78)
Asia	14/28 (50)	12/14 (86)	11/14 (79)
Europe	26/26 (100)	17/26 (68)	24/26 (92)
Oceania	2/2 (100)	0/2 (0)	1/2 (50)
Total	76/107 (71)	53/76 (70)	62/76 (82)

Six countries among the 76 which replied do not notify their National Health Services about infectious diseases occurring in the military environment.

Present situation

Additional questionnaires were sent to the 76 countries which had already replied, asking for more detailed information about the diagnostic capabilities of the laboratories, the characteristics of the notification system, the mandatory diagnostic schedule for infectious diseases on recruitment if present, and the actual vaccination schedule.

Fifty-one countries replied: 15 from Africa, 5 from the Americas, 7 from Asia, 22 from Europe and 2 from Oceania **(Table II)**.

Military Laboratories

Among these 51, 38 have a military laboratory to diagnose infectious diseases, 23 of whom declare to be able to undertake at least 4 of the following activities: Bacteriology, Virology, Parasitology, Immunology and Molecular Biology **(Table II)**. Thirty-four out of 51 declare their willingness to participate in the WHO antibiotic resistance monitoring and containment programme

Military Notification System.

Twenty-six (51%) of the countries are equipped with a computerized network for surveillance and 16 countries (31%) report not having a system to avoid duplicate notification of the same disease by the National Civilian Health Service **(Table II)**.

Table II. **Range of activities performed in the military laboratories and state of computerization/potential for duplicate reporting**

Continent	N° of countries replied/total	N° of activity areas All	1-4	No	Computerized	No system to avoid duplicate notification
Africa	15/25 (60%)	1	12	2	5	7
Americas	5/9 (55%)	1	3	1	5	1
Asia	7/14 (50%)	3	4	0	2	4
Europe	22/26 (85%)	3	11	8	13	3
Oceania	2/2 (100%)				2 1	1
Total	51/76 (67%)	8	30	13	26	16

Recruitment Screening

Eighty-two percent of the countries perform mandatory screening on recruitment for tuberculosis and/or syphilis, 26 (51%) for HIV infection, while some screen for other viral diseases, such as HAV, HBV and/or HCV (one country in Africa requires screening for HAV and HBV, but not for HIV). Thirty-seven percent perform a mandatory screening on recruitment for intestinal, urinary and/or blood-borne parasitic diseases **(Table III)**.

Immunization Requirements

Five of the 51 countries have no mandatory general immunization schedule; of the remaining 46, 44 require immunization against tetanus toxoid, 30 diphtheria toxoid, 22 typhoid fever, 16 BCG, 16 polio, 11 meningococcal meningitis and 10 trivalent measles/mumps/rubella **(Table III)**. Two countries still report vaccinia vaccination as compulsory for military recruits

Table III. Mandatory screening and vaccination on recruitment

Continent	Screening on recruitment Viral	Tub/Syph	Paras	Vaccination schedule T/d/Ty/BCG/P/Mn/MMR
Africa	12	14	9	11/9/10/5/2/3/3
Americas	4	5	2	4/3/3/0/2/1/2
Asia	5	7	5	5/2/2/3/2/2/1
Europe	5	15	3	22/14/7/7/8/5/3
Oceania		1	1 0	2/2/0/1/2/0/1
Total	27	42	19	44/30/22/16/16/11/10

Situation in NATO countries

A panoramic view of NATO countries shows that 10 have a central military laboratory for the diagnosis of infectious diseases, half of which are able to perform activities in immunology, bacteriology, virology, parasitology, and molecular biology; 10 countries have a computerized military notification system for infectious diseases and 2 countries report not having a system to avoid duplicate notification with the National Civilian Health Service; 3 countries perform compulsory HIV screening and 7 compulsory chest radiograph on recruitment; and the mandatory vaccination schedule ranges from 1 to 11 vaccine antigens **(Table IV)**.

Table IV. Range of activities performed in the military laboratories, and mandatory screening and vaccination activities in NATO countries.

Country	Laboratory All 5	1-4	Computer System	Screening HIV	X-ray	Vaccinations
1) Belgium		x	x		x	T/d/HepA
2) Canada			x			T/d/HepA/B/Ty/Mn/MMR/P/YF
3) Denmark						T/d
4) France	x		x			T/d/Mn/P
5) Germany	x		x		x	T
6) Greece		x	x	x	x	T/d/BCG
7) Italy			x		x	T/d/Ty/Mn/BCG/MMR/HepB
8) Luxembourg						T/d/P
9) Norway	x		x	x	x	T/d
10)Portugal		x			x	T/Ty/BCG
11)Spain		x	x			T/Ty
12)The Netherlands						T/d/Ty/MMR/HepA/B/P
13)Turkey	x				x	T/Mn/BCG
14)UK		x	x			T/Mn/P/YF
15)USA	x		x	x		T/d/Pt/P/MMR/Inf
Total	5	5	10	3	7	1 - 11

Future directions

WHO is making plans to include some developing country military laboratories in training courses on bacteriology, with the aim to bringing them into the network of antibiotic resistance monitoring. This will be the first step to allow the laboratories to actually work together. Once organized, the military network for surveillance of infectious diseases and antimicrobial resistance will be useful for detecting and monitoring both naturally occurring or deliberately caused outbreaks of infectious diseases.

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Prevention of HIV Infection and Sexually-Transmitted Diseases in Contingency and Peacekeeping Operations

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SUMMARY

Armed forces personnel are at special risk for exposure to STDs and HIV. The HIV risks are related to sexual activity and injecting drug use, and they are much higher during deployment.

Military readiness can be compromised by these diseases through sick leave, loss of training input, loss of experience/skills, and cost of replacement training. HIV-positive personnel jeopardise field safety of blood supplies during contingency operations. Providing first aid in the field is also more complicated, and interaction with the local population carries its special risks.

Expanding STD/HIV Prevention Efforts *before* deployment on contingency operations is the way to ensure effective prevention.

Elements include:

- training of medical and nursing staff
- reinforcement of prevention education
- explicit instruction in the use of condoms
- improved and accessible STD services
- voluntary testing and counselling services
- universal precautions and blood safety
- avoid R&R in high STD/HIV-risk resorts
- non-stigmatising environment for the HIV+
- civil-military collaboration
- continuum of care back to the community for those who are living with HIV and AIDS, and their families.

Testing for HIV: mandatory or voluntary? This remains a contentious issue. The paper looks at current practice around the world and the arguments pro and con.

In particular, HIV testing for pilots is examined in the light of what is known about the presence of cognitive and neuropsychological impairment which may appear in early HIV infection. The need to assess neuropsychological functioning is important for those whose job performance has a potential impact on public safety. This is of concern not only in relation to HIV infection but for many other factors that have an impact on performance.

Neurocognitive testing is an essential part of "fit-to-fly" certification. Use of computerised simulators such as the CogScreen™ applications is an efficient and cost-effective approach to accomplishing this testing.

1. INTRODUCTION

Armed forces personnel constitute a population group at special risk for exposure to sexually transmitted diseases (STDs), including infection with the human immuno-deficiency virus (HIV) that leads to the acquired immunodeficiency syndrome (AIDS). It has long been known that soldiers are prone to get what we used to call venereal diseases, or "VD". This bit of conventional wisdom is rooted in sobering facts; STD rates among the military are generally two to five times higher than STD infection rates in comparable civilian populations -- even in peace times.

In conflict situations, the risk of transmission of these diseases is much higher. STD rates in the United States military have been documented to rise 50 or more times in each period of war engagement (1).

2. UNDERSTANDING THE RISKS

The reasons for this heightened susceptibility are not hard to find. Military and peacekeeping service regularly takes one away from home, spouses, regular partners and community for long periods of time. Thus, troops and officers are often in search of ways to relieve loneliness and stress. The military is a profession which excuses or even encourages risk-taking. Its personnel are largely in the age group at greatest risk for HIV infection -- the 15-24 year old age group. On top of all this, military camps, including the installations of peacekeeping forces, attract sex workers and those who deal in illicit drugs.

Off-duty times, particularly when alcohol or drugs are consumed, are the times of risk. Off-duty soldiers can be counted on to have cash -- but not necessarily condoms -- in their pockets. And those who remember to take condoms with them are likely to forget them, or fail to negotiate their use, while under the influence of alcohol or drugs (2).

Soldiers on deployment regularly have sexual contacts with prostitutes and the local population. For example, 45% of Dutch navy personnel on peacekeeping duty in Cambodia had sexual contact with prostitutes or other members of the local population during a five-month tour (3).

The risks posed by this type of behaviour are confirmed by studies which reported that 10% of American naval personnel and marines got a new STD during trips to South America, West Africa and the Mediterranean during 1989-1991.

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In another survey in 1995, 42% out of 1,377 U.S. rapid deployment personnel reported having more than one regular partner and/or at least one casual partner during the preceding year (4). The French Army Medical Service studied their own troops after deployment, as recently reported by Médecin-Général Jacques Abgrall, and concluded that tours of duty overseas multiply the risk of HIV infection by a factor of 5, compared to troops based on French soil (5).

Partner-related risk of exposure to STDs and HIV is high during sexual contacts with partners who are "one night stands" or local sex workers. Having multiple sexual partners multiplies the level of risk. The chances of encountering someone with prior exposure to HIV go higher as the number of partners goes up. The number of partners is a much more important determinant of risk than the number of contacts per partner. Unprotected sex -- not using a condom -- is very risky, of course.

Having a male sexual partner who has had sex with other men also raises the risks -- in this case, for *both* men and women. There are many studies which have shown that HIV prevalence is higher among men who have sex with other men. The fact that there are men who have sex with men in the military is a sensitive issue in many countries. Partner-related risk in this type of activity is seen in the sexual contacts between homosexual or bisexual men. But, it may also be seen in experimentation with oral and anal sex among men who identify themselves as heterosexual, but who try this, for example, during long periods of isolation from female companionship (6).

It is also important to understand the special vulnerability of women in relation to the risk of STD and HIV transmission. Women are biologically at greater risk since they are more likely to acquire any STD from a single sexual exposure than men are. They have more asymptomatic STDs that are more often difficult to diagnose. And women military personnel are often at a disadvantage in sexual negotiations, or subject to sex under duress or even rape.

There is evidence that personal and family stresses are rising in the military community in the 1990s -- and stress has a bearing on vulnerability to these types of illness. 63% of the U.S. army today is married, compared with 22% at end of WW II -- that in itself is positive. Keep in mind that these are young men and women in young marriages with the pressures of long separations and rather unpredictable deployments. This is seen by some as a very real health, resiliency and readiness issue.

3. THE EXTENT OF THE PROBLEM

The military leadership in a number of countries are concerned that military readiness, security and leadership can be compromised by this particular group of health problems. The loss of training input, the loss of experience and skills, the cost of replacement training -- all have their impact on military readiness.

The actual or potential presence of HIV-positive personnel in the ranks becomes more important in times of foreign deployment and in conflict situations. It calls into question the safety of blood supplies in field situations (although newer methods of dealing with blood loss in the field make this less of a problem now than it was previously). Providing first aid and health care in the field may also be regarded as more complicated, though these can be managed by properly teaching and observing *universal precautions.*

Among the less direct consequences of HIV infection is the impact on the individuals concerned. A member of the armed forces who has admitted, or who is known or suspected of being HIV-positive, will often be stigmatised and discriminated against in both official and social settings. It may arise out of fear of close contact with someone who may be viewed as a source of serious disease. It may reflect distaste for being with someone who is assumed to have become infected with HIV through injecting drug use or through homosexual activity. It may be a fear of going on field exercises with someone who is thought may not be able to hold up to the demands, or whose blood -- spilled through injury or donated as a member of the "walking blood bank" -- is assumed to be contaminated, infected, a hazard.

For those members of the armed forces who are infected with any of the STDs, including HIV, there is the *risk of onward transmission* of these infections to spouses (and children), partners, commercial sex workers, and other members of the community. A critical point here is the issue of responsibility for partner notification and for adopting safer sex practices. If it is known that an HIV positive person has not informed his or her partner or continues to practice unprotected sex -- who then is responsible or has the right to do something? (7, 8, 9)

Well, all of this simply means that STD and HIV *prevention* is a priority issue for the military.

4. HOW DO WE GO ABOUT EXPANDING HIV PREVENTION EFFORTS IN THE MILITARY ?

4.1 HIV prevention begins with prevention education -- first through the training of medical and nursing staff, and then through the regular and repetitive briefing and preparation of the troops themselves (10).

- All personnel must know the facts of how this infection is transmitted, and the circumstances in which they put themselves at risk.
- They must be aware of the implications and long-term consequences of risky behaviour.

- They should be encouraged in their motivation to sustain a certain standard of behaviour, understanding that mutual fidelity in a sexual partnership -- and abstinence when one is away from that partnership -- is the best start on practicing safer sex.
- They need to learn the skills of negotiating the conduct of sexual relations and of using condoms.

4.2 An essential element in this prevention education is regular, explicit instruction in the use of condoms, including demonstrations on how to apply both male and female condoms, giving all personnel the chance to practice handling and applying condoms.

4.3 The promotion of STD care-seeking behaviour and the provision of accessible STD drugs and services are further key elements.

4.4 Another key element is the provision of counselling and voluntary testing services, with regular encouragement to the personnel to take advantage of these services.

4.5 Universal precautions and blood safety -- the precautions taken in the handling, screening and transfusion of blood products in health facilities and in the field -- are essential skills and practices to be taught and reinforced. This also refers to how one deals with spilled blood and open wounds, and both health care personnel and the troops themselves need to know the principles of universal precautions.

4.6 A prevention measure often overlooked is the avoidance of organised rest and rehabilitation ("R&R") visits to resorts with high HIV prevalence in the local sex worker population. These visits can add significantly to the risk that troops will be bringing STDs and HIV home (as they did after the Gulf War).

4.7 Not always stressed is the need to create a non-stigmatising, non-discriminating environment within the military population for those who are HIV positive. This begins with full respect for confidentiality of the outcome of any HIV testing. HIV positive individuals should be given every opportunity to fulfil the tasks for which they have been trained and are fit to perform.

4.8 Finally, prevention needs to be paired with care and support for persons living with HIV/AIDS, including care for them *and their families* as they return to civilian life. All HIV/AIDS prevention and care efforts must recognise the constant interaction between the military and civilian populations through spouses, partners, families and other community contacts.

5. HIV TESTING

One contentious issue that has been exercising military leadership around the world has been this matter of *testing for HIV -- mandatory or voluntary* (11).

First, let me offer a brief look at the history of mandatory HIV testing in the military. Mandatory testing for the U.S. military was established in 1985 on the premise that protection of individual and public health required early diagnosis of HIV infection. The rationale was also based on certain military-specific concerns: health and safety of the individual in the face of multiple live vaccines and potential exposure to "exotic" infections; maintenance of a safe "walking blood bank"; military readiness; and world-wide deployability. Making such a diagnosis would allow those who are HIV-positive to receive the benefit of targeted behavioural and therapeutic interventions (12, 13).

Those who defend mandatory pre-recruitment and periodic HIV testing also point to the psychological value to HIV-negative individuals of knowing that they have been tested and are not infected (14).

Those who oppose a policy of mandatory testing offer a number of counter-arguments:

- many legal and human rights experts maintain that mandatory testing is a violation of individual rights and privacy which cannot be justified by military-specific demands;
- a positive test in an asymptomatic individual does not bear on that person's right to work or "fitness for work";
- one also must be concerned about the rate of false negatives and false positives, as well as the pre-seroconversion "window"; and,
- finally, it must be said, mandatory testing is a weak prevention measure. It is certainly less effective than good prevention education. A voluntary testing and counselling programme, coupled with prevention education, will provide all that one would ever ask of any testing effort.

6. CURRENT HIV TESTING PRACTICE

What is known about the current policies, practices on HIV testing in the armed forces of countries in the various regions? Over the course of 1995/1996, the Civil-Military Alliance to Combat HIV and AIDS and UNAIDS carried out a 120-country survey on "HIV/AIDS Prevention, Testing and Care in Current Military Medical Practice" (15). 63 countries returned fully completed questionnaires.

The following data reflects the position in the 63 countries which replied:

43 of the reporting countries (68%) stated that they impose mandatory HIV testing in some situations. Among these 43 countries, the most frequently mentioned mandatory test settings are pre-recruitment (25 countries, or 58% of the 43), prior to foreign deployment (24 countries), before separation from active duty (12 countries), periodically (9 countries), and before new assignment (8 countries). Rejection of

candidates for recruitment on the basis of known HIV positive status is the rule in 83% of responses (45 of 54 respondents), 79% of countries impose restriction of duties for those who are HIV-positive (exclusion from combat and from piloting aircraft), and 90% practice exclusion of those who may be HIV-positive from overseas deployment.

7. WHAT ABOUT TESTING FOR PILOTS ?

There is accumulating evidence of cognitive impairment in some HIV+ individuals (a minority), measured by neuropsychological tests, even before the onset of AIDS. In a recent review of 57 studies and reports on this topic, *sub-syndromic neurocognitive impairment* (i.e., impairment that is not yet AIDS-defining) was found in a median of 35% of HIV+ asymptomatic individuals, compared with a median of 12% among appropriately matched HIV-uninfected controls (16).

However, a number of important factors besides HIV infection will also affect the manifestation and/or the measurement of neurocognitive impairment, including:

- alcohol and drug use;
- prescription medicine use;
- prior or concurrent psychiatric, neurological, or medical conditions;
- demographic factors - age and education; and
- nutritional status.

There is also a body of evidence linking neuropsychological performance to occupational competence. Not all cognitive deficits, of course, have implications for real-life performance. At this moment, there are only a few studies regarding the relationship of *HIV neurocognitive impairment* to real-life performance in specific occupations or job classifications among individuals with early HIV infection. More research in this area is urgently needed (17, 18, 19, 20).

Where potential neurocognitive impairment in performance has implications for public safety (that is, occupations or situations in which large numbers of persons could be affected by impaired performance or error by one individual, such as a pilot, train engineer, bus driver, or the like), it is recommended that all such individuals undergo neurocognitive evaluation on a periodic basis, perhaps every 6 months. This will be important with respect to those who are known to be HIV positive -- or those who may be HIV positive and no one knows it yet -- but also for those who may have unforeseen neurocognitive deficits from any other cause.

Periodic neurocognitive evaluation should assess skills and abilities relevant for their occupation or performance requirements, and would ideally be based on computerized simulators depicting real-life performance conditions. In the absence of such simulators, it is recommended that neurocognitive evaluation be based on a comprehensive battery of neuropsychological tests, which assess the following:

- speed of information processing, including simple and complex (choice) reaction time;
- learning efficiency;
- attention, both selective and divided;
- executive functions, including planning and flexibility;
- working memory;
- delayed retention; and
- motor and perceptual-motor speed.

It is not recommended that HIV+ individuals be excluded from any occupation on the basis of HIV infection alone (21).

An extremely useful software programme has become available recently to assess skills presumed important for aviation as an alternative to mandatory exclusion of HIV+ pilots from flying: **COGSCREEN™** and **COGSCREEN™ AEROMEDICAL EDITION**.

CogScreen™ is an 11-test, 45-minute computer-administered and scored neurocognitive battery, designed to assess deficits or changes in attention, immediate and short-term memory, spatial-perceptual functions, calculation skills, reaction time, simultaneous information processing, and executive functions. It is carried out entirely with the use of a light pen and touch screen interaction. Thus, it does not require computer keyboard skills of any those who are being tested.

CogScreen™-Aeromedical Edition is designed to detect subtle changes in cognitive functioning which, left unnoticed, may result in poor pilot judgment or slow reaction time in critical operational situations (22, 23).

The CogScreen™ software and the first set of 10 tests together sell for around US$500. After that, test sets can be purchased for about US$15 for each administration. The light pen costs approximately US$200. Organizations with multiple test sites only need to buy a single copy of the software per site. For the other computers at the same site they only need to purchase the "testkey", a software piracy and data protection device that attaches to the printer port. The testkey sells for US$75.

Key words:
acquired immunodeficiency syndrome (AIDS); human immuno-deficiency virus (HIV); mandatory HIV testing; military; neurocognitive impairment; peacekeeping; sexually transmitted diseases (STDs); voluntary counseling and testing.

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Useful reading may also be found in the Newsletter of the Civil-Military Alliance to Combat HIV and AIDS - a worldwide non-governmental organization representing both civilian and military organizations concerned with HIV/AIDS.
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PRIORITIES IN IMMUNIZATIONS FOR PEACEKEEPING FORCES

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Abstract

Previous experience shows wide differences in the immunizations status among contingents arriving from different nations for peacekeeping missions.

This seems to be due to lack of knowledge, lack of coordination, and lack of financial support.

To obtain logical priorities for immunizations in peacekeeping forces, one must primarily assess the risk of infection, to a lesser degree consider the impact of infection. Host factors, legal aspects and vaccine safety and efficacy also play a role.

Usually, peacekeeping missions take place in regions with impaired hygienic conditions. in non-immunes, the risk is greatest for hepatitis A, hepatitis B, thyphoid fever and measles in most target countries. Yellow fever, Japanese encephalitis, poliomyelitis, and plague are of no concern at many destinations, but the risk may be substantial at others. Cholera, diphtheria, rabies, tetanus and tuberculosis are a lesser, albeit

almost worldwide risk for troops. Depending on the type of mission, immunization against influenza needs to be considered. Future oral vaccines against gastrointestinal infections may become relevant issues in near future..

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(Introduction)

Whenever peacekeeping missions are planned, the question on the need of immunization arises. For larger missions, the United Nations (UN) Headquarters issue recommendations. In the past, non-medical operations officers issued these recommendations on the basis of older handbooks of tropical medicine. For Namibia in 1989 for instance immunization was strongly recommended against cholera, poliomyelitis, tetanus, typhoid and there was a requirement for yellow fever vaccination. Immunization against hepatitis A was only given as an option, whereas vaccines for diphtheria, hepatitis B, measles, meningococcal disease, plague and rabies were not recommended. Medical experts in many countries sending contingents to Namibia set different priorities on immunizations, and protected their troops rather against diphtheria, hepatitis A, meningococcal disease and rabies than against cholera[1]. Contingents from developing countries often arrived without immunization coverage and for financial reasons requested to be immunized upon arrival. This resulted in a widely differing protection against various infections amongst the troops and civilian employees involved in the Namibia mission. Uncertainties about immunization may not only lead to health risks for individuals, inadequate immunization may also lead to unnecessary costs and theoretically even compromize a mission, should an epidemic occur.

Lately, the UN are consulting with experts of the World Health Organization before issuing recommendations and the advice has become adequate. However, medical officers should understand the rationale of these recommendations and be able to develop those for smaller missions themselves. For this, a range of criteria needs to be considered (table 1).

Risk of infection

Data collection: Ideally, data on the incidence of vaccine preventable diseases within a military population that has fulfilled similar duties in the same locations should be available. This is rarely available, but in Namibia it has been possible to analyze data kindly provided by the South African Medical Services which surveyed all of the armed forces stationed there.

When military data from the respective region are not available, incidence and/or prevalence data on the population in the host country may be substituted. This may, however, be misleading as the military often does not share the same life style with the native population. Plague, for instance, had an incidence rate of 8 per 100,000 at the time in

Namibia, but not a single case has been observed in the South African Armed Forces.

Often when a peacekeeping mission becomes necessary, civil services have been disrupted and no up-to-date epidemiological documentation may be available. To some extent, it may then be useful to study data from neighbouring countries.

Incidence rate of infections in travelers: In the past two decades, data on travel related infections have been compared (figure 1).

Traveller's diarrhoea is no doubt the most frequent health impairment abroad. Although being self-limited and lasting only an average of 1 day with appropriate treatment, 4 days without, it has a well known potential for wrecking these few days. For a military mission this may be detrimental. In 1-2% diarrhoea lasts for longer than 1 month. The most frequent pathogens causing traveller's diarrhoea are enterotoxigenic *E. coli, Campylobacter* spp., and rotavirus. Oral vaccines against all three have been developed, some of them will be marketed in near future[2].

Hepatitis A is the most frequent among the currently vaccine preventable diseases[3]. All surveys show that it is 10 to 100 times more frequent than typhoid fever. Hepatitis B occurs only in expatriates or in tourists who break fundamental hygienic rules, such as having unprotected casual sex. The incidence rate of rabies is unknown, but animal bites which have a potential of rabies virus transmission and thus necessitate post-exposure prophylaxis are rather frequent[4]. Only anecdotal cases of diphtheria, tetanus and tuberculosis have been published. Poliomyelitis, yellow fever, Japanese encephalitis and plague occur only in limited parts of the world[5].

Experience shows similarities in travel statistics and reports on peacekeeping missions. In Namibia not only the South African Armed Forces had most often observed hepatitis (unspecified), with rare cases of tuberculosis, typhoid and meningitis reported. The same experience was acually made later in the UN mission to Namibia where within 12 months and at an average strength of 7,114 military, police and civilian employees seven cases of hepatitis (mostly hepatitis A, some unspecified as lost in follow-up after evacuation)[6]. No other vaccine preventable infections, were diagnosed in this UN mission. Rabies has repeatedly caused concern, such as in a hospital group whose pet animal died of rabies and in individuals who were bitten in remote areas.

Impact of infection: As described, already a trivial infection such as traveller's diarrhoea may particularly in a military setting have a considerable impact. In table 2 an attempt has been made to define both risk of infection and impact according to objective criteria and to set an order of priority for immunization.

There is an arbitrary decision to be made basing on the type of mission, financial means, etc. as to how far down the list in table 2 one wishes to protect the individuals. But never should one give priority to immunizations against the less frequent, less severe infections while leaving the troops unprotected against other which would be higher up on that list.

Host factors

Immunological status: It is unnecessary to immunize persons who are already immune, be that by previous immunization (often the documentation is lacking!) or by immunity after having been infected. The latter is particularly aften the case in hepatitis A; in troops recruited in developing countries an anti-HAV seroprevalence rate close to 100% can be expected[7]. Hepatitis B immunization, except for non- and low-responders, probably grants lifelong protection[8], the same is likely for measles vaccine.

Particular exposure: Subpopulations in a peacekeeping mission may have particular health risks, such as those fulfilling medical duties for hepatitis B. So far, there has been no risk of biological warfare agents in classical peacekeeping missions, but that may change[9].

Intervention data

The characteristics of the various vaccines with a varying rate of efficacy and very different durations of protection must be known. A synopsis is found in table 3.

Cost-benefit evaluations are unlikely to be performed in view of the many uncertainties to be faced, but decisions will often depend on the available budget.

Legal and ethical aspects

Sometimes the host country may require proof of some specific vaccination basing on the International Health Regulations[10, 11]. It can be imagined that there may be an irrational psychological pressure to use some vaccine, for instance in the event of unsubstantiated rumors or clearly wrong notions about an epidemic in the target area.

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Figure 1 Incidence rate/month of health problems during a stay in developing countries

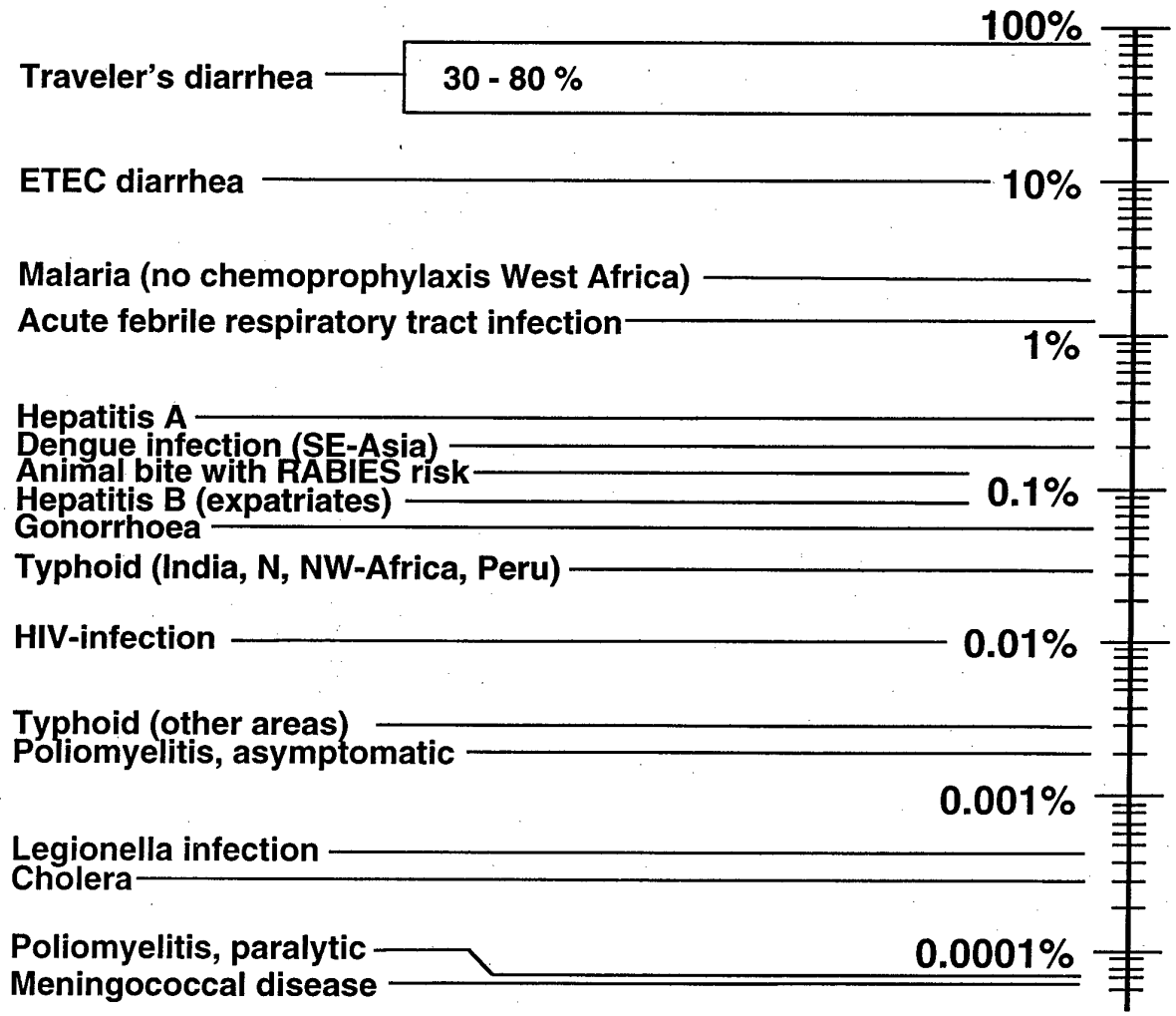


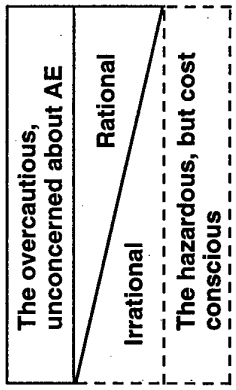
Table 1 —

Data needed for the development of immunization recommendations

INFECTION	
- Occurrence in target country	yes/no?
- Incidence rate	in military population?
	in travelers?
	in local population, where?
- Impact of infection	incapacity, case fatality rate?
HOST FACTORS	
- immunological status	natural immunity, previous immunization
- particular exposure to risk	special tasks, e.g. medical?
INTERVENTION DATA	
- Vaccine/drug safety	
- Vaccine/drug efficacy	
- Cost-benefit evaluation	
LEGAL AND ETHICAL ASPECTS	
- required vaccination	entry restrictions?
- ethical	potential media pressure?

Table 2:
Rationale for immunization of travelers

Infection	Incidence	Impact	Total
Hepatitis A	+++	++	+++++
Hepatitis B	++	+++	+++++
Rabies	++	+(++)	++++
Poliomyelitis	(+)	+++	+++(+)
Yellow fever	(+)	+++	+++(+)
Typhoid fever	++	+	+++
Influenza	++(+)?	(+)	+++
Diphtheria	(+)	++	++(+)
Tetanus	(+)	++	++(+)
Meningo. disease	(+)	++	++(+)
Jap. Enceph'itis	(+)	++	++(+)
Cholera	+	+	++
Measles	(+)	+	+(+)



Rate per 100'000: +++: >100, ++: 1-99, +: 0.1-0.9, (+): <0.1
Impact:
+++ high case fatality rate, serious residuals
++ ≥2% case fatality rate or incapacitation >4 weeks
+ low case fatality rate, brief incapacitation

Table 3: Vaccine characteristics

Vaccine Lv = Live vaccine Iv= Inaktivated vaccine	Effectiveness (%)	Protection begins on day	Duration of protection	Basic immunization for adults (doses/administration) d=days, otherwise months
Cholera CVD-103HgR (Lv) Cholera, traditional (Iv)	65-80% 50%	8 6	> 6 months 6 months	1x p.o. 2x s.c (0/7-28)
Diphtheria (Iv), usually with tetanus	>99%	28	5 years	3x i.m. (0/1/3-12)
Hepatitis A (Iv)	>99%	14 probably from day 1	10-30 years	2x i.m. (0/6-12)
Hepatitis B (Iv)	>95%	28	life long when titer >100 IU/l	3x i.m. (0/1/6), titer control month 7
Japanese Encephalitis (Iv)	90%	10-14	>2 years	3x s.c. (0/7d/14-21d)
Meningococcal Meningitis (no B) (Iv)	75-90%	14	>2 years	1x s.c.
Poliomyelitis (Sabin, Lv) Poliomyelitis (Salk, Iv)	>95% >95%	28 28	10 years 10 years	only boosters in adults 4x s.c. (0/1/2/12)
Rabies (Iv)	>99%	14	2-5 years	3x s.c. (0/7d/21-28d)
Tetanus (Iv), usually with diphtheria	>99%	28	10 years	3x i.m. (0/1/3-12)
Tick-borne Encephalitis (TBE) (Iv)	>90%	28	3-5 years	3x i.m. (0/1/9-12)
Tuberculosis (Lv)	>80%	42	10-15 years	1x i.d.
Typhoid fever Ty 21a (Lv) Typhoid fever, Vi (Iv) Typhoid fever, TAB (Iv)	60-70% 60-70% 50-70%	14 14 28	1 year 1 year 1 year	3x p.o. (0/2d/4d) 1x i.m. 2x i.m. (0/14d)
Yellow fever (Lv)	>99%	10	10 years	1x s.c.

COMPLIANCE WITH ANTI-MALARIAL PREVENTIVE MEASURES BY DEPLOYING USAF PERSONNEL FOR OPERATION ASSURED RESPONSE

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SUMMARY

In April 1996, the United States deployed military personnel to three locations in sub-Saharan Africa (Liberia, Sierra Leone, and Senegal) as part of a Non-Combatant Evacuation Operation (NEO) to evacuate endangered Americans and other foreign nationals from Liberia following a total breakdown of civil order. The majority of U.S. Air Force (USAF) personnel sent for this NEO, ASSURED RESPONSE, deployed from two locations within the European theater, but were from the same unit and thus, available for evaluation of compliance with antimalarial preventive measures. A total of 365 USAF personnel were deployed. All received a pre-deployment briefing and 88% complied with doxycycline chemoprophylaxis, but only 26% used permethrin clothing spray and DEET insect repellent. Nevertheless, no cases of malaria were contracted by USAF members. Also participating in the operation were 225 US Army (USA) personnel in whom four cases of *Plasmodium falciparum* malaria developed post deployment—a statistically significant ($p<0.05$) difference in attack rate (A.R.). USA compliance data was obtained from an outbreak investigation and compared to that of the USAF. Statistically significant differences were found for attendance at pre-deployment medical threat briefings, doxycycline compliance, and use of personal protective measures (use of DEET and permethrin clothing spray). Although there may have been differences in where members of each service branch lived during the deployment, it appears that the differences in compliance contributed to successful malaria prevention in USAF personnel. Commanders and personnel need to be cognizant of the importance of compliance with these preventive measures and made personally responsible for their use. Non-compliance could be causative for unit illness and loss of mission effectiveness in prolonged contingency operations to malaria endemic geographical regions.

LIST OF ABBREVIATIONS AND DEFINITIONS

A.R.	Attack Rate (occurrence of a disease among a specific population at risk for a limited period of time)
COMPLIANCE	Tendency to act in accordance to a recommendation
DEET	N,N-Diethyl-*m*-toluamide (34% Lotion or 25% Liquid insect repellant)
NEO	Non-combatant Evacuation Operation
PPM's	Personal Protective Measures (Proper wear of clothing, use of insect repellant, permethrin spray, and mosquito nets)

1. INTRODUCTION

Persons from North America and Europe traveling to certain parts of the world endemic for malaria are at increased risk for contracting it. This is especially true for those going to sub-Saharan Africa[1]. Although effective anti-malarial preventive measures exist (chemoprophylaxis with use of personal protective measures or PPM's), there often seems to be an over reliance on chemoprophylaxis. PPM's are also a vital component to anti-malaria prevention in military operations in malaria endemic regions.[2] Further problematic is the fact that many of the drugs used have significant toxicity and may lack efficacy.[3] It has been well documented that chemoprophylaxis compliance has been a problem in non-military travelers.[4,5] Both chemoprophylaxis and PPM compliance has been documented to be a problem with US Marine personnel.[6] However, compliance rates for chemoprophylaxis and use of PPM's had not been ascertained in deploying USAF military personnel.

Background

A great amount of effort is invested by supporting flight surgeons to insure that deploying USAF personnel receive medical threat briefings, supply of appropriate chemoprophylaxis medication, and personal protection supplies before supporting contingency operations. However, because of concerns for flight safety and the effects of drugs on performance, anti-malarial chemoprophylaxis drugs available for use in USAF flyers is limited. Air Force regulation[7] limits aircrew to chloroquine for chloroquine-sensitive malaria, doxycycline for chloroquine-resistant malaria, and primaquine for terminal prophylaxis and prevention of *P. vivax* and *ovale* malaria. Thus, when deploying to geographic regions of chloroquine-resistant malaria, the requirement to take daily doxycycline chemoprophylaxis has the potential to adversely affect compliance. Non-flying USAF members can be given mefloquine which can be dosed once weekly, but advanced notice of deployment must be known in order to start one to two weeks prior to movement—a condition often lacking in contingency operations. Thus, in many contingencies, doxycycline is also used for non-flyers and potential problems with compliance continues.

In order to determine if compliance was a problem for USAF flyers and other personnel, a deployment was necessary in which to ascertain it. In April 1996, the opportunity arose with the short-notice tasking for U.S. military units to participate in Non-Combatant Evacuation (NEO), ASSURED RESPONSE, to Liberia to rescue endangered Americans and

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other foreign nationals following a breakdown in civil order in that country. US personnel also deployed to Sierra Leone and Senegal for staging operations. All three countries were located in sub-Saharan Africa where chloroquine-resistant *P. falciparum* malaria and *P. ovale* and *vivax* malaria are endemic. US military personnel also included U.S. Army (USA), U.S. Navy (USN), and U.S. Marines (USMC).

The majority of USAF personnel deployed from two geographic regions within Europe. However, they were all from the same unit and available for study. All (100%) personnel from both locations received a pre-deployment medical threat briefing, initial two week supply of doxycycline for anti-malarial chemoprophylaxis, DEET insect repellent, and permethrin spray to use on their clothing. During the pre-deployment briefings, the magnitude of the potential medical threat from falciparum malaria and other vector-borne diseases was stressed, and members were instructed on the need to start their doxycycline immediately, comply with taking it daily, proper wear of clothes, use of permethrin spray on them, and use of DEET insect repellent. Mosquito netting was not available for issue, but fortunately, most USAF personnel slept indoors during the deployment which averaged about three weeks. Doxycycline was re-supplied as necessary.

2. METHODS

The aforementioned actions were documented for each deploying person on a pre-designed medical record overprint sheet which also contained a questionnaire for post-deployment doxycycline and PPM compliance determination. It was later incorporated into their medical record. Also included was information on terminal chemoprophylaxis with primaquine and individual G6PD status. Primaquine was not issued until near the end of the deployment, but was continued for three weeks post-deployment. Upon returning from the deployment and completing travel claims, all unit personnel who participated were interviewed and their individual compliance with doxycycline, PPM's, or both determined.

Post-deployment it was learned there were 4 cases of *P. falciparum* malaria contacted by deploying USA members to ASSURED RESPONSE (Personal Communication) while no USAF malaria cases occurred. With this information, it was decided that contact with the USA might yield additional information for comparison. A preventive medicine specialist who conducted an outbreak investigation was located and shared information. Although USA compliance determination was done under different circumstances, useful comparison data was obtained.

Test for significance in compliance differences were accomplished using Pearson's chi-square ($\chi 2$) statistic, or Fisher's exact test (when expected cell sizes were small).

3. RESULTS

Deployment Outcome

Out of 365 USAF personnel who deployed to Operation ASSURED RESPONSE, 165 were on flying status, and 200 were not. There were no cases of malaria reported in the ensuing six months afterwards. Out of 225 deploying USA personnel, there were four cases of *Plasmodium falciparum* malaria diagnosed by thick and thin smears within two weeks of return to their home station (Personal Communication).

There were an additional five cases of malaria reportedly diagnosed in USN/USMC members, but the total number deployed and other compliance data were not readily available for comparison. The difference in USAF vs. USA attack rates (0 and 18/1000, respectively) was statistically significant ($\chi 2$ p=0.011).

USAF Compliance Data

USAF compliance data is summarized in Table 1.

	Fly	NonFly	Total	Percent
DOXY ONLY*	112	116	228	62.5*
DEET ONLY	0	0	0	0
PERMETH ONLY	0	0	0	0
DOXY/ DEET	4	2	6	1.64*
DOXY PERMETH	0	1	1	0.27*
DEET/ PERMETH	0	1	1	0.27
DOXY +ALL PPM	39	50	89	24*
NONE	10	30	40	10.96
TOTAL	165	200	365	100

*Total doxycycline compliance = 88.4%

Table 1. USAF Compliance Data

Results of USAF anti-malarial compliance were mixed. For doxycycline chemoprophylaxis it was 88.4% (obtained by adding doxycycline only use, plus doxycycline with DEET, plus doxycycline with permethrin spray, plus doxycycline with all the PPM's). However, compliance with PPM's alone or, ideally with doxycycline was disappointing. Only 24% used doxycycline with both DEET and permethrin spray while only another 2.18% used one of the PPM's (DEET or permethrin) alone with doxycycline. No one used only the PPM's alone.

Comparison Data

Comparative USAF/USA compliance data is summarized in Table 2.

	USAF N=365	USA N=225
Pre-deployment Briefing	100%	56%*
Doxycycline Compliance	88%	79%*
Permethrin Spray	25%	3%*
DEET	25%	1%*
Proper Clothing	Not Questioned	Not Questioned
Mosquito Netting	0%	3%*
Malaria Cases (Attack Rate)	0 (0)	4 (18/1000)*
Billeting Location	Indoors	Indoors/Bivouac

*P<0.05

Table 2. Comparison USAF/USA Compliance Data

Comparing compliance data between deploying USAF and USA members yielded a number of statistically significant differences. Only 56% of USA personnel attended a pre-deployment briefing, compared to 100% of USAF personnel. Furthermore, USA compliance with doxycycline was significantly lower than that of the USAF, 79% vs. 88%, respectively ($\chi 2$ p=0.01). USA compliance with PPM's was also lower than that of the USAF in a statistically significant sense, although the clinical significance is questionable with such a low USAF PPM compliance rate.

4. DISCUSSION

USAF compliance data exhibited the expected over-dependence upon chemoprophylaxis. PPM's compliance, even though statistically greater than that of USA personnel was disappointing. In contingency operations, the likelihood of a short stay in an area having a large mosquito population make permanent vector control methods difficult or inappropriate.[8] Thus, PPM's become a vital part of malaria prevention in such conditions and operations.

Comparison data show significant differences in compliance rates between USAF and USA personnel for taking doxycycline chemoprophylaxis and using PPM's, even though USAF compliance with PPM use was not great. These outcomes began with a marked difference in attendance at a pre-deployment threat briefing. This suggests that the pre-deployment briefing in which the magnitude of the disease threat and the importance of taking chemoprophylaxis and use of PPM's was discussed, along with the issuance of supplies, made a difference.

Supporting this observation is the fact that the USA outbreak investigation revealed that three of the four malaria cases were without doxycycline for the first three to four days and that in all cases, they did not attend a pre-deployment briefing, pre-treat field clothing with permethrin spray, use bed nets, or insect repellent (DEET), although two of the four cases reported intermittent use of an over-the-counter commercial insect repellent (Personal Communication).

Important observation bias may be present in this data, especially if deployed USA and USAF service members were exposed differently. Even though services' members were deployed to the same countries for approximately the same duration of time, where they lived during deployment would affect exposure. For instance, if USA personnel lived in field conditions while USAF members slept indoors, USA exposure would have been much greater. Indeed, this may have been the situation as all four USA malaria cases occurred in personnel who deployed to Sierra Leone and lived under field conditions in tents (Personal Communication). Billeting or living conditions information was not specifically ascertained for deployed USAF personnel in the questionnaire, but was reportedly indoors. Personal communication with a participating USAF flight surgeon who also deployed to Sierra Leone indicated that for the first two weeks of the deployment, the majority of USA and USAF members stayed in local hotels. Nevertheless, USA malaria cases reported living under field conditions where they were at greatest exposure. However, they also reported virtually no use of anti-malarial preventive measures which were used by a significantly higher percentage of USAF personnel.

5. CONCLUSIONS (LESSONS LEARNED)

Whatever effect exposure may have had, USAF compliance rates with anti-malarial preventive measures was significantly better in virtually all categories and there were no cases of malaria out of 365 deployed USAF members compared to 4 cases out of 225 deployed USA personnel. This difference in compliance appears to have had its beginnings in the pre-deployment briefings and issuance of supplies of doxycycline, DEET, and permethrin spray. Differences in exposure needs to be addressed in any follow-on studies, but for now, the better compliance rates among USAF coupled with a significant difference in outcome, argues strongly for the efficacy of these combined measures, even when compliance is not perfect.

For physicians who will be responsible for personnel deploying to geographical regions of endemic malaria, good chemoprophylaxis compliance will be important, but appropriate medications should be issued and started before departure. Additionally, high compliance with PPM's may be just as important and issuance of supplies before departure will help improve it.

The results of this study also indirectly suggest that reducing exposure in-country is a very important factor. If keeping personnel indoors can be accomplished, mosquito bite exposure, especially during evening hours when they are most active in feeding, would be beneficial. If sleeping indoors is not feasible, limiting exposure would next be best accomplished with the issuance and proper use of mosquito netting.

6. RECOMMENDATIONS

Unit compliance rates must be pushed as high as possible. Good compliance rates begin with the pre-deployment briefing. Make the pre-deployment brief concise, stress the threat, and the proper use of the prescribed countermeasures.

Keep in mind up front that using DEET, usually along with sunscreen (in the case of doxycycline), is greasy and not pleasant and will be quickly shunned. Furthermore, USAF personnel have expressed concern for harmful skin effects and even the possibility of "Persian Gulf Syndrome" from using the permethrin spray (Personal Communication with Personnel). These tasks will not be easy and will require command influence. Commanders should be educated and their support and influence enlisted prior to the urgent times associated with a short-notice contingency operation where other problems demand the commander's attention. For extended operations in malaria endemic regions, poor compliance could adversely impact unit health and destroy mission effectiveness.

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AIR EVACUATION UNDER HIGH-LEVEL BIOSAFETY CONTAINMENT: THE AEROMEDICAL ISOLATION TEAM

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SUMMARY

Contingency operations in tropical environments and the potential use of biological weapons by adversaries place troops at risk for potentially lethal contagious infections. Examples include viral hemorrhagic fevers, plague, and zoonotic poxviruses. Rapid diagnosis and basic research regarding countermeasures for such illnesses would be facilitated by evacuating a limited number of patients to a facility with containment laboratories. In order to safely evacuate such patients to our institute via military aircraft and to minimize the risk of transmission to air crews, care givers, and civilian communities, the U.S. Army Medical Research Institute of Infectious Diseases has developed an Aeromedical Isolation Team (AIT). The AIT is a rapid response team with worldwide airlift capability designed to evacuate and manage patients under high level containment. Teams consist of a physician, a registered nurse, and four to six medics. The teams are accompanied by a fully functioning diagnostic laboratory utilizing genetic typing methods and immunoassays. Protective equipment includes impermeable portective suits equipped with powered HEPA-filtered respirators and patient isolators equiped with negative-air pressure, HEPA-filtered ventilation systems. Technical aspects of AIT equipment, training, deployments, and capabilities are discussed.

LIST OF SYMBOLS

AIT	Aeromedical Isolation Team
ELISA	enzyme-linked immunosorbent assay
HEPA	high efficiency particulate air
PCR	polymerase chain reaction
PVC	polyvinyl chloride
SI	stretcher isolator
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
VATI	Vickers aircraft transport isolator
VHF	viral hemorrhagic fever

INTRODUCTION

Air evacuation of patients with potentially lethal, contagious infections poses unique challenges and risks to air crews and medical personnel. Evacuation of such patients is relevant to military contingency operations, as troops are placed at risk for hemorrhagic fevers and other exotic infections during deployments to tropical environments, and by the possible use of biological warfare (BW) agents by adversaries.

Rapid identification of an etiologic agent is essential for optimal medical care, and the implementation of preventive measures. Basic research on highly hazardous pathogens requires high level containment for laboratory safety. Containment facilities are available at a limited number of laboratories. To safely evacuate a limited number of patients to our institute, and to provide medical care while minimizing the risk of transmission to air crews, care givers and civilian communities, the US Army Medical Research Institute of Infectious Diseases (USAMRIID) has developed an aeromedical isolation team (AIT) (1-3).

The purpose of the AIT is to safely transport patients with potentially lethal communicable diseases for which there are no effective vaccines, chemoprophylaxis, or therapies. These would include patients with an unknown emerging disease pending identification of the pathogen, patients with viral hemorrhagic fevers (notably those due to filoviruses and arenaviruses), and victims of a suspected biological attack (Table 1)(2). Identification of

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victims of a suspected biological attack (Table 1) (2). Identification of the pathogen and medical care would be provided at USAMRIID. Indications for deployment would include cases of a highly contagious, lethal, or unidentified disease, laboratory exposures to potentially lethal, communicable pathogens, or, in certain cases, a biological attack or terrorist incident.

Maximum biological containment is designed to prevent transmission of highly hazardous pathogens. Blood and body fluid precautions are combined with respiratory precautions (3). Nosocomial transmission following exposure to blood and other body fluids has been a prominent feature of viral hemorrhagic fever (VHF) epidemics in Africa (4). While epidemiologic studies indicate that respiratory transmission of viral hemorrhagic fevers does not occur among humans, such transmission has occurred among nonhuman primates (5). In addition, subclinical human infections due to Ebola-Reston, a filovirus virulent for monkeys, have occurred after respiratory exposure to infected animals (6). The potential risk of person-to-person transmission of zoonotic viruses is underscored by a recent report from Argentina suggesting secondary transmission of hantavirus pulmonary syndrome (7). In addition, infectious aerosols may be generated during endotracheal suctioning and other medical procedures. Although nosocomial transmission of VHF in Africa has been interrupted by standard universal precautions without additional respiratory measures, adding respiratory protection as an infection control measure is advised by the Centers for Disease Control and Prevention because information regarding exposure and transmission in humans is limited (5).

USAMRIID can simultaneously deploy two teams, each consisting of one physician, one registered nurse, and four to six medics. Each team can transport and manage one patient. In addition, the team can deploy a portable containment laboratory with rapid diagnostic assays using enzyme-linked immunosorbent assays (ELISA) and polymerase chain reaction (PCR), as well as standard clinical laboratory support.

The team is deployable on rotary and fixed-wing military aircraft, including the C-5, C-130, and C-141 aircraft. The team conducts in-flight training at one to three month intervals, and is capable of deploying within four hours of notification.

BIOSAFETY CONTAINMENT UNDER FIELD CONDITIONS

Biosafety containment is accomplished by two methods. The first method puts the health care worker in an impermeable suit consisting of a lightweight polyvinyl chloride (PVC) coverall, a separate hood, and vinyl boots. A high efficiency particulate air (HEPA) filtered respirator powered by a rechargeable battery supplies air under positive pressure for breathing and cooling. Air enters at a rate of 170 L/min though an intake port near the top of the hood, and exits though an exhaust valve at the base of the hood. Two-way radios are used for communication between team members and patients.

The second method isolates the patient within a sealed container under negative air pressure maintained by a battery powered HEPA-filtered ventilation systems providing five air exchanges per hour. Two isolators are used: the stretcher isolator (SI), a lightweight unit for initial patient retrieval, and the Vickers aircraft transport isolator (VATI), a larger unit for definitive transport and in-flight care (Table 1).

Both isolators feature transparent PVC envelopes suspended from metal frames by detachable plastic rings. Both envelopes include gloved sleeves. In addition, the VATI contains half suits, 12 cones at the base of the envelope for introducing wires and tubing, two sleeves for intravenous therapy, and two large PVC pockets for placing waste supplies. The envelopes contain transfer/docking ports for patient entry and transfer and supply ports for introducing supplies. Electrical current is supplied by rechargeable batteries or the aircraft electrical system.

The patient is initially evaluated and stabilized in the field, placed inside the SI, then carried to a transfer point near the aircraft. At the transfer point, the SI and team members are decontaminated using a 5% hypochlorite solution. During the decontamination procedure, the patient breathes portable oxygen

sealed to prevent chlorine gas from entering the isolator. The portals of the isolators are then connected with an airtight sleeve, and the patient is transferred to the VATI. The sleeve is clamped at two points before being heat sealed and cut, maintaining air tight seals throughout the transfer. The cut ends are decontaminated, and are covered with PVC seals which are then attatched to the isolators with pressure-sensitive tape. Both isolators are maintained under negative air pressure until decontaminated at USAMRIID. Suits are removed, bagged, and returned to USAMRIID for decontamination of respirators and radios, and disposal or decontamination of coveralls.

The patient must be stabilized before transport to ensure survival en route. Considerations include the physiologic effects of altitude, the psychological effect of confinement within the isolator, and effect of confinement on patient care delivery. Diagnosis and therapy, which can be delivered to the patient in the VATI, include cardiac monitoring, pulse oximetry, blood pressure monitoring, and intravenous therapy. To minimize the risk of puncturing the isolator, no glass bottles or instruments with rough or sharp edges are used. Phlebotomy is minimized, and a needle-less intravenous system is used.

After arriving at USAMRIID, the patient is transferred from the VATI into the containment care suite through a plastic sleeve connected to a port on an outside wall.

AIT DEPLOYMENTS

During October of 1989, an epizootic of a lethal hemorrhagic illness occurred among cynomolgus monkeys (*Maccaca fascicularis*) imported from the Philippines and held at a primate quarantine facility in Reston, Virginia, a suburb of Washington, D.C. Simian hemorrhagic fever, a disease of monkeys caused by a flavivirus not virulent for humans, was confirmed in three of the 10 monkeys initially tested, however, Ebola virus was isolated from five of the animals (8). Ebola virus had previously been isolated only in association with epidemics of human disease in Africa, with case fatality rates of 53-88% (9). There were concerns regarding the potential transmission of Ebola to animal handlers in the facility, and secondary transmission to other members of the community.

The AIT and additional personnel from USAMRIID were deployed. Animal handlers were trained in the use of suits and respirators, containment methods, decontamination and waste disposal. Four hundred fifty monkeys were humanely euthanized using an anesthetic overdose. Specimens of blood and tissue were obtained on site and sent to USAMRIID for histopathologic and virologic studies. The facility was sealed and decontaminated by paraformaldehyde fumigation followed by the use of conventional disinfectants (10).

The Ebola isolate, Ebola Reston, was a newly identified strain closely related to Ebola Zaire, the strain that caused epidemics of lethal disease in western Africa in 1976 and 1995. Respiratory droplet transmission was suggested as the epizootic spread among monkeys housed in separate cages, with no opportunity for contact (10), and by subclinical human infections. Four of the five animal handlers who worked in the facility developed serologic evidence of recent Ebola infection; only one had a percutaneous blood exposure (6). No seroconversions occurred among the 42 USAMRIID personnel participating in the operation. This operation has been described by author Richard Preston in *The Hot Zone* (11).

An AIT member was deployed to Linkoping, Sweden during January 1990 to assist in implementing biosafety containment for the care of a patient suspected of having a viral hemorrhagic fever after returning from travels in eastern Africa (1). The team was on alert during 1994 for a laboratory acquired Sabia virus infection (Brazilian hemorrhagic fever) at Yale University (12), and during the 1995 Ebola epidemic in the former Zaire.

During November 1995, construction workers at Wright-Patterson Air Force Base, near Dayton, Ohio, uncovered a buried cache of M114 biological munitions. These munitions had been produced during the now defunct US offensive biological warfare program, which was begun in 1942, and terminated by Presidential order in 1969. These munitions were 54 cm long and 3 cm in diameter, and typically contained 320 ml of biological agent. Some of the munitions were intact, but most were perforated due to corrosion of the munition casings (13).

The AIT was deployed with a senior medical advisor. Munitions were brought inside a bunker by the U.S. Army Technical Escort Unit. Munitions were sampled inside the VATI. Twenty-samples of liquid bomb fill and soil samples taken adjacent to perforated munitions were transported in sealed containers on ice packs in accordance with US Department of Transportation regulations via military aircraft to USAMRIID, the Naval Medical Research Institute, Bethesda, Maryland, and the Armed Forces Institute of Pathology, Washington, D.C. Testing done on liquid-bomb-fill included Gram stain, rapid slide agglutination and fluorescent antibody testing for *Brucella*, two fluorescent stains with affinity for either live or dead bacterial cells, and genetic typing by PCR for *B. abortus, B. melitensis, B. suis, Bacillus anthracis, Yersinia pestis, Coxiella burnetii*, and *Francisella tularensis*,(13, 14), the bacterial agents weaponized by the U.S. military during the former offensive biological program (15). Additional studies were done to test for toxins weaponized by the U.S. military during the offensive biological warfare program (botulinum toxins A and B, ricin, and staphylococcal enterotoxin B) (13). The bomb fill contained approximately 10^8 /ml non-viable gram-negative bacteria identified as *B. suis* by strain-specific PCR (13, 14). Soil samples obtained near perforated munitions tested positive for *Brucella* DNA and antigens; cultures yielded normal commensal flora but no growth of *Brucella* sp. Background soil and groundwater tested negative for *Brucella* DNA and antigens. Tests for toxins were negative (13).

The cache contained 2306 munitions, of which 650 were intact. Additional samples were analyzed on site; 218 bombs were analyzed, exceeding the 95% confidence limit for identifying the biological fill of the 650 intact munitions. On site testing included rapid slide agglutination for *Brucella*, rapid presumptive viability staining for bacteria, fluorescent antibody testing for *Brucella*, and PCR for *B. abortus, B melitensis*, and *B. suis*. These tests confirmed the liquid bomb fill as non-viable *B. suis*, with no other agents identified. All munitions were drained, and the fill and casings were autoclaved before disposal (13, 14). Documents were later retrieved that confirmed that the munitions were M114 bomblets filled with *B. suis*. They were used at Wright-Patterson Air Force Base during Operation White Floor (June-October, 1954) to train personnel in viability testing and handling of biological weapons; accordingly, they were not armed with explosive charges. After completion of Operation White Floor, the munitions had been heated in a ground portable heater with an ambient temperature of 104° C for 4 hours each of 2 days, with the temperatures of the innermost munititions reaching 70-74° C. The munitions were then buried (13, 14).

CONCLUSIONS

The AIT offers worldwide aeromedical evacuation under maximum biological containment to transport a limited number of patients with highly contagious, lethal diseases while protecting air crews, care givers, and civilian communities from risk. The AIT also offers a portable containment laboratory, limited environmental decontamination, and specialized consultative expertise. These capabilities are of critical importance in an era of emerging pathogens, frequent deployments, and the possible use of contagious biological weapons.

TABLE 1

Indications: Containment Care During Transport

Arenavirus Infection
- Argentine hemorrhagic fever (Junin virus)
- Bolivian hemorrhagic fever (Machupo virus)
- Brazilian hemorrhagic fever (Sabia virus)
- Lassa fever
- Venezuelan hemorrhagic fever (Guanarito virus)

Bunyavirus Infection
- Congo-Crimean hemorrhagic fever

Filovirus infection
- Ebola
- Marburg

Orthopoxvirus infection
- Monkeypox
- Variola

Pneumonic plague until sputum cultures are negative

Victim of unknown virulent, communicable disease pending diagnosis

Victim of suspected biological attack

TABLE 2
Dimensions of Portable Isolators

	SI	VATI
Length (cm)	221	221
Width	69	91
Height	86	152
Weight (kg)	45	112

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Discussion #8

MACEDONIA, US: Dr Kingma, HIV infection is dramatically altered by the institution of new combination medications involving protease inhibitors. I have many patients who have absolutely no virion (complete virus particles) detectable in the blood stream, which is absolutely amazing. Could you comment on whether or not this is influencing policy at the United Nations (in reference to Paper #43)?

KINGMA, US: It is a fascinating question, and it is creating a great deal of interest around the world because of the widespread impression that, suddenly, HIV infection is not a problem anymore. That is far from the case. Dr Anthony Fauchi of the US National Institutes of Health recently released information that what is more apparent than real is this loss of circulating, identifiable virus in the blood stream. There are viruses still present in other parts of the body and in circulating cells in the blood. We are too early in our investigations to start making judgements. Of course, there is a great deal of attention being paid to some of the 'morning after' approaches to protection against HIV infection, which may also be illusory and require a great deal more investigation. I think, at this point, judgement on that kind of an issue needs to be held in abeyance until more experience is available. Incidentally, the whole question of the neurocognitive impact of some of the combination treatments for those who are still asymptomatic is also under serious consideration because of the differential penetration of the blood-brain barrier and other factors. So the introduction of the new anti-retroviral drugs including the protease inhibitors needs a lot more investigation before we know the impact on the individual and the evolution of the disease.

SICARD, FR: I would like to thank you for the non-passionate way you treated such a highly sensitive subject in our community. I do have a technical concern, however. As flight surgeons we know how difficult it is to assess flying skills and to tell if a pilot is fit to fly because there are numerous factors like experience, type of aircraft, etc. that must be considered. Therefore, regarding your cognitive test, how will you decide if a pilot is not fit to fly? Who will be in the control group, and how will you determine, from a very wide range of technical skills, which pilots have lost the 'right stuff'?

KINGMA, US: This is a subject which has interested me a great deal in the past three years, and I was very happy to convene a meeting of some 18 experts in Washington two months ago. We are still clearing and clarifying the wording - which needs to be extremely carefully chosen - for the conclusions and recommendations of this meeting. The conclusions were summarized a bit in my talk and for countries of the NATO group, which are basically low prevalence countries for HIV infection. Numerically, there will be many reasons, other than having HIV infection, why a pilot might not be fit to fly, either during a certain period in his life or at a given moment in a deployment. The advantage of **CogScreen** is that it is a highly-verified new technology that has been widely used in civil aviation as well as in some militaries. It's available in English, French and Russian editions and it is now moving into large scale production so that it can be widely available. The simplicity and the capacity of doing this testing, and getting an immediate printout in a very carefully scaled manner that indicates that this particular person has reached a certain level of acceptable performance or not has been highly refined by the experts that

have worked on the system. I would be very happy to make more widely available some of the documentation on **CogScreen** that I have if anyone is interested.

GERZER, GE: Dr Steffen, I was very surprised about your priority listing for vaccinations in the general traveler because you later showed that you find hepatitis B and rabies very important, but tetanus as only of intermediate importance. This surprises me because we generally think that tetanus immunization should be something which everyone should have; so do you think that tetanus immunization is not so important for the general population (in reference to Paper #44)?

STEFFEN, CH: If we look back at the records we find that tetanus immunization is a traditional immunization; however, if you look at the medical literature you will probably find only a single case of imported tetanus in a traveler. That was actually the case of a German traveler returning from Spain. From that alone, I would not conclude that we could not recommend tetanus immunization generally for the population. That recommendation is not so much linked to travel as it is to those staying at home, who should be immunized against tetanus.

LYONS, US: I think the gathering of some baseline data is the key to using **CogScreen** effectively. We found that in head injury evaluations, if you have a baseline, it significantly aids the use of **CogScreen**. I have a question regarding the antimalarial drugs, mefloquine and doxycycline. We don't use mefloquine in flyers because we are afraid it will make them 'crazy'. There is a concern also about how far in advance one has to administer mefloquine before it becomes effective. Of course, doxycycline is a daily administration. Does anyone have any comments about the use of mefloquine in flyers, or the relative efficacy of doxycycline and mefloquine (in reference to Paper #45)?

WILLIAMS, US: Of course, I follow the US Air Force policy on mefloquine regarding its administration to flyers. The incidence of neuropsychiatric complications or cognitive impairment with mefloquine is actually quite low, but in an aeromedical environment we tend to be very conservative and use a 1% incidence as a cut off. Thus, the use of mefloquine for flyers is not acceptable to the US Air Force. In terms of using it in advance notice, it has always been recommended that it be started a week or two prior to deployment. However, I think there are some recent changes or new recommendations regarding this. From our experience, the issue is compounded when using two different drugs for two different types of aviators during a short-notice deployment. It would be easier if everyone could take the drug once a week, but that is not possible because of differences in policy regarding flyers and non-flyers. So if it was a short notice, we would opt for a single drug and ask that it be taken daily by everyone.

KINGMA, US: The World Health Organization still recommends conditions for taking antimalarial prophylaxis one week in advance. These recommendations allow for good drug saturation of the tissues, which should ensure maximum protection. However, for a number of the drugs, one probably obtains near full protection by taking them the night before arrival in a country. Taking them after that time starts to open up a window in which some forms of infection could begin to take root.

CHRISTOPHER, US: The reason we give mefloquine one week prior is to test for tolerance to be certain that the person taking it can tolerate the medication.

STEFFEN, CH: The manufacturer, Roche Laboratories, has just issued new recommendations regarding the use of mefloquine. The customary procedure is to start one week prior to departure, not only to obtain some indication on whether the agent is going to be tolerated but also to obtain an indication of satisfactory blood saturation. However, when deployment is imminent, then one should give mefloquine on three consecutive days on a daily basis starting on the day of departure; from then on one switches to weekly medication. There are two different mefloquines available: the one produced by Roche, which comes in two slightly different doses according to whether it is purchased in the United States or Europe, and mefloquine, the generic compound. It has recently been determined that the generic compound has a reduced bioavailability of about 70% compared to that of the original drug.

D'AMELIA, IT: I'd like to ask Professor Steffen his thoughts for protecting the troops during contingency operations with immunization, where some of them are given live vaccines, and the right timing of chemoprophylaxis so that it does not interfere with these live vaccines.

STEFFEN, CH: The main concern here is the interaction between the chemoprophylaxis of malaria and the typhoid vaccination with the oral Ty 21a vaccine. However, nowadays, we have an escape route in that we can use the inactivated Vi vaccine for immunization against typhoid. With respect to all immunizations and interactions with anti-malarials, there has been some concern expressed with respect to rabies vaccination. In that case, it takes a little longer to take effect and one may then be too late for providing a pre-deployment immunization.

KILPATRICK, US: Dr Williams, I think a conclusion one might draw from your presentation on anti-malarial preventive measures is that it is safer to wear a blue uniform and live in a hotel than it is to wear a camouflaged uniform and live in the dirt, which is a valid observation. However, from my own personal experiences as a supporting flight surgeon, we frequently hand out to our deploying members their chemo-prophylactics, and ask that they take them immediately. In the case of the personal preventive measures, we provide them with a list regarding the use of insect repellent - in particular if it's combined with sunscreen - as well as the mosquito netting. We are not quite as proactive in handing these items to them and asking that they start to use them right away. So I think that we have an additional disconnect here in deployment preparation between our attitude regarding the pharmacological preventive measures and the other ones.

WILLIAMS, US: When you educate the troops up front you let them know exactly what they need to do and make sure they have the supplies to do it. In this particular deployment, I made my own personal staff upset with me over my persistence in seeing that we had accumulated sufficient amounts and supplied the troops with **DEET** and permethrin spray. Initially, the reaction was that we take care of the drugs and Supply takes care of the permethrin spray. There is big disconnect in our supply mechanisms there (re Operation ASSURED RESPONSE), but I was very insistent that we get it done and we were able to make sure that everybody that deployed had permethrin spray. We could not comply with giving them mosquito netting, we just didn't have it. To enhance the use of mosquito netting, we tried to make sure that it was covered in our pre-deployment briefing. I would like to point out an interesting sideline to the pre-deployment briefing that is not

covered in my presentation. I was in one location and did all the briefings myself while at another location, the briefings were carried out by an enlisted public health person under my direction. I was convinced that compliance rates would be greater with my briefing than they would be with the other individual because I tried to 'scare people to death'. I tried to explain to them that the benefits from the personal protective measures may be far greater than what they would obtain from chemoprophylaxis. I told them that chemoprophylaxis was only going to give protection from malaria, maybe from some diarrheal diseases but it wasn't going to protect them from any other vector-born diseases with which they might come in contact. However, after the deployment, I was very disappointed to find out that the briefings of the enlisted military public health person were probably more effective than mine. I don't know what that really says; it may say something about my personal briefing skills. In any event, we tried very hard to make sure that they had to comply with these measures and that they had the medication and the supplies when they deployed.

KILPATRICK, US: You are reconfirming that, as operational flight surgeons, it is our responsibility to actively engage the supply system. If we believe in the personal protective measures in addition to the drugs, we need to take the responsibility to make sure that these are as readily supplied and as conveniently available to the deploying troops as are the drugs.

D'AMELIO, IT: I think there is now the feeling by everyone in this room that there is a gap between the decision makers' position and that of the experts. I think it is very important that all of the discussions by all of the professionals in this room should be transferred to the decision makers' table so that it is possible to coordinate our intentions. From my observation in the World Health Organization (WHO), I can see that the vaccination schedules are largely different in the NATO countries. In NATO countries, there is an even more severe situation than elsewhere because there are many decision makers that must create the coordination agreement. For all contingency operations all over the world; for example, in peacekeeping operations, the immunization situation is normally an urgent operation. It is necessary to create an immunization schedule for everybody, for all troops so that it is possible to avoid an intervention in the last hour and prevent inconveniences from occurring.

MEDICAL GLOBAL COMMAND AND CONTROL SYSTEM

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1. SUMMARY

In response to known deficiencies and advances in technology, information systems within the Department of Defense are migrating to compliance with the Defense Information Systems Agency's (DISA) Defense Information Infrastructure Common Operating Environment to ensure interoperability.[1] The Medical Health Services System (MHSS) has been working to condense its myriad of non-interoperable systems into a family of interoperable systems that meet the needs of all the Services for the same functions and that follow the same architecture protocols as the tactical and operational systems.[2] This interoperability will contribute to improved situational awareness, tactical integrity, and command and control while supporting the warfighter.

2. INTRODUCTION

The end of the Cold War started a transition to a period of changing requirements, focus, and priorities. The Command, Control, Communications, Computers, and Intelligence (C^4I) for the Warrior concept is a direct result of this changing focus. This concept was directed by the Chairman, Joint Chiefs of Staff, to implement a single joint command and control system to integrate all functional requirements. The Global Command and Control System (GCCS), the flag-ship program, forms the foundation for medical command and control.

The impact of this shift and focus is evident in many projects underway, namely the Global Command and Control System (GCCS) and the Global Combat Support System (GCSS). The Military Health Services System (MHSS) is a full participant in C^4I to provide direct support to the warfighting commander for medical information. By linking information databases and integration centers that are accessible to the Warfighter at the right time, right place, in any mission, the Medical Global Command and Control System (M-GCCS) will provide the Commanders in Chief (CINCs) with the full spectrum of health care and medical information for contingency operations.

3. BACKGROUND

Reports from Operation DESERT STORM re-confirmed the requirement for fully integrated Service, Joint, and Combined communications and seamless data sharing to reduce loss of life and diminished personnel accountability. Some of the information management deficiencies noted were:

- Inadequate automated command and control systems,
- Insufficient interoperability between systems and between Services,
- Limited electronic data collection, and
- Inadequate communication support

For example, each Service used separate systems in each of its functional areas that were not compatible with either the software or hardware of the other Services' functional areas. As a result, we were not able to achieve automated transfer of information among systems for command and control, situational awareness and tactical integrity.

In response, the GCCS was designed to support deliberate and crisis planning with the use of an integrated set of analytic tools and flexible data transfer capabilities. The primary objective of the GCCS is to have an architecture consisting of command and control forces and elements within a highly flexible system that must be able to collect, process, disseminate, and protect information.[3] The Medical GCCS was developed to consolidate the medical command and control requirements into a single interoperable capability as part of the GCCS/GCSS environment.

4. DISCUSSION

The challenge facing the Department of Defense is the integration of existing systems into a "system of systems" to effectively meet the needs of the combatant commands, Services, agencies, and the Joint Task Force Commander. To achieve this goal,

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Tri-Service subject matter experts panels have been formed to design systems that meet the needs of all the services for the same function. By doing so, the number of systems that have to be maintained is drastically reduced and the information provided by each Service is the same for that functional area. This facilitates the aggregation of data into reports that can be used for decision making.

Existing computer systems that meet these requirements are migrating in a way to conform with the Defense Information System Agency (DISA) worldwide technical requirements and implementation standards supporting the Defense Information Infrastructure Common Operating Environment (DII COE). These protocols provide for the entry of data once and use of it anytime, anywhere, from the deployed environment reaching back to the sustaining base, through the GCCS/GCSS and by integrating with tactical and operational systems of the warfighter, the theater CINC and Joint Task Force Commander. Any new systems being developed must meet the DII COE requirements to ensure they are interoperable within this environment.

The Medical GCCS, an integral part of this system of systems, provides medical information for decision making to all levels in the chain of command in order to coordinate resources toward support of the warfighter. Medical resources are a critical player in mission success and the medical systems must be interactive and interoperable to rapidly update plans, view current operational status, and support patient care. The information must be universally viewed, represented, and updated by the combatant commands, Services and agencies.

The Department of Defense's Medical Readiness Strategic Plan (MRSP)[4] addresses how we are reengineering the changes of the Military Health Services System (MHSS) to support changes in the National Military Strategy and Defense Planning Guidance. The MRSP states that "we must satisfy the validated requirement for a seamless medical information system serving contingency support ... across all echelons" or levels of care. The seamlessness is in terms of *users* - so we can move from non-contingency to a contingency environment without additional training; *data* - it is entered once and used anytime, anyplace after that; and *applications* - they are available from any platform where there is a legitimate requirement.

Medical Aligned With Line

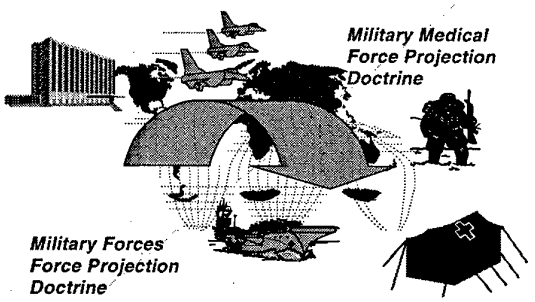


Figure 1

Because operations can be anywhere in the world, and because force projection is lift constrained, the projected forces must be tailored to the need, tri-service, integrated, and flexible. The latest weapon systems leverage today's information technology to provide accuracy, quick reaction, the ability to mass offensive fires, and command and control. Medical systems need to leverage equally on this technology.

To achieve these goals, medics must support the new doctrine of force projection just as the warfighters do, as depicted in Figure 1. Rather than having prepositioned assets near a proposed theater of operations, we are both positioned in the continental United States, ready to deploy.

In line with the smarter result of fewer interoperable systems is the strategic vision of the operational continuum. Figure 2 represents not only the operational continuum but how the MHSS is structured to support that continuum. Systems, grouped into the functional areas of clinical, resources, logistics and corporate executive information systems, are being developed not only for our peacetime facilities, but for use in a contingency environment as well. This will decrease the need for additional training when forces are called upon to deploy.

MHSS IM Strategic Direction

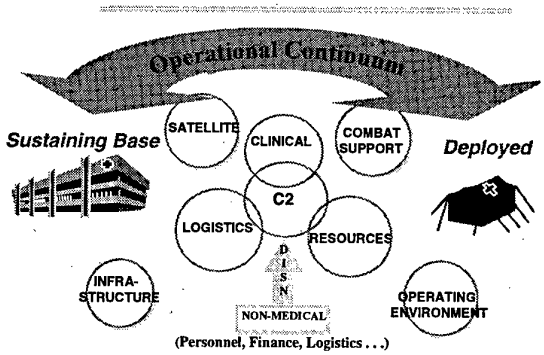


Figure 2

The systems our personnel take with them will be the same systems they use on a day to day basis in their peacetime mission. The goal is for all of the Services to use the same systems for the same functions in all environments.

As shown in Figure 3, the medical functional area is only one of several functions which must integrate into the GCCS/GCSS family of systems. The medical systems are being developed following the same guidelines of the DII COE as the systems used in the Federated system of cross-functional areas such as Personnel, Logistics and Finance. In order to provide automated updates to other areas, such as Personnel, with status, location and condition of a patient, all systems must conform to the same protocols. So, not only are all medical systems being updated or developed according to the same standards, the operational and tactical systems are also adhering to the same guidelines to ensure full interoperability.

Our aim is to ensure we are aligned technically and simultaneously with the other combat service support functional areas to maximize support to the warfighter. The ultimate goal is full interoperability among all Combat Support System functional areas.

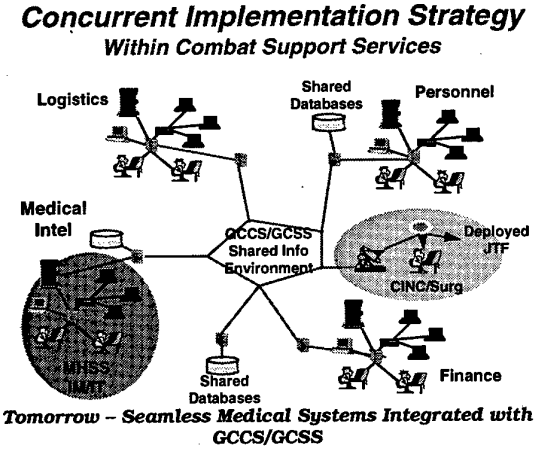


Figure 3

Figure 4 shows a conceptual view of how we can use this interoperable environment to respond to the CINC's requirements. Information must flow anywhere and everywhere so the information moves ahead of the patient to ensure the patient is moved to the required healthcare environment the first time. The foundation of this process is the Computerized Patient Record begun close to the point of injury[5] with a Smart Card plus handheld and laptop computers used in conjunction with the Smart Card at initiation of medical care. The data collection begins with the combat medic who enters data about the care and condition of the patient on the smart card rather than on a DD 1380, Field Medical Card.[6] As the patient moves through the system, additional data is stored on the card and is used by the next provider.[7]

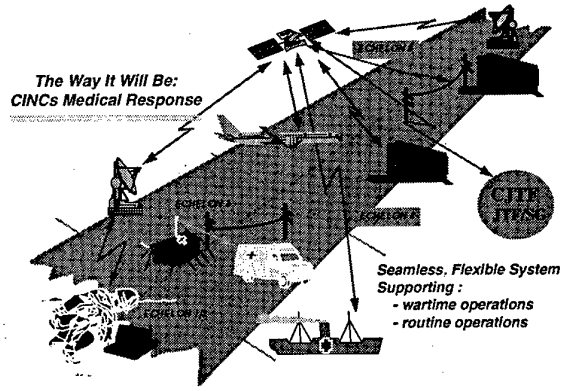


Figure 4

This information can be updated electronically as the patient progresses through the medical system. As the information is being collected, it is either sent directly to the using system, such as the Transportation Command (TRANSCOM) Regulating and Command and Control System (TRAC^{2}ES), or it is sent to a server where it can be accessed by various functions to produce combat casualty reports, request ground or air ambulance evacuation, and produce aggregated reports to study injury and disease incidence[7] by Service, unit,[8] age group, gender, nationality, military specialty code or rank.[9]

Early notification of TRAC^{2}ES allows the Theater Patient Movement Requirements Center (TPMRC) to begin planning for the movement of patients, coordinating with the Global Transportation Network (GTN) to schedule required airlift.

The collection and storage of the patient related information on the smart card can contribute to the provision of "care in the air" where again the card can be read and updated with data concerning condition and care aboard the aircraft.

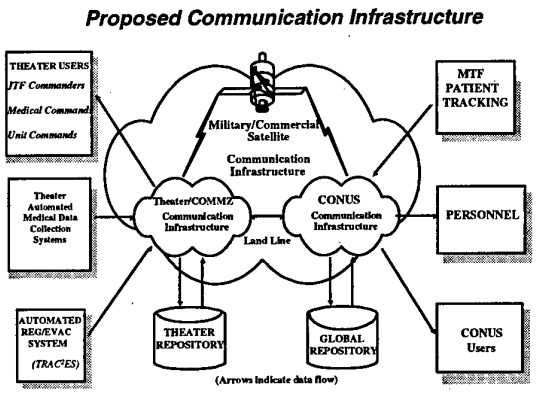


Figure 5

Not only is information regarding patient care and evacuation available, at the same time data is aggregated and sent to the Joint Task Force Commander or Task Force Surgeon. The aggregated information is used for Force Surveillance,[10] Preventive Medicine measures planning, and response planning. As data is collected in the Area of Operations, it can be stored in a theater or local repository (see Figure 5) where it can be accessed by other systems or it can be transferred directly to other interoperable systems. The constant stream of updates can be accessed at any time to provide up-to-date information for course of action analysis and decision making. The repository concept also provides for those occasions when communications are not available, and also provides redundancy and backup of data.

The combat multipliers that the Department of Defense will realize from implementing this medical integration effort include both operational improvements and potential savings. The operational improvements will allow us to interoperate with the warfighters in order to provide better support. We will have the ability to flex with the Warfighters and achieve interoperability with them. We will be able to provide total visibility of personnel and assets for command and control. Our systems will include Decision Support. We will achieve a seamless transition from peace to war that will contribute to continuity of care and medical surveillance. The potential savings will enable us to deploy with a smaller footprint, provide accurate information more quickly, and maximize evacuation resources. We will be able to provide accurate and reliable patient Command and Control level data.

5. CONCLUSION

In conclusion, the requirement for information dominance in the Joint battle space has moved to center stage in modern warfare. The efforts of the MHSS to ensure all systems conform to the same infrastructure and common operating environment as the tactical and operational systems, ensures we are wholly integrated into the warfighting environment.

The Medical Global Command and Control System moves medical information onto this stage, synchronized within the GCCS/GCSS common operating environment.

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Evolution of a Global Military and Civilian Telemedicine Network for the 21st Century: Near Future on Demand, Space Based Delivery of Multimedia Services

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Abstract

The Medical Defense Performance Review (MDPR) was established in 1993 to help "reinvent" how health care is provided to the US military servicemen and their dependents. One of the MDPR initiatives has been to rapidly insert video conferencing, telemanagement and telemedicine technologies to improve the quality and reduce the costs

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of delivering that care from major and minor medical treatment facilities, to wherever the need exists, e.g., to patient homes and to remote military communities. The technologies and the processes now being reinvented have the potential to provide excellent access to quality health care anytime, anywhere.

A major over arching issue is the need to facilitate the evolution of high quality, financially self-sustaining telemedical services. An earlier paper[1] provided an overview of the medical initiative of the National Performance Review which stressed the initial testbed and initial interregional telemanagement deployment efforts.

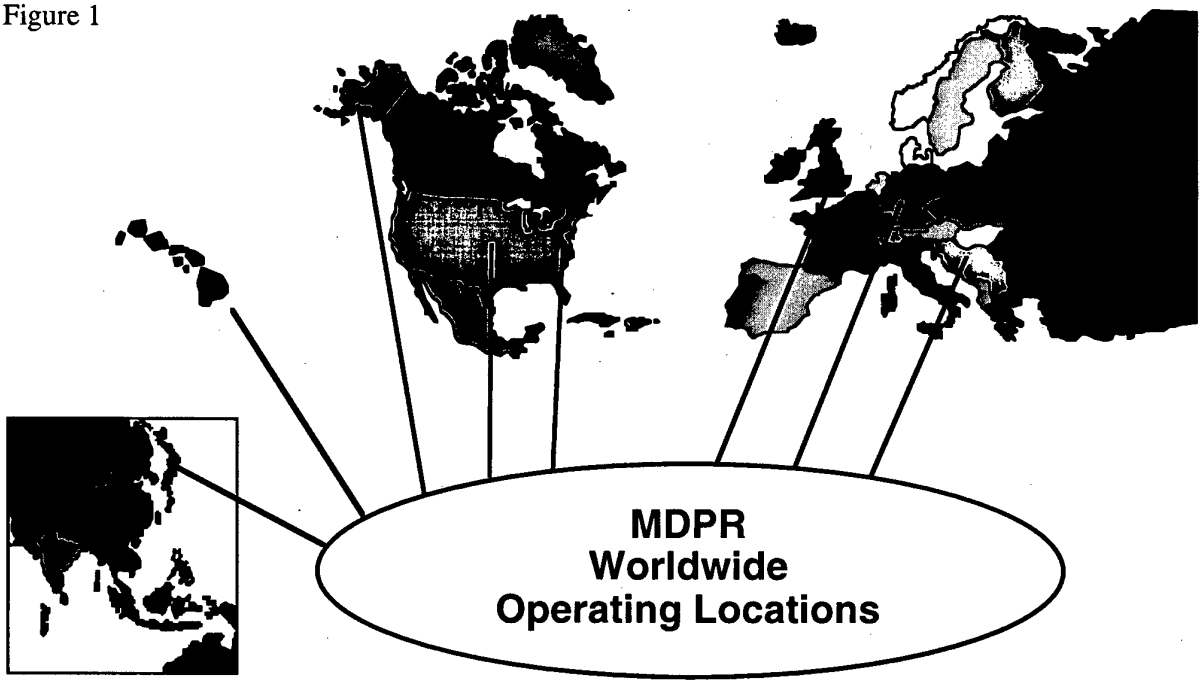
This paper stresses the more recent intraregional telemanagement and telemedicine efforts and synthesizes key success factors essential for evolving self-sustaining global telemanagement and telemedicine networks for the twenty-first century. Finally, future directions are proposed which could adapt these kinds of networks to bring about healthier military and civilian communities.

1.0 Introduction

We are pleased to be here today at the Aerospace Medical Panel Symposium. This paper updates our earlier work investigating the application of video conferencing, telemanagement and telemedicine technologies to improve access to health care, to improve the quality of care, and to reduce the cost of health care in the military. We believe these technologies have direct application to the problems that will be faced in the future to provide quality health care at reasonable, i.e., sustainable, cost. Secondly, this paper retrospectively synthesizes critical success factors and projects future directions with the assistance of the coauthors.

The opinions expressed are those of the authors and do not reflect the policy of the United States Air Force.

Figure 1



2.0 Project Background

U.S. Vice President Al Gore established a National Performance Review, the purpose of which is "to reinvent government" both to improve government services and to reduce the cost of providing these services.[2] Under the sponsorship of the National / Defense Performance Review, the Medical Defense Performance Review was established under Lieutenant General Thomas McInerney who brought in Brigadier General Peter Hoffman to direct a two-pronged effort.

One prong of the effort was focused on developing a medical provider workstation. This prototype is being developed at Scott AFB, and is documented separately.[3]

The other prong of the effort was conceived as a joint civilian and military initiative with the Office of the Air Force Surgeon General as the executive agent. This focused on a user-evaluated and user-guided, phased deployment of computer communication networks emphasizing group and desktop voice, data, image and video conferencing to support telemanagement and telemedicine. Concurrently, emphasis was given to inserting high-value-added reengineered management and clinical processes based on collaborative experiences with best-of-breed leaders of civilian telemedicine and newly-empowered military users of telemedicine.

These broad-based MDPR efforts recently received the Vice President Gore Hammer Award for excellence in reengineering. This paper focuses on the emergence of the network and its reengineered management and clinical processes which are currently being inserted and evolved worldwide. (See Figure 1, "MDPR Worldwide Operating Locations")

Collaboration of the MDPR with the joint military and civilian community has been paramount throughout the four years of the project. The MDPR has been working with the Army Medical Advanced Technology Management Office , the Naval Medical Information Center and the Office of the Assistant Secretary of Defense for Health Affairs to improve access to health care, to improve the quality of health care, and to reduce the cost of health care — goals that must be met in an environment of reduced resources in the military and civilian health care communities. Much of the current work being done by these and supporting organizations was presented at the first National Forum on Military Telemedicine in March of 1995[4] and at the Telemedicine 2000 conference held in June 1995.[5] An overview was presented to a meeting of NATO Partners for Peace in September 1995. And, more recently an overview was presented at this summer's Global Telemedicine and Federal Technologies symposium at Williamsburg, VA.[6]

Because the ability to outsource military medical services on a global basis has always been envisioned,[7,8] we have concurrently sought opportunities to work with best-of-breed military and civilian leaders and facilities, ultimately contributing to healthier military and civilian communities.[9,10] For instance, from the beginning we sought the guidance of and collaborated with best-of-breed leaders in telemedicine, such as Dr. Jay Sanders at the Medical School of Georgia, currently President of the American Telemedicine Association and coauthor of this paper. We collaborated with Jay at the First Congress of the Atlantic Rim in Boston, 1994.[11,12,13] This telemedicine presentation and demonstration reported on the pioneering efforts of the US Army (Dr. Ed Gomez, Walter Reed) and demonstrated a US Navy-developed, Joint Chiefs of Staff award-winning Multilingual Translator (Commander Lee Morin, Naval Medical Research Institute).

This collaborative activity has matured to the point where joint presentations have been delivered at Monaco, November 1995,[14,15] at the 100th Boston Marathon, July 1996[16] and at the Global Telemedicine and Federal Technologies Symposium at Williamsburg, VA, July 1996.[17] Another milestone was reached when a Collaborative Research and Development Agreement was struck between Lahey Hitchcock Clinic and the Electronic Systems Center in July 1996.[18] This agreement will enable the military medical regions within the US and Europe to import and leverage medical expertise and reengineered clinical processes in exchange for providing Lahey with expertise in the deployment of global computer communication infrastructure.

Thus, the MDPR initiative we focused on was intended: 1) to improve the medical management, acquisition, operational and support processes within the Air Force medical community; 2) to promote collaboration among the other military services, NATO, the United Nations, other coalition partners, and the civilian health care communities. This top-down and outreach approach has successfully extended the enabling technology across regional medical organizations to evolve incrementally to a true telemedicine system serving health care providers and their patients.

The major constraints are technical interoperability and, especially, cultural issues.[19] Cultural issues most inhibit taking advantage of rapidly developing technology. To reap the full benefits of new technology requires reengineering of the organizational[20] and medical processes themselves. Health care providers and management executives who are experts in their fields are best positioned to redefine these processes and lead the changes.

3.0 Video Conferencing (VTC)

Essentially, video conferencing is a television link between two or more locations. Most early successful systems were installed in government and large corporation conference facilities. The widening acceptance of this VTC technology has lowered the cost of working and collaborating together on common projects and issues from remote sites.

The fundamental components of video conferencing systems are the basic video and audio capabilities. Other audio-video capabilities are typically integrated into corporate VTC-equipped conference rooms. These include graphic display systems such as overhead viewgraphs and 35 mm slide projectors. Auxiliary video sources such as video cassette recorders and players as well as facsimile capabilities for the exchange of printed material are often also included.

Video conferencing technology is now being extended to the desktop in personal computer systems. This has made the full range of capabilities found on personal computer systems (office automation, engineering, computing, file transfer and networking) inherent components of desktop video conferencing systems. Important among these capabilities is the ability to share computer applications, allowing conference participants to work on a shared electronic copy of documents such as budgets, reports, plans, engineering drawings, and multimedia patient records.

The market for video conferencing systems is experiencing explosive growth. This has been made possible by commercialization of technical advances in video and audio compression technology, by acceptance of internationally promulgated standards supporting proliferation of the technology, and by the increasing availability of low-cost dial-up digital communication services.

The high information content of television signals, typically computed at 90 Mbps, inhibited the development of video conferencing systems prima-

rily due to the high cost of communication services. Contemporary compression technology enables effective interactive video and audio communication at data rates of 128 kbps, a compression ratio approaching 700:1.

Complete standards-based add-on systems for personal computers including the television camera, an audio speaker, and communication network interface are available today at costs ranging from $1300 to $8000. International standardization of video conferencing, increasing product integration and increasing production levels are expected to continue to cause prices to decline dramatically.

Worldwide dial-up digital communication services at a rate of 128 kbps are becoming increasingly available today through the ISDN BRI service offered by most telephone companies. The cost of ISDN BRI in most areas is comparable to that of two analog voice-grade telephone lines. The service is widely available today in western Europe and Japan and at many of the local exchange offices in the US. The service is expected to be a worldwide standard in the future.

4.0 Prototype Telemanagement Network

As a first step in meeting the goals of the MDPR, we focused on improving communication among top medical executives, the decision makers, in the Air Force health care community by acquiring a prototype telemanagement system. Most of the top executives are also physicians, thus providing early insight into the value of VTC, a key enabling technology supporting not only telemanagement but also later-to-be-deployed telemedicine. The prototype was installed at key locations to enable early user participation in the system design and to validate the system capability and performance prior to larger-scale deployment.

Early user participation also provided the opportunity for the real system experts, the system users, to work with and understand the possibilities of the technology, and then to reinvent how they do their jobs.[21,22] As we noted, only with changes in work processes can the full benefit of enabling technologies, such as video conferencing, be realized. Success of a prototype doctor-executive telemanagement system would also predispose support for continued infusion of the capability into the health care delivery community, thus metamorphosing to a true telemedicine system providing improved access and quality of care at reduced cost.

Data rates of 128 kbps are suitable for most medical applications. However, some future medical applications may require better video quality for video exchange. Consequently, our system has been made scalable and suitable for incremental change to provide higher performance where and when needed.

The prototype system now extends to the managers' desktops, providing live dial-up video conferencing capabilities as well as application sharing capabilities, allowing real-time collaboration on budgets, policies and other management tasks. The prototype has been found by the users to dramatically reduce the time required to make decisions. In addition, decision quality has improved through increased access to subject-matter experts. Further, greater real-time staff participation in the decision making process has created a better understanding of policies being promulgated. This has produced a greater sense of identification with new policies and hence better and quicker compliance.

The conference room and desktop video conferencing systems are installed at locations across the continental US, Hawaii and Germany. (See Figure 1, "MDPR Worldwide Operating Locations") Regional telemanagement extensions in progress

include locations in Japan, Okinawa, Korea, Guam, Alaska and other countries in Europe, such as England, The Netherlands, Turkey and Italy.

In addition to the conference room and desktop capabilities, a twelve-site multipoint conferencing capability is installed in the Air Force Surgeon General's headquarters conference room in Washington, DC. The multipoint system allows twelve other locations around the world to participate in a conference, with each remote location being simultaneously both seen and heard. This system enables the Air Force Surgeons General, Lieutenant General Edgar R. Anderson, Jr. and Lieutenant General (select) Charles H. Roadman, II, and their staff to interact frequently and in real time with the corporate executive group that runs the Air Force medical service, and to have them contribute to and participate in the decision making process, resulting in better and more timely decisions. Regular meetings now include a Monday staff meeting conducted at 12:30 PM Eastern Daylight Time, with participants on-line in Germany at 6:30 PM local time and in Hawaii at 6:30 AM local time.

The primary communication services are provided by the ISDN worldwide network where available; otherwise dial-up dual switched 56 kbps services are used. In addition, INMARSAT satellite services are used to reach remote areas such as the United Nations Medical Field Hospital in Zagreb, Croatia.

The system has dramatically improved communication between the decision makers at these locations, and reduced from months to days the time to discuss, resolve and promulgate major policy and budget decisions. The reengineered management processes facilitated by this new technology have also expanded participation in decision making. This has improved the quality of the decisions and facilitated implementation of the deci-

Figure 2

The Video Wall



Lieutenant General Anderson, MD, Surgeon General of the Air Force, applauds his new "Video Wall," which provides him and his deputies the capability to conference with his global staff. Previous to this "Video Wall," his staff spent days away from work travelling to meetings and had to defray huge travel costs – allowing only quarterly staff meetings. Now the general and his deputies can have weekly meetings with global staff, dramatically reducing the time required to make decisions and increasing the involvement of the global staff, resulting in faster, better, more effective decisions and policy changes. These photos were taken during the general's first use of the Wall on 7 July 1995. Electronic Systems Center, supported by MITRE, designed the Wall based on its previous designs used in other Command Centers; this dual-use of design experience made it possible to deliver the system to the Surgeon General in only seven months.

sion as all participants have buy-in to the decision process. (See Figure 2, "The Video Wall")

5.0 Telemedicine

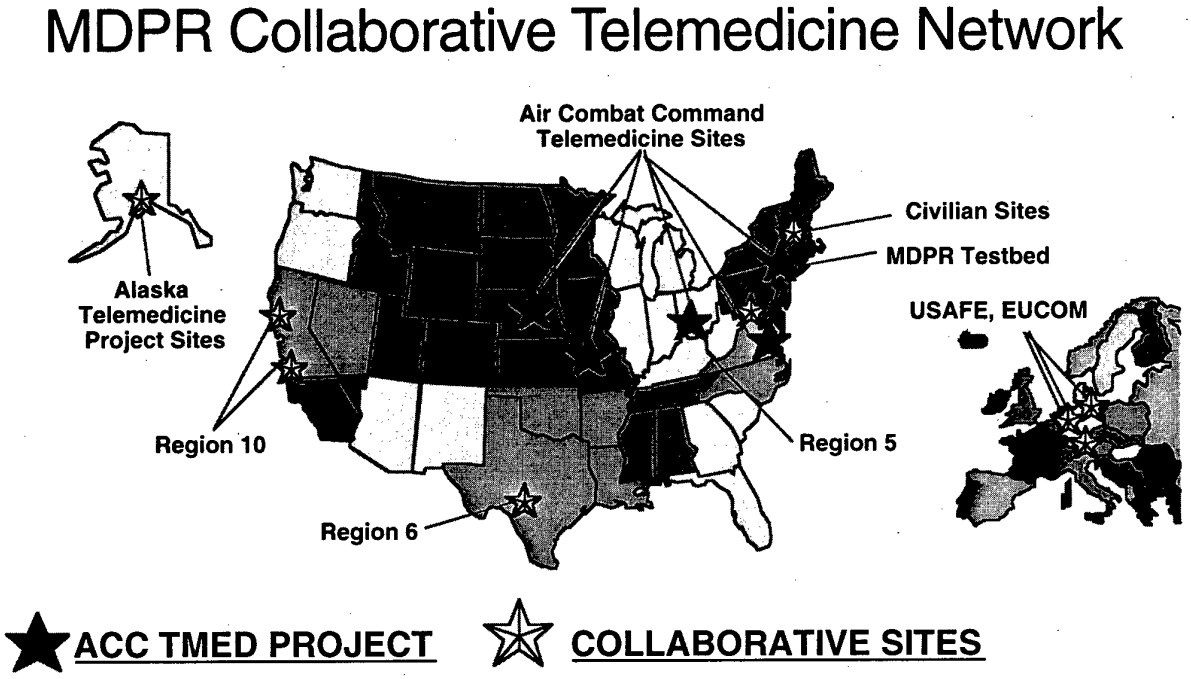
As video conferencing is changing the way the world meets, telemedicine will change how health care providers are trained and how health care providers deliver medical services to their patients. Video conferencing is a key enabling technology for telemedicine applications. Pioneering efforts to develop telemedicine capabilities have been done by Dr. DeBakey of the Baylor College of Medicine,[23] Dr. Jay Sanders, Director of the Telemedicine Center at the Medical College of Georgia,[24] and others.[25] Continuing medical education and consulting services are becoming increasingly available via telecommunications links. The future promises to include operations conducted on patients by remote physicians.

In support of the MDPR, we are now reaching out across various regional organizations towards the health care providers and remote patients and adding telemedicine capabilities to existing systems. Our first application has been to fill in the specialty and subspecialty gaps at smaller hospitals and remote military communities, under the direction of Colonel Klaus Schafer, MD, Command Surgeon, Air Combat Command. The concept for a prototype "Telemedicine Consultation Suite" that follows was prepared by Dr. B. Hadley Reed.[26]



Figure 3 – Telemanagement of medicine uniquely provides cost-saving capabilities to the medical manager. Telemanagement of medicine also provides important insights which can be used by senior management to assess telemedicine projects particularly when those projects have key elements which include "soft dollar" justifications. The pictured office includes desktop VTC, a VCR for recording or showing videos and a document camera to show the picture or briefing slide "worth a thousand words." Because the equipment is standards-based, it can be used to interact with the Video Wall (See Figure 2), other individual colleagues or multipoint meetings of colleagues who use standards-based equipment.

Figure 4



Empowered regional champions spearheading collaborative telemanagement and telemedicine efforts in other areas are: Colonel Locker, MD, US Air Forces Europe; Colonel Farmer, US European Command, Office of the Command Surgeon; Lt Colonel Sietsema, California; Dr. Pierce, Alaska. Overall telemedicine concept of operations and guidance is being provided by Dr. Sanders. US Air Force strategic management guidance and vision is being provided by Colonel Benge, MD. Significant clinical insights are being provided by Boston area hospitals and clinics. (See Figure 4, "MDPR Collaborative Telemedicine Network")

The heart of the system is the prototype telemanagement system components. (See Figure 3, "Telemanagement of Telemedicine") To these we are adding a suite of medical equipment that allows a specialist at a remote facility to see and hear the patient, in conjunction with a general practitioner, nurse or other health care aide with the patient.

Importantly, the initial MDPR clinical trials are driven by the needs of the users, and so are not "technology push driven," but are based on the business case analysis referenced above. The most promising specialty areas for telemedicine applications have been identified as allergy, cardiology, dermatology, mental health, neurology, pulmonary / respiratory, and ophthalmology. Underutilized specialists in these areas are available at military medical centers.

The prototypes will be tailored to the needs of the provider facility, and outfitted with suitable medical instrumentation to provide a remote specialist at the military medical center audio, visual, graphic (e.g., EKG) and other real-time medical data to enable an effective consultation with the patient and the local health care provider. The goals of the clinical trials are to assess the cost and benefits of telemedicine capabilities in the selected environments. Our measures of effectiveness are now being defined, but they will address the need to capture and document expected cost savings resulting from decreases in outpatient referrals and expected improvements in the quality of care. The results of the prototype evaluation should be able to guide planning for future use and deployment of telemedicine capabilities in the Army, Navy, Air Force and civilian communities alike.

We believe this medical technology has the potential to have an even greater effect than the advent of the telephone, which enabled a local healthcare provider with a question simply to call a remote expert with a quick question. The obvious limitation of telephone technology has always been the difficulty the local provider has had in adequately describing the situation to the expert over the phone without the clarifying assistance of pictures, graphics or motion.

The ability to dial up the expert consultant in such a way that the consultant can see the patient with the physical finding, even hear the auscultation and view the x-rays, will dramatically enhance any provider's ability to deliver the best care to each patient fast, with less cost for outside consults. Further, the local provider gains insights and expertise from the remote consultant, thus providing better patient, provider, consultant teamwork in the course of treatment and specialized teaching for the provider at the time of relevance and need.

Other cost reductions are related to reduction of lost patient work time. Reduction of lost work time includes travel to and from remote medical facilities, processes that today can take as long as five to seven days for a single appointment. In addition, the loss in work-related productive effort resulting from this travel is a more subtle, but significant, cost. Employers who are mindful of the full cost of the medical benefits they provide do not find these work- and travel-related costs trivial.

Deployed Telemedicine Concept

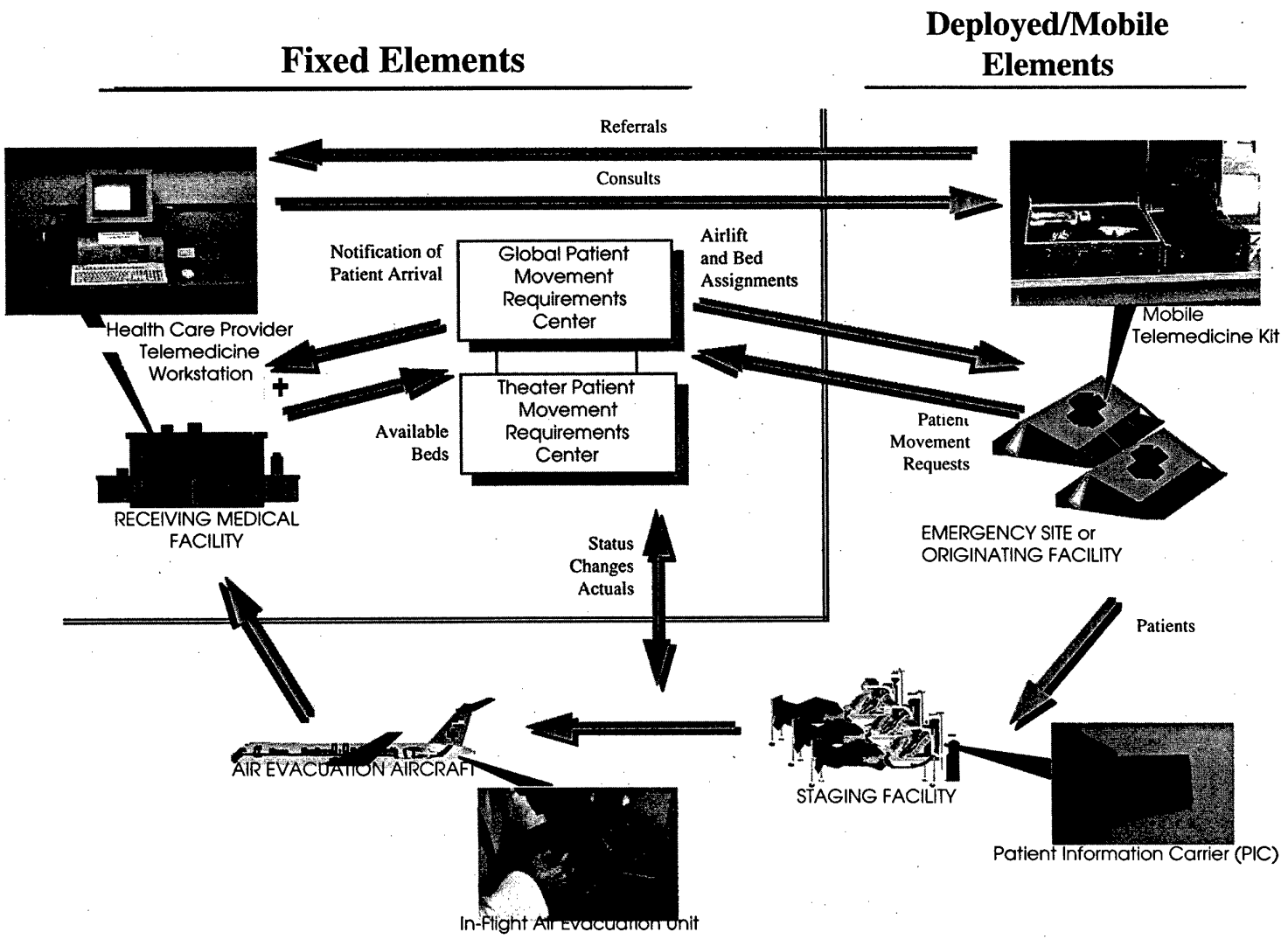
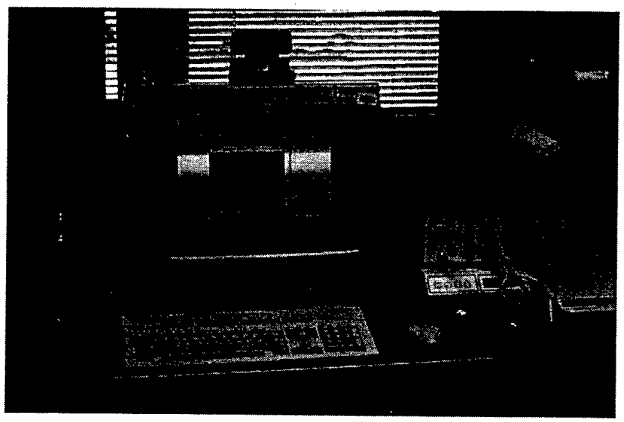


Figure 5

Deployed Telemedicine Concept (Selected Equipment)



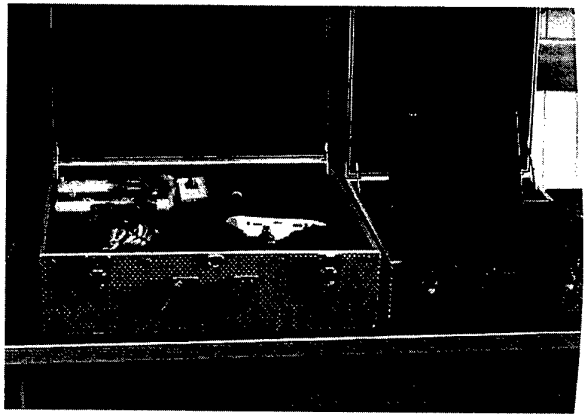
Health Care Provider Telemedicine Workstation

The Health Care Provider Telemedicine Workstation needs to be part of the provider's normal work space. In the case of a local health care provider, appropriate specialty peripheral medical equipment is part of the Workstation. Our experience to date indicates that the document camera is valuable to many specialities. This scene depicts also the electronic equivalent of a stethoscope and a pharyngoscope. A consultant may not need all the data acquisition equipment needed by the local health care provider because he or she will evaluate, not generate, the data. (See Figure 5 on the previous page for a more Spartan suite of equipment.)

The ability to have, to generate and to communicate essential patient information in-flight is one important part of providing an uninterrupted continuum of care to a patient being evacuated. This hand-held computer for recording in-flight patient information is being developed and refined for Air Mobility Command in partial fulfillment of this requirement.



In-Flight Air Evacuation Unit



Mobile Telemedicine Kit

By selecting and integrating telemedical equipment which can be carried easily to the patient in the field, medical expertise can be brought to the patient and consultative services can be delivered from afar. In effect, the doctor with the needed specialty expertise is brought to the patient, rather than taking the time and wasting the "golden hour" taking the patient to the doctor.

Figure 5 continued

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Further, greater timeliness of treatment has always been known to have great medical benefit as well as to be a major cost reducer.

6.0 Telemanagement and Telemedicine Testbed

While group video conferencing technology is mature and to a large extent interoperable due to the international video conferencing standards, desktop technology is just emerging. Many different incompatible approaches are being pursued. Telemedicine technology is even more immature.

Proprietary video and audio compression techniques are being implemented by some vendors to optimize performance over local area networks, which are outside the scope of the current H.320 international VTC standard designed for ISDN services. Other vendors are using techniques to transmit out-of-band in a local area by using spare telephone wire, or by riding on the copper conductors that may be used for the local area network transmission media. Further, standards are not yet in place for applications sharing and other features now part of desktop video conferencing systems.

The desktop products also differ in terms of performance and features. Similarly, telemedicine systems which are based to a large extent on integration of other commercial off-the-shelf medical, video and audio components, also represent a new technology which is yet to be proven in use.

To address these kinds of interoperability issues and to evaluate and test candidate products, we have put in place a distributed interoperability and product evaluation testbed. (For example, see Figure 5, "Deployed Telemedicine Concept" and Figure 6, "A Spectrum of Needs Met by a Spectrum of Equipment")

The testbed has been instrumental in helping us achieve our success in many ways. It has:

- facilitated product evaluation and selection,
- provided a means to evaluate alternative system's performance and stability,
- allowed early user participation in defining requirements, evaluating system concepts, and in selecting products,
- helped vet potential system alternatives with selected users prior to deployment. This has facilitated our providing the right technological tool to the user as opposed to mandating the use of a technological tool on the user,
- provided a tool for the project office — improving communication among the project team members, i.e., the customers and the project office, and
- functioned as an important tool for providing telemaintenance and teletraining support, thus reducing operations and maintenance costs.

7.0 Prototype Network Current Status

7.1 Significant New Global Capabilities Achieved Rapidly by Investing $10 Million from Multiple Sponsors and Leveraging the Billion Dollar Public Network

Over the past four years a number of sponsors have augmented the efforts of the Air Force Office of the Surgeon General, our primary sponsor. The funding provided by the Office of the Air Force

A Spectrum of Needs Met by a Spectrum of Equipment

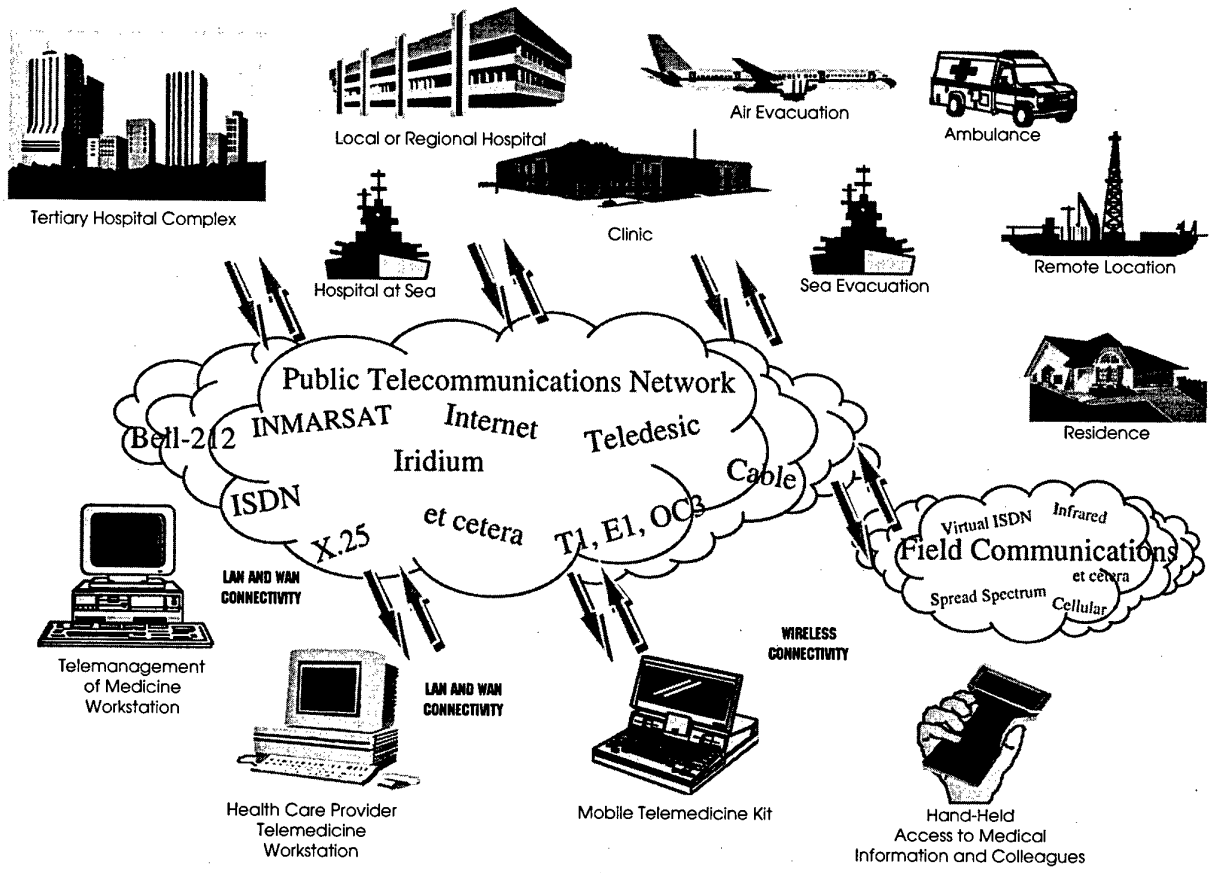


Figure 6 – To achieve its promise, telemedicine must link the patient and the proximate health care giver to the expert, the consultant. This requires that telemedicine be globally interoperable, just as the telephone has achieved such interoperability to maximize utility and, in turn, to maximize resultant markets.

Surgeon General was nearly doubled by others who saw the value of deploying a global network to support an integrated telemanagement and telemedicine network. Further, this network leveraged the hundreds of millions of dollars being invested by commercial enterprises in the global information infrastructure. Beyond this, another form of leverage was taken advantage of by employing the talents of the Air Force's Electronic Systems Center and the MITRE Corporation who had over decades been developing and deploying command and control centers and interoperable networks which had very similar characteristics to the telemanagement and telemedicine network needed by the Surgeon General.

7.2 Air Force Surgeon General Network Achieving $3 to $6 Million in Savings Annually from Investment of $4.5 Million over Four years

The Surgeon General's telemanagement system, has significantly enhanced the capability for mak-

ing timely decisions. Annual savings have accrued not only in the form of improved decision making, but also in reduced management, training and medical travel costs and reduced time away from primary duty station conservatively estimated at $3 to $6 million per year,[27] a half-year payback, which can be leveraged to extend the global network and further enhance the savings.

Awareness of the improvements generated by the interregional medical decision support capability has stimulated regional medical commanders to provide similar capabilities on an intraregional basis. Supplementing the Surgeon General's regional VTC bridging capabilities, the intraregional VTC bridging capabilities will dramatically reduce telephone costs and increase the flexibility of how doctors and medical executives can be brought together while working apart. Thus, the enhanced decision support and cost savings generated by the system will intensify as the intraregional bridges are brought on line.

7.3 Spectrum of Interoperable, Integrated, Commercial-Off-the-Shelf Telemedicine Prototypes Developed and Currently Being Deployed That Can Rapidly be Adapted to Military and Civilian Local Telecommunications Infrastructures and Medical Needs

Our challenge in 1996 and 1997 is to reengineer the clinical decision support processes to facilitate communications between patients and their local doctors who can then collaborate with a distant medical consultant to create a close patient-doctor-consultant treatment team. This will result in quicker and more accurate treatment in cases requiring consultations and will result in CME-like experiences by the local doctor. (See Figure 5, "A Spectrum of Needs Met by a Spectrum of Equipment")

As of 1996 progress towards this end has been made by designing and implementing a telemedicine testbed in collaboration with the Air Force Air Combat Command. This testbed's design followed the expert leadership of Dr. Jay Sanders and Lahey Hitchcock Clinic and relied on experience gained during the Texas Prison Telemedicine project led by Dr. Bob Brecht.[28] An important testbed design feature stemming from this collaborative approach was to integrate the telemedical instruments into the physician's desktop computer along with video teleconferencing.

Our design contrasts with placing a telemedicine center hundreds of feet from the normal examining room environment. The technology-driven design of these large telemedicine centers has generally resulted in expensive centers, and limited use has resulted from the distance from the patient. These two factors, high cost and low usage, have reduced the actual and perceived cost-effectiveness potential of telemedicine. The cost-effectiveness of our efforts has been increased from this perception in a number of ways, two of which are: 1) to lower the equipment cost by scaling the equipment to the needs of the user as articulated by the user and 2) to emplace the equipment where needed as articulated by the user, typically the examination room or the doctor's office.

Further, deployment of the testbed equipment has been such that existing consultative patterns are duplicated. This results in the least perturbation of already existing doctor-consultant relationships. Both fiscal and medical impact measurement techniques have been overlaid on the testbed trials in a fashion which will also allow comparison of results with other telemedicine trials.

7.4 Stage Set for Further Enhancing Delivery of Medical Care by Integrating Telemanagement, Telemedicine and Continuing Medical Education (CME)

In 1996 we also learned how to deliver telemedicine when the patients and the doctors are far apart from each other. The stage has been set to link isolated patients and care providers to distant, more capable care providers. This form of telemedicine will at first be used to provide better and more timely care for Air Force personnel in isolated locations or locations where limited military medical staff is available. As this technology and clinical practice evolves, we anticipate that better medical care will become available to many who now have medical care constrained because of distance between patient and provider. Beyond this, the interaction between the remote higher-qualified or more specialized doctor and the on-scene provider will enhance the on-scene provider's medical skills much more effectively than current approaches to CME.

8.0 Near Future on Demand, Space Based Delivery of Multimedia Services

8.1 Air Force, Joint Community and Civilian Trends

Our sense is that the thrust of our current efforts could help the Air Force, as well as NATO and Transatlantic communities, to enhance current telemedicine initiatives by making them more mobile, to provide in-flight capabilities and to assist in consolidating, integrating and standardizing capabilities useful to the joint community. (See Figure 5, "Deployed Telemedicine Concept")

Alongside Air Force initiatives, Army and Navy telemedicine initiatives are rapidly emerging.[29] Ongoing telemedicine initiatives are available by accessing the Office of the Secretary of Defense for Health Affairs Home Page, http://www.ha.osd.mil/index.html. The major challenge will be concurrently to reduce medical and command and control fragmented development efforts, to insert new technology and to make the new capabilities interoperable and easier to use.[30,31,32]

Healthy cities and regional networks are paralleling military telemedicine efforts. Civilian efforts could leapfrog military efforts once the commercial communications infrastructure becomes more robust, secure and less costly and once state licensing constraints are removed. Significant telemedicine efforts are currently under way at leading-edge cities and regions with extensive medical facilities, such as those in Massachusetts, Texas, Georgia and Washington, DC. Each of these regions is also beginning to link with each other and reach out to global sites in significant need of health care.[33,34]

8.2 New "Race In Space" To Support Contingencies, Trade and Tourism

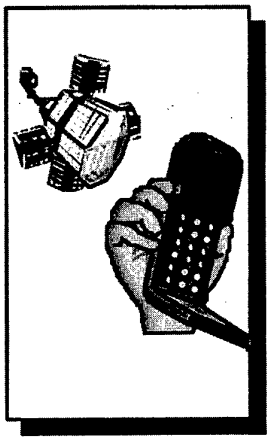
Annually, hundreds of billions of dollars are being spent by international consortiums to build and enhance a commercial global grid of telecommunications networks linking continents under the sea, on the ground and in space.

Medical teams, as well as warriors and businessmen should be ready to benefit from this huge commercial and military investment.

In space there is a new economic war[35] and satellite race[36] (See Table 1, "The New Satellite Race") being driven by common needs for multimedia services of globally deployed military, businessmen and travelers, (See Table 2, "Information Service Needs of the Modern Traveler"), rapid advances in infrastructure (See Figure 7, "Rapidly Emerg-

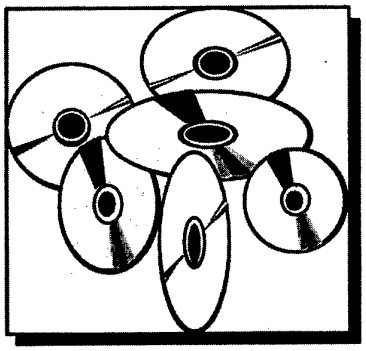
Rapidly Emerging SATCOM Services

Odyssey



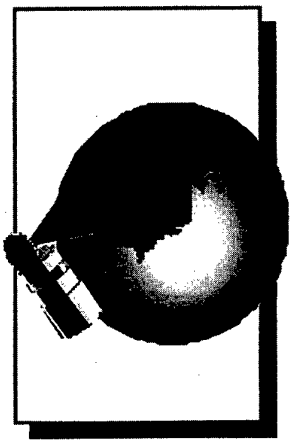
Personal Communications Systems
- **"Big LEOs"**
- **Voice and Data**
- **Odyssey, Iridium, Globalstar, ICO**

CD Radio



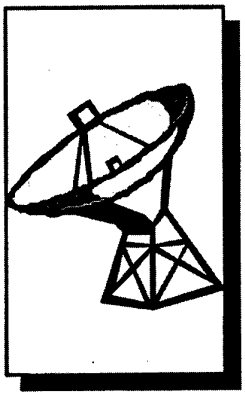
Digital Audio Radio
- **CD Quality Sound**
- **Mobile Terminals**
- **CD Radio, Primosphere**

Orbcomm



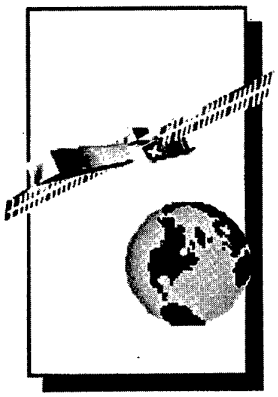
Global Data Services
- **"Little LEOs"**
- **Email, paging, telemetry**
- **Orbcomm, Starsys, VITA**

DirecTV



Direct Broadcast Systems
- **High Power Satellites**
- **18" Terminals**
- **Future data/Internet Services**
- **DirecTv, Primestar, Dish Network**

Spaceway



Ka-Band Broadband Services
- **New 20/30 GHz Band**
- **Bandwidth on Demand**
- **Spaceway, AT&T,**
- **VoiceSpan, GE Amercomm,**
- **AstroLink, Cyberstar**

Figure 7

Table 1. The New Satellite Race (Major Players)*

PROJECT	FUNCTION	SATELLITES	COST (in billions)	LEAD BACKER
Teledesic	High-speed data, teleconferencing	288	$9.0	Craig McCaw
Iridium	Voice, fax, paging	66	5.0	Motorola
SkyBridge	Data	64	3.9	Alcatel-Loral
Celestri	Data, broadcast and video	63	12.9	Motorola
Globalstar	Voice	48	2.5	Loral
ICO Global Communications	Voice	12	4.6	Hughes/Comsat

* Source: The Wall Street Journal, 17 June 1997, page A3

ing SATCOM Services") and profitable communications ("to/from") products and services.[37]

8.3 US Joint and Transatlantic Community Recent Efforts To Commercialize and Share What Works to Accelerate Growth of Healthy Regions

The purpose of this section is to highlight recent US, joint community and international efforts to commercialize low cost, interoperable telehealth products and stimulate in various Transatlantic and other regions, KISS-proof (Keep It Simple, Sam, proof of concept) initiatives.

For instance, by replicating in various NATO countries, easy to implement, low-cost, self-sustaining projects that leverage or link to the rapidly emerging global communications grid, isolated, remote NATO military units can become familiar with basic store and forward clinical decision support services augmented as required by low-data-rate video conferencing to emergency rooms in NATO countries. *This model can then be shared, adapted and enhanced to support the global needs of businessmen and tourists and vice versa.* Furthermore, as we attempt to expand NATO and transition downward the American presence in Bosnia, we can leave in place a "Medical Partners for Peace" service delivery system that, hopefully, will be used to reduce tension.

To achieve this vision and strategy, KISS-proof products (i.e., low cost, commercial off the shelf desktop/laptop computers with attachable medical devices and standards based collaborative software capable of performing in low cost "store and forward" internet and ISDN video conferencing modes, with optional wireless and satellite capabilities for even more remote and aeromedical evacuation environments) were acquired, integrated and tested in conjunction with Air Force, Army, DOD Health Affairs, civilian testbeds and the Combined Unified Battlefield Environment (CUBE) of the Electronic Systems Center (ESC). Next, a phased worldwide telemanagement network was implemented. Subsequent steps implemented telemedicine and/or teletraining capabilities in Missouri, Nebraska, Ohio, California, Alaska

and NATO countries. (See Figure 4, "MDPR Collaborative Telemedicine Network" and Figure 5, "Deployed Telemedicine Concept")

To share these ABCs of telemedicine, the Atlantic Rim Network, led by James H. Barron, JD, organized an historic first: a Transatlantic Telemedicine Summit in Boston in May 1997. Nearly 250 leaders in telemedicine (policy makers, health care and technology providers) from various countries convened (under the chairmanship of Doctors Jay Sanders and Jean-Pierre Thierry) to learn of residual constraints and to share lessons-learned insights.

Concurrently, these leaders were exposed also to a dozen specific examples of low-cost interoperable telemedicine projects which could be replicated in their various Transatlantic or NATO countries.[38] One result is an accelerated NATO related regional effort which is now underway in Canada. The initiative is led by The Augmented Reality Testing Integration and Communications (ARTIC) LAB (www.digital-fx.ca) which was recently opened by the Right Honorable Jean Chrétien, Prime Minister, Canada, who was also a VTC participant at the Summit.

The Atlantic Rim Network is preparing multimedia proceedings and organizing follow on activities to assist US Joint Community, Health and Human Services regions, NATO and other countries[39] to rapidly digest, adapt and adopt insights presented at this Symposium. Plans are also underway to hold a 1998 Transatlantic Telemedicine Summit in Europe.

Key among the insights presented at the Boston Summit were telemedicine, trauma care training, disease control and aeromedical evacuation. This Rotterdam Symposium highlights the pioneering efforts of USTRANSCOM/Air Mobility Command[40] and DOD Health Affairs Region 6[41] in aeromedical evacuation and NATO efforts in telemedicine.

Table 2. Information Service Needs of the Modern Traveler[43]

Information User:	Military Commander	Business Executive	Global Employee
Information Need:			
Telephony (Voice)	x	x	x
Voice recognition	x	x	x
E-Mail	x	x	x
FAX	x	x	x
File exchange	x	x	x
Application download	x	x	x
Remote database access	x	x	x
Internet Access	x	x	x
High resolution image	x	x	x
Video conference	x	x	x
Audio broadcast	x	x	x
Data broadcast	x	x	x
Receive video broadcast	x	x	x
Transmit video broadcast	Possible	Unlikely	Unlikely
Data security	Multi-level classified	Privileged	Privileged

x = strong requirement

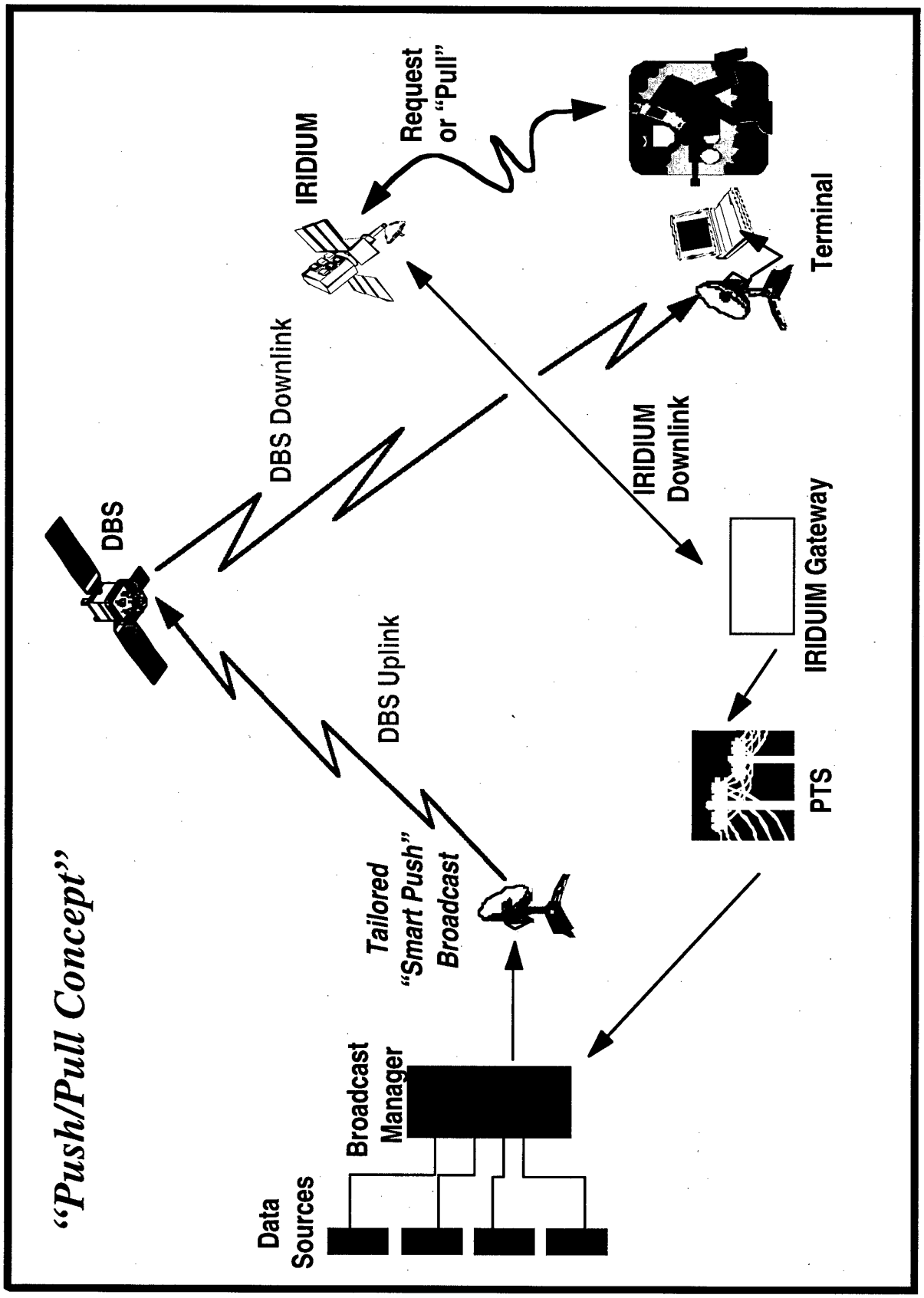

"Push/Pull Concept"
Data Sources
Broadcast Manager
Tailored "Smart Push" Broadcast
DBS Uplink
DBS
DBS Downlink
IRIDIUM
Request or "Pull"
IRIDIUM Downlink
IRIDIUM Gateway
PTS
Terminal

Figure 8

8.4 Revolutionary New Space Based Services in 1998

This ongoing activity sets the stage for near future, on-demand, space based delivery of multiple information services.

The basic concept of how these new services will be requested and delivered is illustrated by the "Push/Pull Concept." (See Figure 8) An information request or "pull" is executed by a remote warrior, medic, businessman or tourist using a hand held device similar to a cellular phone (e.g., Iridium subscriber set). The signal is picked up by a constellation of low earth orbiting satellites (Big LEOs) which use "on board processing" and "cross linking" capabilities to hop across satellites and down to the regional "gateway" nearest the desired destination. Here the signal is converted to a format understood by the phone system and sent to the intended receiver.

If a response requires a multimedia high speed broadcast the return broadcast is sent to the appropriate mix of commercial and/or military "direct broadcast satellites" (DBS) to the requester's earth station. This ground terminal could be a low cost, commercially available "lapsat" (e.g., Direct PC) or a more complex and costly terminal, depending upon security and access issues or desired format of the request (e.g., text).

Motorola's Iridium capabilities will be globally operational starting in the fourth quarter of 1998. Shortly thereafter, US/NATO units, as well as businessmen, will be able to call in "information strikes" tailored to their warfighter, medical or business needs anytime from anywhere.

An airborne delivery of similar services to enroute or returning or evacuating global military, business or civilian travelers is shown in Figure 9. Envisioned here is a similar request for a "common operating picture" by the warrior or just-in-time trauma care training by an air crew/attendant.

The "push/pull" is handled through a space network ("internet in the sky") similar to that just discussed. The return signal could be received by a phased array antenna on the skin of the aircraft and distributed via an on-board "server" to satisfy the differing needs of crew and passengers.

Space based (direct broadcast satellite) delivery of television and data services to aircraft has already been demonstrated (e.g., in the Joint Warrior Interoperability Demonstrations). On demand, space based, transmission of voice and data from aircraft (e.g., via INMARSAT and AFSATCOM) has been a reality since about 1980. Integration of the two functions into a push/pull service should not be a major undertaking.

Therefore, such a system shortly can be delivering a variety of entertainment, business and aid services to airborne civilian and military travelers which will augment today's civilian and military aeromedical evacuation.[42]

8.5 The Future IS Conditional

In conclusion, this revolutionary delivery of robust space based information services will soon be able to augment deploying and deployed contingency units. However, cost effective, medically valuable services will depend upon how well we learn success/failure lessons from the already deployed KISS-proof concept initiatives and the growing investment being made in high cost, pro-

Civil/Military Joint Operational Concept

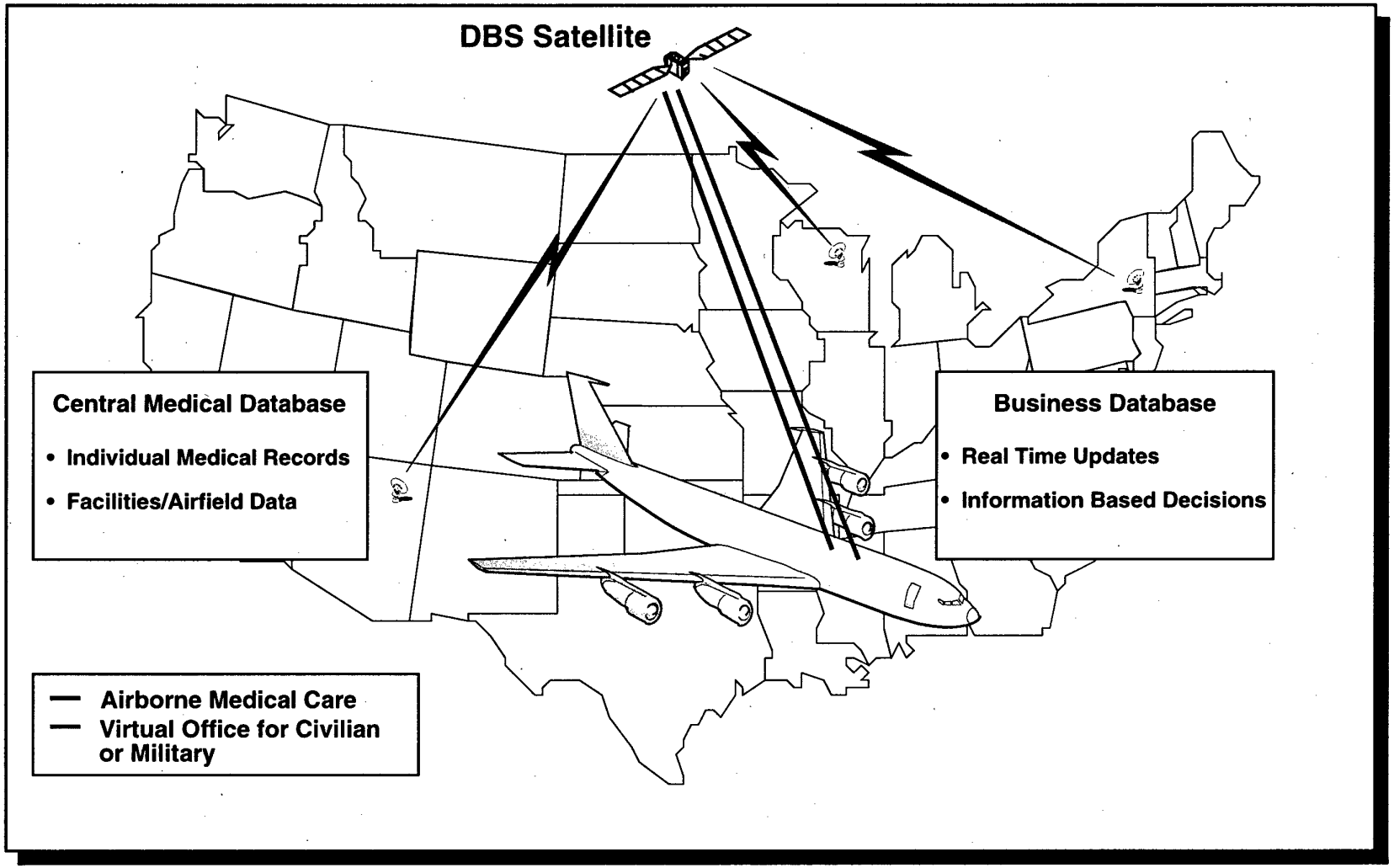


Figure 9

prietary equipment acquisitions.

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[39] We are reminded by Frank Davidson, JD, DHL (Hon.) of the worldwide interest and building recognition and support of telemedicine:

> The Transatlantic Telemedicine Summit has had global repercussions, thanks to the presence of a strong team of liaison participants not just from the West, but from Japan and other countries outside the Western Hemisphere. Governor Ota of Okinawa dispatched a group of experienced specialists: Professor Manabu Nakagawa, advisor to the Prime Minister, and Mr. Kada, both of the burgeoning Peace Engineering Institute, who emphasized how telemedicine and teletraining will enhance trade and tourism, along the lines discussed at the Spring 1997 meeting at Harvard and MIT with the governor where he was presented the Rensselaerville Institute's Theodore Roosevelt Peace Engineering Award. More recently, the Tama Conference in Japan presaged a substantial development program for the widespread application of telemedicine training and technology in Asia and elsewhere.
>
> All in all, we are witnessing a prototype for the next century of macro-engineering: the coalitions now abuilding are intersectoral, interdisciplinary and international; there is a dynamic and cooperative relationship between civilian enterprises and military institutions, with university campuses in the role of catalytic centers for specific, practical initiatives. This ripening technology has enlisted the support of the younger generation of doctors and engineers, with leading roles being played by pioneers such as Dr. Jean-Pierre Thierry and Marie-Gabrielle Verdier. France's Association Louis Armand, led by Henri Teissier du Cros (a conseiller d'état honoraire) has provided intellectual support; Thierry Gaudin of the Foundation Prospective 2100 follows these events closely and with understanding. And the International Association of Macro-Engineering Societies, headed by Uwe Kitzinger, CBE, has provided diplomatic and practical insights that have helped keep the entire program "on track."
>
> In this context, the proliferation of telemedicine initiatives may be viewed as a harbinger of still further macro-engineering initiatives from whose accomplishment may emerge a unified whole. For, as Arthur Waldron has taught us, the Great Wall of China was, in fact, the end result of centuries of local and regional efforts to build defensive works of limited range and purpose. Dr. Peter Glaser, the famous inventor of the Solar Power Satellite, has dubbed this process "terracing." Each terrace of achievement , once built and operational, serves as a foundation for ensuing steps. And the habit of collaboration across institutional and

geographical boundaries will foster a nurturing climate that will indeed accelerate the establishment of "a sustainable health care society," in the words of Manabu Nakagawa, chair of the Tama Renaissance Symposium.

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TELEMEDICINE IN SUPPORT OF OPERATIONS IN REMOTE LOCATIONS

Mr. Tommy Morris, COL Robert H. Vandre, Ms. Mitra Rocca, COL Jeffrey I. Roller, Mr. Timothy Salisbury

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United States military services deploy to isolated locations with integral medical support. In most small deployments the unit has a General Medical Officer and/ or a Physician's Assistant as well as a compliment of Medics to provide primary medical care to the assigned personnel. The goal of telemedicine is to increase the quality of care given to the soldiers by providing access to specialty care providers utilizing satellite communications and commercial off the shelf technologies

Since 1993, The Department of Defense has augmented the medical support for military operations Outside the Continental United States (OCONUS) through the medium of telemedicine. This initiative was the first satellite based telemedicine system to support remotely deployed primary care providers. The goal was to provide a cost-effective means to: **a.** Improve the standard of health care **b.** Reduce the amount of evacuations **c.** Improve readiness of the deployed unit.

The deployed telemedicine flyaway kit is a combination of off the shelf technologies supported by satellite communications to provide a communications links between a remote site and a fixed facility and/ or another remote site.

In 1992, the first flyaway telemedicine kit weighed approximately 125 lbs., 7 cubic feet, and cost $60K. It provided high-resolution still imagery using a Macintosh power book 180 and a Kodak DCS 200 still image camera as well as voice and fax at a data rate of 2400 bps using a Magnavox MagnaPhone.

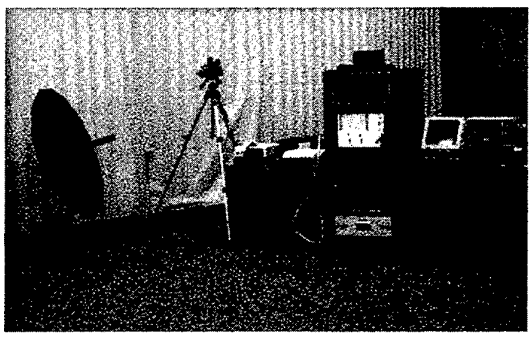
In 1993, the second flyaway kit weighed approximately 330 lbs., 40 cubic feet, and cost $150K. It provided interactive video teleconferencing using a CLI video codec, high-resolution still imagery utilizing a Macintosh 840AV computer and a Kodak DCS 200 Camera. For video imaging the system used a variety of Andries Tek Video scopes to include a Dermatology scope, ent/opthalmoscope, dental scope and a Canon L-2 video camera, voice and fax at a data rate of 56 Kbps using an MTI Inmarsat "A".

In 1996, the third and current flyaway kit deployed to Bosnia. It weighs approximately 112 lbs., 6 cubic feet and cost $68K. It consists of a Pentium based Dolch computer with PictureTel PCS50 video cards installed and a comprehensive software package to include Eudora for store and forward, adobe photoshop for image compression, filemaker pro for medical consults as well as Microsoft Word, Excel and Powerpoint. For imaging, the system uses a variety of Video scopes to include a Dermatology scope, ent/opthalmoscope by AMD, dental scope by Air Techniques and a Canon L-2 video camera. Also included is a HP 1600 fax/printer. For communication the system uses a Nera Inmarsat "B" terminal at a data rate of 64Kbps, or the Hughes Demand Net VSAT which provides Bandwidth on demand at data rates from 64Kbps to 384Kbps.

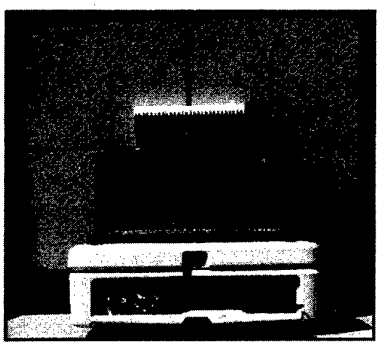
These telemedicine flyaway kits were prototyped and deployed by the Medical Advanced Technology Management Office (MATMO) now known as the Telemedicine and Advanced Technology Research Center (TATRC) which is the technical lead for DOD telemedicine.

As technologies improve telemedicine becomes more valuable and cost effective as a tool to augment medical support to remotely deployed units.

This article was presented at the 84th AEROSPACE MEDCIAL PANEL SYMPOSIUM RTO Meeting October, 1997 held in Rotterdam, Netherlands.



1993 set: 330 lbs., 40 cubic feet, $150K



Current Flyaway set: 112 lbs, 6 cubic feet, 112 lbs, $68K

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

Title: **"The Potential Uses of Telemedicine to Augment Critical Care In-the-Air"**

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Introduction:

Recent advances have allowed us to expand the realm of intensive care medicine into the aeromedical evacuation arena. The rate limiting step to the full scale development of this concept is sufficient numbers of trained critical care personnel. For the military this is especially problematic, given that sufficient readiness directed numbers would not be gainfully employed during a peace time environment. Therefore, we must look to alternate personnel sources to provide this care with sophisticated medical backup. In this regard, telemedicine provides an excellent vehicle to leverage the sophisticated medical care into the hands of other healthcare providers with intensivists backup. Air to ground telemedicine may expand the functionality of available non-physical providers during military medical contingency operations.

Discussion:

Telemedicine has been a well-funded "buzz word" of the US military medical services over the last several years. This exciting area of development holds great potential in the air evacuation world. We expect telemedicine to allow us to provide sophisticated, long duration, in-flight intensive care medicine with other than physicians. US civilian air ambulance services do this routinely with flight nurses only. Notably, these are usually rotary ring transfers involving only resuscitative care and are almost always of less than two hours flight time duration. In contra-distinction, the US military intends to accomplish movement of similar types of patients, in addition to patients already in the throws of multiorgan dysfunction, over long duration "greater than 10-12 hours" flights. Air to ground transfer of pertinent diagnostic and clinical information via telemedicine channels will allow us to utilize, other than physicians, for this advanced medical care. These include flight nurses, advanced care nurse practitioners, and physicians assistants.

In this paper we will discuss the following elements:

1. Review of basic telemedicine precepts.
2. Intensive care in the air versus on the ground.
3. Elements required for transport telemedicine.
4. Difficulties and problems remaining to be solved.
5. A summary and future directions to be discussed.

Basic Concept of Telemedicine:

Telemedicine involves the use of technology to link together physicians and patients in geographically dispersed healthcare facilities. This implies the use of real time or near real time transfer medical information between medical facilities. It further implies the use of a two-way video to connect a physician in one location with a patient in another. For the purposes of aeromedical evacuation, this allows us to provide intensivist oversight for the enroute care of critically ill patients, without them being physically present.

Telemedicine allows us to transport information instead of patients. However, telemedicine is a tool rather than a goal. It involves the use of interactive work stations to link providers with patients or with other providers. As suggested, this can be accomplished in real time or can be stored and sent forward. For the purposes of this discussion, in the air evacuation arena, storing and forwarding the information provides sufficient clinical oversight and guidance for most circumstances.

These types of telemedicine consultation, as suggested, fall in two broad categories. The first category is interactive video consults. These are typically doctor to doctor communications where video, audio, text and free-hand are exchanged between locations. This is contrasted with non-

Paper presented at the AGARD AMP Symposium on "Aeromedical Support Issues in Contingency Operations", held in Rotterdam, The Netherlands, 29 September - 1 October 1997, and published in CP-599.

interactive consults which utilize the store and forward technology. Generally these contain text documents as well as some still and full motion images. These images are captured or imported and then sent forward as a data file to be replayed.

As suggested in the introduction, telemedicine provides a bridge between disparate clinical arenas. These are peace time or managed care type medicine and contingency operations. It is interesting to note, however, that many similarities in personnel management exist in between these two. In a managed care environment we are attempting to leverage care to the lowest skill level required while maintaining a high throughput and thus achieving a lower cost ratio. Similarly but for different reasons in a contingency operations environment, we are also faced with limited personnel resources. Because of potential mass casualty circumstances, we must also maintain a high throughput capability while working in an austere environment. It is our opinion, again, that telemedicine provides an innovative vehicle to accomplish these goals in both environments.

Finally, a brief discussion of transport versus stationary care is needed to highlight the role of telemedicine in this environment. While on the ground, healthcare communications are more straight forward, in general the operating environment is more conducive and less austere. In contrast while in the air, all medical devices impose a potential navigational interference. Furthermore, once you depart with a patient, if things go badly, then you are faced with the "land or die" dilemma. This is a particularly chilling feeling without additional clinical backup to help you through this "rapid fire" decision making process. It is clear from this comparent contrast, that again telemedicine bridges some of these gaps.

Elements of air Evac Telemedicine:

Air evac telemedicine may be considered in two broad categories. Those related to the transmission of the medical record, and those elements which are clearly diagnostic data. Transmission of the medical records includes items such as enroute charting of care provided, medications administered, procedure notes, progress notes, and charting of all vital signs inputs and outputs, etc. In addition, other elements of the medical record include monitoring data such as hemodynamic waveforms, cardiac rhythm strips, ventilator mechanics, and flow-volume loops, etc. The distinction between these two areas is that one is clearly text based in nature while the other is graphical in format. In essence, this telemedicine capability needs to encompass not only ASCII information, but an ability to transmit graphics as well. Again for most of this information, store and send forward technology should be sufficient.

Elements of diagnostic data which may need to be reviewed via telemedicine include predominantly imaging and laboratory results. Again, things such as laboratory results from point-of-care testing, basic chemistries, hemoglobin and hemacrit, and arterial blood gases are all predominantly ASCII formatted. And again, in contrast, imaging is predominantly graphical in nature. For the most part at this time, given the forward location of these units, we are referring specifically to ultrasound imaging. These would include images of the cardiac system, intratracheal tube placement and assessment of the pleural space for fluid or pneumothorax.

The Use of Substitute Personnel:

As we have suggested, contingency operations requirements provide air medical transport using strictly intensivists significantly exceeds our peace time requirements for these same specialists. Options that are available to us to meet this readiness shortfall include the use of other physician types whose residency training included substantial exposure to critical care, and the use of other providers such as physician assistants, nurse practitioners and/or skilled paramedics. It is our intention to utilize all of these options as part of the overall solution. In this regard, telemedicine is an essential link to perform this credibly.

High-tech versus Reality:

In a perfect world where design constraints not limited by engineering and cost realities, the following elements would be included and available for telemedicine. They are, a computerized automated medical record, total in transit patient tracking, automated capture of graphical information, voice links, computer links, static and real time imaging, a "man portable" system, and onboard reference library, and scanning and digitizing capabilities. This non-obtrusive system would provide definitive communication links to those on the ground.

Having stated the above, we find that practical reality is far from these goals. At this time, our clinical communications are so primitive that it is oftentimes difficult to even communicate air-to-ground and provide those receiving medical personnel an assessment of the patients who are enroute. I am referring specifically and simply to verbal communications. Beyond that, any textual data into a computerized system is done manually.

Furthermore, any transmission of graphical data is basically accomplished via digital photography of an oscilloscope or CRT screen shot. The above stated goals are achievable but will require deliberate planning and coalition efforts to ensure that uniformity needs are met and universal standards are developed.

Problems to Solve:

In order to accomplish the above stated goals, a number of problems must be solved. First of all, all devices certifiably must not interfere with aircraft navigational systems. These systems include US, NATO, and coalition aircraft of opportunity. Secondly, all the data gathering interfaces to medical devices also will require some uniformity and standardization. Equipment that must be standardized in order to ensure compatibility includes ventilators, cardiac monitors, point of care laboratory devices and other diagnostic devices such as portable ultrasound machines.

It is clear that by defining standards that are too high it stymies initial development in the near term. This is further compounded by non-uniform clinical standards. Furthermore, in order to accomplish telemedicine successfully, we must have defined and standardized patient treatment and resuscitation algorithms for hemodynamic management, fluid resuscitation, and ventilator management. Otherwise, we will be mired not only in the confusion of nonstandard clinical interfaces but also the confusion of differing treatment protocols.

Summary:

At this point in order to initiate a successful project several issues should be addressed. First of all, we must pick a "doable" pilot project. I would recommend limiting this to the transmission of textual clinical data from air-to-ground to perhaps transmission of isolated static images. This should be coupled with in-transit patient tracking. The initial project should be accomplished with fully qualified critical care physicians on both ends of the linkup. In order to test the concept of other than intensivist providers for critical care, this should be first accomplished ground-to-ground. I recommend the use of perhaps a physicians assistant or the like to provide the care with an intensivist telemedicine backup within the same building. In summary, this is an area of terrific potential where clinical investigations must be precisely controlled and monitored. To the greatest extent possible these efforts should be standardized using the same tools and same treatment protocols.

Light Weight and Portable Telemedicine Workstations: The MUSTPAC Experience

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MC US Army, Georgetown University Med. Center
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Washington, DC 20007, USA

Abstract:
Background: Advanced imaging and telecommunications capabilities are becoming commonplace in major university hospitals. The availability of such services to people in remote or deployment environments is not always certain. To address this issue, the US Army and the Battelle Memorial Institute developed a family of telemedicine workstations. One device, the MUSTPAC (***M***edical ***U***ltra***S***ound, ***T***hree-dimensional and ***P***ortable with ***A***dvanced ***C***ommunications) was deployed to the 212th Mobile Army Surgical Hospital in Tuzla, Bosnia-Herzegovina from 6 August 1996 to 7 September 1996 in a feasibility study investigating its potential as a remote diagnostic tool.
Methods: The MUSTPAC portable telemedicine workstation used a continuous linear acquisition method to upload evenly spaced, parallel frames of real time two-dimensional ultrasound images into a volume data file. The files were transferred to teleconsultants using standard Internet protocols. The data were subsequently projected using Tele-InVivo version 2.5 as a shaded three-dimensional volume with a two-dimensional cutting plane transecting the midline. Using a three-dimensional virtual ultrasound probe, the teleconsultants interrogated the data set, moving the cutting plane in the same manner as performing conventional B-mode scan on live patients.
Results: A total of 72 3D scans were performed by the personnel of the 212th MASH. The quality of the image data appeared to be independent of the level of medical or ultrasound training of the scanning sonographer. The system also proved to be a useful means of transporting other types of medical exam data such as stored movies or still images. Digital movies of representative scans are available as publicly accessible files on the worldwide web at www.dml.georgetown.edu/mustpac.
Conclusions: The MUSTPAC feasibility study provides a methodology by which remote 3D ultrasound diagnostics can be performed with minimal operator training. The system worked with a broad range of available telecommunications bandwidth. This backpack portable telemedicine workstation proved to be rugged and reliable. Further studies are needed to determine if the system provides a comparable degree of diagnostic accuracy to conventional scanning techniques.
Keywords: Ultrasound, three-dimensional ultrasound, telemedicine, rural health care.
Disclaimer: The opinions expressed in this article are those of the primary authors and do not necessarily reflect official policy of the United States Department of Defense or Department of Energy.

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Background:

Health policy experts have become increasingly interested in finding solutions for the mal-distribution of physician resources in remote and rural environments.[1 2] These problems are magnified in certain situations such as in disaster relief or the deployment of military personnel.[3] Based on what was perceived to be a significant need, the Army Medical Department and the Pacific Northwest Laboratory of the Department of Energy initiated a research project on the feasibility of remote diagnostic ultrasound using volume acquisition techniques.

The Battelle Memorial Institute (which operates the Pacific Northwest Laboratories in Hanford Washington for the Department of Energy) and the Madigan Army Medical Center in Tacoma Washington signed a formal agreement to jointly develop advanced medical technologies. Their intent was to convert cold war technologies into peacetime medical use. The first project launched under this unprecedented agreement was three-dimensional ultrasonographic telediagnosis.

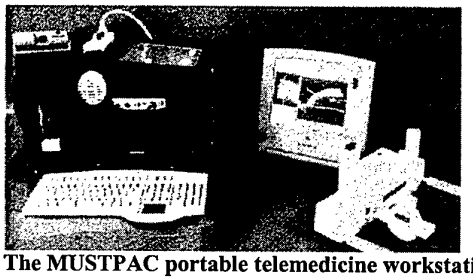
Three-dimensional ultrasound is a three decades old topic that has recently been reexamined in the light of new computer processing technologies.[4 5 6]With the advent of RISC (reduced instruction set computing) processors, small computers now have the capability to process the complex 3D algorithms. Our team has used the power of RISC processors to create a tele-ultrasound system that is both fast and portable.

The research team was asked to redesign MUSTPAC to support peacekeeping operations in Bosnia-Herzegovina. The improved MUSTPAC was delivered to the US. Army in June of 1996 and underwent pre-deployment performance evaluations under the supervision of the Center for Total Access (CTA, Fort Gordon Georgia). After the performance evaluation was completed, the MUSTPAC system was delivered to the European Command (EUCOM) on August 4, 1996.

Methods And Materials:

The MUSTPAC is an 85 pound backpack consisting of a Hitachi EUB 905 portable ultrasound device, a Silicon Graphics INDY Graphics Workstation and Flat Panel Display, a battery operated linear translation device custom constructed by the Battelle Memorial Institute, a commercial pack and frame modified for deployment purposes, an Immersion Probe, and Tele-InVivo (Version 2.51) visualization software (Fraunhofer Center For Research in Computer Graphics , Providence Rhode Island and Darmstadt Germany).

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The MUSTPAC portable telemedicine workstation.

After passing CTA supervised testing and review by the Medical Research And Materiel Command (MRMC) investigational review board, the MUSTPAC was shipped to the Landstuhl Regional Medical Center along with a second MUSTPAC system (MUSTPAC2).



Dr Macedonia (sitting next to MUSTPAC and a much larger Diasonics TM Ultrasound) in the telemedicine isoshelter at the 212th MASH.

On August 7, 1996, one of the authors (CM) deployed the MUSTPAC to the 212th Mobile Army Surgical Hospital, Camp Bedrock, Tuzla Bosnia. The machine was operational upon arrival and communications links were established using standard Internet protocols. Data were transmitted back through a microwave link to Eagle Base Tuzla (12 km away) and then fed through a Ku Band Satellite link to MUSTPAC2 in Landstuhl Germany . The machine also operated in a stand-alone mode. The unit was redeployed to Washington D.C. , September 8, 1996.



The 212th MASH in Tuzla Bosnia.

During the test period, 72 scans were performed on a total of 42 volunteers. The scans were performed in the following manner:

The procedure was explained and written consent obtained from the volunteers. The machine was placed into standard 2D mode and the region of interest was scanned using conventional techniques by an experienced sonologist. The ultrasound probe was then placed into the linear translation device. The MUSTPAC was set into "3D Capture and Visualize" mode. After the calibration screen was checked, the linear translation device was placed over the patient region of interest and a sweep was performed at a speed of 1.0cm/sec. When completed, MUSTPAC automatically presented the user with a 3D reconstruction of the sweep as well as the first 2D slice from the immersion probe.

Using the Immersion Probe, the user then evaluated the sweep by performing a "virtual scan" of the data. The data set was then sent to MUSTPAC2 in Landstuhl Germany via a simple drag-and-drop, mouse command. Transmission of the 5-10 Mb files averaged 3-5min over the E-1 line. Transmissions were also sent over the tactical packet network (TACNET) with effective bandwidths as low as 9 kbps. At each scan, the patient's chief complaint, age, sex, and the level of training and experience of the operator were all recorded.



Mr. Littlefield demonstrating the use of the virtual ultrasound probe (immersion probe).

Results:

During the deployment, a total of 72 scans were performed on 42 volunteers. Three patients from Landstuhl Regional Medical Center and 39 from IFOR personnel in Tuzla Bosnia were enrolled. The distribution of scans were as follows:

Scan Type	Number
Right Upper Quadrant:	55
Pelvis/Uterus/Posterior Cul-de-Sac	7
Placenta	5
Renal	3
Extremity	1
Aorta	1
Total	72

Volunteers:

Sex	Number	Age(Avg)
Male:	28	31.9
Female:	14	25.8

Discussion:

Those physicians who use ultrasound on a regular basis and are skilled in its use find it an invaluable diagnostic tool. Using ultrasound, however, is fraught with challenges and pitfalls. Combining ultrasound with video-teleconferencing has had limited success. Virtually all ultrasound

teleconsultation systems require an experienced operator at the remote site.[7]

The steep learning curve of ultrasound operation prevents its more widespread use outside of radiology and obstetrics departments. This is true despite other advantages such as real-time display of physiologic data, use of non-ionizing/non-destructive energies, and portability.

The United States Army, like the rest of the nation, has a problem in distributing medical resources over broad geographical areas. This problem is only magnified in a setting such as the current deployment of forces in Bosnia.

MUSTPAC is designed to specifically address the issue of experience/operator difficulties by making the process (acquiring large three-dimensional data sets of sonographic images) simple. By providing a pre-formatted means of 3D data acquisition and display, the MUSTPAC channels information forward to an experienced sonologist. They can then interpret the data as though they were scanning the patient in the office. In fact, the teleconsultation workstation has the look and feel of a conventional 2D scanner. This removes another barrier to ultrasound teleconsultation since the consultant really does not have to acquire any new skills to interpret the 3D data set. They simply "scan" the data set with a virtual probe and perform conventional 2D interpretation.

The system was operated over the army's deployed telemedicine network using 10BaseT connections but was also successfully used over the International Maritime Satellite System (INMARSAT) and the Tactical Packet Network (TACNET). These tests were performed to show that simple Ethernet connectivity provided multiple network options for MUSTPAC. We were also able to show that it could operate over a broad range of telecommunications bandwidth (as low as 9kbps).

The MUSTPAC is a rugged portable telemedicine workstation that provides first-line providers (medics, trauma nurses, surgeons) the ability to perform ultrasound and receive rapid interpretation of the images over standard Internet protocols. It thus bridges a time and distance gap. Providers who might find this useful are those in rural settings, at sea, or in deployment/peacekeeping operations.

We found that image quality was largely independent of an operator's formal level of training. In nearly all cases, the scanners had ten minutes or less of training. Transmitting the images was a simple "click and drag" operation and required no training. While the system does display the 3D data sets as a volume projection, we found that using the virtual probe and performing virtual 2D scanning provided a simpler means of interpreting the results.

Conclusions:

The deployment of the MUSTPAC system into the Former Yugoslavia provided a safe, easy-to-operate, and portable diagnostic imaging system for the care of patients in remote environments. Inexpensive, easy-to-use, and portable three-dimensional ultrasound has the potential to provide rural and remote health care practitioners with advanced imaging tools; thus, aiding in diagnosis and reducing the number of unnecessary evacuations. The advanced communications features made it also a useful telemedicine workstation providing routine voice and image data transfer functionality. Further studies are needed to determine if tele-ultrasound component of MUSTPAC provides a comparable degree of diagnostic accuracy as conventional techniques.

The authors wish to thank the soldiers of the 212th Mobile Army Surgical Hospital, the Landstuhl Regional Medical Center, and to our allies in IFOR/SFOR. We are truly grateful, not only for their help in this project, but also for their service in bringing peace to the Former Yugoslavia.

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StatRad
A Portable Imaging Center for Remote/Hostile Environments

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Summary

Until very recently, radiological imaging centers have been restricted to large medical institutions within large, fixed facilities. Although there is no diminution in the need for diagnostic imaging in remote or hostile environments, many factors including equipment size, weight, power/water supply, narrow temperature thresholds, etc., have precluded all but the most rudimentary radiological imaging in austere locations. StatRad is an ongoing effort to develop not only imaging equipment, but the components of an integrated and scaleable imaging center for use in circumstances which cannot be controlled for environmental factors, and where the medical response must be rapid and decisive.

Introduction

The usefulness of diagnostic imaging in major medical centers, community hospitals, and even outpatient clinics is indisputable. The ability to properly treat any illness or injury is predicated on the ability to accurately diagnose the condition. Although such diagnostic imaging is considered a minimum standard of care in most health centers within the industrialized world, this standard of care is infrequently extended to people who find themselves in remote or hostile conditions. These "radiology free" areas include most of the developing world, regions of natural disaster, and of course, areas involved in armed conflict.

Adding to the difficulty in properly treating medical conditions in austere environments are several exacerbating factors:

- It may be difficult or impossible to transport physicians or other care-givers to the site of disease or injury.
- It is often impractical or impossible to transport large equipment to areas of critical need, especially if equipment tolerances are exceeded by local environmental factors, or renewable supply demands can't be met.
- Diseases or injuries are often very acute, requiring immediate life-saving interventions that may be unavailable within the constraints of local resources.
- Diseases or injuries are often chronic and advanced. Staging the disease or injury becomes critical in treatment or withholding treatment to preserve limited resources.
- Health workers tend to be unfamiliar with maladies that they don't see in their own routine practices. Endemic diseases or battle-specific injuries may go unrecognized by care-givers not familiar with them.
- Proper treatment may require patient transport. Triage becomes a critical factor in areas where human transport is limited or impaired. Only in concert with accurate diagnostics is triage a science.
- The ability to transmit patient information out of the local area for consultation may be severely limited or compromised.

StatRad is being developed to address the basic diagnostic imaging needs of this very large group of medically underserved people by integrating key capabilities into a scaleable, modular, and ruggedized system. Key elements of StatRad will include portable:

- Imaging equipment
- Telecommunications capability
- Distance learning/reference

Methods

In the effort build StatRad, we've been exerting an ongoing effort to find or develop key components of an imaging center that will allow radiology to extend out of the large medical centers and into the most austere environments. As indicated above, key components will address equipment, telecommunications and educational capabilities.

Equipment: The equipment developed for deployable radiology systems must have dual use within fixed diagnostic and treatment facilities. In other words, equipment for StatRad must have application within our traditional treatment facilities.

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Using a military paradigm, we must "train as we fight". It makes little sense to have systems designed only for emergency use which don't undergo regular maintenance, and on which personnel are not regularly trained. Far better is a system which sees daily use by the same personnel who will be expected to use the equipment during deployment. We foresee the equipment needs of a portable imaging center to include major imaging modalities used at fixed-facility medical centers today, including Ultrasound, X-ray, Fluoroscopy, and CT. At this time Nuclear Medicine and MRI capabilities seem less urgent in our target environments.

Ultrasound: Currently, gray-scale ultrasound equipment is available that would fit the description of small and portable. Because ultrasound is primarily a digital technology (or analog converted to digital), it has little requirement for stable water, chemical or film supplies. There are other obvious benefits for field use in that there is no production of ionizing radiation. We have used battery-powered weighing as little as 25-30 pounds, and found them to work very well even in extreme environments. The development of new ultrasound equipment will therefore focus on three things:

1. Insertion of Doppler and duplex capabilities: Doppler and duplex capabilities are seen as essential in major medical centers today. The ability to evaluate vessels and blood flow becomes critical in evaluation of many body regions, including the neck, solid organs, splanchnic vessels, and extremities. The need for such evaluation in extreme environments will be at least as critical in terms of diagnosis, triage, treatment and transportation.

2. Miniaturization: Although a 25-30 pound unit is certainly "portable", new computer chip and beam-forming technologies show promise for making ultrasound units that not only have superior performance, but are significantly smaller than existing systems. Our goal is to have full-function gray-scale, Doppler and duplex systems that are no larger than a lap-top computer.

3. Assisted diagnosis: Because ultrasound interpretation is notoriously operator-dependent, we're looking at solutions that can simplify image acquisition as well as image interpretation. Such capabilities might include 3-dimensional scanning, computer assisted diagnosis, teleradiology, etc.

Portable X-ray: The ability to provide diagnostic X-ray images in the field presents an array of challenges. As mentioned above, requirements for stable environment and a reliable source of resupply makes X-ray a difficult technology to carry into the field. Other requirements of current X-ray systems, including heavy/bulky equipment, need for dark-rooms, requirements for handling film, etc., make X-ray an untenable technology in most austere environments. Our goal is to integrate currently-emerging digital X-ray technologies with other imaging components of StatRad to provide a "portable" solution to this essential imaging tool. Requirements for this system will include:

1. Filmless: By eliminating film, one eliminates the need not only for expensive and heavy film, but for the film processor, dark-rooms, clean water supply, chemicals, waste disposal, etc. A filmless system will be totally digital, with a digitally-acquired image being displayed on a resolution monitor, and/or transferred electronically to a distant imaging center.

2. Ruggedized primary image receptor: Although several companies are presently working on solutions to make X-ray truly digital, these systems are primarily intended for use in fixed facilities. In order to incorporate these systems into field use, the imaging plates and other components will either need to be ruggedized, or retrofitted into ruggedized containers.

3. Integration with a portable X-ray source: Not only is the imaging receptor plate key to digital radiography, the receptor must be electronically coupled to the X-ray generator for synchronization. It would appear that the digital imaging systems being developed will require special coupling with X-ray generators that will be portable, and, therefore, of use in extreme environments.

4. Integration with other diagnostic/imaging equipment: To obviate the need for multiple processors and display devises, the digital X-ray computer system should be integrated with other systems, such as the ultrasound and fluoroscopic units.

Fluoroscopy: Like other imaging modalities, fluoroscopy has an array of uses that make it valuable not only in fixed medical centers, but in a field environment. Such uses include orthopedic manipulation, localization of foreign bodies, angiography and other intervention procedures, etc. It would appear that fluoroscopy will be included as a component of at least some of the digital imaging systems, and should be easily integrated, as such, into a StatRad system. Like other components of a field-portable imaging system, fluoroscopy will have to maintain high quality standards in terms of image formation and display, and be compatible with other components of the system.

CT: Presently, although "portable" CT scanners exist, they weight exceeds 1,000 pounds. Such systems are obviously not "man portable", and have limited use in extreme environments. Technologies which will allow digital image formation for X-ray and fluoroscopy will probably be valuable in developing axial tomography capabilities that might be transportable into the field.

Telecommunications Capabilities

The intent of a portable imaging center will be to allow flexibility interns of how diagnostic images are acquired and then interpreted. In any situation where a qualified radiologist could be on hand, images could be interpreted locally and transmitted only for consultation and/or storage. Because a radiologist might not be on site where a portable imaging center has been

deployed, the expertise of the radiologist would need to be "virtually" available. This availability will depend on access to telecommunications equipment and bandwidth which will support data transfer. Without going into great detail, telecommunications capabilities of the StatRad system will include:

1. Flexibility: Flexibility will be key to the effectiveness of any deployable telecommunications system. This versatility must apply to hardware components as well as bandwidth. The system must allow the user to tap into communication services based upon availability either locally or via remote services. It must also employ "on demand" bandwidth capability, thus providing high transfer rates during peak hours, and cost savings during times of limited use. StatRad is conceptualized as a store-and-forward solution, however live teleconsultation could be added at minimal cost using available services if bandwidth allows. Bandwidth requirements will be prescribed by the size and urgency of data files to be sent, taking into consideration available connectivity and its associated cost. The system must also be designed in such a way that it can take advantage of newer technologies that will certainly arise in the future.

2. Redundancy: Given the uncertain nature of most telecommunication services, redundancy must be built into the system to assure continued data transmission should the primary telecommunication source break down.

3. Security: Given the sensitive and private nature of patient medical records, any system proposing to transport this data must assure confidentiality. There are various ways of maintaining this confidentiality, but some reliable means for data encryption will probably be required.

4. Reduced costs: Many medical telecommunications systems have not proven to be cost effective. Flexibility and redundancy built into the StatRad system will allow a choice of lowest-cost pathways. Bandwidth on demand capabilities will also reduce the costs of expensive point-to-point systems. Design, implementation and deployment of the system must always consider cost containment as an essential element. Obviously, any telecommunications system will benefit from the current trend of higher bandwidth at lower cost.

5. Ease of use: Because of the cost of training, maintaining and transporting personnel, all components of the StatRad system, including telecommunications components, must be simple and easy to use by individuals with minimal communications experience. In most instances the telecommunications equipment should be operable by the medical personnel working in a given area.

6. Support to other medical services: Although the equipment components of StatRad are primarily meant for diagnostic imaging, the telecommunications pieces should obviously be available to other medical services. Considering the very large data files used in radiology, and strict requirements for accuracy of transmitted data, any system which supports satisfactory radiology requirements will almost certainly support any other medical telecommunications needs.

Distance learning/Reference

The rate at which knowledge in the medical sciences is increasing precludes any single practitioner from knowing everything about every medical condition. In large medical centers, consultation with specialists is a routine part of patient care. In the field, however, such consultations are frequently unavailable. In addition, educational resources such as text books and journals are scarce. Because health care givers will often find themselves in unfamiliar environments, treating unfamiliar diseases, any medical system should allow three essential educational tools:

1. Primary education: This refers to the ability of a student to learn about a topic in which he/she has little or no knowledge. Primary educational tools place an unfamiliar topic within a familiar environment, allowing the student to understand the material in the context of other, related information.

2. Review: Because very few individuals can remember everything they ever learned, medical education requires constant review. This may take place in many forms, but should include summaries, courses, lectures, self-tests, etc., to assure continued competency.

3. Reference: A practitioner's access to reference material is often critical in daily medical practice. Such reference may provide information re: diagnostics, prognostics, treatments, follow-up, etc. Reference texts provide a huge volume of information, and are constantly being updated. Although there is no less requirement for such reference information in hostile environments, it is far less available, and when found, is often outdated.

The need for educational materials is clear, both in major medical centers as well as in extreme environments. The computer and telecommunications components of StatRad which will allow rapid image processing and data transmission should also be useful in bringing key medical information to the point of need. We are currently developing an Internet-based tool called Medical Central Resource (MCR), located at the following URL: http://206.39.77.2/MCR.HTML MCR is a database-driven archive of medical information that can be reached from any Internet client around the world. Currently efforts are being made to link databases from any number of medical web-servers to provide a much larger archive of educational material.

Discussion:

As presented above, StatRad is a concept in development. There is very little hard data to support integration of a diagnostic imaging center into a portable

medical center for remote/hostile environments. It seems reasonable, however, to extrapolate the importance of diagnostic imaging as proven over the last 100 years, into environments where it has been traditionally excluded because of its size, weight, and resource requirements.

New technologies are being praised for providing superior medical care throughout the industrialized world. Some of this technology will now be available to provide improved medical outcomes in areas formerly inaccessible to such intervention. Through the development of a portable diagnostic imaging center, one of the major hurdles of medical treatment, i.e. diagnosis, will be largely overcome. The ability to perform high-quality diagnostic X-ray, fluoroscopic and ultrasound imaging in areas of poverty, natural disaster or armed conflict will greatly improve medical care in such areas. When telecommunications and educational capabilities are added to such a system its function will approach that of a true imaging center.

Other Considerations:

As high-tech medicine moves into more extreme environments it must fall under the same scrutiny for accuracy and effectiveness as more traditional medical care. Studies must be conducted to assure not only a high quality of care, but an overall improvement in outcomes which justify the expenditure of money and time. Any medical system, including a portable diagnostic imaging center, must be integrated into the broader system of medical care. The role of technology must also be considered in light of the most urgent needs in a given situation. In many parts of the world where poor sanitation and preventable infectious diseases form the greatest health threats, it will be important that technology play a complementary role to basic level health needs. In its complementary role, it would appear that technology, rather than simply driving up the costs of health care, can more efficiently and even cost-effectively help deliver essential medical intervention for people to whom it has traditionally been denied.

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Visit Medical Central Resource at: http://206.39.77.2/mcr.html

Teleradiology in the Armed Forces of The Netherlands

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Summary
In general terms the telemedicine project of the Armed Forces of the Netherlands is described. The system is not suited for use during acute situations in the field with large numbers of casualties. The surgical team will then be busy with life and limb saving procedures. In a later phase the technique can be used to consult colleagues to optimise the results of the treatment. Problems experienced in the past are discussed. Telemedicine will never be a substitution for medical or surgical expertise in the field.

General considerations.
Telemedicine is the combination of communication technology and medical expertise with the aim of delivering medical care and medical education.
The technology developed due to the need of managing pictures at radiology departments (PACS = picture archiving and communications systems) and the need of transferring pictures to other institutions or persons for first or second opinion.

There are many forms of telemedicine; teleradiology, telepathology, telecardiology, teledermatology, telepsychiatry and tele(medical)-education.
At this moment teleradiology is the most advanced subspecialty.
The first telemedicine project was a telepsychiatry project that took place in the USA around 1960.

Recently the interest in telemedicine is growing explosively, caused by the fast developments in telecommunication technology and the growing need for high quality medical care against achievable costs.

A major player in this field is the ministry of defence of the USA. Every year they show their impressive improvements at the exhibition of the Radiology Society of North America.
They consider telemedicine as the way to deliver high quality medical care to military personnel and their families in remote areas in time of peace as well as in time of peace-keeping and peace-enforcing operations. During operations in Somalia and former Yugoslavia the number of medevacs could be reduced and more specialised care could be provided in a faster way.
A new development is the electronising of battlefield medicine which brings medical care to the wounded soldier in the field by high-tech devices such as personal status monitors, meditags and helmet mounted video cameras.

Digital technology.
All these developments have been made possible by the progress of digital technology.
The profits of digital transmission and storage are:
- no distortion
- no loss of information
- no increase of noise
- wide dynamic range

A digital image has two dimensions:
- The matrix consisting of a number of n x n picture elements (pixels), where n can vary from 256 to 2048.
- the greyscale value of the pixels. The number of these values can vary from 256 up to more than 4000.

It can be concluded that a digital image contains a lot of information. A chest x-ray contains 6 MB of digital information.
The amount of information causes difficulties in transmitting and storing these data.
Compression of data is the solution of these problems; it can be compared with the vacuum extraction of a sponge before transmitting and storing and the subsequent return to its natural form.

Peace-keeping operations of the armed forces of the Netherlands.
The armed forces have taken part or are taking part in peace-keeping operations in Cambodia and in former Yugoslavia.
The government has guaranteed that the quality of the medical care provided during these operations must be equal to that provided in our country itself.
The care is provided by a medical company with an additional surgical team, consisting of a general surgeon, anaesthesiologist, and amongst others a radiographer.
The radiographer uses x-ray equipment (stationary and mobile) and an ultrasound machine.
He (or she) has to make his (hers) own diagnoses; there is no radiologist available. This little group of specialists has to deliver care of high quality without the possibility of consultation. So this situation differs completely from that in a regular hospital.
To make consultation a real possibility a telemedicine system was developed.

The telemedicine system in the field hospital.
The system consists of a computer (regular PC) with a 17 inch monitor. Connected with the computer are a storage phosphor reader, digitizer, ultrasound machine, cardiograph and a video camera (the whole system is present in two-fold).
X-rays are made with conventional x-ray machines on photostimulable phosphor screens. Advantages of these systems are;
- no developing machines
- no chemicals
- the phosphor plates are re-usable
- the plates can be used in existing x-ray machines.

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The generated data are transferred to the hard disk of the computer. The information can also be transferred to CD-Rom by a CD-Romrecorder. The images are viewed and interpreted on the monitor and can be printed by a video printer.

Consultation.
The data are transmitted to the Central Military Hospital (CMH) by a VSat-connection. The images are viewed on black and white high-resolution and on medium-resolution colour monitors.
Images can be stored on CD-Rom in a juke-box. While looking at the images one can discuss them with colleagues in the field via a telephone connection.

The CMH has also a connection with the Central Sickbay of the Navy in Den Helder and the Defence Selection and Recruiting Centre in Amsterdam.
They send 150 investigations/month for primary and secondary opinion. The Central Sickbay uses storage phosphor radiography too, the Selection Centre digitizes conventional x-rays. An identical system as used in the field hospital is present in the CMH for training purposes, so that radiographers working in the department and who are send out to the field hospital on a regular basis can be properly trained.

We also use part of the system to begin a cautious digitalisation of the radiology department itself (storage phosphor radiography, HIS-RIS connection and dry laser printer).

Acute incidents.
The telemedicine system is of no use in acute traumatic situations. The members of the surgical team are then busy with life and limb saving procedures. In a later phase the system is useful in optimizing the results of the treatment by consulting colleagues in the Netherlands or elsewhere.
The system is also used in non traumatic situations (cardiology, internal medicine, ophthalmology and dermatology). It will never be a substitute for local expertise of the surgical team itself.

Problems
In the past we have experienced some problems;
- Acceptance of the system by the surgeons. Partly caused by the low level grade of the injuries and perhaps caused by psychological reasons.
- Problems with diagnosing cases on a monitor screen. Our surgeons are not used to this; they seem to prefer to look at conventional x-rays.
- Unsatisfactory quality of the video prints, which is another factor leading to requests for conventional x-rays.
- Insufficient bandwidth to transmit real-time ultrasound- and video pictures.
- Luckily the injuries experienced were of a low level grade (mostly sport injuries and some traffic accidents). However this makes it difficult to prove the surplus value of the system.
- It is not always easy to maintain the connection between Bosnia and the Netherlands. This can be caused by technical factors, human factors and competition with operational goals.

When one will be sure of the operability of the system during emergencies one has to use the system on a daily basis in spite of the low level grade of the injuries.

Soon the system will be evaluated under the responsibility of the director of the medical facilitating service. The outcome of this will decide about the future of telemedicine and teleradiology in the armed forces of the Netherlands.

Discussion #9

WALLACE, UK: Maj Hughes, in reference to the Global C4I system; in particular the Smart Card aspect, will it allow for non-US personnel going through the system. That being the case, will they be issued with Smart Cards as they enter your evacuation system. How much memory capacity will then be on each card? I ask the question because, in the United Kingdom, we are looking at a system that will be Smart-Card based (in reference to Paper #47).

HUGHES, US: Initially, the Smart Card concept that is being proposed in the United States will have an 8K integrated circuit. The Joint Program Office for the Department of Defense has been set up to begin issuing Smart Cards to all of the military. The contractor for that program has also been working with the United Kingdom. I don't know if we are that far along in the planning yet to consider distributing cards to non-US personnel. It's very easy to issue these cards to every person before they go into a theater of operations. The cards may have a picture on them. We are still defining the exact data to put onto the cards. At the moment, it may include blood type, allergies, significant medical conditions; e.g., if someone had only one kidney, and any medications being taken. To non-medical personnel, inquiring about the type of card information, I usually explain that if someone who was unconscious was presented to an emergency room, what knowledge is required for the health care provider to give emergency care. If we treated someone who did not have a card or the card was lost, the medics could issue a card. It wouldn't have the digital photograph on it but one could still put the name and some identifying number - for the American military that would be the social security number - on it. There is the problem of software compatibility in issuing Smart Cards to non-US personnel; i.e., can the card be read back home with the software there.

MACEDONIA, US: Maj Hughes, I would like to add something to your comment. DICOM (Digital Imaging and Communications in Medicine), which is the international format for exchange of radiological information, and HL7 (Health Level 7) are the international standards of medical informatics. As long as medical information systems and storage systems comply with either DICOM or HL7 (depending on the type of information), then that should work. It may also be prudent that any medical informatic system developed in a country be compliant with Windows 95/Windows NT.

SALISBURY, CA: I'd like to amplify on those previous comments and make a plea that for those who think that STANAGs no longer need to be developed and that we don't have anything new to talk about, that they reconsider their position. NATO has been woefully behind in identifying a NATO Standard for information exchange on the electronic format. We have not, as an organization, agreed that HL7 will be the NATO Standard, nor have we agreed that DICOM 1, 2, or 3 (depending on which one you want to use) is going to be our NATO Standard. This will prove to be a real problem because increasing interoperability, and joint and combined operations will mean that our patients will be in each other's medical system. If we can't exchange information then we will not be able to look after the patients correctly.

HUGHES, US: The Smart Card that is being issued to the US military is an ISO-Standard card; of course, the software is different.

SALISBURY, CA: Unfortunately, there is also the issue of people concerned with security not allowing certain information to be released to other people. Information that needs to be stored, for example, identification numbers and units, and what a person needs to be contacted about will not be allowed to cross other information systems because one can do aggregate studies and determine facts like parade states on tactical units and so forth, which become vital information. We need to be thinking about the creation of a mechanism and a forum for establishing the kinds of standards that the medical people need because those in security and others will put forth their own agendas.

HUGHES, US: The information on the Smart-Card chip is compartmentalized so that the medical people cannot read the financial information, and the finance department cannot read the medical information. The people who are authorized to read the various data elements must have a special card that they put into the card reader to read the appropriate data elements. Also, the information is encoded, and, in certain instances, it is necessary to enter the personal identification number and other data to activate the reading device.

Coping with Stressors in Peacekeeping Force Deployments: The Role of Medical Leadership

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1. SUMMARY

This paper combines the author's 28-year experience as a U.S. Air Force flight surgeon and psychiatrist with a review of recent military psychiatric literature about stress-related deployment issues. The result is some "lessons learned" for medical support to NATO peacekeeping missions. Such lessons include: Be prepared to give care from the announcement of mobilization until the dispersal of the troops after homecoming, and even after that. Plan to be self-sufficient for 24 hours after arrival at a deployment site. Use a well-equipped ambulance as a portable dispensary. Learn to use the local communications systems as soon as you arrive. Civilian, political, medical and line authorities will all issue directives, and a clear chain of command is essential. Flexible leadership in a novel and chaotic situation is a crucial talent in the medical commander. Health care professionals are particularly stressed by lack of power and priority in a deployed situation. Changes in technology and troop demographics should temper one's dependence on past lessons. Mental health problems during active operations tend to be "stress reactions" or "acute adjustment disorders." As operations wind down, more "personality disorder" situations will occur. The immediate effects of stressful missions may be reduced by applying principles of treatment involving immediate, brief interventions on the spot, rapidly returning the individual to duty. Recent literature suggests using rapid crisis interventions after traumatic events to diminish later post-traumatic stress disorders. After-actions troop debriefings also have therapeutic value. Specific aircrew issues are addressed, too, including use of sedative and stimulant medications.

2. INTRODUCTION

During 28 years of active duty in the U.S. Air Force from 1957 to 1984, I experienced one year of real war in Vietnam, several three-month NATO deployments with fighter squadrons, many brief deployment exercises, two extended exercises, and a few contingencies (deployed to Puerto Rico during the Dominican Republic crisis, was alerted for deployment from Spain to Jordan when the PLO was expelled, and was in training during the first U.S. deployment to Beirut and during the Cuban missile crisis). I served as Director of Base Medical Services for five years (including the year in Vietnam), and was on active mobility orders for two years as an Air Transportable Dispensary Commander and four years as an Air Transportable Hospital Commander. Thus, seven years (25%) of my career was composed of combat, or readiness for combat, during the Cold War.

The general nature of military experience among the NATO forces has changed since the Cold War ended, and peacekeeping missions are now commonplace. In recent years, the diffuse stressors encountered during peacekeeping operations have been increasingly acknowledged, although they are less dramatic and distinct than those encountered on the battlefield. During Stability and Support Operations (SASO), deployed troops' distress may be heightened by the lack of public gratitude and recognition for their unglamorous and oft-ignored service. Stressors during such missions include abstract or unclear goals, possible or actual terrorism, witnessing atrocities, exposure to dead bodies, fear for own safety in ambiguous situations, risk of capture, inability to defend self or others, and frustrating or frightening situations not covered by rules of engagement. (1-3)

Medical leadership requires several different sets of skills: medical, military and political. One of my first commanders, Brig. Gen. James Humphreys, stated in a staff meeting in 1960 that if your staff did not respect you as a physician, then you could never be an effective medical commander. He went on to point out that command abilities were not the same as medical abilities, and had to be learned separately. I would summarize his comments thus: "The military will assume you are a good physician until you prove that you are not; they will not assume you are a good officer until you prove that you are." My subsequent experience proved him right, and others have made the same observ1ation. (4, pp. 132-133)

Medical leadership during peacekeeping duties requires all of the abilities needed for military operations in war: leadership, flexibility, foresight, imagination, a talent for improvising, and knowledge of communications, transportation, logistics, and medical strategy, tactics and intelligence. Such duties may also involve a keen political sense of how to deal with people who may or may not depend upon you for medical care, and who may or may not see you as a friend.

This presentation on medical leadership will concern two groups of people:

- Medical personnel under your own command
- All troops for whose care you are responsible

3. MEDICAL PERSONNEL UNDER YOUR OWN COMMAND

Deployment begins with preparation, including selecting and training people to deploy. Contingencies can occur with no warning—at least, none at the working level, and so medical troops who are on call for quick response must be disciplined to take their readiness seriously. This can involve continuous work regarding day-to-day location and actual health status of members. Affairs must be kept in order, physical fitness to deploy accurately assessed, immunizations kept up to date, uniforms and equipment kept ready, and location of key

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personnel constantly known. (5) In my opinion, the recruitment, selection, training and retention of such personnel may be one of the most challenging facets of future military duty.

Specific deployment stressors begin for an individual with the first suspicion that he or she may be deployed. Medical leaders should be prepared to deal with such stressors from the moment of announcement of mobilization until the dispersal of the troops after homecoming, and even after that. Specific stressors include:

- Initial shock, fear of the unknown
- Disruption of occupation, possible financial burden
- Separation from and concern for families. (6-8) This is more acute in newly married or new-parent families, or in single parent or two-parent deployments, with concern for child care, or where there is family illness or another such significant family burden. Family stressors are major contributors to deployment stress-related symptoms, and I emphasize that *providing appropriate support to families left behind during the deployment will be a crucial positive contributor to unit morale*. Develop family support systems before deployment is imminent, so that troops will know their families have local resources available. This topic deserves a presentation all its own.
- Uncertainty as to length of deployment. "When will we be coming home?" is a recurring and important question, and its answer may be hard to find.
- Deviation from plans. This contributes to uncertainties and a feeling of lost control. Do all that is possible to deploy on time. "Hurry up and wait" is a well-known military circumstance, and troops should be mentally prepared for unforeseen delays.
- Waiting, boredom. If there is a known waiting period before the deployment, provide well-designed and evaluated training and exercises to encourage bonding, familiarity and confidence. Cross-training some basic skills may increase redundancy of their availability.
- Jet lag, fatigue, especially during the initial phase. Management of fatigue may depend as much on attention to individual symptoms of fatigue as to sticking to some kind of schedule. Never miss a chance for the troops to get some sleep, even if just brief naps during slack periods. Four hours of uninterrupted sleep per 24 is the minimum required; 6-8 hours is ideal. Give priority to providing the troops a time and place to rest or sleep. Appendix A below discusses the use of sedative or stimulant medications in deploying aircrew. Monitor the emerging literature on use of medications in this regard. (e.g., 9-12)
- Poor mail service, lack of personal communication and information. (This works both ways. Good communications means bad news comes faster.)
- Lack of privacy
- Physical discomfort
- Unpleasant climate
- Unpleasant food
- Lack of supplies and equipment

Pack, or at least inspect, your own gear before deploying. Don't depend on someone who is not deploying to do this. Include some provision for individuals' preferred items to be packed and shipped at the last minute (e.g., special surgical instruments). If unit equipment is shipped separately from the deploying troops, arrange for a few troops to escort it for security.

In addition to emphasizing unit pride, work hard on team bonding within the unit, both for long-time members and newly assigned troops. After initial notification, or even deployment, you may receive further "outside" troops assigned to your unit who arrive one at a time. Such "outside" assignees are especially stressed: they may have no friends in the unit, and are not bonded to the unit. Avoid making these new arrivals cope alone the first day when they arrive: provide personal welcomes, escorts, sponsors, orientation in-briefings, a buddy system, drills and exercises to speed their integration into the unit and their work teams. (13, p. 10) Watch for misassigned personnel: the only thing worse than being deployed may be to be deployed with no job to do.

Plan to be self-sufficient for at least one day after arrival at a deployment site. Bring your own 24-hour supply of drinking water and food. Make yourself as comfortable as possible. If you are to set up in a "tent city," select the site carefully. Consider geography, weather conditions, prevailing winds, local disease vectors, access by land and air, and security. Bring work gloves for everyone, to avoid blisters and splinters (particularly disabling to surgical teams). If possible, arrange for your own communications net, generator, and tents.

Pay attention to basic amenities: sleep, water, food and comfort. Provide the best quarters, work/rest schedules, latrines, showers, and messing facilities possible. Field sanitation must be strict concerning mess gear, water supply and latrines. Enforce latrine discipline from the first moment you arrive—don't let troops urinate anywhere they please as they get off the trucks, or the whole area will smell of it. Hot showers are a morale boost. Problems with these basic amenities will be more readily detected and corrected if the officers share them. Stay in touch with your troops—don't send the officers or non-commissioned officers away to sleep in distant (and more comfortable) locations.

During such uncertain times, many people draw strength from their religious faith. Actively support chaplain programs and religious observances.

Resupply may be uncertain at first. Experience has shown that messages back to the home unit may provide a good alternate source for quick resupply via opportune airlift until things settle down. Consider having both re-usable and disposable items in your inventory; e.g., sponges, needles, syringes, etc. If resupply is poor, sterilization and re-use of such items may be necessary.

Learn how to use the local communications systems as soon as you arrive. People are accustomed to instant communication with anyone they want, and lack of that convenience may be stressful to the organization and to individuals. The proliferation of portable phones may change the situation, and the availability of worldwide communication to almost every individual may pose its own problems in ways that none of us foresee. The presence of media coverage with world-wide

dissemination is also possible, and some deployed troops have been in the position of seeing themselves on the news almost as soon as events occur. (7)

Most health care professionals are accustomed to being regarded as valuable resources, and treated with respect. Being deployed may reduce them to "just another unit," and a medical group may find this lack of power and priority to be a true stressor. Formal stress inoculation training may also help: focus on mission, mastery of relaxation and breathing techniques, positive self-talk, and talking with buddies. (1; 13, pp. 11.4-11.6; 14; 15, p. 221)

Professionally useful activities may be carried out during slack periods (health and first aid education, facility improvement through self-help), as well as local tours, local history and language courses, non-contact sports, entertainment shows, etc. (16) Look for chances for local civic action missions (for example, working with a local orphanage may be quite rewarding), but be certain of security. If conditions permit, consider pass, leave, or rest and recreation (R and R) programs.

4. ALL THE TROOPS FOR WHOSE CARE YOU ARE RESPONSIBLE

The arrival of a medical unit anywhere will automatically generate patients before the engines are turned off. Be prepared to give round-the-clock care the instant you arrive, even before unpacking. Use a previously prepared and well-equipped ambulance as an interim dispensary and first-aid station: place a well-qualified medical care provider and a few good technicians in the ambulance, slightly away from the set-up site. If possible, bring portable radios that communicate with your ambulances. These may serve as an immediately available internal communications system. Be prepared for alcoholic withdrawal episodes in just-arriving troops.

Civilian, political, medical and line authorities will all want to tell you what to do as soon as you arrive, and a clear chain of command and sense of mission is essential. The medical commander may need to become acquainted with the local situation while the deputy commander supervises setting up operations. Coordination between the two is essential.

Flexible leadership in a novel and chaotic situation is a crucial talent in the medical commander as well as in the supporting headquarters. Have a good plan, and be prepared to deviate from it if necessary. As in football, you need both a good playbook and a good broken-field runner. Keep plans and training updated as the situation progresses. Consider contingencies. The leader on the scene knows more about the actual situation, and needs to be confident of support from medical and line headquarters (HQ) to the rear. Be careful of "us vs them" situations with distant HQ. Personal contact with medical and line HQ is critical, and staff assistance visits can be helpful if they don't degenerate into over-detailed inspections. People have a well-documented tendency to blame everything on someone who is not a member of their own group, and local commanders may be tempted to blame local problems on absent authorities in discussions with their troops. This can backfire when the local leadership is not aware of the problems HQ is facing, and makes intemperate public statements about perceived lack of support. Provide a good information flow—make the chain of command the most reliable information source in order to keep demoralizing rumors at a minimum.

On deployments lasting longer than six months, establish leave, pass and rotation policies that are clear and fair. Consult with local line commanders on an adequate rest and leave program and other factors affecting morale of the troops.

Don't make promises based on circumstances outside your personal control, and especially don't make promises you can't keep about when troops will go home. *If at all possible, do not extend the tour involuntarily.* If tours are extended by higher headquarters, try to "grandfather" those troops already there, so that the new policy applies only to new arrivals.

The military learns from its past, but changes in technology and troop demographics should also influence present plans. Technological changes are accelerating, and today's medical leadership must deal with factors unknown only a few years ago. Older medical leaders may resist full use of such innovations as telemedicine, telepsychiatry, computers, and cellular telephones. Today's leaders need a keen sense of balance between tried and proven older methods and the benefits of new technology, the same sense of balance needed by line officers who are faced with similar challenges. This challenge is not new; senior physicians throughout history have had to deal with their juniors, fresh from academic training, who seem unable to work without the latest medical advances.

Many mental health problems during active operations tend to be of the "stress disorder" nature. (See Appendix B below.) As operations wind down, more "adjustment disorder" or "personality disorder" situations will occur. (17) Medical leaders must have a firm grasp on the options open to them for dealing with such problems, particularly in crisis situations involving potentially hostile local populations, or troops from another nation.

Stress-related misbehavior may occur, especially if the troops feel frustrated by the situation that brought them there. Commanders must be alert for signs that the troops view the local inhabitants as inferior or contemptible. Lead by example. Do not use or tolerate the use of derogatory nicknames, or racial or ethnic slurs. Correct such language, and comparable behavior, as soon as it occurs.

If the unit is involved in a traumatic event that shakes morale or confidence, consider use of mental health professionals to conduct a formal Crisis Stress Debriefing. This is somewhat similar to an After-Actions Debriefing (13, pp. 13-17) This process is increasingly used in natural or man-made disasters, and seems to be effective in alleviating immediate stress responses, although its effectiveness in diminishing post-traumatic stress disorders has not yet been conclusively demonstrated. (1; 4, Chaps. 9 & 11; 18) In my opinion, as a part of their own pre-deployment training, medical commanders should become familiar with the theory and practice of debriefing techniques. By their very nature, events

that make debriefings necessary make it difficult to learn about this technique on the spot.

If the deployed medical unit is supporting aircrew, some specific factors need to be addressed. Examples are given in Appendix C below.

During draw-down at the end of the deployment, maintain as many medical services as possible for as long as you can. As people start to leave, the basic rule is usually: "First in, first out." Manage exceptions with exceptional care. When a specific medical specialty service is to be closed down, be clear how its type of patients will now be covered. For example, when your last ophthalmologist goes home, exactly how will eye injuries be managed? Be sure that those outside consultants upon whom you now depend know that they are on call for you. If possible, go through one trial of the new procedure before you lose your own capability.

At the end, arrange for some sort of formal closure, farewell party, or ceremony (recognition, awards, retiring the colors) before the draw-down begins, or at least before the unit returns to its home. The value of such closure is well known, but delaying it until after the return may mean that it will be disrupted by circumstances beyond your control. (4, Chap 4.)

A considerable body of literature attests to manifestations of stress after return from deployments, both in military members and in their families. (e.g., 2, 15). Although beyond the scope of this presentation, such circumstances should be considered in after-action planning and follow-up, especially in those individuals who leave the service after return, thus being deprived of unit support.

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7. APPENDIX A. Using sedatives and stimulants in aircrew in deployment situations.

The use of sedatives and stimulants in aircrew for operational reasons is and will continue to be controversial. The following remarks are the author's opinion, based on his experience, and do not represent any current official policy. Whatever the policy is now, it will undoubtedly change in the future, and so it is well to have some prior knowledge of how such medications may be used, and perhaps to institute the ground-testing procedures that keep the option open.

Sedatives may be used to help the flier get to sleep at an unusual hour, so that he or she may be rested when the flight begins. For example, if the time for takeoff is 0400, then the flier may have to sleep from 1900 to 0130. A sedative medication may be taken at 1830 to help with this schedule. In some circumstances, preparation for a high-risk mission may involve long hours of work, and the emotional tension may be so high that aircrew cannot get to sleep before the flight, even at an accustomed hour. Here, too, sedatives may be considered for use. (19; 20, pp.185-187)

Stimulants may be used in flight when the flier has been awake for many hours, and is expected to be fatigued at the end of a long flight. Generally, the idea is to take the stimulant about two hours before penetration, descent and landing, so that the flier will be wide awake and alert during this most critical phase of flight. An example would be a 15-hour transoceanic deployment of single-seat fighters with multiple mid-air refuelings. The landing might occur at sundown, after the flier had been awake for 18 hours, strapped into the seat, with only fair nutrition and hydration.

Using such medications exposes fliers to a risk beyond that of ordinary flight. Clearly, then, *such medications should not be used unless the estimated risk of* ***not*** *using them exceeds the risk of using them.* Assessment of such risk factors involves a joint line-medical judgment As with any situation in aviation, one should make every effort not to take risks that one does not understand.

In order to understand the risks, the flight surgeon must be familiar with the flying unit, the nature of the proposed mission, and the proposed medications. Knowing the medications involves studying their pharmacokinetics and pharmacodynamics, their primary and possible side effects, idiosyncratic or allergic reactions, and other medical aspects. *Never use a medication in flight that the aviator has not previously taken on the ground.* Obtaining information for use of stimulants or sedatives in connection with a flight should involve ground-testing the flier in advance of their use in actual flight.

To ground-test, arrange for a two-day period when the aviator will not be flying. Usually, a weekend will serve. For example, on a Friday afternoon, confer with the aviator about the test. Emphasize that no other medications, and no alcohol or caffeine are to be taken during the test period. Inquire after any previous experience with the medications to be tested, and any adverse effects. Explain the nature of the medications to be tested, and the ground-testing procedure. On Friday night, the aviator will take the sedative medication one hour prior to retiring. Upon awakening the next morning, the aviator will assess the quality of sleep, and note any subjective symptoms upon an "effects" form provided by the flight surgeon. The flier should specifically note whether he or she feels any effects upon arising that might affect flying abilities.

If all seems well, the aviator will then take the stimulant medication, and will note its effects, especially the onset and duration of stimulation. Any "let-down" symptoms should specifically be noted. A second dose of stimulant may be taken four hours later, if this fits the operational profile, and any effects noted. For instance, 5 mg of dextroamphetamine may be taken at 0800 Saturday morning, and 5 mg more at 1200. Assuming all goes well, 1600 marks the end of the test. The flier should specifically assess whether the sedative affected sharpness for flight, and whether the stimulants might have had any adverse affects on perceived ability to fly. Monday, the flier will return to the flight surgeon and go over the experience. Together, the flight surgeon and the flier will decide whether the flier may be able to use these medications in actual flying conditions. The decision will be marked on the "effects" questionnaire that the flier filled out, and signed

by the flier and the flight surgeon. The form is then put into the flier's permanent medical records. Once this process is completed for the squadron fliers, the squadron commander is notified.

If a future operational situation arises in which flying without medications seems more hazardous than flying with the medications, then the commander and the flight surgeon will decide if medications will be offered to those fliers who have been previously cleared to use them. If the medications are offered, *each flier will decide for himself or herself whether or not to use them on this mission.* This should be emphasized: the commander and the flight surgeon decide that the medications may be offered to the cleared fliers, but each flier makes a personal decision whether or not to take the medications.

The flight surgeon should brief the squadron before the mission in question about the use of the medications, and should debrief and record afterward the use or non-use of medications, and any comments about their efficacy or ill effects. *All medications carried on the flight but not used must be taken back from the fliers, to avoid unsupervised future use.*

Squadron policy should be explicit that whether a flier has been cleared or not cleared to use the medications will have no bearing on being chosen for a mission, or on being cleared for full duty.

The procedure noted above was in common use in the Tactical Air Command during the Cold War for trans-Atlantic squadron deployments. Generally, less than half of the fliers would opt to take the medications (secobarbital 100 mg and dextroamphetamine 5 mg, in those days). The author recalls no ill effects or adverse incidents being reported by anyone during this era. For an account of a more recent unexpected secret mission requiring such action, see Senechal (19).

8. APPENDIX B. Stress Reactions

Early Acute Stress Reactions may occur even before departure, in the mobilization area, or the waiting room of the departure airfield. These reactions may be manifest as tearfulness, hyperventilation, palpitations, fine tremors or generalized trembling, sweating, agitation, gastrointestinal distress, or a childlike (regressive) refusal to cooperate. Treat with rapid intervention (on the spot, if possible), explanation, reassurance and return to duty. Act as a commander, not as a medical person. Your role may be that of an understanding but firm parent with high standards for yourself and those under your command. Remind them of previously learned relaxation techniques. Find easy tasks for agitated troops to do, to keep their minds off their troubles. "I know you're up-tight—we all are—but we're counting on you to do your duty along with everyone else. We'll all look after each other—you'll be okay. How about helping the sergeant refill those water coolers." You must set the example of calmness. Appeal to their sense of duty. Keep your troops focused on the mission; get them talking about how to do it successfully. Joke about the situation. Keep everyone informed. When problems arise, make timely and productive decisions. If symptoms occur, minimize their secondary gain (the benefits of being symptomatic, such as being inappropriately relieved from duties).

Later Chronic Stress Reactions may occur in response to cumulative stresses that finally overcome physical and psychological resistance. Although everyone in the unit may show signs of the strain, a few individuals may become clearly ineffective because of them. Initial symptoms requiring unit support for any individual may include:

- Irritability
- Social withdrawal
- Loss of sense of humor
- Change of habits—beware of alcohol abuse
- Personality change
- Poor performance
- Tremors, jumpiness
- Continuing sleep disturbance

If mild or early, these symptoms may respond to something as simple as a day off, three good meals and a chance to rest. If such unit "first aid" measures do not restore the individual, the next level of medical response should involve brief, immediate, central, expectant, proximate, simple ("BICEPS") factors, similar to those used in combat situations [see below].

Stress reactions may progress to a spectrum of disorders of varying severity, ranging from extreme agitation to severe regression. Striking symptoms may result—marked agitation, aggression (even including weapons), panic behavior, hallucinations, nightmares, involuntary flinching, cowering, gross whole-body tremors, incontinence of bowels or bladder, withdrawal, apathy, loss of use of a limb or a sense (e.g., "hysterical blindness"), amnesia, or loss of speech. Treatment includes remaining calm yourself, "talking him/her down," using relaxation techniques (muscle relaxation, calm abdominal breathing, visualizing a calming scene), talking out the problem, involving the victim's buddies, reassurance that stress does this at times—and that a good troop can remain a good troop in spite of fear. If you are concerned about the trooper's reliability, unload his/her weapon (take it away only as a last resort—this is a serious symbolic act of lack of trust). Have a friend stay with the trooper in a safe place. Physically restrain the trooper only if it is necessary for the safety of that trooper, or other troops, or possibly for safe transportation to a medical facility. Be sure the trooper is not physically ill—one of the shaking troops that Gen. Patton slapped actually had undiagnosed malaria. Be aware, also, that true mental illnesses may occur in military members anywhere. The methods of treatment used for acute or chronic stress disorders will not be effective for true mental illnesses that may occur in deployed troops. Such mentally ill troops should be treated by mental health specialists.

When the symptoms go beyond unit levels and necessitate medical intervention, the unit physician may follow the BICEPS principles (18; 20 pp. 202-203):

- **B**revity—keep the intervention to three days or less.
- **I**mmediacy—treat as soon as the symptoms are recognized. Use medications sparingly, and only for acute management.

- Centrality—keep the victims together for mutual support and a consistent treatment plan. This should be given locally in a Rest Camp setting, not a hospital.
- Expectancy—reaffirms that you expect them to get well (firmly defined as returning to duty!).
- Proximity—treat near the unit to maintain bonding. This means that commanders and comrades should be able to—and must—visit their comrades to counter any sense of shame and separation. The trooper may be ashamed of perceived "weakness," and such visits imply continued acceptance by comrades, and their desire to have him or her back in the unit.
- Simplicity—keep the treatment focused on getting the trooper back to duty. This is not the time or the place for deep-seated analysis of the trooper's personality makeup. Use medications only for a brief period, since troops should not be taking tranquilizers while on duty in a dangerous situation.

9. APPENDIX C. Specific comments regarding deployed aircrew

On deployment, whether in combat or not, the flight surgeon must be to the fliers as the Maintenance Officer is to the aircraft. The flight surgeon's message: "My duty is to help you to fly, not to rescue you." The flight surgeon must do some observer flying while deployed in order to establish and maintain credibility with the fliers, as well as to maintain personal familiarity with the stressors of the various flying missions.

Trust the wisdom of experienced line officers about what the squadron can and cannot do, and remain aware of the opinion of the squadron members themselves about when fellow fliers have "paid their dues." As is true with non-flying units, knowing what the organization expects may help the flight surgeon decide when to be tough and when to be sympathetic whenever symptoms of fear become evident.

Flight surgeons help provide:
- Good medical care
- Healthy coping skills to deal with stress
- Reinforcement of trust in the fliers' own skill and training
- Best possible living conditions (flight surgeon should be billeted with assigned squadron)
- High motivation
- Group cohesion and a desire to succeed
- Trust in comrades ("You're not the only one who's tense. If they can do it, so can you.")
- Trust in equipment
- Accurate information (May serve as an informal link in the chain of command.)

Note that quality of sleep is essential. Pay attention to the sleeping conditions and facilities for the aircrew, especially those with night missions. This is not coddling, but a wise investment in a crucial asset. You may not be able to use crew rest regulations in some situations. Depend upon close observation of the fliers, and if groundings for fatigue are likely, make such decisions in conference with the operations officer and the aircrew involved. (21) Remember that you are in a zero-balance system: if you ground one flier, another will be assigned the flight. The replacement flier may be almost as fatigued as the one you grounded.

"Rest" may involve several factors: the interval between missions, the duration of the missions, having one or two days ("weekends") off at predictable intervals, and the length of the combat tour, however it is defined.

1. Interval between missions and duration of missions:
- Short: Israeli pilots flew up to 10 missions per day during the 1967 Sinai Peninsula War; some missions were as short as 20 minutes.
- Long: USAF B-52 crews flew 19-hr missions (26 hr crew day) over North Vietnam in Dec 72, and flew similar missions during the Persian Gulf War.
- Longest: British Vulcan crews flew 26-hr missions (40-hr crew day) from the Ascension Island base to the Falklands Islands during the 1982 South Atlantic War.

2. Rest includes attention to scheduled days off or "weekends" off, as well as longer rest periods such as "R&R" if the combat tour goes beyond about six months. If possible, the unit commander should relieve combat aircrew of all additional administrative duties, so that time off from flying is not eaten up by having to catch up on their paperwork.

3. Rest is also implicit in the concept of "flying tours." The type of combat tour creates different kinds of reactions:
- If the tour is based on number of missions flown (e.g., a "100 mission tour"), aviators want to get them finished, and may not want to take breaks even if they need them.
- If the tour is based on a specified length of time (e.g., one year in the combat zone, regardless of number of missions flown), aviators are more willing to take time off.

Whatever the rule, try not to lengthen tours once established.

CONTINGENCY OPERATIONS: THE CHALLENGING NEW PARADIGM

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Introduction

For almost 50 years NATO forces planned and trained for the defense of western Europe. The fall of the Soviet Union and the breakup of the Warsaw Pact has greatly changed the focus of NATO operational and strategic focus and planning. The new focus of NATO and other military forces is Contingency Operations (CONOPS). This paper will discuss planning factors and considerations for medical support of CONOPS.

Background

There are many working definitions and descriptions of contingency operations. CONOPS have been discussed and described as part of Operations Other Than War, Low Intensity Conflict, Stability Operations, Peace Operations, Humanitarian Assistance, Disaster Relief and other terms. A U.S. Marine Corps Manual from 1940 states "... a vague name for any one of a great variety of military operations..." Regardless of the name or title, these operations form a continuum of military force used to attain an operational or strategic goal in an environment short of war. Tactical combat operations may have to be performed in the context of these operations.

Military organizations have always planned contingency operations; a variety of rapid response operations or actions in support of operational or strategic objectives short of general war. The quality and the quantity of the force used will vary with the military and political objectives.

For the purpose of this paper the working definition of CONOPS will be multinational operations short of war.

In this century an early example of a CONOP was the implementation of a multinational force to rescue diplomats and their families from Peking during the Boxer Rebellion in China. This multinational force was composed of forces from the U.S., Great Britain, France, Austria, Russia and Italy. Today this would be termed a Noncombatant Evacuation Operation (NEO).

During the first 40 years of its existence, the United Nations conducted only 13 CONOPS; since 1988 it has sponsored over 26. Dag Hammarskjold, a former Secretary General of the UN, stated that "Peacekeeping is not a job for soldiers, but only soldiers can do it." Military forces are the best entity to initiate and execute CONOPS. Military forces have trained and disciplined individuals, logistics, mobility, and communications. The similarities in preparation and planning for conventional combat operations aid the military response to CONOPS.

Contingency operations are not new, but they have become more frequent and are a much more likely deployment opportunity than ever before. During the last 2 years there were numerous CONOPS planned for and executed. These include the initial preparations and deployment of a multinational force to conduct CONOPS (humanitarian assistance) for Rwandan refugees and a NEO for the former Zaire. Additional CONOPS were conducted in Liberia and Albania. Presently the largest CONOPS is the mission to the Former Republic of Yugoslavia.

It is imperative that all medical forces be capable to rapidly transition between combat health support and CONOPS health support. The additional requirement is the readiness and capability to transition back to combat health support during the CONOPS deployment. We must prepare to execute appropriate medical support across the potentially lethal continuum of CONOPS.

Mission Planning

Even though there are a wide array of situations related to CONOPS there are certain general questions to be asked and answered . There are also some general principles that need to be applied to the planning and execution. Versatility, agility, initiative and synchronization are four tenants that should be applied to every situation.

Versatility is the ability to shift focus, train and tailor your force to accomplish the mission. It is essential for medical forces to train and prepare to transition between trauma and disease requirements of combat operations and CONOPS. An example of versatility was the rapid transition of medical requirements in Somalia from mainly disease and minor trauma, to the mass casualty situation from the rapid onset of tactical combat operations.. Forces must be prepared to work with civilian, relief and other military medical forces as a tailored package.

Agility is the ability to react faster than the other parties. The key to agility is adequate intelligence, preparation and planning. This could be preparing a number of alternative plans to support mission changes, predetermined force packages to increase your capability, and on call specialist support. Public and force information (classes,

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presentations, posters) must be prepared, focused and available to support operations.

Initiative is the ability to control events. This may include the requirement to anticipate, preempt, mitigate and provide information to shape present and future events. This is critical with respect to the media, other organizations, and potential disease factors.

Synchronization is the ability to maximize the effectiveness of every resource. Events may be synchronized on a temporal basis such as timing of movement by an air or land route. Synchronization also means the integration of various capabilities from similar or dissimilar sources to create a more effective force/medical package. This may be the creation of multinational medical task forces or military and civilian sharing of resources.

Unity of command and effort are essential for a successful operation. Know who you are working for and who / what you will support. There is no substitute for establishing a reputation as a credible staff officer/commander who will always find a way to support the mission. It is also essential to know the medical chain of command and support. It is imperative to clarify who can provide additional medical forces, logistical support, evacuation etc.

Always remember and apply security and force protection throughout the mission. Never expose your personnel to any unnecessary risk. This may involve everything from medical aspects of force protection such as immunizations and preventive medicine, to security and use of security forces to protect ground and air evacuation routes and vehicles. Security and crowd control may also be required around medical treatment facilities.

Be firm, fair and neutral in the conduct of medical support; in many missions this is critical for success. Do not do anything that would give any faction the perception of favoritism or messages counter to the overall mission objectives. Control perceptions; in CONOPS perceptions may become reality.

The classic mission planning factors are listed in Annex 1.

Mission Analysis

It is imperative to read the operations order / mission statement, mandate or terms of reference for your organization and at least the next higher organization. It is imperative to determine the specified and implied tasks of your mission. Implied tasks are those enabling tasks or requirements that are a prerequisite to accomplish the specified tasks. Limitations may be stated or implied. These may include limits in personnel, amount of equipment deployed and funds to be expended. Limits or restrictions may include limits on who you will support, what organizations you may share resources with and cross servicing or reimbursement options. Definitive guidance from national or multinational headquarters regarding which individuals or parties are eligible for care and support is essential for a successful operation. Another critical coordination requirement is the planning of air evacuation out of the area of operations; who can be flown by which organization to which receiving airport and medical facility.

Force Design

To achieve success there are 11 basic capabilities that each medical force must have in its force structure or be able to share or contract These are listed in Annex 2.

Of these 11 capabilities there are potential capabilities that may be partially substituted or exchanged for one another. Geographic dispersion and distances may determine how much of a medical force is required to deploy and how much medical force may remain in support but outside the area of operations. A force may decrease its number of deployed beds with increased evacuation capabilities. The surgical capability package may be smaller if there is enhanced evacuation capability. Predeployment dental examinations will decrease the need for dental care during a deployment. A robust preventive medicine package will decrease the need for hospitalization from food and rodent borne diseases.

It is extremely difficult for the medical planner to ascertain the true medical capabilities of different military and civilian medical forces due to differing terminology's, levels of training, standards of care and cultural norms. It is essential to obtain the information about medical organizations by specific types of capabilities (numbers and types of surgeons, number of intensive or minimal care beds, radiology and laboratory capability, etc.) and not generic terms such as Level or echelon X or surgical/combat support hospital. Specific knowledge of capabilities and quantities is essential to synchronize the force and tailor appropriate medical packages.

After the initial medical force package is designed and validated it is imperative to create medical decision points. These will be objective, quantifiable, mission oriented criteria that will be used to determine when an increase or decrease in medical capability is required. These are most effective if they are briefed to the force commander and validated prior to the actual deployment. This prevents emotional and or subjective decision making at crucial and stressful times. These decision points may be based on or specified by mission type, troop density, geographic considerations or intelligence indicators.

Team Building

The most challenging area of CONOPS is the requirement to assemble and form an effective staff. Some of the challenges include language, terminology, area of expertise, expectations, cultural differences, standards, personalities and national agendas.,

An old Vermont farmer stated that "...Every time that you move the cows it takes three days for the milk

production to return to normal." This also applies to staffs and personal interactions. There are no magic answers or solutions there are however various techniques to form a cohesive team. It is important to rapidly create a sense of unity, cooperation and ownership within your personnel. The earlier that you can assemble prior to the deployment the better it is. If possible, identify personnel before the crisis; create a standing augmentation package. Try to exercise this package twice a year. If possible develop and disseminate some standard operating procedures, algorithms or checklists. These may not be perfect for any one specific mission but it is easier to modify known requirements and standards than create these kind of documents in a crisis situation. .

NOTE: 1. The views expressed in this paper represent those of LTC Alan Moloff and do not represent the views of the U.S. Army or Department of Defense.

2. There is no classified information in this paper. No classified sources were used in preparation of this paper.

3. During the past three years LTC Moloff has served as the V Corps Surgeon, Deputy USAREUR (FWD) Surgeon, Joint Medical Task Force Commander and Joint Task Force Surgeon. During this time he participated in Operations Joint Endeavor, Joint Guard, Guardian Assistance and Guardian Retrieval. He is presently the Commander of the 212th Mobile Army Surgical Hospital located in Wiesbaden, Germany.

ANNEX 1

CLASSIC MEDICAL SUPPORT PLANNING FACTORS

Population to be supported.	Geographic factors and dispersion
Casualty estimates	Disease and environmental threats
Base support / living conditions	Refugees
Health status/immunizations of deploying force	Evacuation times
Health service logistics	

Indigenous resources available (to include medical facilities, food and water supply, sanitation)

ANNEX 2

REQUIRED CAPABILITIES

Surgery	Evacuation	Preventive Medicine
Hospitalization	Medical Logistics (Blood)	Command and Control
Dental Services	Veterinary Services	Laboratory Services

Stress Control Area Medical Support

STRESS FACTORS IN THE SPAF PERSONNEL ASSIGNED TO HUMANITARIAN AND PEACE KEEPING OPERATIONS.

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SUMMARY

In this paper we describe and analyze the stress factors associated to a sample of military personnel currently in flying status, who has been deployed in critical areas where a wide range of missions has been conducted. In addition to that, we have studied the adaptation to the environment, sequelae and possible techniques to minimize such aeromedical issue. In order to evaluate this medical aspects, an interview and survey of factors related to perception of stress has been performed in 107 individuals. Analysis of data has been conducted according to a cognitive model of stress.

INTRODUCTION

The increasing participation of NATO troops in peace keeping operations and humanitarian missions, plus operations to mantain international UN agreements, has raised numerous problems among the NATO military personnel.The study of this problems are the only way to make the mission safe and favourable. The aspects we more often observed, can be classified as is shown in table A.

The stress consequence of this situation can be analyzed by following the conceps which consider cognitive aspects. Lazarus and Folkman model of "learned helpnessless theory" have depicted a design based in the learning process of traumatic experiences which lead to realized the ineficient conduct followed in similar situations(20). These authors define stress as a particular relationship between the person and his/her surroundings which is considered by him/herself to be a burdensome or an overwhelming situation which exceeds his resources and it means a risk for his/her well-being or health.

Based on this aproach,we propose a model in which the close evaluation of the stressors by the individual, determine the strategies to cope the problem (7,9) in order to adapt the proper response, without exceeding the normal physiological resources.This is the way to

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reach an eficient behaviour and to avoid conductual disorders(17,25,29,32). This model can be sumarized as follow(see Table B).

This paper describe and analyse from a sample of professional military personnel deployed in critical risk/areas, those factors that we consider relevant in the perception of stress. In addition to that we have evaluate the most suitable proposals they consider in order to cope the problem and avoid any physical or psychological sequelae promoted by the stress of the mission. Also we have reviewed "ad hoc" related literature.

MATERIAL AND METHODS

The sample was selected among the aircrew members who regulary are aeromedically checked at the SPAF Aerospace Medical Center. The total number of subjects was 107. They were informed of the purpose of the study and a questionaire specially designed for them voluntarily filled. In this survey, personal data(age,rank, marital status, numbers of children, time in service, flying time, professional activity) were included plus questions related to place of deployment, time and mission accomplisment. Also the survey included a blocked "choose question" related to factors which contribute to physical or psychological stress. At the end open questions asked to describe specific experiences of life threathening situations and how to prevent it. Results were analyse by SPSS (Statitiscal Package for Social Sciences).

RESULTS AND DISCUSION

The statitiscal outcome obtained from the 107 members interviewed is shown in table I. The mean age was 32.1 (SD=6.5).A number of 45(42%) were fixed wing or helicopter pilots,48.6% were paratroopers and the 9.3% left they belongs to other specialities. Most of the subjects(58.9%) were Air Force personnel and 38.3% assigned to the Army and 2.8% the Civil Guard.

Data regarding marital status showed 65.4% married. The time in service was an average of 12 years(SD=6.65), most of them officers(56.2%) and 22.4% non commisioned officers(NCO) and 21.5% troops, according to table II.

In relation to the geographical deployment,as can be seen in Table III, most of them were stationed in Bosnia(49.5%), 18.7% in Aviano AB(Italy) with an average tour of 5.4 months months(SD=4.1).

A number of 44.9(48 subjects) out of 107 will repeat the same mission in the same place,50.4% will repeat other mission in a different location, the subjects left(4.7%) refused another mission in the future.

The results and information provided by the personnel studied has been divided in four different sections according to the model proposed and above mentioned.

a) Stress factors:

The stressful life events or stressors according to Rahe and Holmes (22), are enclosed in the most adverse aspects and events which has ocurred during the tour of duty. First as it is shown in table IV, the most stressing one was the family separation with significant differences ($p<0.05$) between those stationed in Bosnia and Aviano AB(Italy). Then, factors to be into account are: language barrier,duty shifts,sleep deprivation, home country comunications dificulties and adverse climate, this one more relevant in the subjects stationed in tropical countries like Guinea and Namibia($p<0.05$). Finally, risk of injuries and disaster situation(pilots and paratroopers).

As we can see above, the most frecuent stressors found is the family separation included in the psychosocial factors, still considered the most important stressors by its physiological consequences(6,10,19,24). By reviewing the current data avalaible several other authors agree with our findings regarding the relevance of psychosocial factors in spite of the circumstances of the war-like situation experienced by the population studied (27,28,30,31). Language barrier is considered one of the psychosocial factors because of the social isolation. Home country communications dificulties is a disturbing factor which increases the level of stress(3,4,21) by diminishing social support.

The other stressors can be considered as physical stress as adverse climate and sleep deprivation. We found sleep deprivation a significant factor by comparing paratroopers and pilots ($p< 0.05$), also more frecuent among officials and NCO. Duty shifts was a significant problem among the aircrews, stationed in Aviano A.B. by comparing with shifts in other deployments (Bosnia $p<0.01$, Sicilia & Bulgaria $p<0.001$, Guinea & Namibia $p< 0.001$).

Personal physical risk (life treathening) and disasters (2)assessment depends on many variables and it was a point of consideration according to the cognitive theories.

Finally, physical risk was a concern among officers rather than in NCO or troops ($p<0.05$), mostly among the military personal stationed in Bosnia againts other locations as Aviano, Bulgaria, Namibia, Kenia, Sicilia or Bulgaria ($p<0.01$).

b) Evaluation,strategies and proposals:

The evaluation and processing of the stressors, as we have shown in the proposed model it is subjected to a variety of

factors (23,26). In this paper we have not discussed genetic or constitutional factors or evaluation of the personality,"Locus of Control" and other constructs which could acting by modulation the stress mechanism (5).

The evaluation made by the subjects of stressors as well as the strategies and measures to carry out are showed in table V.First, a decrease in the worktime (24.2%). Then a better logistic arrangemnts(18.6%), next better comunications with home country (15.8%) and finally to extend the rest periods (14%). Worktime /rest ($p<0.01$) and lack of personnel ($p<0.05$), plus better training before starting the mission was a consideration among aircraft pilots and paratroopers against helicopter pilots. Shifts scheduling was sugested more for officers than troops ($p<0.05$).

In summary the measures suggested by the population studied can be divided in two main areas. First, solutions oriented to a better management of the family separation(shorter shifts, better comunications,etc.)and secondly, measures oriented to improve the resting time.

Better inteligence data was a remark among the officers (pilots) stationed in Bosnia ($p<0.05$) in relation to the officers stationed in Aviano AFB, also among the NCO stationed in Bosnia againts the troops. Troops and paratroopers needed more social and staff support ($p<0.05$).

c) Adaptation symptoms and disorders:

The incidence of adaptation disorders and psychiatric problems was not relevant according to the data collected in spite of the stressful situation. Data shows that 34.4% of the interviewed personnel denied any specific symptoms.

Anxiety symptons were mentioned in 14% of the cases and the proportion was more significant in aircraft pilots and paratroopers ($p<0.01$) by comparing with helicopter pilots. We should take into account that anxiety is a quite frequent answer to stress situations and able to remain and to lead to a disease in cronic stressful situations.Both terms are not the same(1,15).

Only 28.2% of the persons do recognized subjective experiences of psychic anxiety under stress (1) and in our survey, in spite of the belic environment the incidence was lower. We should point out that we have not distinguished between an anxiety disorder once the traumatic experience had dissapeared and the progressive recovery of the psychic disfuntion after the exposure to an stressing situation. We have not consider in this study the genetic factors involved and vulnerability to stress which could lead to a mood disorder.

Depresion symptoms was describe in the 7.4%, and the second more frequent finding after anxiety. It was significantly ($p<0.01$) more

relevant among the NCO stationed in Bosnia against those deployed in Aviano AB.In clinical practice depression and afective disorders can be found as a mixed presentations of anxiety-depression symptoms acording to the International Clasifications of Mental Disorders(11,12), but not showed in our study.

Sleeping and eating problems have been described in the 2.8% of the cases as we can see in table VI,can be considered in the context of mood disorders. Personality changes was described in the 4.6% mostly among paratroopers ($p<0.05$). It mean that the incidence of afective disorder could be more frecuent.

Other consequences discussed in the answers to the survey are related to social and diseases problems observed among the local population(5.6%) which directly impact in the military personnel. That observations occurs mainly among Air Force personel stationed in Guinea ($p<0.01$).

d) Life threatening situations:

It was denied or not mentioned by most of the subjects (44.8%), but bombing or shooting were events often showed (14.9%), mostly among officers stationed in Bosnia ($p<0.05$)by comparing with other places of deployment.

Incidents with the local police or paramilitary personnel was described (8.4%)more frecuently in paratrooper deployed in Guinea. Also with the local population was informed with lower frecuency(6.5%).

Presence of shooting or mines was described(5.6%) in Bosnia ($p<0.01$) by comparing with other locations not actually in war. A 3.7% of the subjects were considered prisoners and 4.6% of them got a serious threatening experience but not described by them.

Other life threatening event are shown in table VII. Among the aircraft pilots stationed in Aviano AFB, the threat of shut down was a permanent concern.One aircraft was shut down.

As you know,life threatening situations can lead to neuronal changes in a variable period of time. Those changes can be permanent in the afective life as a consequence of the psyquic or physic trauma recorded (8,14). One of them is described as Postraumatic Stress Disorder(PSD). In this study we have not seen any individual with PSD, but it would be necessary a long term follow up of these individuals in order to detect such desease.

CONCLUSIONS

Finally, conclusion can be summmarized as follow:

1. Despite the war conditions in the deployment area, the psychosocial stressors are more relevant than the physical stressors.

2. We found aspects to be a point of study and consideration such selection of personnel according to psychological aspects: personality assessment, selfcontrol, social support perception and experience, because they can modulate level of stress.

3.Agreement between the evaluations performed and the solutions proposed among psychosocial factors(shorter shifts,better comunications, social support,..) and physical factors(rest periods,personnel resources, improve logistic,..). We should take into account those aspects in future missions.

4. Minor presence of psychic dosorders, most of them related to anxiety and depression symptomatology, Neverthless more wide assessment is required in order to detect them.

5.Finally, no evidence of Postraumatic Stress Disorders, in spite of the serious threat experiences of the personnel surveyed. A long term follow up of this personnel is recomended.

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TABLE A

1) Related to adptation to the physical environment stress:

- -Selection and training of personnel
- -Acclimatization, prevention and treatment of adverse effects producted by exposure to extreme climatic conditions
- -Local interaction with the local population
- -Disaster situations

2) Sustained operations and long haul flights:

- -Sleep deprivation and alertness management
- -Circadian rythm disruption

3) Remote and hostile environments: Infectious diseases, medical care, air evacuations, ...

TABLE B

INPUT	INDIVIDUAL	OUTPUT
Stressor		Physiological
		-Behaviour
-Pychosocial factors	-Genetics	-Vegetative
	-Personality	-Endocrine
	-Social support	-Inmunologic
-Environment	-Locus of Control	
	-Evaluation	
	-Coping strategies	Psychologic
		-Adaptation (eficiency)
		-Disadaptation (illness)

TABLE I

Especialty	n	p
-Fixed Wing Aircraft Pilots	39	36.4
-Helicopter Pilots	6	5.6
-Paratroopers	52	48.6
-Cabin Cargo Supervisor	1	0.9
-Mechanical Engineer	5	4.7
-Engineering	1	0.9
-Physicians(Flight Surgeons)	2	1.9
-Others	1	0.9

n=number ; p= percentage

TABLE II

Rank	n	p
-Troops	23	21.5
-NCO	24	22.4
-First Lieutenant	3	2.8
-Second Lieutenant	16	15
-Captain	19	17.8
-Major	17	15.9
-Lt.Colonel	5	4.7

n= number ; p= pertentage

TABLE III

Place of deployment

	n	p
-Bosnia	53	49.5
-Aviano(Italy)	20	18.7
-Vicenza(Italy)	8	7.5
-Namibia	6	5.6
-Guinea	5	4.7
-Kenia	4	3.7
-Irak	4	3.7
-Bulgaria	3	2.8
-Croacia	3	2.8
-Sicilia	1	0.9

n= number ; p= percentage

TABLE IV

Stressors more often related by the personnel studied in order of frecuency.

-Family Separation
-Language Barrier
-Shifts Duties
-Sleep Deprivation
-Home Country Communications Dificulties
-Adverse Climate
-Risk Physical injuries
-Disaster Situation
-Contact with Local Population
-Risk of tranmisible deseases
-Jet Lag
-Others:lack of resources,poor coordination,social and political situation of the country.

TABLE V

More adecuate solutions choosen by the sample in order of frecuency.

-Shorter Shifts
-Improve Logistic
-Better Communications
-Rest periods
-Free Time for Physial Fitness Activity
-Staff Coordination and Support
-Fitness Program
-Personnel Resources
-Foreign Language Training and Tuition
-Intelligence
-Scheduling
-Workload
-Peer comunication
-Others

TABLE VI

Symptoms or Disorders Showed by the Personnel Studied During and After the Deployment

	n	p
-No or denied	39	36.4
-Anxiety	15	14
-Depression	8	7.4
-Close relationships with misfortune locals	6	5.6
-To Better Value the Lack of Facilities	6	5.6
-Change of Personality	5	4.6
-Sleep Disorder/Eating Disorders	3	2.8
-Lost of Weight	3	2.8
-Behaviour Disorder	2	1.8
-Tireness/Fatigue	2	1.8
-Stress	2	1.8
-Blood Disfunction/Visul impairment	2	1.8
-Change in the Self-Scale Value	2	1.8
-Others	12	11.2

n=number; p= percentage

TABLE VII

Life Threatening Situations Observed

	n	p
-No	48	44.8
-Bombing/Shooting	16	14.9
-Relationship with paramilitary/Policemen	9	8.4
-Relationship with local population	7	6.5
-Mines/Snipers	6	5.6
-Yes(no comments)	5	4.6
-Aircraft Shut-Down Risk	5	4.6
-Prisoner/Threats	4	3.7
-Nearby Criminal Assault	3	2.8
-Others:		
Siege	1	0.9
Aircraft Shut Down	1	0.9
Flight Incident	1	0.9
Risk of Automobile accident	1	0.9

n=number; p=percentage

A CONCEPTUAL APPROACH TO THE STUDY OF STRESS IN PEACEKEEPING PERSONNEL

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SUMMARY

This paper outlines the current conceptual model utilized in Canadian Forces psychological research of the stress of peace operations. The model incorporates stressor, moderator, outcome and intervention components at the individual, group and organizational levels. Previous research has illustrated many of the various sources of stress on peace operations. Individual and organizational level resources that could serve as moderators of operational stress include individual coping skills, satisfiers of the peacekeeping experience, perceived organizational support and unit climate. Outcome measures include signs and symptoms of stress: both commonplace and more serious stress reactions. Other outcome and intervention components will be explored in future research. This theoretical framework should aid our understanding of the human dynamics of the deployment cycle and suggest appropriate training and interventions to enhance individual and organizational well-being and performance.

1 INTRODUCTION

Optimum operational effectiveness is the goal of every military. Conventional efforts to enhance operational performance generally focus on training and materiel aspects such as equipment acquisition and streamlined logistic support. In recent years in the Canadian Forces, there has been growing awareness of the importance of undertaking research into the human dimension of operational performance. This awareness is reflected in the degree of personnel research conducted throughout the organization: for example, studies aiming to enhance force generation and maintenance procedures, foster conditions of service, integrate social policy and increase operational effectiveness (Ref 1). At the vanguard of research into operational effectiveness, is the *Human Dimension of Operations* project.

2 THE HUMAN DIMENSIONS OF OPERATIONS PROJECT

There were several catalysts behind the Human Dimension project. One was a recognition that the stress of operations can adversely affect both individual and group performance, as well as the short and long-term well-being of Canadian Forces personnel - and consequently their families. Another impetus to the project was the acknowledgment that empirical measurement of particular aspects of morale and leadership could assist commanders to command more effectively. Furthermore, while previous research has illuminated many psychological aspects of wartime service, and the post-combat adjustment of veterans has become a *cause célèbre* over the last two decades, peace support operations since the demise of the Cold War are in many respects a new phenomenon. There is clearly a need to study the diverse factors associated with contemporary peacekeeping.

The Human Dimension project is a broad, long-term, dynamic study. It has as its cornerstone a conceptual model of stress and performance. The study nonetheless attempts to unite the often uneasy bedfellows of theory and practice. This paper presents the conceptual side of the project. The presentation to follow will outline some of the more pragmatic outcomes and uses of the *Human Dimension of Operations* project.

3 A MODEL OF STRESS AND PERFORMANCE

As shown in Figure 1, the model incorporates stressor, moderator, coping, and outcome components. Each of these components has individual, group and organizational levels to be considered. You may already recognize the need for a multi-disciplinary approach in such a design.

Stressors. The model begins with a stressor component. Stressors are events or conditions that can cause stress in individuals. There is of course great individual variability in reactivity to stressors, just as there is great situational variability within and across peace support operations. While this study is building upon previous research that sought to identify the stressors experienced by Canadian Forces personnel on peacekeeping tours, each deployment appears to be fundamentally different. We recognize that stressors may be acute or chronic, they can be specific to the operational theatre or more occupational in nature, or they may be general life events or daily hassles that are not specific to the military. Our emphasis is on the chronic and cumulative stressors of deployment as these are more generic across peace operations and presumably more amenable to study and intervention. In a sense, the deployment cycle - including pre and post-deployment phases - is considered one large composite stressor made up of numerous potential component stressors. For various reasons, not least of which is to develop comparative data, the project is also studying occupational stressors in samples of nonoperational personnel.

Moderators. Moderators are factors which have the potential to impinge upon the appraisal process and hence alleviate the impact of a stressor. Moderators can include perceptions of organizational support, task satisfaction and effective leadership. Specific interventions such as psychological debriefing are tailored to act as moderators of stress. Many moderators are essentially resources. Our model adopts many tenets of the Conservation of Resource Theory expounded by Steven Hobfoll (Ref 2). In this approach, it is postulated that those with the greatest resource pool are most resilient when under stress, while those with the fewest resources are likely

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to be both more vulnerable to stress and to act defensively - and hence maladaptively - when faced with the loss of scarce resources. Groups under stress and with minimal resources may use existing resources inappropriately, unwisely or destructively. Furthermore, some research suggests that the loss of resources is a critical determinant of adverse psychological and health outcomes in many individuals. The intention of many support programs and interventions is to provide or replenish individuals and groups with resources: be they personal, social, informational, financial, materiel or other assets.

Coping. There is a great deal of conceptual and research activity surrounding psychological coping. In our model, coping is regarded as the appraisal process whereby an individual evaluates a stressor, may classify it as a threat or a challenge, and may determine how to adapt and which coping resources to marshal. Much of this appraisal process may occur subconsciously and can be governed by habitual response patterns. Our model views coping as a process with both trait - or personality - and situational components; that is, we accept both the dispositional and contextual approaches to determining coping responses as having value. We assume that individuals have a range of coping behaviors available and that they will selectively use those behaviors in light of stressor characteristics, situational factors such as prevailing group norms and organizational culture and individual preferences and tendencies. At this stage of the project, greater emphasis is placed on the intraindividual approach to coping and appraisal, that is, attempting to identify basic behaviors and strategies used by military personnel on deployment. We believe that the study of group coping processes is a potentially valuable field for research.

Outcomes. There is ample research documenting the potentially deleterious effects of stress on well-being. Adverse outcomes in the physical, affective, cognitive and social/behavioral arenas are widely recognized. A particular interest of the project is the constellation of serious post-deployment reactions that constitutes posttraumatic stress disorder. In an effort to transcend the usual emphasis on health outcomes in studies of occupational stress, our model addresses several additional consequences such as changes in commitment and morale.

It is hoped to eventually measure and predict 'key *performance* outcomes.' However, as peacekeeping missions can offer extremely complex and demanding task environments, we are finding it difficult to identify and operationalize pragmatic, universal and meaningful performance measures. Of interest to many commanders are morale and leadership outcomes. In these areas we appear to be making considerable progress, as I shall outline in the next presentation. Of course, many of the postulated outcomes may function dually and link back into our cyclic model as moderators.

4 RESEARCH DESIGN

The Human Dimension of Operations project is ambitious. With over 2000 Canadian Forces personnel currently deployed overseas on peace support operations, this amounts to a commitment to surveying about 300 personnel each month in the field. The project has been active for two years though we have only recently reached a 'critical mass' stage where continuous data is flowing in. We attempt to measure each contingent at five stages of the deployment cycle: pre and post-deployment, and three times during the tour: early, mid and late. The project is in a constant process of development. At this stage, we cannot measure all the constructs recognized in our model - and in all likelihood we never will. Construct validation of our instruments is slow and, due to related issues of response bias, confidentiality and sampling, we are unlikely to achieve a neat, classical longitudinal research design. For example, a repeated measures design would require a questionnaire taking several hours to complete, clearly an unacceptable demand on deployed personnel. We are confident that our measures - and the overall model - are being refined through the constant interplay of theoretical and applied research considerations.

5 UTILITY

The Human Dimension of Operations project has significant potential and is already paying dividends. It attempts to measure the impact of stress on the performance of effective task performers in authentic military work environments - not a common subject of research. Each survey administration rewards us with useful information about aspects of the human dimension of operations. Component projects such as measuring dimensions of unit climate are assisting commanders understand sub-unit dynamics and make command decisions. Component instruments such as the Unit Climate Profile are being requested for use in applied and other research projects. The growing database has been used in comparative research with operational groups other than peacekeepers. Nonoperational personnel and those with prior peacekeeping experience are also being surveyed in order to develop comparative norms and to monitor the long-term impact of peacekeeping duties.

The model is suitable for causal modeling, which can reveal interrelationships among the numerous constructs and hence information useful in prediction. With this information the Canadian Forces can determine the need to develop and implement numerous interventions and programs such as selection for peacekeeping duties. Another potential use is designing and targeting stress prevention for personnel at risk of serious post-deployment maladjustment. Stress prevention programs could also be evolved to address the more common stressors and 'subclinical' stress reactions of generic peacekeeping duties (Ref 3) which may nevertheless impact significantly on operational efficiency and effective management and leadership of deployed personnel.

6 CONCLUSION

The bottom line of the Human Dimension of Operations project is research that will lead us to effective interventions at individual, group and organizational levels which will improve future operational effectiveness and enhance the well-being of service personnel - and their families.

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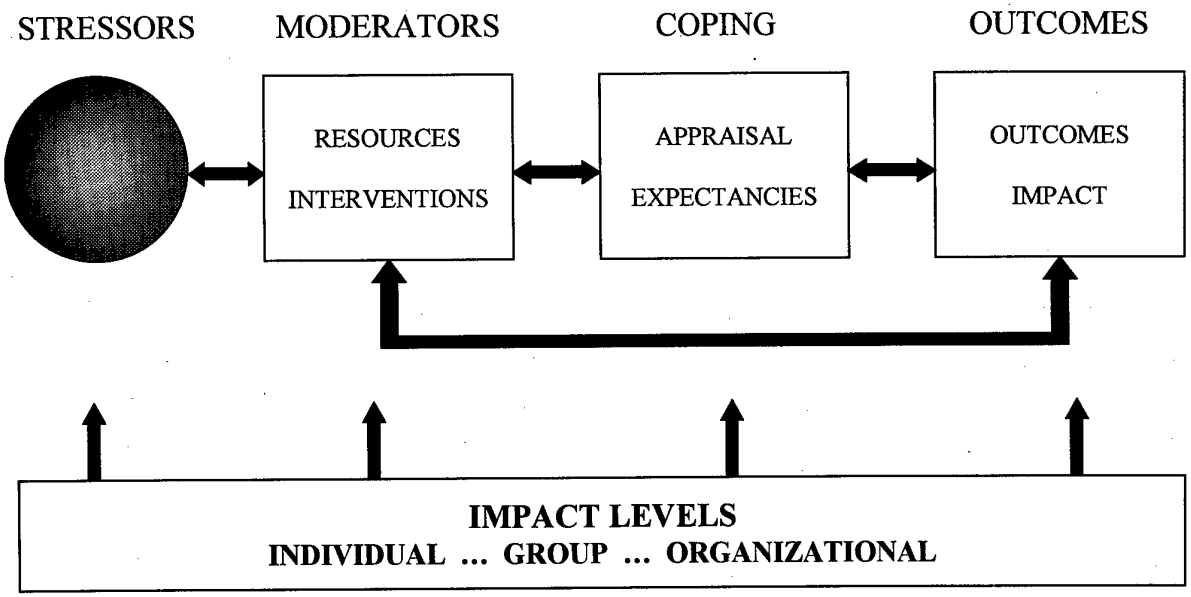


Figure 1. A Model of Stress and Performance

STRESS IN PEACE SUPPORT OPERATIONS: RECENT CANADIAN EXPERIENCES

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SUMMARY

The Canadian Forces continues its high profile involvement in peace operations in various parts of the world. At present, over 2000 Canadian Forces personnel are deployed overseas in peace support roles, largely in Bosnia and Haiti. A long-term research project into the human dimension of operational performance has monitored several aspects of deployment. This paper addresses research findings relating to the stress of peace support operations and other human factors. Select details of significant stressors, the stress-strain relationship and several moderating factors (satisfiers, group cohesion, coping styles and perceptions of organizational support) are presented.

1 INTRODUCTION

The Canadian Forces is one of several countries with a long history of participation in peace support operations in various parts of the world. At present, over 2000 Canadian Forces personnel are deployed overseas in peace support roles, largely in Bosnia and Haiti. A long-term research project into the human dimension of operations was commenced two years ago to study several aspects of the deployment cycle from a stress and performance perspective. The cornerstone of the project has been the refinement of an instrument called the Unit Climate Profile (Ref 1) which attempts to measure several dimensions of morale and leadership at the sub-unit (that is, platoon to company) level. More recently, the project has developed a broader conceptual model of performance during operations and significantly expanded its field research. The project attempts to survey a sample of contingent personnel from each major peace support deployment at five stages: pre and post-deployment and at three phases while deployed: early, mid and late tour.

At this time, data has been collected for three stages of one rotation in Bosnia and for the pre-deployment and early stage of a second rotation in Bosnia. The project has just completed the late tour survey of the contingent in Haiti which supplements the pre-deployment and early and mid-tour data already collected. In just the next month it is intended to administer a post-deployment survey for personnel returned from Bosnia, a mid-tour survey of the current contingent in Bosnia and a pre-deployment survey for the next contingent going to Haiti.

This presentation will detail a selection of research findings from the available data of the Human Dimension of Operations project.

Unit Climate Profile. The Unit Climate Profile has been developed and validated by Canadian Forces military

2 RESEARCH FINDINGS

psychologists, notably Major Kelly Farley (Ref 2). The profile has been designed for use in Army units, although other variants are being considered. The instrument contains about 60 self-report items with a 5 point response scale ranging from 'strongly disagree' to 'strongly agree'. At present two versions of the scale - one for soldiers in support roles and one for combat arms troops - are undergoing further validation trials to develop normative data. An example item is: "My platoon is ready for combat" or, for support troops: "My work team is ready for combat-related duties." The instrument measures four dimensions of morale and unit climate and several aspects of leadership, such as perceived competence, at different levels of command. The Unit Climate Profile is included in every survey administration of the *Human Dimension of Operations* project.

Figure 1 presents an actual profile for the early, mid and late tour phases of a deployed unit. Eight dimensions are presented along the horizontal axis. The first is 'morale/cohesion' which taps perceptions of group readiness, role clarity, confidence, effectiveness, teamwork, trust and social cohesion - to name a few. The next dimension is labeled 'professional morale' and deals with self-appraisals of constructs such as confidence and pride. 'Ideology' essentially measures commitment to one's role in the military. The dimension of 'leadership skills' probes management and supervision practices of the soldier's immediate superior. The remaining dimensions deal with various levels of leadership in the unit or sub-unit, normally from section commander or equivalent to company or sub-unit commander. In some instances unit commanders have requested that their level of leadership be included in the survey. Each leadership dimension reflects perceptions of respect, support and confidence in the event of combat. The scores along the vertical axis represent average scores, prorated around zero, with zero representing a neutral level of response. Scores above zero represent positive scores; scores below zero indicate negative or adverse scores on each climate dimension.

Commanders are briefed on the results of the Unit Climate Profile. The role of the briefing military psychologist is often analogous to the role of an X-ray technician in a medical team: providing information that a specialist - in our case a commander - interprets from a broader perspective. Commanders have shown amazing diversity and creativity in how they utilize and promulgate the information from the unit climate profile. More recently the researchers have adopted

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an increasingly prescriptive approach in briefing commanders - and this has generally been well-received.

Both the research team and many commanders have been impressed by how sensitive the Unit Climate Profile appears to be to the dynamics of morale and leadership within units. It appears to be fulfilling its promise as a valuable adjunct for command decision-making.

Satisfiers. It has been postulated that satisfiers - the positive, motivating factors of peacekeeping service - may act to moderate the impact of stressors. A scale measuring satisfiers has been administered on one occasion during deployment to contingents in both Bosnia and Haiti. Principal components analysis reveals similar factor structures in the two response sets. The common dimensions of general satisfaction to emerge are: humanitarianism and cross-cultural contact, professionalism or professional pride and development, personal development, personal rewards, social relations in the contingent and with those back home, and the novelty of the deployment. We have yet to explore the interrelationships of this data with other variables, however, by itself this information is potentially useful for commanders and policy-makers eager to maximize the individual rewards and satisfaction of peace support duties.

Stress and Strain. A self-report measure of stress symptomatology is included in every survey administration as an individual-level stress outcome. The 36 item checklist is a modified version of the General Health Questionnaire (Ref 3) and contains three dimensions of strain: physical, psychological and behavioral. Preliminary comparative analyses suggest that Canadian service personnel in Bosnia experience more signs of stress than their counterparts in Haiti and these symptoms are more serious in nature. This finding appears consistent with general impressions that conditions in Bosnia are more dangerous than Haiti. However, comparisons of major stressors for the two contingents - drawn from a 105 item checklist of stressors - do not support the assumption that threat is the key reason for higher strain in the Bosnia contingent. In fact, the only threat stressor to feature highly in both contingents' lists of stressors is the risk of traffic accidents. For the contingent being studied in Bosnia, the external environment had become less dangerous than previously experienced. When external threats decline, other stressors rise in importance and, consistent with previous experience, these relate mainly to issues of organizational climate and leadership. In Haiti, more dimensions are apparent in the major stressors, including several environmental stressors such as "the local system of justice" and "poverty and/or begging."

Another preliminary finding relating to stress and strain is that in the Canadian contingent in Bosnia the most prevalent strain dimension is psychological symptoms, followed by behavioral and then physical signs. If additional support programs or interventions were to be considered for personnel in Bosnia, this information seems to suggest quite clearly the most appropriate form of such support - psychological.

Coping. Coping styles and resources are considered an important link in the stress-strain relationship. The current psychological literature abounds with research into the key dimensions of coping. These coping dimensions are generally considered to be twofold: *problem-focused* coping and *emotion-focused* coping; although many theorists add a third, *avoidance* dimension. Our research incorporates a scale developed by Charles Carver and his colleagues (Ref 4) which measures 14 subscales of the three previously mentioned coping strategies.

A selection of our findings relating to coping techniques are that Canadian Forces personnel in both Bosnia and Haiti report a preponderance of functional coping strategies, notably planning, positive reinterpretation and growth (managing one's reactions rather than focusing on the problem itself), active coping (taking steps to resolve or remove the problem) and acceptance (accepting the problem as unresolvable or unavoidable). This is a reassuring finding, however, emotion-focused strategies were employed to a greater extent in the contingent in Bosnia compared to Haiti. Theory suggests that emotion-focused coping prevails when people believe a stressor cannot be resolved or removed. This finding is a source of some concern considering that the major stressors in Bosnia were related to organizational climate and leadership, which should be amenable to change through active coping. A third finding from our analysis is that no gender differences were found in coping strategies in the Bosnia sample yet a significant gender difference was found in the Haiti sample (consistent with research in the general community, female service personnel in Haiti were more likely to seek social support for both emotional and instrumental reasons). Such differences between contingents are intriguing and will be the subject of further analysis. Nevertheless, commanders could benefit from an understanding of gender differences in coping techniques.

3 THE FUTURE

It is hoped that this presentation has provided a taste of the great potential that the Human Dimension of Operations project promises. There is a mountain of data waiting to be analyzed, including other measures and constructs not mentioned above, such as traumatic stress and perceived organizational support. For example, one finding is that perceptions of organizational support are significantly correlated with the leadership skills dimension on the Unit Climate Profile. The Leadership Skills dimension is basically a measure of the management skills of the immediate supervisor. The correlation suggests that Canadian service personnel perceive their immediate supervisors as representing the Canadian Forces organization. This has implications for change management and other human resource matters throughout the organization.

One lesson already learned from the data is that there is significant variability at the sub-unit level in almost all components of our model of the human dimension of operations. For example, in Haiti, one unit identified only five stressors of the deployment experience causing considerable levels of concern whereas another unit identified 35. Results indicate that morale does indeed vary during a deployment - but not along a consistent temporal path related to elapsed time on the mission - rather it appears that situational and group determinants are more important in explaining changes in morale. Such findings suggest that situational variables should be a focus of further research and that sub-units and units should be a main level of analysis.

4 CONCLUSION

Many, many questions remain to be explored. Is cumulative, long-term stress as debilitating as traumatic stress (as proposed by Scott & Stradling in Ref 5)? What are the major influences on changes in morale? Can we predict post-deployment maladjustment? Which satisfiers of deployment moderate the impact of stress? As the Human Dimension of Operations project reaches maturity, and answers to such questions emerge, it is hoped to proactively assist prospective commanders of Peace Support Operations from all nations involved in these missions to improve the performance and well-being of individuals and groups under their command.

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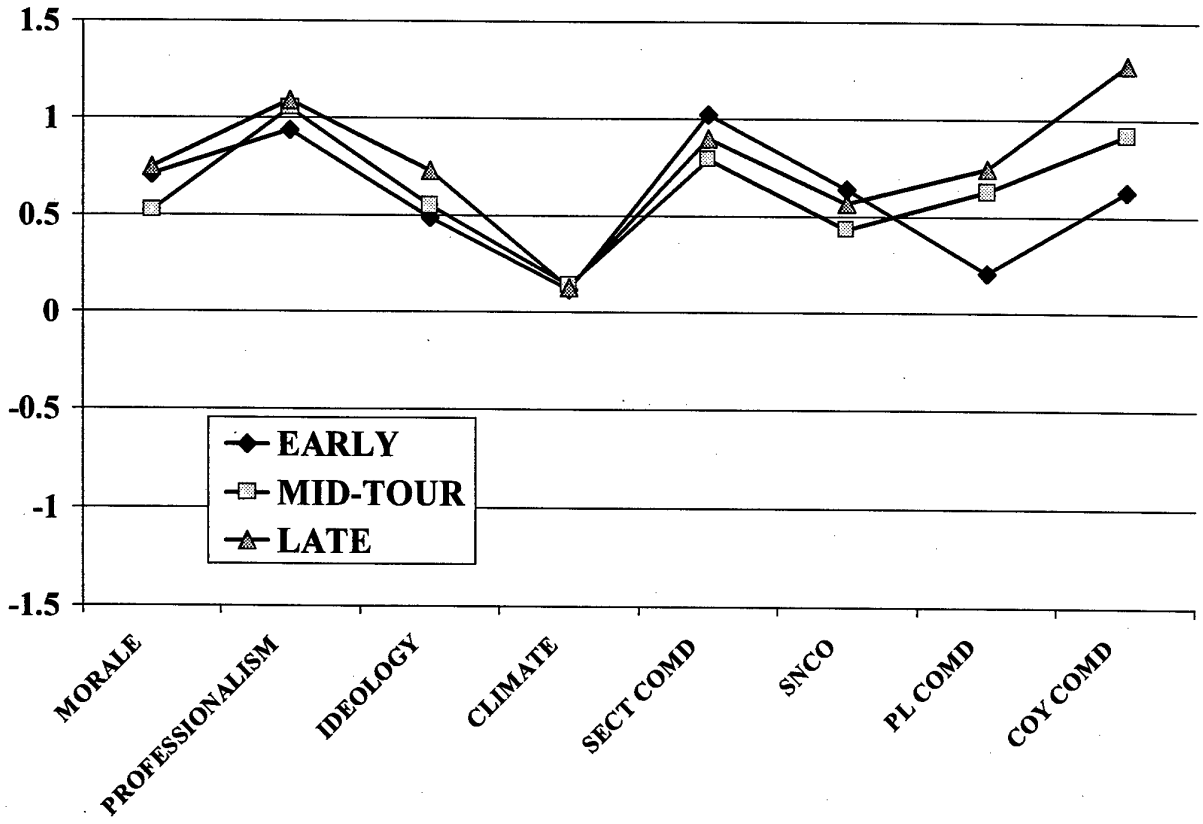


Figure 1. Example Unit Climate Profile

MOTIVATION STRUCTURES OF THE CZECH SFOR UNIT MEMBERS

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SUMMARY

The Army of the Czech Republic has been actively participating in peace-keeping missions of the United Nations and NATO from 1991 until today.

The goal of my paper is to describe the motivation structures that led our soldiers to participate in the last of the mentioned missions.

The motives of unit members for participating in foreign missions are dissimilar. The external socio-demographic characteristics, i. e. social class, financial income and the region of origin play a significant role in case of the off-duty volunteers.

The internal motivational structures can be tracked down to the level of verbally proclaimed motives and life standards and to the level of usually unspoken, and possibly less conscious, psychological causes, that express certain lifestyle.

The financial motivation is very high for all categories of participants. A category with very different motivation is formed by active-duty soldiers on commanding positions who enter missions repeatedly. The dominating motive of this group is self-satisfaction and more or less conscious lifestyle habit.

1. INTRODUCTION

First of all, let me define several terms used in my paper as they should be understood.

Motivation *is a process of behavioural structuring, it gives behaviour its unity and sense. P. G. Zimbardo stresses upon the fact that motivation has not been ever seen by anyone, that it is a term expressing certain results of what has been observed. It is a psychological construction identifying and explaining the psychological background of behaviour.*

Motivation is a process initiated by the original motivation state of being, characterised by the experienced deficiency in physical or social being of a human.

As far as unconscious motivation is concerned, S. L. Rubinstein may be cited: "...the content of human mentality is not satisfied with the conscious motivation, it includes the unconscious tendencies, not realised by the subject." [1] *Human behaviour is often initiated by these unconscious tendencies, the person then rationalises the actions taken by various made-up explanations that actually cover the inapprobated tendencies.*

The original motivation state can be described as ***"need"****, that is the absence of a value. A acquiring reaction, fulfilment is the aim. The term "need" can be outlined as the original motivation relation while "motive" depicts the content of satisfaction and as such it can not be further analysed as psychological ground of behaviour.*

Motives are usually understood as internal causes, psychological grounds for human behaviour, consciously and unconsciously oriented towards goals. Nevertheless, both the personality structure and given situation have a motivating impact. Situation is the collection of the existing conditions surrounding the subject and distinguished by the subject.

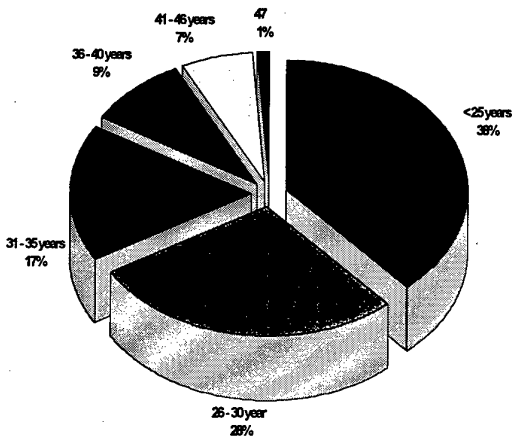
In the light of the above stated arguments human motivation structures as well as outer socio-demographic influences are included in the overall motivation structures.

1.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS OF THE RESEARCH SAMPLE

Over 1.800 soldiers of the Czech Army participated in the IFOR and SFOR missions in former Yugoslavia between the years 1996 and 1997. A greater number of both active and off duty volunteers have participated in the selection.

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The ***present age composition*** of the contingent is depicted in **fig. 1.**

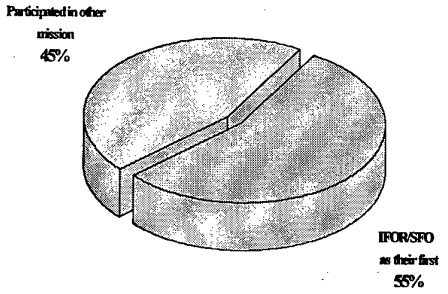


It can be observed that most of the personnel ages up to 31 years. With increasing age the number of soldiers diminishes. The mean is 28 years, median 24.

Social state of the respondents

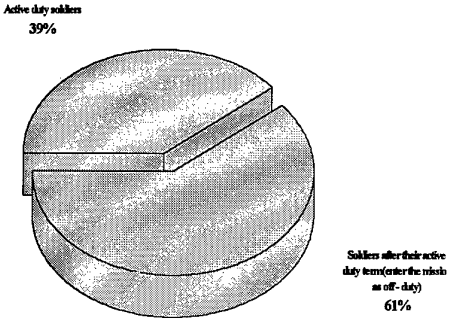
The respondents have been divided into two main groups of married (48%) and single (45%), the remaining 7% are divorced.

The ***division by former mission participation*** is shown in **fig. 2.**



About 55% of the respondents have stated the IFOR/SFOR mission as their first, the remaining 45% had formerly participated in other mission(s).

The ***division by duty category*** is depicted in **fig.3.**



The mission participants belong mainly to two categories: active duty soldiers, who take up 39%, the remaining 61% are soldiers after their active duty term (most of whom enter the mission as off-duty).

The above given statistics and other document analysis show that despite the tendency to form professional units within the Czech Army a greater part of the participants are off active duty. These persons entering the missions come mainly from regions with higher level of unemployment. These regions include Northern Moravia, parts of Southern Moravia, Southern, Eastern and partially Northern Bohemia. With the exception of the Kladno region, there is a minor number of volunteers form the regions of Prague and Central Bohemia. A town until 100.000 inhabitants is the home of a typical mission participant.

2. METHODS

The research was carried out over the years 1996 and 1997 with 405 respondents, all participants of the IFOR and SFOR missions. Secondary documents and Reports of the Research centre of the Ministry of Defence of the Czech Republic analysis were used to acquire mainly quantitative data.
I used the method of direct interview both during the selection process on the Cesky Krumlov base and more importantly on the site of the mission, as the questionnaire method was found to be rather inadequate.

3. RESULTS

The financial reward was widely proved by the respondents as 75% of them stated that salary was a deciding issue. Almost a third stated that the financial issue had a 50% impact on their decision-making process.

The financial issue had an greater influence on the ***after-duty category*** (77% of their decision-making was influenced by the financial subject) than on the active-duty category (70% of the decision-making was influenced). Those giving the greatest priority to

financial reward (90% and above) do not intend to plan to stay in the army after the mission.

From the given list of reasons for participation the respondents choose the following as motivating:

1. Financial situation, need of funds, possibility to raise their own living standard;

2. More than a half of the respondents declared career and future perspective as reasons:

- to find out the own capability of completing the task; new experiences for work after return; to undergo something exceptional; to improve language skills;
- to afford one's own place to live.

3. For about 40% of the respondents the following reasons played a role:

- prior experiences form another UN mission;
- dissatisfaction with present employment;
- a group of friends with whom the decision to take part had been made.

4. A reason for about a quarter of the participants was:

- to earn money and start one's own business after return.

5. Another important reason to participate was:

- the recommendation from friends with a mission experience (23%)

6. A part of the respondents (14%) stated that a reason to participate was the need to get away from family, to solve personal problems.

7. Media information had played rather insignificant role (10%)

The more financial reward was preferred as a reason, the less important seemed such qualities of the IFOR soldier as "personal sacrifice", "patriotism" or "courage". These respondents were more afraid of a stereotyped and repeating assignments during the mission, they were not willing to test their capabilities, and did not longer for exceptional experiences. The participants of this group did not plan to utilise their experiences for future work. The members of this group intended to use the financial means earned to enhance their living standards, to start business or to get an accommodation to live.

Fig. 4

Participation reason structure [4]

(Result of factor analysis - consistency of the reasons)

Factor of informational stimulation (20,5 %)
- ***a group of friends with whom the decision to take part had been made;***
- ***media information;***
- ***to earn money and start one's own business after return;***
- ***recommendation from friends with a mission experience.***

Financial factor (15,2 %)
- ***possibility to raise their own living standard;***
- ***financial situation, need of funds;***
- ***to afford one's own place to live.***

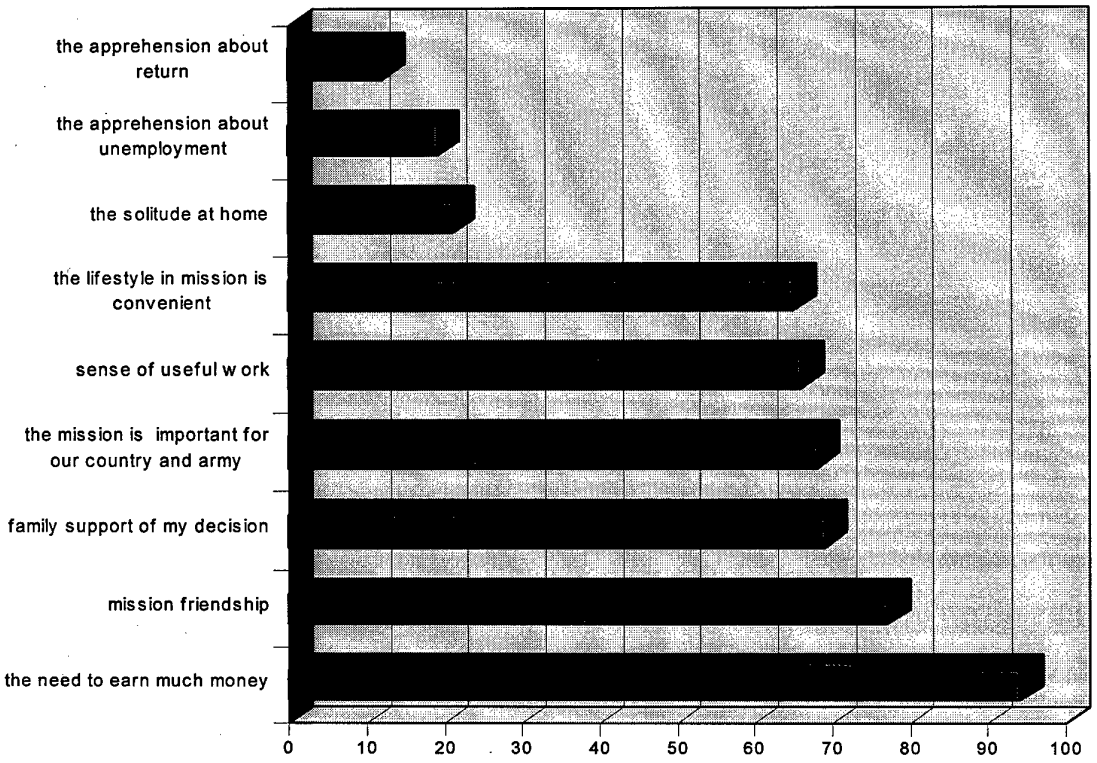
Factor of experience (10,8 %)
- ***to undergo something exceptional;***
- ***to find out the own capability of completing the task.***

Factor of profession (9,2 %)
- ***to find out the new experiences for work after return;***
- ***to improve language skills.***

Factor of problem compensation (6,8 %)
- ***the need to get away from family, to solve personal problems;***
- ***dissatisfaction with present employment.***

The respondents were interviewed again one month prior to return.

Fig. 5 *Continuance reasons* [4]



Roughly 40% of the respondents decided to stay or return to the mission. The strongest motivation was based on the chance of financial reward, mission friendships, family support of the decision and non-personal reasons. Reasons such as unemployment or return to normal life considered as of minor importance. It can be stated that in the mission participants there exists a rather low and uncertain anticipation of adaptation process difficulties.

Fig. 6

Continuance reasons structure [4]

(Result of factor analysis - consistency of the reasons)

Interpersonal factor (31,1 %)
- ***family support of my decision;***
- ***the lifestyle in mission is convenient;***
- ***mission friendship.***

Adaptation factor (21,5 %)
- ***without apprehension about return, about difficulties of current life;***
- ***without apprehension about unemployment;***
- ***the need to earn much money;***
- ***the solitude at home is not reason for decision to stay in mission.***

Super - personal factor (12,6 %)
- ***sense of useful work;***
- ***the mission is important for our country and army.***

- The motivation structure can be illustrated by the interaction of motives. The factor analysis shows that the group of interpersonal reasons is the most homogenous. These reasons document an addiction to the mission lifestyle.

- Lower adaptation process apprehension is increased with the effort to earn as much money as possible. Also the feeling of general usefulness provides a reason for continuance.

- Only 19% of the active duty soldiers wish to stay in the mission for financial reasons while this number of off-duty soldiers is as high as 30 to 40%, as far as category preferences are considered.

- The number of soldiers, ending their first mission, stating money as the reason to participate in the mission(23%) is smaller that of the mission veterans (31%).

- Similarly, the number of first-time participants who wish to continue also for financial reasons is smaller then that of the veterans (10% and 15% respectively). These numbers can be interpreted as a clear and exposed effort to get maximal financial reward.

The first-time participants look forward to the return home more than the veterans; a part of these is trying to inscript for another mission later on. There is no significant difference between active-duty and after active-duty soldiers.

The soldiers striving to continue in the mission for financial reasons critically evaluate their own physical abilities compared to others. They consider fighting capability, courage and willingness to take chances as less important. They do not see the role of today's mission participants in the "Rambo" type of soldiers, but emphasise that the UN missions need professionalism and first of all humanity.

In connection with this I have experienced a great compassion and empathy for the local inhabitants trying to renew the peaceful way of life. The soldiers, witnesses of the explosion in front of CIMIC building in Prijedor, were expressing a contingent cause of such actions of the local inhabitants. They were very critical towards some "professionals" who, during the time of their watch duty, aimed their weapons directly at the celebrating wedding guests. The purely pragmatic oriented after-duty members reveal a more of humanity then some "professionals " in this case..

I should like to emphasise that it would be simplifying to appraise those professionally motivated participants higher than those entering the mission for purely pragmatic reasons.

2.1 MOTIVATION STRUCTURES OF SOLDIERS WITH REPEATED MISSION EXPERIENCE

This is due to fact that the participation in the mission units of the Czech Army is voluntary. There had not been enough fresh volunteers from among both active and after active duty volunteers for some professions. This opened more space for the veterans. Groups of professionals start to form the core of the contingent since the forming of the 6th Mechanised battalion in the IFOR mission. Therefore, increased attention should be paid to the veterans.

The veterans category characteristics

This group of mission participants, with an average of 13.2 months of service, shows many differences compared to the other groups. During a psycho-diagnostic testing of IFOR mission volunteers in January 1996 the veterans had a very high level of L grade - often a 100 percentile in the DOPEN test. [2] The L grade was not taken into account in this light as dissimulation indicator only, but, besides pretending, the L scale was supposed to represent personal characteristics that can describe the degree of social naiveté. A negative answer to the question: "Do you ever show off?" surely expresses some naiveté. [3]

Result of the Expert Laboratory researchers show a level of anticipation in the form of foreseeing the results of certain activities up to the level of excess avoidance of danger in 38% of the sample. As far as motivation is concerned, the same source states that about 30% of the veterans strive for re-joining of the force due to dissatisfaction with the social environment after return, not only for reasons of lesser financial reward, but for reasons of social atmosphere as well.

2.1.1 Motivation due to adaptation difficulties after return is a key one and can be divided into the following areas of outer social and inner psychological drives:

1. One of the outer problems is, surprisingly, the veterans' integration into the Czech Army after return. The participants are granted their positions prior to departure for 6 months. Despite the effort to offer the veterans positions according to their experience this is difficult to carry out due to constant reorganisation, relocation, lowering of numbers of active duty soldiers and yet unresolved position of a professional soldier and solder in further duty. This question should be solved to a greater extent by continuous training after return from the mission.

2. The above stated problem is closely related to the next one - the ***social attitudes towards the veterans***. In very unstable conditions at military bases and great differences between the salaries in the army and on the mission, feelings of distress, aversion, jealousy as well as competition arise.

3. The greatest inner motive is a more or less conscious habitude of the ***lifestyle*** of the mission work. This phenomenon is widely covered, for example in Cloninger's "Novelty Seeking", that shows an internal strive to seek new stimuli and extreme experiences. R. Vodrá ka, 1994, states the return to regular military base life as a significant stressor.

My own interview experiences correspond with his findings as for the soldiers on posts of troop, company and unit commanders of the Czech Army contingent. These people tend to adapt to the role of an army professional. The positive side of such orientation is a high professionality and engagement. The possible negative issue is an extreme output orientation that leads to evaluation of one's self esteem based on meeting the position demands and reduction of one's personality. Unfortunately these people tend to expel out-of-profession relations. If a professional failure comes they stand it much worse compared to people with social contacts. I have met several young promising men, graduates of military colleges, who had started this process... They usually are not willing to go for staff posts but rather wish to stay close to the training and forming of combat units, usually rapid action brigades.

Some expressions of this category members:

"... I can not imagine myself working in the Staff. It would be too little active, dynamic. The only thing I wish to do is run around the woods and train soldiers..."
Woman, company commander, 26 years, 6 months on the mission, wishes to stay.

"...I have worked couple of moths in the Staff. I got sick of the time-consuming bureaucratic ways, I had been used to rapid, dynamic decision-making in an atmosphere where everything was possible one minute and the other nothing seemed to be possible... I thought I would either return to the worse paid post on the base or die..."
Battalion commander, 45 years, repeatedly on commanding posts on missions.

2.1.2 Financial motivation is not primary in the above described group of commanders repeatedly serving in missions only.

These people used to spend most of the year away from their families on military exercises already even at times when Czech Republic did not participate in peace-keeping missions. At the present time they have only moved their "soldier exercises" to a potential real war situation, but their life course did not change much. The primary conscious and declared motive is their self-satisfaction, new experiences and increase of their professional qualities. The financial part plays a role, but not the primary one. The salaries are mostly used to satisfy the family needs and to redeem the separation.

3. CONCLUSION

- The motivation of Czech Army soldiers for joining (repeatedly) the peace-keeping forces of the United Nations and NATO is the result of their professional and social position, personality structure and social conditions.

- The decision to join the force for the first time is usually the result of an interaction of several motives.

- The financial motivation is very high for all categories of participants. The strive to earn money usually comes from the need to solve one's housing situation, to keep or improve one's subjectively experienced lifestyle standard.

- A category with very different motivation is formed by active-duty soldiers on commanding positions who enter missions repeatedly. The dominating motive of this group is self-satisfaction and more or less conscious lifestyle habit.

- The lifestyle habit, peace-time adaptation difficulties, need for extreme emotional experiences show themselves as motives of all categories of veterans.

- The importance of the psycho-social support to the participants and their families that should prevent social damage increases in the light of peace-keeping mission units organic composition.

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Discussion #10

JONES, US: Dr Salisbury, regarding your experience in the Headquarters for IFOR medical support, was it like herding cats to get the medical units to work together or were they inter-cooperative amongst each other (in reference to Paper #56)?

SALISBURY, CA: The general experience was that, because every nation was defined as having to be responsible for its own medical care, there was at times a reluctance to admit a requirement for help. This was very interesting because the Headquarters was set up to be a resource to help people who couldn't look after themselves. We were used sparingly because of the reluctance on many people's part to admit that they needed help. It's been said several times at this Symposium that no nation is totally, logistically self-sufficient and that includes all of us, including the United States in spite of its massive capability on the ground. Every nation utilized other nation's medical resources at one time or another. It seemed to work more on the basis of personal arrangements; i.e., knowing who was doing what and where, than it did because there was a formal structure that mandated what should happen.

JONES, US: As they got to know each other better, was there a more mutual willingness to use each others' resources?

SALISBURY, CA: Yes, the impression I would have is that as the mission progressed, things got better and smoother, and there was more inter-cooperation.

JONES, US: I had rather a feeling of *déjà vu* about some of the things you said because I've been in Tri-Service situations where the United States Army, Navy and Air Force were as far apart as the national groups that you talked about. My perception has been that people coming out of university now, where their classmates are in the three different Services, work together much quicker. A group like this might be a little faster in integrating with counterparts from other nations.

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Sleep deprivation	Casualties	Humanitarian operations
Fatigue (biology)	Field hospitals	NATO forces
Performance	Life support	Medical equipment
Pharmacology	Traumatic disorders	Offensive operations
Drugs		

14. Abstract

These proceedings include the Technical Evaluation Report, two Keynote Addresses, 53 papers and the edited Discussions of the Symposium sponsored by the NATO/RTO Aerospace Medical Panel. It was held in Rotterdam, NE from 29 September - 1 October 1997.

Contingency Operations constitute military missions such as peacekeeping, humanitarian aid, peacemaking/enforcement, full scale offensive operations and relief operations other than war, such as aid to civil powers in counterterrorism and in natural disasters. Increasingly, these operations will involve greater NATO participation in the post "Post-Cold-War" era. Significantly, NATO nations are turning to the application of science and technology, particularly computer resources, to address the unique problems associated with Contingency Operations. From a medical standpoint, there are many logistic, support and environmental factors which impede effective health and critical care medicine in Contingency Operations. This Symposium considered both the aeromedical problems encountered and the role of technological solutions as aids to resolving the issues in: (a) sustained and continuous operations, (b) medical management in remote locations, (c) medical information, and (d) adaptation to operational conditions.

These proceedings will be of interest to heads of military health services, military and civilian officers concerned with the health and safety of personnel in air and support operations, research scientists, and those requiring a state-of-the-art review of medical "lessons learned" in Contingency Operations.

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