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14. ABSTRACT The U.S. Air Force Medical Service presented the sixth annual Air Force Medical Research Symposium coordinated by the Air Force Medical Support Agency's Research and Development Division (AFMSA/SGRS). The symposium was held 2-4 August 2011 at the Gaylord National Hotel & Convention Center, National Harbor, MD. The symposium featured two half-days of plenary sessions, one and a half days of scientific presentations, and a poster session. It was organized into five tracks to include: Operational Medicine (In-Garrison Care), Enroute Care and Expeditionary Medicine, Force Health Protection, Traumatic Brain Injury (TBI) and Psychological Health, and Healthcare Informatics. These proceedings are organized into six volumes to include one that provides a general overview and all presentation and poster abstracts; the other five each address a specific track. Volume 5 contains abstracts and presentation slides for the Operational Medicine (In-Garrison Care) Track.					
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Proceedings of the
2011 AFMS Medical Research
Symposium
Volume 5. Operational Medicine (In-
Garrison) Track
Abstracts and Presentations



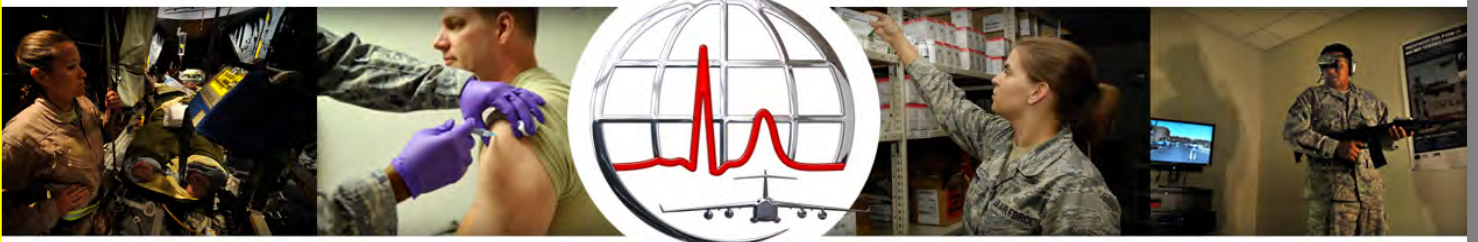
AIR FORCE MEDICAL SERVICE



2011 AFMS MEDICAL RESEARCH SYMPOSIUM

2-4 AUGUST 2011

GAYLORD NATIONAL
201 WATERFRONT STREET
NATIONAL HARBOR, MD 20745
(1-877-677-9352)



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Proceedings of the
2011 AFMS Medical Research
Symposium
Volume 5. Operational Medicine (In-
Garrison) Track
Abstracts and Presentations

Edited by: Lieutenant Colonel Cherri Shireman



Held
2-4 August 2011
at the
Gaylord National Resort Hotel and Convention Center
201 Waterfront Street
National Harbor, MD 20745



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Proceedings of the 2011 AFMS Medical Research Symposium Introduction

The U.S. Air Force Medical Service presented the sixth annual Air Force Medical Research Symposium coordinated by the Air Force Medical Support Agency's Research and Development Division (AFMSA/SGRS). The symposium was held on 2-4 August 2011 in the Washington DC area at the Gaylord National Resort Hotel and Convention Center in National Harbor, MD. The symposium featured two half-days of plenary sessions, one and a half days of scientific presentations, and a poster session.

The symposium was organized into several tracks to include Enroute Care, Force Health Protection, Healthcare Informatics, Operational Medicine (In-Garrison Care), and Psychological Health/Traumatic Brain Injury, as follows:

- The Enroute Care Track addressed science and technology targeted at the continuum of care during transport from point of injury to definitive care including, but not limited to: Casevac, Medivac; Aeromedical Evacuation; Critical Care Air Transport; and Patient Staging. Further areas addressed included: patient stabilization; patient preparation for movement; impact of in-transit environment on patient and AE crew physiology; human factors concerns for AE crew or patient population; AE/medical personnel training; infectious disease/control; burn management; pain management; resuscitation; lifesaving interventions; and nutrition research in the enroute care environment.
- The Force Health Protection Track focused on prevention of injury and illness and the early recognition or detection of emerging threats for in-garrison or deployed operations. Topics of interest include research in bio-surveillance, infectious disease, emerging threats (pandemic response), protective countermeasures, disaster response/consequence management, toxicology/health risks (e.g., particulates nanomaterials, radiation, etc.), monitoring disease trends, other areas of preventive medicine, public and environmental health relevant to the military workforce.
- The Healthcare Informatics Track focused on the use of innovative information management & technology solutions that enhance healthcare delivery at any point of the full spectrum of patient care to include medical simulation and training.
- The Operational Medicine (In-Garrison Care) Track focused on care delivered in the outpatient or inpatient in-garrison setting and on enhancing the performance of airman in challenging operational and expeditionary environments.
- The Psychological Health/Traumatic Brain Injury Track addressed topics pertaining to screening, diagnosis, and treatment of TBI and/or Psychological Health in the military community. Specific focus areas within Psychological Health included depression, substance use disorders, family functioning, and suicide prevention. Topics of special interest included field-deployable diagnostic tests for mild TBI (concussion), blast modeling, large epidemiologic studies of Psychological Health and TBI, and strategies for translating research into practice.

These proceedings are organized into five volumes, as follows:

- Volume 1. This volume is a general overview of the entire 2011 Air Force Medical Research Symposium and includes abstracts of all the oral presentations and posters. First presented is the symposium's opening plenary session, followed by the abstracts from the four technical tracks, and then the closing plenary session. The abstracts associated with the poster session are in the last section of these proceedings. The agenda for the overall symposium is in Appendix A, attendees are listed in Appendix B, and continuing education information is in Appendix C of this volume. Appendices D-J are copies of presentation slides from the plenary sessions.
- Volume 2. This volume contains abstracts and presentation slides for the Enroute Care Track.
- Volume 3. This volume contains abstracts and presentation slides for the Force Health Protection Track.
- Volume 4. This volume contains abstracts and presentation slides for the Healthcare Informatics Track.
- Volume 5. This volume contains abstracts and presentation slides for the Operational Medicine (In-Garrison Care) Track.
- Volume 6. This volume contains abstracts and presentation slides for the Psychological Health/Traumatic Brain Injury Track.

The Armed Forces Institute of Regenerative Medicine: Bone and Nerve Regenerative Programs

AFMS/SG

Brig Gen Michael Yaszemski

The Armed Forces Institute of Regenerative Medicine (AFIRM) is a consortium of military medical treatment facilities, academic clinical and research institutions, and industry partners. The consortium's goal is to provide novel treatment modalities for our nation's wounded warriors in five broad areas: limb reconstruction and regeneration, burn treatment, scarless healing, craniofacial reconstruction and regeneration, and skin regeneration. Several of the AFIRM projects have reached human use, and several more are poised to do so as AFIRM enters its fourth year in the Summer of 2011. This presentation will cover the AFIRM bone and nerve regeneration programs. The nerve regeneration scaffold consists of a biodegradable polymer that is fabricated into a tube and lined with bioactive molecules. A clinical study of 6 cm nerve defects will begin this year. The bone regeneration scaffold to treat segmental bone defects consists of a structural polymer that is fabricated into a porous three dimensional scaffold, surface coated with a calcium phosphate material, and which delivers bone growth factors in a controlled fashion to direct the new bone growth. This treatment enters large animal testing in 2011.

This partnership is committed to providing tools for optimum treatment of those colleagues who have been injured in the service of our country.

The Armed Forces Institute of Regenerative Medicine: Bone and Nerve Regenerative Programs

Michael J. Yaszemski, M.D., Ph.D.

Brigadier General, USAF, MC, FS
AFMS/SG, Washington, DC
Professor of Orthopedic Surgery and Biomedical Engineering
Mayo Clinic, Rochester, MN

2011 AFMS Medical Research Symposium
National Harbor, MD
August 2, 2011

Outline

- The Armed Forces Institute of Regenerative Medicine (AFIRM)
- Clinical needs for bone and neurologic tissue regeneration
- Tissue Engineering: polymer and scaffold design, synthesis, and fabrication
- Preclinical bone and nerve studies, and translation to human use



This is a great start, but we can do better.

Armed Forces Institute of Regenerative Medicine (AFIRM)

- Two consortia working together with the US Army Institute of Surgical Research (230 scientists)
 - 27 Universities
 - 114 investigators – 30% of which are clinicians
 - 46 graduate students
 - 70 post-docs




Armed Forces Institute of Regenerative Medicine (AFIRM)

- Total 5 yr funding (2008-2013) of >\$250M
- \$100M US Government funding from Army, Navy, Air force, VA, and NIH
- \$68M Matching funds from state governments and participating universities
- \$109M in pre-existing government research projects directly related to the deliverables of the AFIRM



AFIRM Goal: To Heal our Wounded Warriors Five Areas of Emphasis

- Craniofacial Reconstruction
- Scarless Healing
- Limb Salvage and Reconstruction
- Treatment of Compartment Syndrome
- Burn Repair



AFIRM Goal: To Heal our Wounded Warriors Five Areas of Emphasis



Craniofacial Reconstruction
 Healing Without Scarring
 Limb and Digit Salvage and Reconstruction
Compartment Syndrome
 Burn Repair

Combat Injury Severity Relative to Civilian Trauma: Fractures



Grade	Military ¹	Civilian ²
I	65%	19%
II	35%	81%
III	0%	0%

¹Johnson, Burns et al. 2007
²Gustilo and Anderson 2002

The Cost of Conflict

OPERATION BRANT FREEDOM (OBF) U.S. CASUALTY STATUS
 FATALITIES AS OF: April 8, 2011, 10 a.m. EST

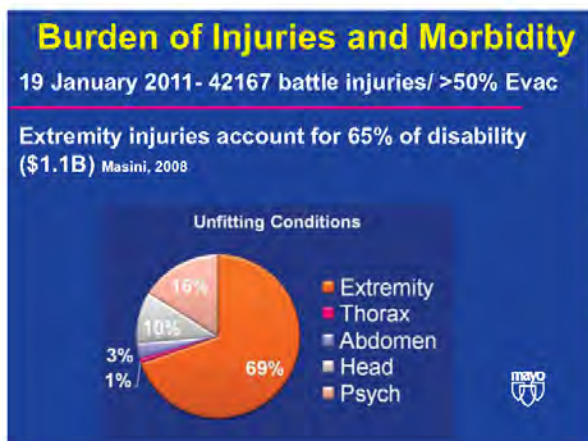
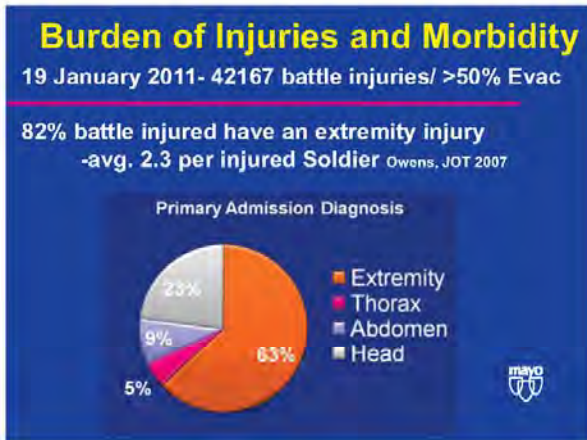
	Total Deaths	KIA	Non-Hostile	WIA
OBF U.S. Military Casualties	4,408	3,492	928	31,921
OBF U.S. DoD Civilian Casualties	13	9	4	
Totals	4,421	3,491	932	31,921

OPERATION NEW DAWN (OND) U.S. CASUALTY STATUS **
 FATALITIES AS OF: April 8, 2011, 10 a.m. EST

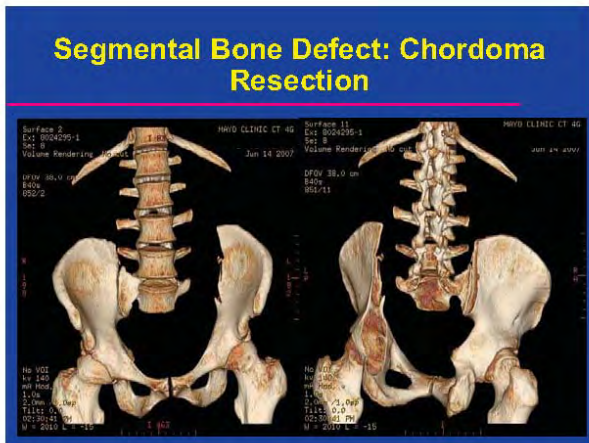
	Total Deaths	KIA	Non-Hostile	WIA
OND U.S. Military Casualties	28	12	16	127
OND U.S. DoD Civilian Casualties	0	0	0	
Totals	28	12	16	127

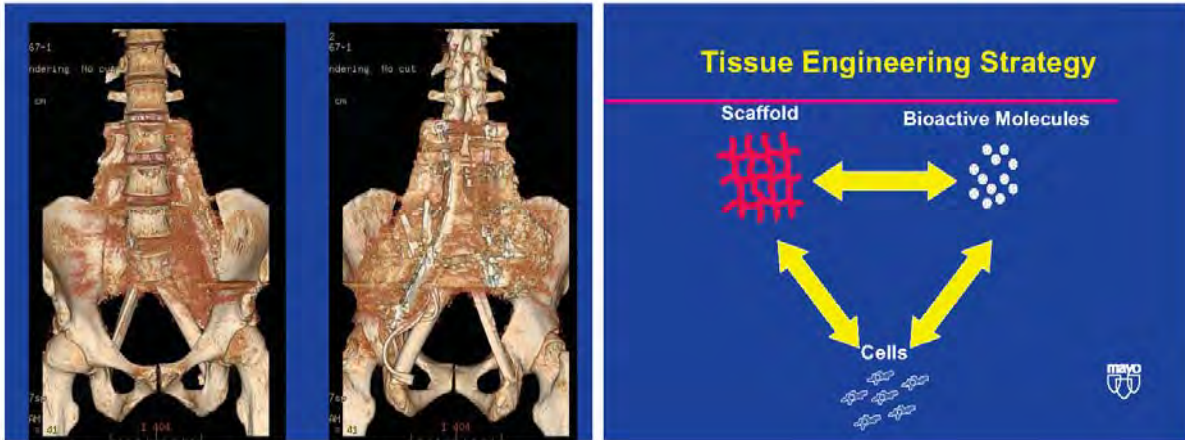
OPERATION ENDURING FREEDOM (OEF) U.S. CASUALTY STATUS
 FATALITIES AS OF: April 8, 2011, 10 a.m. EST

	Total Deaths	KIA	Non-Hostile	WIA
OEF U.S. Military Casualties	1,416	1,167	249	10,855
Afghanistan Only**				
Other Localities***	99	11	88	
OEF U.S. DoD Civilian Casualties	2	1	1	
Worldwide Total	1,517	1,179	338	10,855



- ### Bedside to Bench and Back
- Begin with clear description of a clinically relevant unmet need for patient care.
 - The solution to that need may span the range from basic research to product development.
 - Multidisciplinary input is essential. Teamwork is an absolute requirement for effective translation of a novel idea to practice.
-





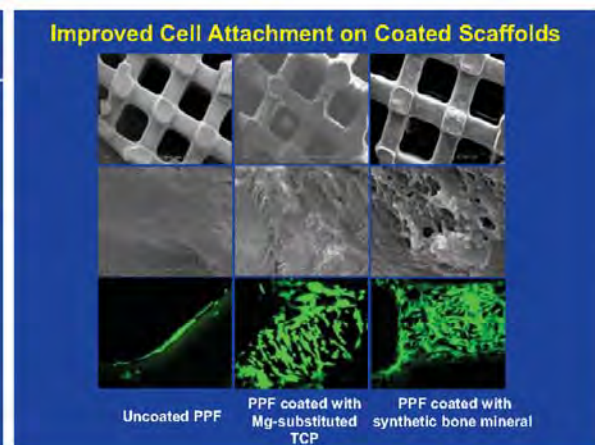
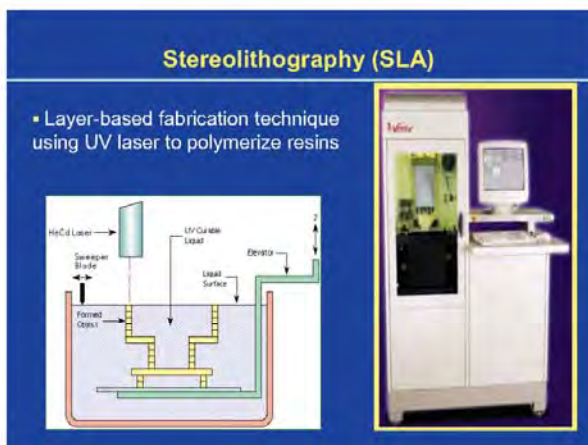
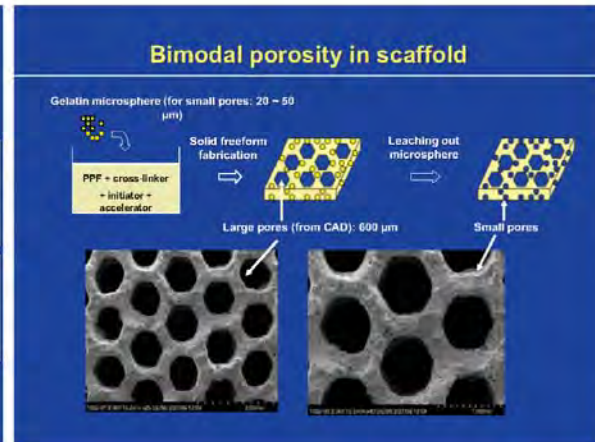
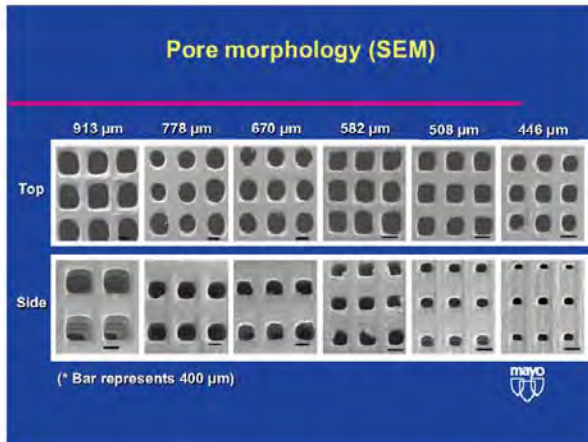
Synthetic Biodegradable Polymers

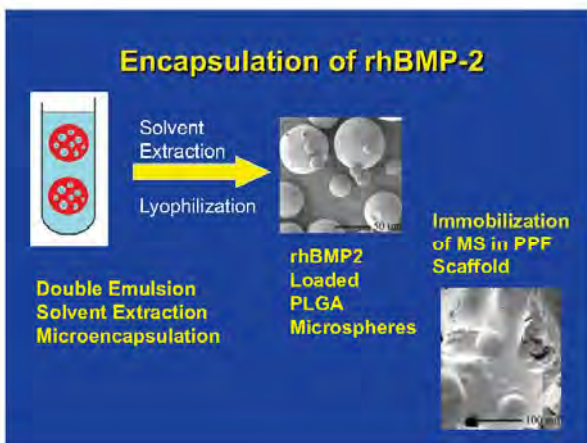
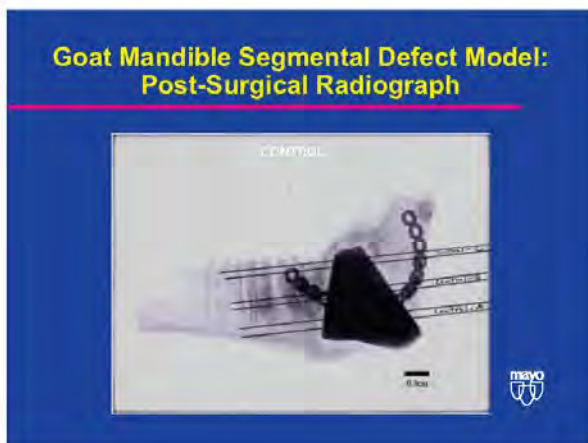
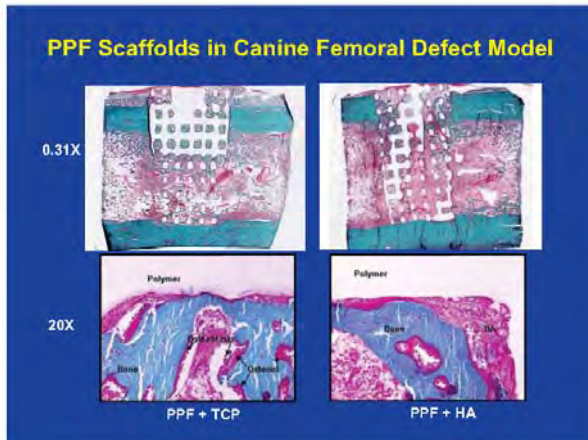
Controllable Properties

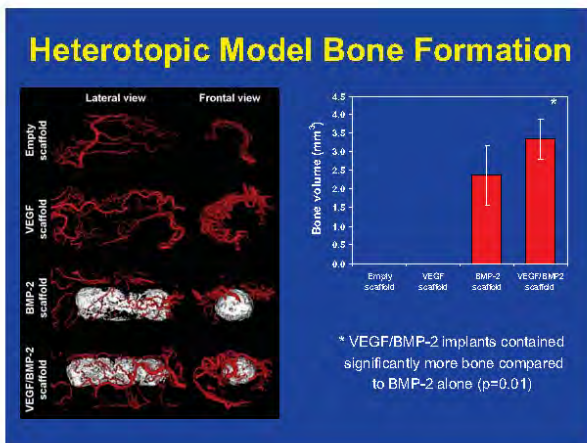
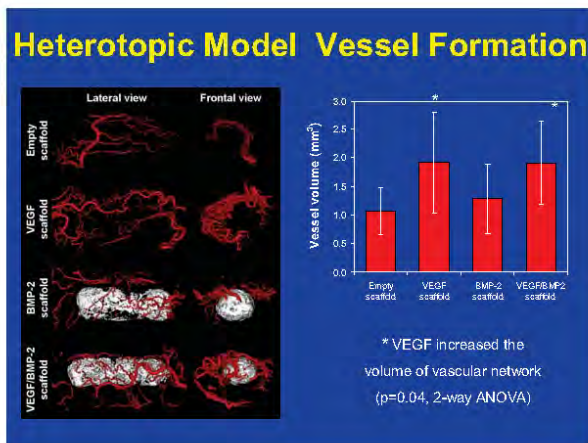
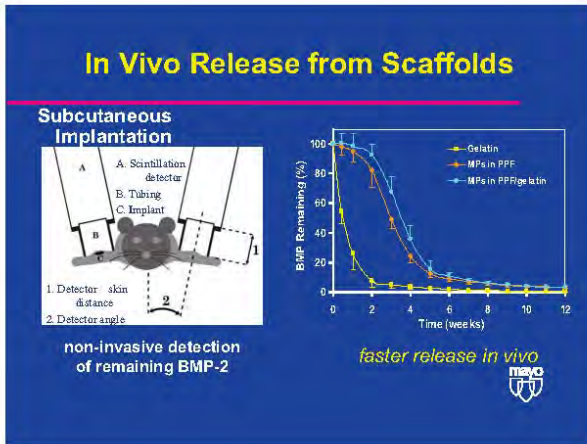
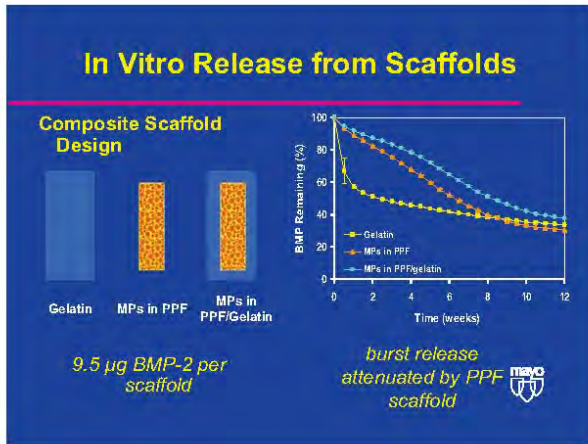
- Physical
- Chemical
- Mechanical
- Architecture
- Degradation
- Drug Release
- Tissue Formation
- Cellular Interaction

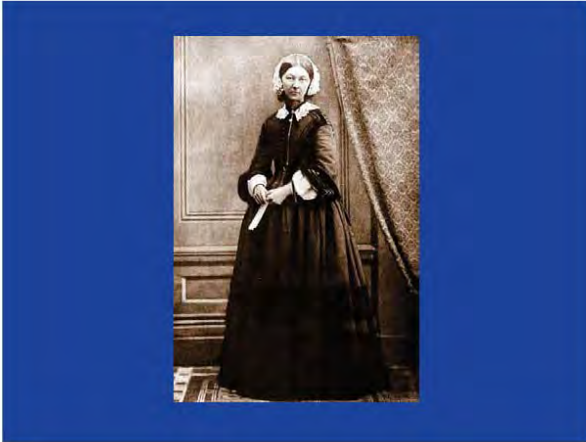
Polymer Scaffolds for Bone Regeneration

- **Preformed**
 Appropriate for non-contained defects of specified shape
 Controllable internal microarchitecture
- **Injectable**
 Appropriate for contained defects of arbitrary shape
 Random internal microarchitecture
 Minimally Invasive insertion









Nerve Regeneration

Challenges:

- Crossing gaps - injuries, tumor resections
- Distal regeneration from proximal injuries
- Accuracy of regeneration



Clinical Practice for Nerve Repair

- autologous nerve graft (sural nerve)

- disadvantages:
 - donor-site morbidity
 - limited availability
 - size mismatch

- less than perfect recovery of function



courtesy of Dr R.J. Spinner

Repair of Segmental Defects in Major Nerves



A: tyrosine-derived polycarbonate - E1002 tube (Rutgers)
 B: tyrosine-derived polycarbonate - E0502 tube (Rutgers)
 C: poly(butyl-co-sebacate) tube (MIT)
 D: PCLF tube (Mayo)
 E: PCLF-OPP tube (Mayo)
 F: PLGA tube (Mayo)
 G: autograft control

The Peripheral Nervous System

Some factors to consider

- 3-D architecture
 - tissue shape
 - extracellular matrix
- Surfaces/interfaces
 - shape
 - chemical composition
 - surface charge
- Mechanical properties
 - elasticity, deformability
 - flexibility
 - tensile strength

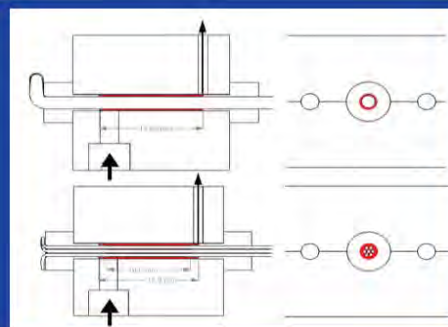


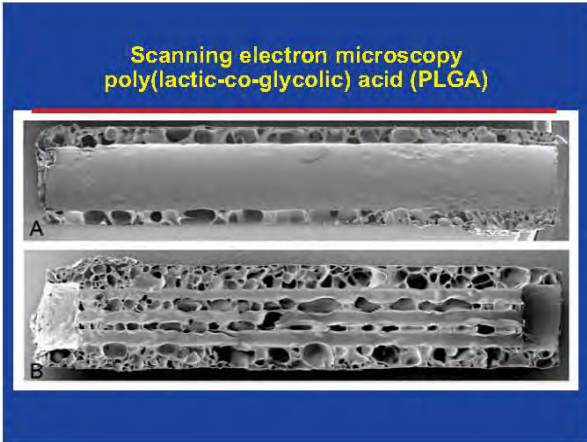
Biomimetic design - mimicking properties of original tissue

Some factors to consider

- 3-D architecture
 - tissue shape
 - extracellular matrix
- Surfaces/interfaces
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 - chemical composition
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 - tensile strength

Vacuum Molding Technique


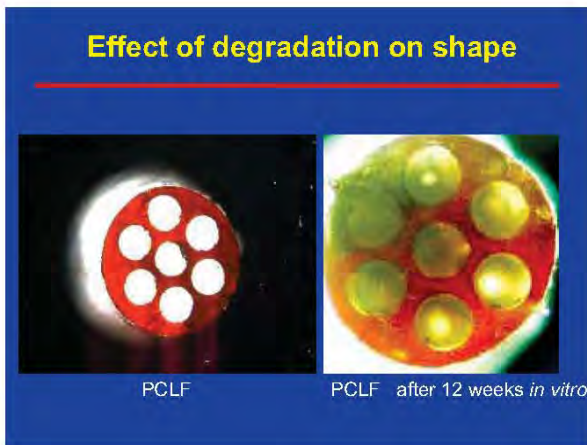
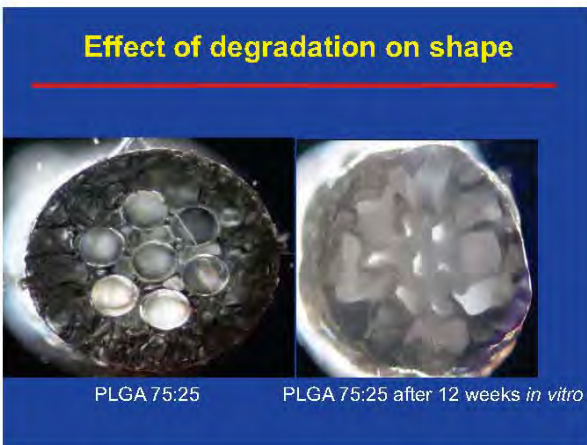


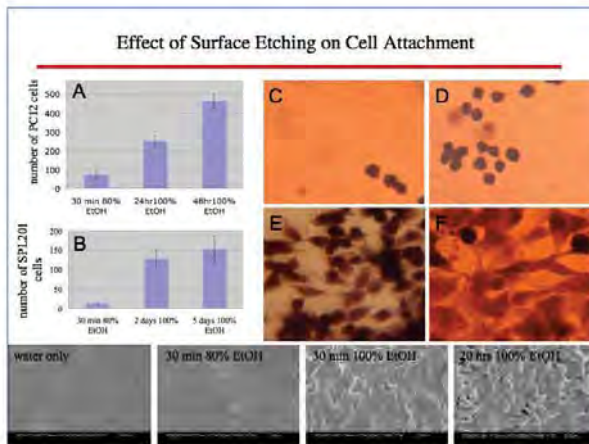


**Biomimetic design - mimicking
properties of original tissue**

Some factors to consider

- 3-D architecture
 - tissue shape
 - extracellular matrix
- Surfaces/interfaces - **shape**
 - chemical composition
 - surface charge
- Mechanical properties
 - elasticity, deformability
 - flexibility
 - tensile strength



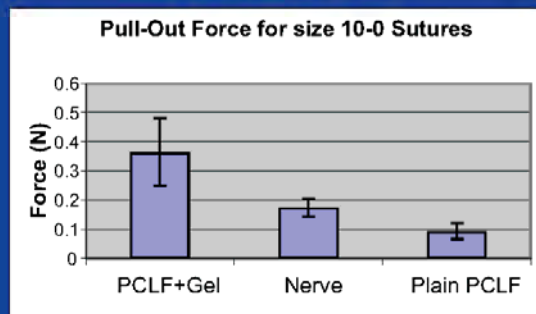
Biomimetic design - mimicking properties of original tissue

Some factors to consider

- 3-D architecture
 - tissue shape
 - extracellular matrix
- Surfaces/interfaces
 - shape
 - chemical composition
 - surface charge
- Mechanical properties
 - elasticity, deformability
 - flexibility
 - tensile strength



Suture Pull-Out



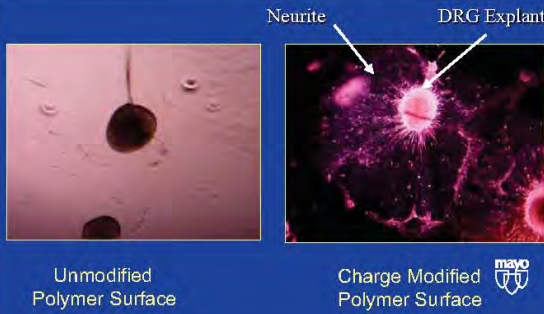
Biomimetic design - mimicking properties of original tissue

Some factors to consider

- 3-D architecture
 - tissue shape
 - extracellular matrix
- Surfaces/interfaces
 - shape
 - chemical composition
 - surface charge
- Mechanical properties
 - elasticity, deformability
 - flexibility
 - tensile strength



Dorsal Root Ganglion Explant Attachment and Neurite Outgrowth

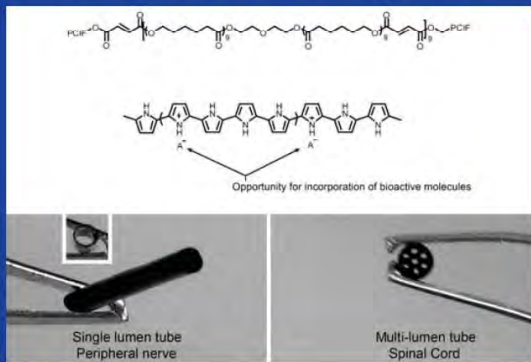


Electrically Conductive Scaffolds

- **Motivation:** direct electrical stimulation at the regeneration site
 - magnitude, frequency, interval
- Semi-interpenetrating polymer network of polypyrrole discontinuous phase within polycaprolactone continuous phase
- Initial studies: conducting polymer implant without imposed potential difference across it



Electrically Conductive Scaffolds





Biomimetic design - mimicking properties of original tissue

Some factors to consider


- **3-D architecture**
 - tissue shape
 - extracellular matrix
- **Surfaces/interfaces**
 - shape
 - chemical composition
 - surface charge
- **Mechanical properties**
 - elasticity, deformability
 - flexibility
 - tensile strength

Nerve Tube Mechanical Properties





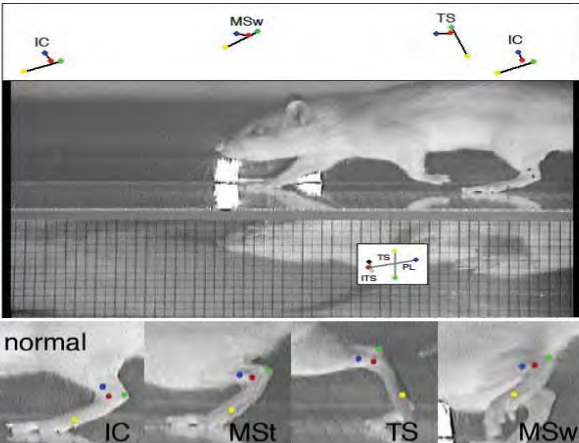
Measurement of Outcomes

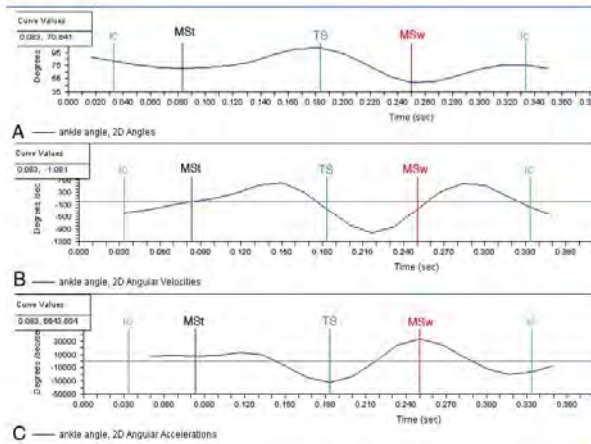
- Retrograde axonal tracing
 - Fidelity of motor re-innervation
- Nerve and muscle morphometry
 - Numbers of axons regenerating
 - Muscle fiber-type distribution
- Electrophysiology (sensory and motor NCV)
 - Electrophysiological function
- Gait analysis
 - Integrated functional analysis



Compound Muscle Action Potential







Clinical Trial

- Clinical Equipoise
- Neuropathy Evaluation: Sural Nerve Biopsy
- Institutional Review Board
- FDA: IDE, GMP



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- DOD (AFIRM)
- Mayo Foundation





U.S. Department of Health
and Human Services

Supported by the



Thank you



Designing a Safer OR to ICU Hand-Off

81 MSGS/SGCX

Lt Col Broadus Atkins

Background: Clinical transfer of patient care from one medical unit/service to another is high-risk and error-prone. We examined a tertiary VA medical center's current OR-to-ICU handover protocols, quality, and provider satisfaction and reviewed available literature on ICU patient transfers to redesign and standardize the handover process. Methods: After institutional approval, data were acquired through (1) observation of 50 OR-ICU handovers, (2) provider surveys eliciting perceived deficiencies and proposed modifications, and (3) 25 focus-group interviews evaluated with 'open coding' strategy. Methodical literature review was conducted using PubMed and ProQuest databases (keywords: 'handover', 'handoff', 'patient transfer' and/or 'post operative', 'post anesthesia', 'anesthesia', 'surgery', 'operating room', 'ICU', 'critical care', 'intensive care', 'surgical intensive care', 'admission', 'communication', and 'team'). Results: 500 published manuscripts were reviewed; 30 (6%) focused on postoperative handovers; 14 manuscripts provided evidential support for proposed solutions to handover difficulties. Handover observations, survey reviews, and interview analysis revealed that technical handover processes were often compromised by ineffective communication (simultaneous conversations or task performance during handover, artificial distractions, inconsistent role participation, inattention due to time pressure), poorly coordinated task prioritization, and incongruous priorities of task performance and information exchanged between transferring and receiving teams. A new, standardized model for OR-ICU handover was devised. Conclusions: Previous OR-ICU handover processes were flawed and not uniformly conducted. Using these data, a redesigned handover, based on structured verbal reporting and establishment of a communication platform, was constructed. High-fidelity patient simulation will allow testing, staff training, and tool refinement prior to clinical introduction of the new handover process.



Durham VAMC
Patient Safety Center of Inquiry

Designing Safer OR-to- ICU Handovers

BROADUS Z. ATKINS, Lt Col, USAF, MC
 2 AUG 11

INTRODUCTION


1999 IOM report: *To Err is Human: Building a Safer Health Care System*

- Up to 98,000 US pts/yr die from medical errors
 - Updated estimate: 191,000 US pts/yr from med errors †
 - At least 90,000 pts die of blood stream infection/year *
- Marked *med systems* as focus of safety movement
"... the biggest challenge to moving toward a safer health system is changing the culture from... blaming individuals... to one in which errors are treated... as opportunities to improve the system..."

* Morb Mortal Wkly Rep 2000; 49: 149-53.
 † HealthGrades Quality Study: Patient Safety in American Hospitals www.healthgrades.com

INTRODUCTION
 IOM Report

- Related medicine to other high-risk industries
 - Suggested "Crew Resource Management" to make medicine highly-reliable org (airline, nuclear)
- Urged health care orgs to assess local safety climate and monitor improvements
 - Heavily investigated area
 - Spawned JCAHO Nat'l Hosp Pt Safety Goals; AHRQ; VA Nat'l Center for Patient Safety (1999); Patient Safety Centers of Inquiry



Durham VAMC
Patient Safety Center of Inquiry


- One of 8 PSCIs funded by VA National Center for Patient Safety (2007)
- 2 - year study FY 2010 - FY 2011
 - Recently extended for FY 2012



Durham VAMC
Patient Safety Center of Inquiry

Investigations

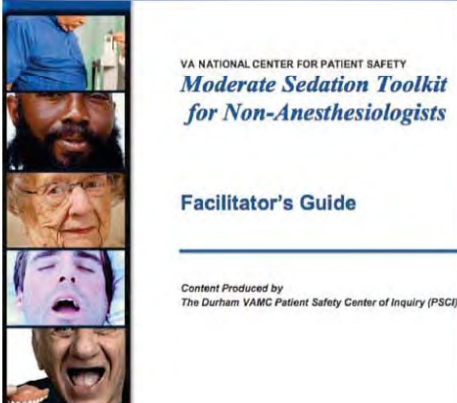
- Perioperative care
- Acute and ICU care
- Procedural care



Durham VAMC Patient Safety Center of Inquiry

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VA NATIONAL CENTER FOR PATIENT SAFETY
Moderate Sedation Toolkit
for Non-Anesthesiologists

Facilitator's Guide

Content Produced by
 The Durham VAMC Patient Safety Center of Inquiry (PSCI)

OBJECTIVE

To design a safer, more reliable process for
 OR-to-ICU patient handovers

Patient Transfer, e.g. "Handover"

"...transfer of responsibility between health care providers to ensure patient safety and continuity of care."

The Joint Commission: 2008 National Patients Safety Guidelines

Critical & vulnerable period in pt care, especially OR>> ICU:

- Complex patients/procedures
- Complex physical transfer (actually 2 transfers!)
- Multiple teams (traditions, hierarchies, different priorities)
- Time constraints

Handover Characteristics

- Increased in frequency since duty hour restrictions
- Informal, non-structured
- Not formally taught
- Subject to interpersonal conflicts

Handover Problems

- Information lapses leads to ¹:
 - Patient care delays (77%)
 - Wasted provider time (50%)
 - SAEs (33%)
- Key clinical info available in handover only 2/3 of time ²
- Handover deficiencies: most prevalent deficiency among closed med mal cases involving trainees ³
- **ICU handovers:** frequently accompanied by technical errors and info omissions ⁴

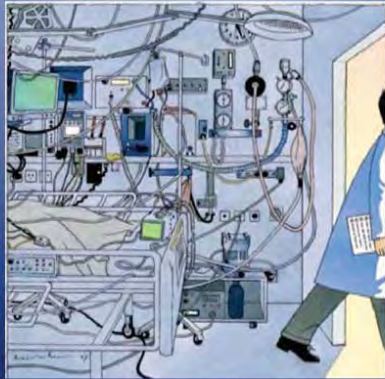
¹ Williams RG et al. Ann Surg 2007; 245: 159-248 ² Horvitz et al. Qual Saf Health Care 2009; 18: 248

*CONSIDER....

- Continuous ICU monitoring and intervention generates large quantities of information
- Information is the platform upon which medical decisions are made
- "Information corruption"
 - distortion and/or omission of patient info compared to med record
 - potential source of medical judgment errors

* Pickering BW et al. Crit Care Med 2009; 37: 2905

How/why do patient handovers fail?



“Communication Breakdown”

“There is mounting evidence that poor communication between hospital support staff and surgeons is the leading cause of avoidable surgical errors”

Landro L. Bringing surgeons down to earth. Wall St. Journal November 16, 2005

- JCAHO traced 2/3 of all adverse/sentinel events to communication errors ('95- '05)
- Etiology of poor communication: lack of standardized communication methods & team integration (Lingard Academic Med 2002)

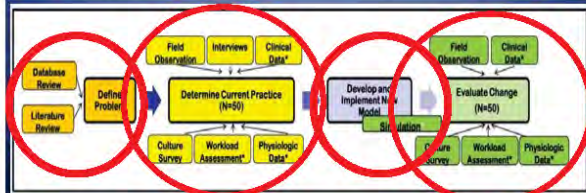
Communication Failures

Lingard et al Qual Saf Health Care 2004; 13: 330

- **Occasion (46%):** ineffective exchange due to timing
- **Content (36%):** missing/inaccurate information
- **Purpose (25%):** issues not resolved
- **Audience (20%):** key individuals were excluded

STUDY DESIGN

Gain a comprehensive understanding of issues and evidence of events surrounding OR-to-ICU handovers



The Setting



- Tertiary VAMC
- Affiliated with Duke University Hospital
- Comprehensive surgical care (CT, Vasc, Neuro, etc)
 - 2,500 surgical cases/year
- 12-bed SICU
 - Closed unit
 - 24 hour ICU attending, fellow, and intern coverage

Define the Problem

Literature Review

Sources: Pubmed, Medline, Proquest, ARHQ

Search Terms: handover, handoff, and patient transfer and combinations of these with the terms post operative, post anesthesia, anesthesia, surgery, operating room, ICU, critical care, intensive care, surgical intensive care, admission, communication, and team

Methods:


- *Titles were reviewed for possible inclusion
- *All papers dealing with OR to ICU handovers were reviewed

Results:

- *500 manuscripts reviewed
- *30 (6%) evaluated postoperative handovers

Recommendations from Literature:

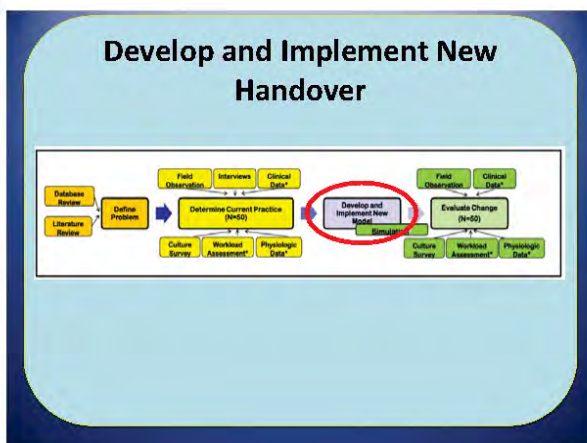
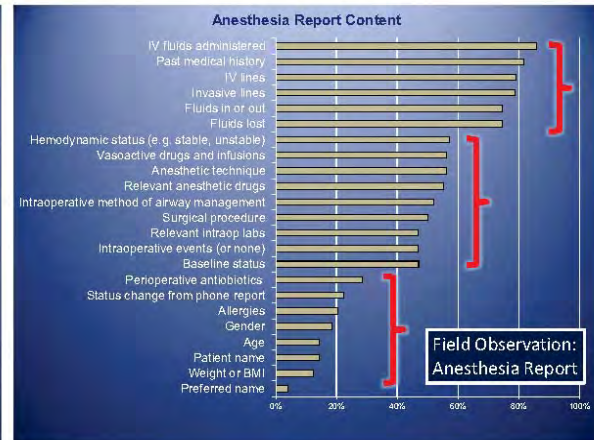
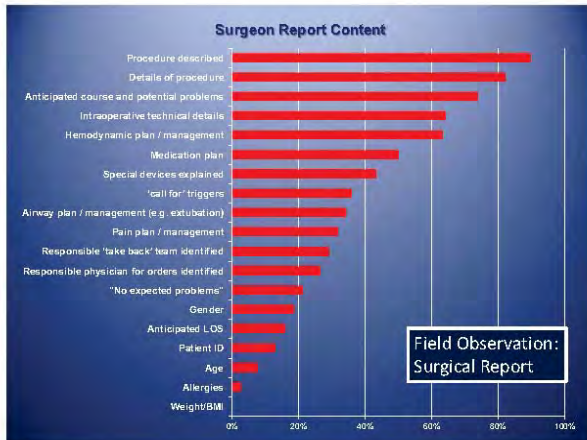
- Complete urgent care tasks before verbal handover
- Set aside time for handover communication. Avoid performing other tasks during this time and limit conversations while performing tasks
- All relevant members of the surgical and receiving teams should be present during the handover and each specialty should take turns speaking
- Provide an opportunity to ask questions and voice concerns
- Document the handover
- Confirm handover completion and readiness of receiving team to accept responsibility for the patient
- Use structured checklists to guide communication and ensure completeness of information. Use forms or reference cards as reminders
- Use protocols to standardize processes
- Provide formal team or handover training



Current Preparation


OR ANESTHESIA / CRNA			Telephone Report	Telephone Rolling Call / CPRS Handover Note			
OR CIRCULATING RN		Close Incision / Off Pump Report		Rolling Report / Surgery Completed			
ICU PRIMARY RN	Room Prep	Receive Closing Incision / Off Pump Report		Rolling Call: Notification of impending pt arrival		Patient Discharge	
			-45min			5min	

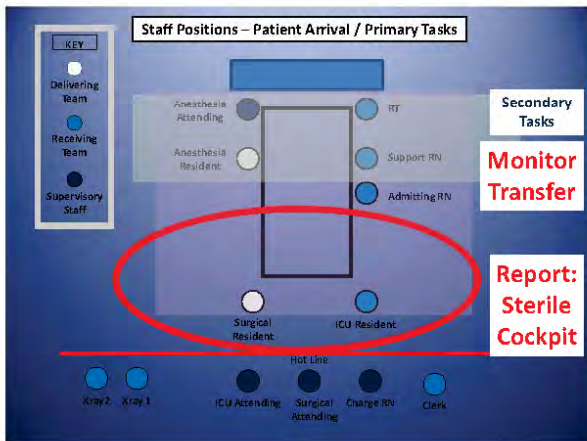
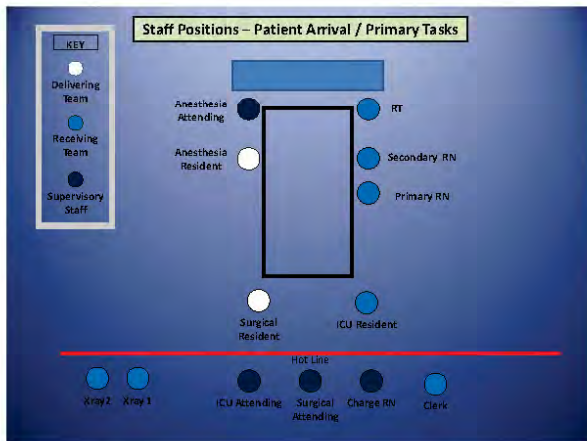
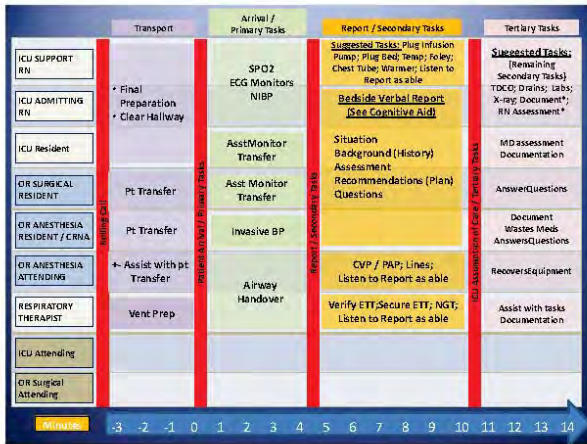
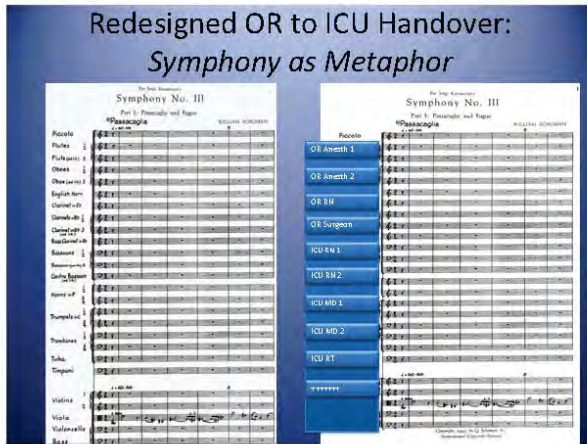
	Min	Primary RN	Secondary RN	Surgical Resident	Anesthesia resident	Anesthesia attending	ICU Attending	Respiratory Therapist
Transfer	-3	Room Preparation	Pt Care	Push Bed	Push Pump	Manual Ventilation	Pt Care	Prep-Vent
Initial Surgery Report	0	Attach Pulse oximeter (24/39)	Prep Report	Position Pump	To Vent	Await Report	To Vent	
Surgery Report	2	Place onto EKG monitor	Deliver Verbal Report	Arterial Line Transfer	Receive Surgery Report	Confirm Placement		
	5	NIBP	Central Line Transfer	Assess Patient	NOT Secure and Suction			
Anesthesia Report	7	Chest Tubes Foley	Temp Chest-Tubes Foley	Speak to Family	Deliver Verbal Report	Pacemaker Adjust	Receive Surgery Report	Assist with Bedside Tasks
	10	Assess Patient	Document	Returns to answer Questions	Completes Notes/Wastes Meds	Recovers Equipment	Departs or Assesses Patient	
Team Depart	14	Draw Labs						



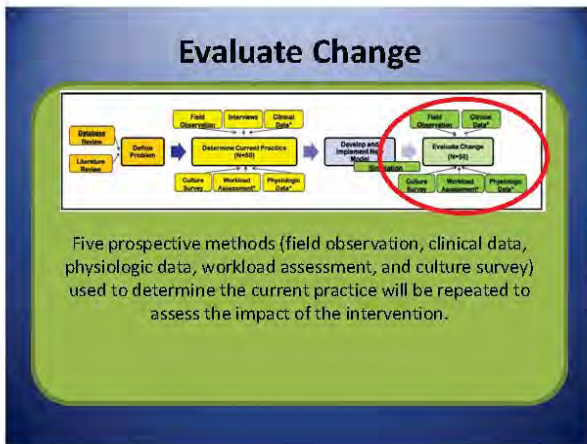
Briefings

- Fundamental to CRM
- Types:
 - Pt-centered briefings
 - Administrative briefings
 - Debriefings
- Goals of briefings:
 - Promotes real-time exchange of information
 - Sets stage for communication and common understanding
 - Gives people permission to be frank and honest
 - Gets all on "same page" & provides structure for collaborative planning





<input type="checkbox"/> Anesthesia: <input type="checkbox"/> Isolation Precautions <input type="checkbox"/> Pt Status Routine vs. Complex <input type="checkbox"/> Patient Name and DOB <input type="checkbox"/> Surgery: <input type="checkbox"/> Diagnosis <input type="checkbox"/> Procedure / Technical Details		Pt Name: _____ DOB: _____ SSN: _____
<input type="checkbox"/> Anesthesia: <input type="checkbox"/> Anesthesia/ Sedation/ Airway <input type="checkbox"/> In / Outs (fluids, EBL) <input type="checkbox"/> Pertinent Intra op Events <input type="checkbox"/> Pertinent Hx / Home Meds <input type="checkbox"/> Allergies <input type="checkbox"/> Baseline VS / Functional Status		
<input type="checkbox"/> Anesthesia: <input type="checkbox"/> Airway <input type="checkbox"/> IV Lines <input type="checkbox"/> Infusions <input type="checkbox"/> Pacer <input type="checkbox"/> Surgery: <input type="checkbox"/> Surgical Lines / Special Equip		
<input type="checkbox"/> Surgery: <input type="checkbox"/> Anticipated Course <input type="checkbox"/> Hemodynamic management <input type="checkbox"/> Pain management <input type="checkbox"/> Call back triggers <input type="checkbox"/> Postrenal Problems All: <input type="checkbox"/> Questions / Concerns Anesthesia: <input type="checkbox"/> Consensus / Conclude Report		
NOTES		



Can Aviation-Based Team Training Elicit Sustainable Behavioral Change?

Harry C. Sax, MD; Patrick Browne, BMT; Raymond J. Mayowski, MD; Robert J. Panzer, MD; Kathleen C. Hinzner, MD; Rebecca L. Burke, RN, MS; Sandra Coletta, MBA

Objective: To quantify effects of aviation-based crew resource management training on patient safety-related behaviors and perceived personal empowerment.

Design: Prospective study of checklist use, error self-reporting, and a 10-point safety empowerment survey after participation in a crew resource management training intervention.

Setting: Seven hundred twenty-two-bed university hospital; 247-bed affiliated community hospital.

Participants: There were 857 participants, the majority of whom were nurses (50%), followed by ancillary personnel (28%) and physicians (22%).

Main Outcome Measures: Preoperative checklist use over time; number and type of entries on a Web-based incident reporting system, and measurement of degree of empowerment (1-5 scale) on a 10-point survey of safety attitudes and actions given prior to, immediately after, and a minimum of 2 months after training.

Results: Since 2003, 10 courses trained 657 participants in multiple disciplines. Preoperative checklist use rose (7.9% in 2003, 8.6% in 2004, 9.4% in 2005, 9.8% in 2006, and 10.0% in 2007). Self-initiated reports increased from 709 per quarter in 2002 to 1481 per quarter in 2008. The percentage of reports related to environment as opposed to actual events increased from 15.9% prior to training to 20.3% subsequently ($P < .01$). Perceived self-empowerment, creating a culture of safety, rose by an average of 0.3 point in all 10 realms immediately posttraining (mean [SD] rating, 3.0 [0.07] vs 3.3 [0.05], $P < .05$). This was maintained after a minimum of 2 months. There was a trend toward a hierarchical effect with participants less comfortable confronting incompetence in a physician (mean [SD] rating, 3.1 [0.8]) than in nurses or technicians (mean [SD] rating, 3.4 [0.7] for both) ($P > .05$).

Conclusions: Crew resource management programs can influence personal behaviors and empowerment. Effects may take years to be ingrained into the culture.

Arch Surg. 2009;144(12):1133-1137

Variations in the Management of Hypertension in Active Duty Airmen – JNC7 Revisited

AFMSA/SG6H

Dr. Celan Alo

A cross-sectional retrospective design was employed to describe the management of hypertension by estimating the patterns of use of antihypertensive agents and lifestyle modification (LSM) counseling in a cohort of hypertensive patients among active duty airmen (ADAF). We compared available data for 2003 and 2009. All eligible ADAF were screened and classified as having hypertension based on two elevated blood pressure (BP) readings, diagnostic information in the form of ICD 9CM codes, and prescription drug use from pharmacy dispensing records. All available BP data were extracted from the Preventive Health Assessment and Individual Medical Readiness (PIMR) files. For this study, we only included the most recent documented BP reading during the reporting calendar year. For each study year, we compared the its representative BP reading with the following year's representative BP measurement to identify those with hypertension based on two elevated BP readings. Data show that the number of ADAF who were hypertensive or had BP in the hypertension range increased significantly from 7 percent in 2003 to 9 percent in 2009 ($p < .0001$). Of these, 91 percent are either diagnosed or treated and about 9 percent are untreated. About 33 percent of study subjects had any LSM counseling. Only 16 percent of study subjects who were receiving antihypertensive drugs were on thiazide diuretics while a large proportion was receiving ACE inhibitors (28 percent) followed by beta blockers (17 percent). Overall BP control rate was 80 percent.

Headquarters U.S. Air Force

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Variations in the Management of Hypertension in ADAF – JNC7 Revisited



Celan Alo, MD, MPH
Lt Col David Carnahan, MD, MSCE
Healthcare Informatics Division,
AFMSA/SG6H

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Background

- Hypertension (HTN) is the most common primary diagnosis in the US with more than 46.3 million office visits annually ¹
- HTN affects 1 in 3 American adults ²
- An estimated ~76 M adults ≥20 years of age have HTN
- HTN is a significant risk factor for coronary heart disease, the leading cause of death in the US

¹ Schappert SM, Reichsteiner EA. *Natl Health Stat Rep.* 2008;6:1-23.

² Fields LE, et al. The burden of adult hypertension in the United States. *Hypertension.* 2004;44:398-404.

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Rationale

- **Costs: estimated at nearly \$73.4 billion for 2009¹**
 - Expenditures for medical services have been rising, especially prescription drug costs²
- Available national data are mostly from cross-sectional surveys, epidemiological investigations, community studies, HMOs, and reports of physician office practices³ using different populations -- **None of these studies are using AF population data**

¹ Lloyd-Jones, et al. Heart disease and stroke statistics – 2009 update. *Circulation* 2009;119(3):e21-181.

² Devine JW, Trice S, Sprigden SL, Bacon TA. Trends in Prescription Drug Utilization and Spending for the Department of Defense, 2002-2007. *Military Medicine.* 174: Sept 2009

³ Wang TJ, Vasan R. Epidemiology of Uncontrolled Hypertension in the United States. *Circulation.* 2005;112:1651-1662.

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JNC7 Features and Key Messages

- Adoption of healthy lifestyles
- Thiazide-type diuretics should be included in initial therapy
- BP control only occurs with motivated patients who trust their clinician
- Benefits of lowering BP
 - Incidence of stroke reduced by an average of 35-40 percent
 - Incidence of coronary events reduced by 20-25 percent
 - Incidence of congestive heart failure reduced by more than 50 percent

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JNC 7 Changes in Classification of Blood Pressure

Changes in Blood Pressure Classification

JNC 6 Category ¹	SBP/DBP	JNC 7 Category ²
Optimal	<120/80	→ Normal
Normal	120-129/80-84	→ Prehypertension
Borderline	130-139/85-89	→ Prehypertension
Hypertension	≥ 140/90	→ Hypertension
Stage 1	140-159/90-99	→ Stage 1
Stage 2	160-179/100-109	→ Stage 2
Stage 3	≥ 180/110	→ Stage 2

¹ The sixth report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Arch Intern Med 1997;157:216-234.
² The seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. JAMA 2003;289:2560-2571

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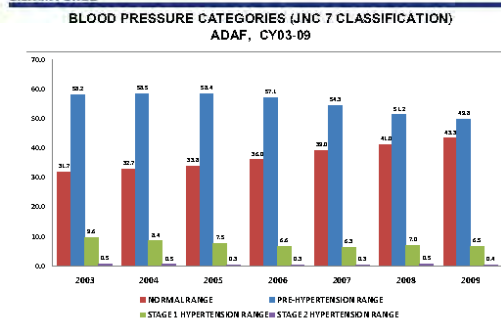
Why Prehypertension

- Based on data from epidemiologic studies that demonstrated a linear relationship between BP and cardiovascular risk¹
- The risk of cardiovascular disease (CVD), beginning at 115/75 mmHg, doubles with each increment of 20/10 mmHg
- Individuals with BP levels in the prehypertension range are at increased risk of developing hypertension and CVD later in life compared with those with BP in the normal range
- Identification of patients will allow early intervention such as health-promoting lifestyle modifications to prevent CVD

¹ Lewington S, Clarke R et al. Lancet. 2002;360(9349):1903-1913

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AF Measured BP Study



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JNC 7 Treatment Guidelines

Treatment Guidelines				
BP Classification	SBP mmHg*	DBP mmHg	Lifestyle Modification	Drug Therapy**
Normal	<120	and <80	Encourage	No
Prehypertension	120-139	or 80-89	Yes	No
Stage 1 HTN	140-159	or 90-99	Yes	Single Agent
Stage 2 HTN	≥160	or >100	Yes	Combo

* Treatment determined by highest BP category
 ** Consider treatment for compelling indications regardless of BP
 FIG Express JAMA 2003 Sep 10;290(11):1314

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Lifestyle Modifications (LSM) To Prevent and Manage Hypertension

Recommendation	Modification	Approximate SBP Reduction (Range)
Weight reduction	Maintain normal body weight (body mass index 18.5-24.9 kg/m ²).	5-20 mm Hg/10 kg weight loss
Adopt DASH ¹ eating plan	Consume a diet rich in fruits, vegetables, and low-fat dairy products with a reduced content of saturated and total fat.	6-14 mm Hg
Dietary sodium reduction	Reduce dietary sodium intake to no more than 100 mmol per day (2.4 g sodium or 6 g sodium chloride).	3-8 mm Hg
Physical activity	Engage in regular aerobic physical activity such as brisk walking (at least 30 minutes per day, most days of the week).	4-9 mm Hg
Moderation of alcohol consumption	Limit consumption to no more than 2 drinks (eg, 24 oz beer, 10 oz wine, or 3 oz 80-proof whiskey) per day in most men and to no more than 1 drink per day in women and lighter-weight persons.	2-4 mm Hg

¹DASH indicates Dietary Approaches to Stop Hypertension.

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HTN Treatment Goal

"THE GOAL IS TO GET TO GOAL"	
Hypertension	-plus- Diabetes or Renal Disease
<140/90 mmHg	<130/80 mmHg

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METHODS

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What we did



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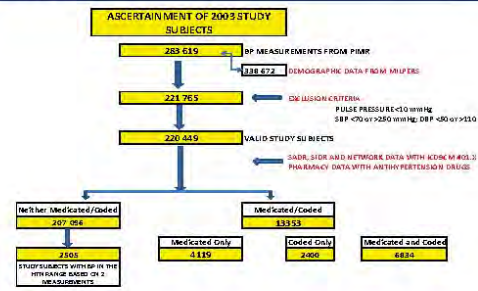
Data Sources

- PIMR – for BP measurements
- SADR, SIDR, and Purchased Claim Data – for coded diagnoses of hypertension
- Pharmacy Data (PDTS) – for data on antihypertensive prescriptions
- Military Personnel Files (MIPers) – for demographic data
- SADR – to identify ADAF who were counseled in lifestyle modifications

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Ascertainment of Study Subjects



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Neither Medicated Nor Coded Subjects with BP in the HTN Range

Study Subjects with BP reading based on 2 Measurements		2004 BP READING			
		NORMAL	Pre-HTN	STAGE 1 HTN	STAGE 2 HTN
NORMAL	37,454	19,780 52.8%	16,685 44.5%	961 2.6%	38 0.1%
Pre-HTN	68,407	18,860 27.6%	45,442 66.4%	5,872 8.6%	233 0.3%
STAGE 1 HTN	10,254	1,062 10.6%	6,810 66.5%	2,211 21.6%	143 1.4%
STAGE 2 HTN	433	41 9.5%	241 55.7%	112 25.9%	39 9.0%
		TOTAL = 2,505			

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Management Patterns

- ICD-9 and CPT codes related to lifestyle modifications (LSM) counseling were identified from the Standard Ambulatory Data Record (SADR)
- Prescription fills for any antihypertensive drugs were identified from pharmacy records (PDTS)

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Analysis

- Describe the study subjects by age groups, gender, race and rank groups and comparing with the total ADAF population
- Proportion of study subjects who were counseled on any hypertension-related lifestyle modifications
- Distribution of drug classes among study subjects who were prescribed antihypertension drugs
- BP control rates (<140 mmHg SBP and <90 mmHg DBP) for those who had any counseling for lifestyle modifications and/or prescribed antihypertension drugs

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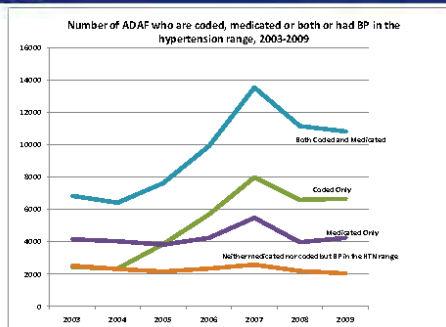
RESULTS

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Overall Results



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Demographics

	STUDY SUBJECTS		TOTAL ADAF	
	7-year average	7-year average	7-year average	7-year average
AGE GRP	(%)	(%)	(%)	(%)
<15	13.9	13.9	13.9	13.9
15-24	12.5	12.5	12.5	12.5
25-34	15.4	15.4	15.4	15.4
35-39	26.1	26.1	26.1	26.1
40-44	21.5	21.5	21.5	21.5
45+	10.7	10.7	10.7	10.7
Age, mean ± SD	39.5 ± 8	39.5 ± 8	39.4 ± 8	39.4 ± 8
GENDER				
Females	16	16	15.4	15.4
Males	84	84	80.6	80.6
RACE				
White	69.7	69.7	74.7	74.7
Black	22.7	22.7	15.8	15.8
Other	7.7	7.7	9.5	9.5
RANK				
Jr. Enlisted	13.8	13.8	21.8	21.8
NCOs	68.2	68.2	47.6	47.6
Officers	18.0	18.0	20.6	20.6

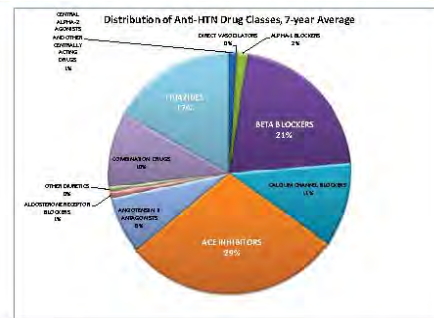
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Lifestyle Modification Counseling

STUDY SUBJECTS	ANY HTN RELATED COUNSELING, %						
	2003	2004	2005	2006	2007	2008	2009
Medicated and Coded Group	9.6	21.5	26.4	32.8	34.3	30.9	32.6
Neither Medicated nor Coded but BP in the HTN range	26.7	29.2	29.5	30.5	22.9	20.4	23.2

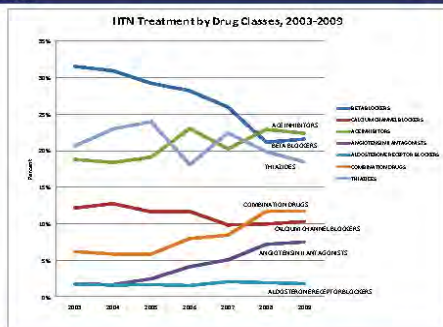
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Prescribing Patterns



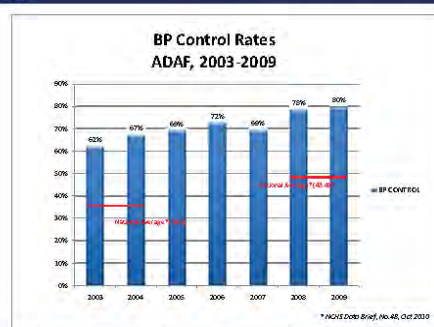
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Time Trends in Use of AntiHTN Drugs



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BP Control Rates



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Limitations

- Blood pressure data was taken within the PIMR system – we know there is variability in the performance of these BPs
- Measured BPs were taken about 12 months apart
- Administrative data
- No medical record review
- Could not ascertain intensity of and adherence to LSM intervention
- Could not ascertain adherence to pharmacotherapy

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Overall Findings

- About 10 percent of total ADAF personnel are hypertensive or have BP in the hypertension range
 - 23 percent are coded only
 - 20 percent are medicated only
 - 45 percent are coded and medicated both
 - 11 percent are untreated
- Substantial improvement in documentation of LSM counseling during the study period
- 17% of study subjects who were receiving antihypertension drugs were on thiazide diuretics
 - A large proportion were receiving ACE inhibitors (27%), followed by BB (22%)
- Overall results showed that hypertension in ADAF personnel are very well controlled

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Background

- AF Hypertension Study Group
 - Col Daniel Burnett, MD, MPH
 - Col Al Bonnema, MD, MPH
 - Vince Fonseca MD, MPH
 - Susan Chao, MS

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Questions

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Clinical Trials

Comparative Drug Trials in Patients with HTN*		
Trial Name	Drug Comparison	Primary Outcome
STODIN-2	Thiazide type diuretic plus beta blocker vs ACE inhibitor plus Calcium Channel blocker	No significant difference
ALLHAT	Thiazide type diuretic vs ACE inhibitor vs Calcium Channel blocker	No significant difference
INVEST	Thiazide type diuretic plus beta blocker vs ACE inhibitor plus Calcium Channel blocker	No significant difference
ASCOT	Thiazide type diuretic plus beta blocker vs Calcium Channel blocker plus ACE inhibitor	No significant difference
LIFE	Angiotensin receptor blocker vs beta blocker	Angiotensin receptor blocker superior
ANBP2	Thiazide type diuretic vs ACE inhibitor	ACE inhibitor superior in men only
ACCOMPLISH	ACE inhibitor plus Thiazide type diuretic vs ACE inhibitor plus calcium channel blocker	ACE inhibitor plus calcium channel blocker superior

*C. Nabelson AM. The Hypertension Paradox - More Uncontrolled Disease Despite Improved Therapy. NBM. 36(5) Aug 27 2009.

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Readiness Optimization through Surgical Outcomes Surveillance

USAF MC

Lt Col John Tokish, MD

Disease and non-battle injuries (D/NBI) of the musculoskeletal system pose a threat to readiness at the unit and individual levels within the US Military. It is known that “in-garrison” musculoskeletal conditions are highest contributor to medical profiles, disability, and separation from military service. Conservative estimates of musculoskeletal D/NBI from 2002 – 2010 within the military active component were 75,000 in the knee and 40,000 in the shoulder. Additionally, 150,000 surgeries to correct these injuries were performed from 2004-2010. To date, a Department of Defense (DoD) surveillance program for musculoskeletal D/NBI or for the surgical outcomes to treat these injuries does not exist. A recent literature review found that cost-benefit studies (using return to duty as the outcome measure) which examine the efficacy of surgical interventions to treat D/NBI musculoskeletal injuries are lacking. In 2004, the Society of Military Orthopedic Surgeons sought to address this void in the literature and the persistent lack of evidenced-based medicine to support surgical decisions to treat musculoskeletal D/NBI; both within the context of the DoD mission. The DoD’s powerful electronic medical records within the Military Health System (MHS) afford the exceptional opportunity to develop a surveillance program for such. This presentation will encompass the development of such a surveillance program that is being led by the US Air Force. Included will be the regulatory and privacy requirements that have been met to establish this central database using health care data from MHS as well as future directions.

Readiness Optimization through Outcomes Research

John M. Tokish, MD
Tripler Army Medical Center
Orthopedic Surgery Residency Program Director
SOMOS Research Consortium Founder/ Director



Scope

- This is a talk about Readiness: as an outcome measure
- Civilian population has nothing like it
- "Return to activity" is subjective, self-limited, and for the most part, optional
- In contrast, physical fitness an occupational necessity- in peace time, physical fitness tied to advancement, promotion



But in War

- Physical fitness is paramount to survival
 - Individual
 - Unit
- In fact, "Readiness" is really just physical fitness on a population level
- Without it, we fight nothing



The Blast injury: The signature wound of GWOT

- GWOT: 2001-2011
- Emergence of the IED
- 1400 amputations since 9-11
- Too many



Advances in Blast Care

- Solemn Obligation to the Wounded Warrior
- Changing attitudes about potentials
- Return to Duty and Readiness
- We have no more important mission



GWOT: The Blast Injury/ Amputation

- Unbelievable progress in the care of the amputee/ blast injured patient
- Congressional research
 - OETRP 2006
 - \$19.5 M
- PRORP 2008: \$40M
- Centers for the Intrepid



But Take a Broader view A Macro-Readiness Perspective

- What keeps our warriors off the field?
- What keeps them from returning to battle?
- What are the big threats to Fielding a Battlefield team?



The ONBI: Readiness' Silent Assassin

- Extremity injuries account for over 2/3 of all inpatient hospital costs and disability payments; warriors
- "In Garrison" musculoskeletal conditions are largest cause of profiles, disability, and separations from the DOD
- Posttraumatic osteoarthritis is single greatest cause of disability in the DOD (Cross, EWI 2010)



But Dr. Tokish, we remain a nation at war: -
 let's concentrate on battlefield injuries

- 60% of all battlefield injuries are musculoskeletal
- Goodman et al (SOMOS 2009) followed an Army Brigade Combat Team during the "Surge" in Fallujah for injuries that removed soldiers from the battlefield
- 75% of injuries were non-battlefield related



Air Force Grenade Launcher

Musculoskeletal DNBI

- In contrast to the 1400 Warriors lost to the fight because of amputation consider:
- ACL injury: 25,000 in the same time period
- Chondral injury: 30,000
- Shoulder labral injury: 20,000



But those are "minor" injuries that can be fixed and returned

- | | |
|--|--|
| <ul style="list-style-type: none"> • Scenario: • A commander has a troop who injures his ACL. He asks the orthopedic Surgeon, "Will this soldier get back to duty, and how long will it take?" | <ul style="list-style-type: none"> • Answer: • Almost unanimous opinion of orthopedic surgeons: • Yes: will get back-90+% • 4-6 months |
|--|--|

This answer comes from CIVILIAN DATA

- If an "elite" athlete can get back 90% of the time, surely an "average soldier can do the same"
- But this has rarely been evaluated
- Is this true in a military population

Return to Duty, ACL injury 2005-2010

- Tokish, unpublished data
- ACL reconstructions done at single institution over 5 year period:
 - 33% remain **MEDICALLY NOT READY** (minimum 2 yr f/u)!
 - For those who did return: only 39% did so by 6 months!
 - Avg return to duty was nearly 1 yr
 - And 16% were still on profile at 2 yrs

Look, there's a limited pot of research money, and there are other groups that can do your "sports research"

- AOSSM, AANA- true
- But completely **WRONG**
- Because our population has RETURN TO FULL ACTIVITY NOT AS A HOBBY, BUT AS A JOB REQUIREMENT
- Can you imagine telling this guy "hey I need the day off- my patella tendon is super sore"



Can we really compare the knee blast injury to the knee "sports" injury

- Depends on your outcome measure
- If we look through the lens of RETURN TO DUTY/ READINESS
- The "sports knee" injury is a temporary setback and should get back, right?



Meet Jake C.

- 25 yo Army Infantry Officer
- Injured his knee in Unit fitness soccer game **2008:**
- ACL, bad medial meniscus tear
- ACL reconstruction, partial menisectomy, standard stuff




Jake C

- Injured October
- **November 2008**: ACLR/ med meniscectomy
 - 6 month profile for “rehab”
- **May 2009**: patellar tendinitis, extended profile 3 mos- missed deployment
- **Sept 2009**, stepped “funny” and felt knee go out
 - Sent to PT for 3 months, but no improvement, so MRI obtained, “Graft re-tear”
- **Jan 2010**, Revision ACL recon, noted “grade 3 chondral damage” in knee-
 - Missed deployment: 3 month extension on profile
- **Sept 2010**: knee pain with running, diagnosed with “early arthritis”
- **March 2011**: Missed deployment, MEB
- “Im done, doc”
- **May 2011**: Pending separation

That’s too bad

- No, it’s too common.
- The ACL is only the beginning:
 - The majority of ACLs eventually develop arthritis
 - Especially if meniscal injury
 - This guy isn’t going back to duty
- 3000 of “these guys” every year



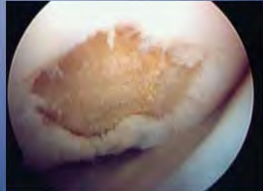
Meet Michael L.

- 22 yo Marine
- Knee pain “since basic”
- Diagnosed with chondral defect of the knee
- Seen by primary care
- Sent to PT 3 mos
- Continued pain
- MRI: dime sized defect




Bad problem for Michael, Bad problem for the military

- 2005-2010
- 13,000 + chondral procedures done in knee in US DOD
- What should we do?



When Can I get back, Doc?

- 6 weeks non weightbearing
- At 3 mos, begin running
- 7-9 mos return to full activity
- Total time on profile: 12 mos so far...
- But then he and his 13000 counterparts go back, right?



ML: Already out 3 mos

- Referred to Orthopedics
- Confirmed diagnosis
- 3 basic choices:
 - Microfracture- simple, good pain relief, but may not be durable...free
 - OATS- surgeon dependent, long recovery, but very good return to sports: \$20k per surgery
 - ACI: Tech challenging/ 2 procedures, not clear if better than other two: \$30k per pop.



- Allograft OATs

So how do we make this decision?

- Want the most cost effective way to maximize return to duty- readiness
- World literature addressing this question:



Goose egg- Zero studies in the literature

Bottom line:

- We have no idea what the return to duty rate is for ANY of these injuries- Because the outcome measure we must have isn't tracked
- We therefore have no idea which approach to take to the chondral defect
- Cost analysis, disability, and most importantly, patient outcome
- Readiness

The SOMOS Research Collaborative

- 2004- SOMOS Annual meeting
- Goals:
 - Establish Standardized Outcomes measures
 - Establish a centralized IRB for multicenter research
 - Establish central database for combining data

SOMOS Research Collaborative Strengths

- Huge Homogenous population
- Single med record system
- Single Payor Health care system
- Culture of collaboration



Strength: Air Force Football: Holders of the CINC Trophy

SOMOS- Weaknesses

- Poor infrastructure
 - Hard to ask a surgeon to do research if he's busy typing his note into ahlt
 - No admin support for the guys in the trenches
- Frequent turnover
 - Commitments / PCS moves- hard to establish patient base
- IRB process in the military
 - Safe, thorough, decentralized, difficult



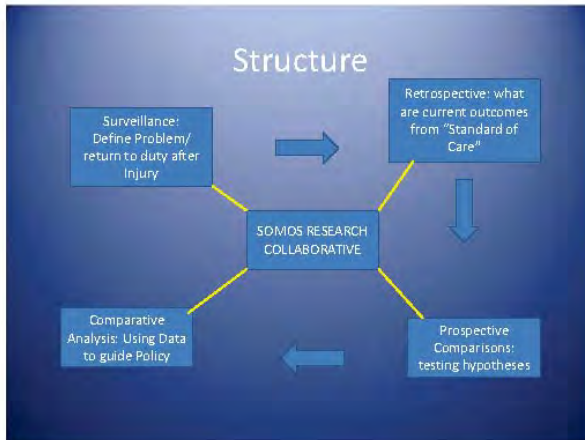
Weakness: Navy Football

Proof of concept: Pan Labrals

Arthroscopic Repair of Circumferential Lesions of the Glenoid Labrum

By LT COL John M. Tokish, MD, USAF, MC, MAJ Gallon M. McBratney, MD, USAF, MC, CDR David L. Solomon, MD, MC, USN, LT Laura LeClerc, MD, MG, USN, LCDR Christopher R. Dering, MD, MG, USN, and CDR Matthew T. Poretschke, MD, MC, USN
 Investigation performed at the United States Air Force Academy, Colorado Springs, Colorado, and the Naval Medical Center San Diego, San Diego, California

- Tokish, JBJS 2009, 2010
- Collaborative effort of USAF Academy/ NMC SD
- AAOS annual award in Sports Medicine
- 41 patients (largest previous series: 7)
- Only 2 MTFs participated: imagine what we can do!



Surveillance: Define Problem/ return to duty after Injury

- Databases- M2, DMED, DMSS, Army Physical Disability Program,
 - Aggregate demographics:
 - How many of which kind of surgery
- Return to duty:
 - Profiles/ MEBs/ Did they return, how long did it take?
- What is the return to duty rate for Orthopedic Surgical Procedures?

Retrospective: what are current outcomes from "Standard of Care"

- Standardized data collection: traditional retrospective cohorts
- Improves on surveillance with validated outcomes measures
- What is quality of life, and patient related outcomes of Orthopedic Surgery in the military? How does it compare to the civilian population?

Prospective Comparisons: testing hypotheses

- Must have standardized set of data:
- Validated outcomes scores:
 - Web based, PATIENT ENTERED subjective scores
 - Simple input from surgeon
 - Combinable and mergeable data sets
 - Modular and adjustable

Translational research: Team approach

- Science and Technology Division: The Engine
 - Deb Niemeyer- Chief Scientist: Engine builder
 - Rose Ramos- PhD Epidemiologist-
- Reach out to experts who can help
 - Program management
 - Contracting/ Logistics
 - Administrative Support
 - Informatics

Musts for success

- IRB processes- IRB net/ Single standardized system: multicenter collaboration
- Access to Databases- Learn to navigate
- All collect the same data- Hand/ Peds/ Spine?
- Prove the concept
- Build a program that outlives us

Final Goals

- Optimize Readiness
- Move beyond "expert opinion" to evidenced based outcomes
- Build an Research Engine that can answer questions no one else can even ask...
- Make it Efficient, Applicable and Sustainable
- Our Warriors deserve nothing less



Thank you



Prevention of Low Back Pain in the Military (POLM) cluster randomized trial

US Army-Baylor University

Lt Col John Childs, Associate Professor

BACKGROUND: Effective strategies for the primary prevention of low back pain (LBP) remain elusive. The prevention of low back pain in the military (POLM) cluster randomized trial investigated whether core stabilization and/or brief psychosocial education were effective in preventing future LBP episodes.

METHODS: Companies of Soldiers were randomly assigned to receive a core stabilization exercise program (CSEP) alone, a CSEP with brief psychosocial education program (PSEP), a traditional exercise program (TEP) alone, or a TEP with PSEP. The randomly assigned programs were performed during 12 week Advanced Individual Training (AIT). Soldiers were followed monthly for 2 years to determine self-report (onset and severity) and health care utilization related to initial LBP episode. **FINDINGS:** Twenty companies consisting of 4,325 Soldiers were enrolled in the trial. There were no differences among the exercise and education programs for self-report of occurrence and severity of LBP during the subsequent 2 years. There was decreased health care utilization related to LBP from the PSEP. This effect was noted in both exercise programs resulting in an overall 3.3% decrease in LBP related health care utilization over 2 years (NNT = 30.3). **INTERPRETATION:** Results from the POLM trial suggest that exercise and education approaches may not offer protective benefit for the development of self-reported LBP. However, decreased health care utilization from LBP may be attainable with education programs that reduce the fear and threat of LBP. Future trials should investigate cost-benefit and determine if larger dosages of psychosocial education result in larger decreases in health care utilization.

FUNDING: Peer-Review Medical Research Program of the Department of Defense (PR054098).

Trial registration: NCT00373009



**Prevention of Low Back Pain in the Military:
 A Cluster Randomized Trial**

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"Promoting Readiness Through Research"


Funding Source & Approval

- ✦ Funding:
 - ✦ Peer Reviewed Medical Research Program (PRMRP) of the Congressionally Directed Peer-Reviewed Medical Research Programs (CDMRP)
- ✦ Approval:
 - ✦ Brooke Army Medical Center (Feb 2006)
 - ✦ University of Florida (Jun 2006)
- ✦ Registration:
 - ✦ <http://clinicaltrials.gov>
 - ✦ NCT00373009



Potential Conflicts of Interest

- ✦ Contributing authors were independent from the study sponsor
- ✦ Study sponsor had no role in data collection, analysis, interpretation of data, or writing of the paper
- ✦ All contributing authors had access to all study data and take final responsibility for paper submission



Potential Conflicts of Interest

- ✦ Minority stockholder in 2 private companies related to physical therapy
 - ✦ Evidence in Motion
 - ✦ Texas Physical Therapy Specialists
- ✦ Neither entity played a role in the study design, funding, data collection, analysis, interpretation of data, or writing of the paper



Background

- ✦ Low back pain (LBP) is one of the most common forms of chronic pain (Martin 2008, Luo 2004, Stewart 2003)
- ✦ Leading factor for medical board processing in the military (Songer 2000)
- ✦ High cost of LBP
 - ✦ Lifetime compensation cost (van Tulder 1997)
 - ✦ High tax payer dollars (Kaufman 2000)
 - ✦ Decrease mission readiness (Knapik 1993, Jones 1999)

Background

- ✦ Low back pain (LBP) is one of the most common forms of chronic pain (Martin 2008, Luo 2004, Stewart 2003)
- ✦ Leading factor for medical board processing in the military (Songer 2000)
- ✦ High cost of LBP
 - ✦ Lifetime compensation cost (van Tulder 1997)
 - ✦ High tax payer dollars (Kaufman 2000)
 - ✦ Decrease mission readiness (Knapik 1993, Jones 1999)

Background

- ✦ Traditional bent sit-ups may increase the risk of injury and development of LBP (Axler 1997, McGill 1988, Nachemson 1999)
- ✦ Evidence supports use of core stabilization exercise (CSEP) to potentially decrease LBP frequency and pain and increase performance (Hicks 2005, Hides 2001, O'Sullivan 1997)
 - ✦ Decreasing recurrence of LBP
 - ✦ Decreasing LE injury incidence (Lectun 2004)

Purpose

- ✦ Determine whether a core stabilization exercise program (CSEP) in combination with a psychosocial educational program (PSEP) prevents low back pain incidence
- ✦ The effect of the combined program will be compared to 3 other programs:
 - ✦ CSEP alone
 - ✦ Traditional Exercise Program (TEP) alone
 - ✦ TEP in combination with PSEP

Methods



Subjects

- 4,325 Advanced Individual Training (AIT) US Army Soldiers (George, BMC Musculoskeletal Disord., 2007)

- Enrolled in POLM study
 - Healthy Soldiers between 18-35 years of age



Exclusion Criteria

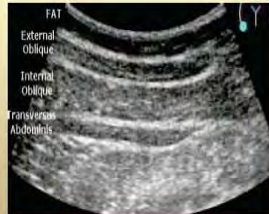
- Prior history of LBP with all of the following:
 - Limited work or physical activity
 - Duration > 48 hours
 - Caused individual to seek medical care
- Currently seeking medical care for LBP
- Previous medical history including surgery for LBP
- Currently unable to participate in unit exercise due to injury in foot, ankle, knee, hip, neck, shoulder, elbow, wrist, or hand
- History of fracture (stress or traumatic) in hip and/or pelvis
- Pregnant
- Transferred from another AIT Company

Cluster Randomization

- Cluster randomization of 20 companies
 - TEP
 - TEP+PSEP
 - CSEP
 - CSEP+PSEP
- Individual randomization was not utilized
 - Detract from unit cohesion
 - Inevitable contamination of treatment groups
 - Burdensome for company instructors

Physical and Ultrasound Exam

- 🌿 371 out of 4,325 Soldiers underwent a detailed examination
- 🌿 Physical Examination
 - 🌿 Lumbar flexion and straight leg raise
 - 🌿 Bilateral hip range of motion assessment
 - 🌿 Trunk endurance tests
- 🌿 Ultrasound Imaging
 - 🌿 Lateral abdominals
 - 🌿 Symmetry of multifidi muscles



Exercise Programs

- 🌿 2 exercise programs: TEP & CSEP
- 🌿 Performed at unit physical training
- 🌿 Frequency: 5 minutes/day, ≥ 4 days/week
- 🌿 Led by Company instructors
- 🌿 Company instructors were provided training and training aids by study personnel
- 🌿 Study personnel routinely observed training
- 🌿 Weekly meeting with Cadre to answer questions/concerns

Exercise	CSEP	TEP
Principle	Lower load, less repetitions	Higher load, more repetitions
Activation	Slower	Faster
Trunk movements	None to minimal	Full
Dosage	5 minutes/day	5 minutes/day
#1	Abdominal drawing-in maneuver crunch	Traditional sit-up
#2	Left and right horizontal side support	Sit-up with left trunk rotation
#3	Hip flexor squat	Sit-up with right trunk rotation
#4	Supine shoulder bridge	Abdominal crunch
#5	Quadruped alternate arm and leg	Traditional sit-up

Table 1. Description of core stabilization (CSEP) traditional (TEP) and exercise programs

Traditional Exercise Program (TEP)



- 🌿 Commonly performed exercises in the military for physical training
- 🌿 Targeted muscles: Rectus abdominis, internal and external oblique, and hip flexor muscles

Core Stabilization Exercise Program (CSEP)



- 🌿 Evidence-based
- 🌿 Targeted muscles: transverse abdominis, multifidi

Psychosocial Education Program (PSEP)

- 🌿 1,994 out of 4,325 Soldiers participated in a 45 minute seminar
- 🌿 LBP prognosis
- 🌿 Anatomical causes of LBP not likely
- 🌿 Importance of decreased fear avoidance beliefs and pain in response to LBP
- 🌿 Issued The Back Book
- 🌿 Q&A with study personnel



Establishing LBP Incidence

- 🌿 The Military Health System Management Analysis and Reporting Tool (M2)
 - 🌿 Maintained by the Tricare Management Activity (TMA)
 - 🌿 Contains a variety of health utilization data from both the direct care system (care provided in military treatment facilities) and network care (care provided to MHS beneficiaries at civilian facilities) worldwide



Establishing LBP Incidence

- 🌿 M2 searched for relevant LBP-related International Classification of Diseases (ICD) codes for Soldiers enrolled in the POLM trial
- 🌿 Utilized similar strategies to operationally define LBP as has been published in other studies using ICD codes to identify subjects seeking health care for LBP
 - 🌿 Gellhorn, Spine, 2010
 - 🌿 Fritz, Med Care, 2007

Data Analysis

- No planned interim analyses/stopping rules
- All analyses performed using SAS, version 9 (SAS Institute Inc, 1996)
- Demographic and baseline levels of clinical variables compared between the 4 cluster randomized groups
 - Analysis of variance (ANOVA) for means
 - Chi-square tests for proportions

Data Analysis

- Variables that differed between the training groups considered in the final analyses
 - In addition to pre-specified covariates of gender and age
- LBP incidence data analyzed with a generalized linear mixed model (GLM)
 - Response variable - # of months in which a Soldier reported LBP

Data Analysis

- Company considered as a random effect since this was a cluster randomized trial
- Planned fixed effects were
 - Treatment group
 - Age
 - Gender
 - Any variables that differed between the clusters after randomization

Data Analysis

- Survival time to the first month a Soldier reported LBP investigated with a Cox proportional hazards model and log rank test to investigate treatment effects
 - Response variable - time to first month in which health care incidence for LBP was reported
- Predictor variables same as those included in the GLM

Results



CONSORT Flow Diagram

- 🌿 Twenty companies consisting of 4,325 Soldiers were enrolled in the trial
- 🌿 No adverse events reported
- 🌿 Figure 1 provides information on study enrollment, participation, follow-up, and analysis for all stages of the POLM trial according to CONSORT guidelines

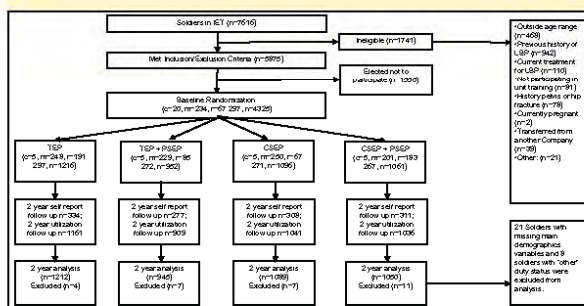


Figure 1. Flow diagram for patient recruitment and randomization

Baseline Characteristics

- 🌿 Baseline differences across individuals in the four companies found in age, education, income, active duty status, time in army ($P < .05$) (Table 2)
- 🌿 These differences were controlled for in subsequent analyses

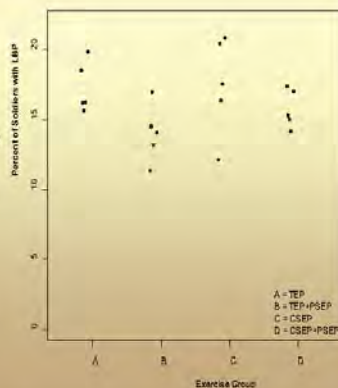
LBP Incidence

- Over 2 years, the number of Soldiers captured in the M2 database was 4,147/4,325 (95.9%)
- 706 (17.0%) identified as having LBP
- Evaluative patient analysis indicated no differences in low back incidence between core stabilization and traditional exercise

LBP Incidence

- However, brief psychosocial education from the combined exercise and education (CSEP+PSEP and TEP+PSEP) prevented low back pain episodes
- Overall 3.3% (95% CI: 1.1 – 5.5%) decrease over 2 years (p=.007)
- NNT = 30.3 (95% CI: 18.2 - 90.9).

Figure 2. Percent of Soldiers who reported incidence of low back pain by company and intervention group

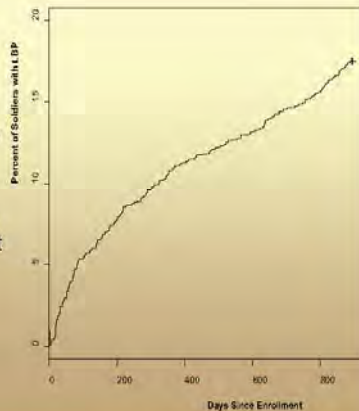


Coefficient of intracluster correlation of 0.0053)

Survival Analysis

- Compared to no PSEP (exercise only), combined exercise and education (CSEP+PSEP and TEP+PSEP) groups experienced 0.49 (95% confidence interval: 0.003-0.983, p=0.048) fewer months in which a Soldier experienced LBP
- Time to the first month of LBP incidence demonstrated a similar pattern
- Preventative effect of PSEP was observed (Hazard ratio=0.90; Log-Rank test, p = 0.021).

Figure 3.
Percent of
Soldiers who
reported
incidence of low
back pain by
intervention
group and days
since enrollment



Discussion

- First large scale trial to test the purported primary prevention effects of core stabilization alone, and in combination with psychosocial education, for LBP
- Trial results suggest no benefit of core stabilization exercises for preventing LBP incidence in comparison to traditional abdominal exercises

Discussion

- In contrast, brief psychosocial education that reduced fear and threat of low back pain decreased 2-year incidence of LBP
 - NNT = 30.3 (95% CI: 18.2 - 90.9)
- Overall decrease in LBP from brief psychosocial education might be perceived as small (3.3%)
 - However, utilization of health care for LBP is very common, so even small decreases in LBP incidence could potentially lessen burden on a health care system

Limitations

- Additional sit-ups performed to prepare for fitness testing
 - Rate at which additional sit-ups performed was equivalent across the 4 groups
- Did not track exercise performance after the 12 week training period
- Did not track if the LBP episode resulted in a medical board or evacuation from theater

Conclusions

- ✦ Potential importance for uniformed service members given high rates of evacuation due to musculoskeletal pain
- ✦ The PSEP was administered in a single, low-cost session, hence potential for similar education programs to be done in an efficient manner across large populations to yield incremental decreases in LBP incidence

Conclusion

- ✦ Potential application in general society because the education program could be adapted to civilian populations
- ✦ Future trials should investigate cost-benefit and determine if larger dosages of psychosocial education result in larger decreases in health care utilization

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Questions?



Spinal Injuries Following Ejection

81st AMDS/SGPF

Lt Col Richard Blair

Vertebral fractures are common in those ejecting from aircraft. High G forces experienced during ejection place significant loading on the vertebral column. The lower thoracic vertebrae are most commonly injured followed by lumbar vertebrae. Following is a case study a student pilot whom ejected from a USAF T-6 Texan training aircraft and sustained a compression fracture of the fifth vertebrae. Initial radiographic studies performed following ejection sequence failed to identify a compression fracture of the fifth thoracic vertebrae. The fracture was diagnosed two weeks later via MRI after patient complained of non-resolving mid back pain. The Royal Air Force identified compression fractures in 30-70% of those whom ejected from aircraft. Fractures suffered during ejection are stable in nature and treatment is conservative. The RAF routinely performs MRI of the spinal column on all those whom eject from aircraft. The USAF may be well served in the future to adapt a similar policy in order to avoid a delay in diagnosis of vertebral fractures in those ejecting from aircraft.

POST EJECTION SPINAL INJURIES AND SCREENING OF AIRCREW



Richard E. Blair, DO, MPH

81st AMDG
Keesler Medical Center, KAFB, MS

Post ejection spinal MRI

- - Case Report
- - Ejection forces
- - Post ejection injuries
- - Screening modalities
- - Foreign Air Forces screening
- - USAF post ejection policy
- - Discussion and Recommendation

Case Study



Raytheon T-6 Texan II






USAF T-6 Texan II

- Routine training flight
- Inadvertent engine shutdown
- Unsuccessful restart
- Instructor (IP) and student (SP) eject
- IP and SP immobilized at scene
- Transported to local ED via EMS

USAF T-6 Texan II

- Radiographic assessment
- Plain films of spine normal
- Dx : Contusions & abrasions
- IP and SP released to FS



USAF T-6 Texan II

- 3 weeks later SP C/O back pain
- Referred to NS at BAMC
- MRI of Spine performed
- Dx: Compression fracture T-5
- Disposition: DNIF

T-5 Compression Fracture



Ejection Seat Forces



Ejection Seat



Ejection forces

- Ejection forces along spinal axis Gz
- Initial ejection Gz up to 25 G
- Sustained forces of 12-20 Gz
- Variable with altitude, temp, pressure, and speed
- Vertebral compression fracture as low as 10z
- Vertebral fracture common above 20z

Post ejection vertebral fracture

- Post ejection vertebral fracture in 40-70 % of aircrew.
- Lower thoracic spine compression fracture common
- Highest Gz loading per unit area

Location and type of bony injuries post ejection (n=33)

Location	Number	%
·Cervical	2	6
·Thoracic (T1-10)	7	21
·Thoracolumbar (T11 to L1)	18	55
·Lumbar (L2-L5)	6	18

Post ejection spinal imaging

- Spinal injuries may be ill defined on plane films
- Plane films 75% sensitive
- CT/MRI of spine preferable
- MRI sensitivity 100%

Post ejection spinal imaging



Royal Air Force



Royal Air Force

"all UK military personnel who eject from aircraft will have an MRI of their spine prior to returning to duty"

" the ejectee shall have a neurological assessment by a consultant neurologist or neurosurgeon at an approved specialist centre"

Indian Air Force



Indian Air Force

“ all cases of aircraft ejection should undergo magnetic resonance imaging of the spine as MRI excels in evaluation of spinal injuries”

USAF

“Post ejection physical exam with particular attention directed to the spine”

Conclusion

- Ejection associated with high incidence of vertebral fracture
- Spinal fractures may not be evident on plain films
- MRI highly sensitive in diagnosis of compression fractures
- USAF should consider post ejection MRI for all aircrew

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A New Paradigm for Conducting Air Force Research Air Force Diabetes and Obesity Research Working Group

59 MDOS/SGO5E

Lt Col Mark True

INTRODUCTION: Diabetes mellitus is costly and presents a major burden on Military Treatment Facilities (MTFs). There are insufficient clinicians to effectively manage the 47,000 AFMS patients with diabetes mellitus, and over 100,000 patients with pre-diabetes. Research is needed to determine the optimal use of personnel and technology to affect the greatest good for these populations. **METHODS:** A call for multi-base participation in diabetes research occurred in April 2009, and attendees responded with great interest. AFMSA/SG9 contracted for research coordinators at six Air Force MTFs. Formal research priorities were established in Feb 2010, laying the groundwork for future activities. The Air Force Diabetes and Obesity Research Working Group was formally chartered in November 2010. Its membership consists of clinicians and research coordinators from Andrews, Keesler, Lackland, Nellis, Travis, and Wright-Patterson AFBs.

RESULTS: The working group produced a Research Development Document, which defines research priorities; Working Group Charter; Annual Plan; and Strategic Plan. The research priorities include: Primary Prevention of Diabetes, Technologies to bridge current resource gaps, Models of care to improve outpatient care, Inpatient diabetes care, Biomarkers to define diabetes populations, and Safety/operational concerns. The working group also established a coordinated framework by which research concepts are structured and pursued within these priorities. To date, over 10 new research projects have been established. Of note, 4 multi-base trials are underway. **CONCLUSIONS:** The Air Force Diabetes and Obesity Research Working Group can serve as a effective synergistic model for structuring, conducting, and accomplishing research within the Air Force Medical System.





Overview



AF Diabetes and Obesity Research Working Group


A New Paradigm for Conducting Air Force Research

Mark W. True, Lt Col, USAF, MC
 Chair, Air Force Diabetes and Obesity
 Research Working Group



- Why diabetes and obesity research?
- Recent diabetes efforts in AFMS
- Establishment of Diabetes and Obesity Research Working Group (DORWG)
- DORWG Progress
- Challenges / Lessons Learned

Providing Great Care...Building Warrior Medics


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Why diabetes and obesity research?

Obesity Trends* Among U.S. Adults BRFSS, 1990, 1999, 2008



- Focus of AFMS should be on wartime priorities first and peacetime care of our beneficiaries second
- We exist for wartime...this is why we wear the uniform
- **However, diabetes and obesity affects MORE of our patients than all physical wartime casualties combined!**
- If we don't control the diabetes and obesity epidemic, we will bankrupt the MHS and hinder our ability to focus on our primary wartime requirements
- Additionally, we need to ensure that we have an optimum fighting force through diabetes prevention measures

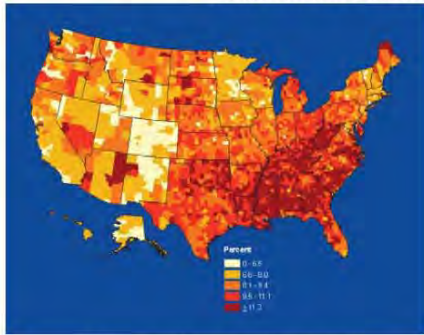
(*BMI ≥30, or about 30 lbs. overweight for 5'4" person)

No Data	<10%	10%–14%	15%–19%	20%–24%	25%–29%	≥30%	CDC

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County-level Estimates of Diagnosed Diabetes for Adults aged ≥ 20 years: United States 2007



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Diabetes Complications

- Heart disease → 2-4x more likely
- Stroke → 2-4 x more likely
- Blindness → 12-14k new cases each year
- Kidney failure/dialysis → 46k new cases yearly
- Nervous system disease → amputations → 71k/yr

CDC. National Diabetes Fact Sheet, 2011.

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Diabetes Epidemiology

- US: 25.8 million diabetics, 79 million pre-diabetics
 - Endocrinology shortage: only 4,000 in clinical practice
 - Certified Diabetes Educators shortage: 30,000 diabetes educators (15,000 certified diabetes educators)
- USAF: 47,000 diabetics, >100,000 pre-diabetics
 - 8 endocrinologists, ~ 20 CDEs in dedicated positions
- Result: bulk of chronic diabetes care provided at primary care level

US Figures from CDC. National Diabetes Fact Sheet, 2011.

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Estimated prevalence of diagnosed and undiagnosed diabetes in people aged 20 years or older, by age group, United States, 2007

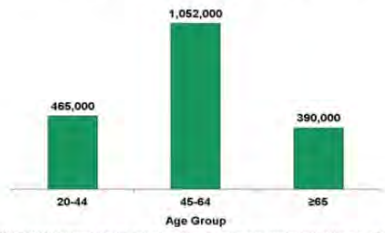


CDC. National Diabetes Fact Sheet, 2007.
 Source: 2003-2006 National Health and Nutrition Examination Survey estimates of total prevalence (both diagnosed and undiagnosed) were projected to year 2007.

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Estimated number of new cases of diagnosed diabetes among people aged 20 years or older, by age group, United States, 2010



Source: 2007-2009 National Health Interview Survey estimates projected to the year 2010.
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Unique features of AF Medicine

- AF has unique patient population
 - Active duty population is forced to maintain fitness standards
 - There is great need to maintain fit force in order to maintain readiness capability
 - Diabetes prevention in this population is necessary
 - Majority of AF personnel retire in their 40's
 - Majority of diabetes cases occur at/after this time juncture
 - To reduce overall MHS, preventing diabetes here is crucial
 - Study of this population, after fitness standards are no longer imposed, presents great research opportunity
- Additionally, AF population is true cross-section of American society

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Not just a problem for retirees

Weighing in on Type 2 Diabetes in the Military

Characteristics of U.S. military personnel at entry who develop type 2 diabetes

ROBERT M. PUGH, MD, MPH¹
 SHERIL A. BEHNSA, BA, MS²
 MARGOT R. KRUMSA, MD, MPH³

LISA W. KILP, MD, MPH⁴
 MARK V. RICHSTONE, MD, MPH⁵

OBJECTIVES — Current incidence trends in type 2 diabetes portend a significant public health burden and have largely been attributed to similar trends in overweight and physical inactivity. Medical surveillance of the U.S. military indicates that the incidence of all types of diabetes is similar to that in the civilian population (1.9 vs. 1.6 cases per 1,000 person-years).

CONCLUSIONS — Individuals with type 2 diabetes in the U.S. military have risk factors similar to the general U.S. population. Because diabetes is a preventable disease, it is of concern that it is occurring in this population of younger and presumably more fit individuals. This has significant implications for the prevention of diabetes in both military and civilian populations.

Diabetes Care 24:1804-1808, 2001

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TOBESAHOL Study

- Financial analysis performed to assess direct and indirect costs of tobacco, obesity/overweight, and alcoholism in TRICARE Prime population (under 65)
- Annual cost to system (2006 dollars)
 - Obesity/overweight -- \$1.1 billion
 - Diabetes -- \$300 million

Am J Health Prom 2007; 22(2): 120-139.

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Importance in Pediatrics

Develop America's Medical Airmen Today ... for Tomorrow


A Message from America's Retired Generals, Admirals and Civilian Military Leaders:

As retired Generals, Admirals, and other senior leaders of the United States Armed Forces, we know firsthand that national security must be America's top priority.

Our organization recently released a report citing Department of Defense data indicating that an alarming 75 percent of all young Americans 17 to 24 years of age are unable to join the military because they failed to graduate from high school, have criminal records, or are physically unfit.

Being overweight or obese turns out to be the leading medical reason why applicants fail to qualify for military service. Today, otherwise excellent recruit prospects, some of them with generations of sterling military service in their family history, are being turned away because they are just too overweight.

Mission: Readiness, an organization of retired senior military leaders, is warning Congress that at least nine million 17- to 24-year-olds in the United States are too fat to serve in the military. That **27 percent of all young adults** obesity rates among children and young adults have increased so dramatically that they threaten not only the overall health of America but also the future strength of our military.



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AFMOA AFSO21 Strategic Management of Diabetes

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- AFMOA's Problem Statement: The AFMS does not have a comprehensive, informed, and aligned strategy for diabetes care.
- As evidenced by ...
 - Poorly characterized AFMS diabetes populations.
 - AFMS has not defined an expected standard of diabetes care
 - AFMS metrics of care and outcomes are not comprehensive
 - Workflow management of diabetics is not standardized
 - Inability to capture all necessary data for care obtained outside the MTFs
 - MTF-level variation: some do well, others are challenged

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Initial Diabetes Translational Research Mtg

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- Air Force Diabetes Translational Mtg, Apr 2009, Bethesda, MD
 - Hosted by Diabetes Technology Society
 - Attended by Lackland, WP, Keesler, Andrews, and Travis
- Several research areas of interest identified in diabetes technology/IT/primary prevention areas
- Common Themes:
 - Great interest in conducting research
 - Inadequate research infrastructure/staff to effectively engage

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Building AF Research Infrastructure



Develop America's Medical Airmen Today ... for Tomorrow

- AFMSA/SG9 contracted research coordinators specifically dedicated for diabetes research at six AF medical centers
 - Fuchsia Plan
 - 1 research coordinator at Keesler, Wright-Patterson, Nellis, Travis, Andrews
 - Blue Plan
 - 1 research coordinator at Lackland
- Good start!
- Needs to be broadened and continued....

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Diabetes Research HPT



Develop America's Medical Airmen Today ... for Tomorrow

- Feb 2010 – representation from Andrews, Keesler, Lackland, Nellis, Travis, and Wright-Patterson
- Product: Diabetes Research Development Document
- Research priorities were established:
 - Primary Prevention of Diabetes
 - Technologies to bridge current resource gaps in outpatient diabetes care
 - Models of care to improve efficacy of outpatient diabetes care
 - Inpatient diabetes care
 - Biomarkers to better define diabetes populations
 - Safety/operational concerns

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Establishment of DORWG



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- Nov 2010 – Charter established
- Multi-base participation, voting members
- Quarterly face-to-face meetings, monthly teleconferences

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DORWG Membership



Develop America's Medical Airmen Today ... for Tomorrow

- Chair – Lt Col Mark True, Lackland
- Vice-Chair – Col Marcus Cranston, Keesler
- Voting membership from all six bases
 - Multi-disciplinary government (endocrinology, family medicine, internal medicine, diabetes educator, behavioral health)
- Non-voting membership
 - AFMSA/SG9S government
 - AFMOA government
 - CPRT contractor team
 - Clinical research coordinators (contractor)

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DORWG Mission

Develop America's Medical Airmen Today ... for Tomorrow

- The Air Force Diabetes and Obesity Research Working Group mission is to promote and conduct diabetes research for prevention, identification, education and treatment of diabetes in all military beneficiaries.**



DORWG Duties

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- DORWG will:
 - Work with AFMSA/SG9 to build and implement an Annual Plan
 - Submit, revise proposals
 - Conduct research projects
 - Work towards practice management change
 - Report research progress
 - Publish research outcomes
 - Advise and serve as subject matter experts on matters related to diabetes and obesity research within the Air Force

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Current Projects

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Project #	Project Name	Project Description	Lead	Status	Priority
1	Diabetes Prevention of Active Duty Personnel
2	Diabetes Prevention of Reserve Component Personnel
3	Diabetes Prevention of Family Members
4	Diabetes Prevention of Retirees
5	Diabetes Prevention of Veterans
6	Diabetes Prevention of Civilian Employees
7	Diabetes Prevention of Contractors
8	Diabetes Prevention of Dependents
9	Diabetes Prevention of Spouses
10	Diabetes Prevention of Children
11	Diabetes Prevention of Grandchildren
12	Diabetes Prevention of Great-Grandchildren
13	Diabetes Prevention of Nephews
14	Diabetes Prevention of Nieces
15	Diabetes Prevention of Cousins
16	Diabetes Prevention of Uncles
17	Diabetes Prevention of Aunts
18	Diabetes Prevention of Granduncles
19	Diabetes Prevention of Grandaunts
20	Diabetes Prevention of Great-Granduncles
21	Diabetes Prevention of Great-Grandaunts
22	Diabetes Prevention of Great-Grandchildren
23	Diabetes Prevention of Great-Granddaughters
24	Diabetes Prevention of Great-Grandsons
25	Diabetes Prevention of Great-Granddaughters
26	Diabetes Prevention of Great-Grandsons
27	Diabetes Prevention of Great-Granddaughters
28	Diabetes Prevention of Great-Grandsons
29	Diabetes Prevention of Great-Granddaughters
30	Diabetes Prevention of Great-Grandsons
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43	Diabetes Prevention of Great-Granddaughters
44	Diabetes Prevention of Great-Grandsons
45	Diabetes Prevention of Great-Granddaughters
46	Diabetes Prevention of Great-Grandsons
47	Diabetes Prevention of Great-Granddaughters
48	Diabetes Prevention of Great-Grandsons
49	Diabetes Prevention of Great-Granddaughters
50	Diabetes Prevention of Great-Grandsons

30+ projects total, 4 multi-base



Annual Plan

Develop America's Medical Airmen Today ... for Tomorrow

- Predominant focus this year
 - Finalization of planning documents: RDD, charter, strategic plan
 - Progress on current and new projects
 - Tracking established milestones for each project
 - Identification of research gaps to plan future projects
 - Progress will be documented and summarized in an Annual Report

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Strategic Plan



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- 5 year plan, still in development
- Large emphasis of strategic plan is survivability
 - Greater marketing of group's efforts
 - Broader efforts to include grants external to AFMS
 - Infrastructure building
- Expanded research priorities to include greater emphasis on obesity-related subjects for future projects

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Challenges / Lessons Learned



Develop America's Medical Airman Today ... for Tomorrow

- Leadership recognition of the importance of diabetes and obesity research
 - Need to build convincing story....tell it often
- Instability of personnel to provide stable program longevity (deployments, contractors)
 - Need for more stable, permanent, civilian research staff
 - Until available, find interested parties and build team

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Challenges / Lessons Learned



Develop America's Medical Airman Today ... for Tomorrow

- Bureaucratic challenges (research leadership changes/role changes, multiple IRBs)
 - Clear leadership structure needed
 - Single IRB preferred
- Funding / rules of R&D funds and how they apply to desired projects
 - Standard, uniform guidance needed, perhaps in workshop or "how to" booklet format
 - 59 MDW/ST is building to this purpose

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Conclusions



Develop America's Medical Airman Today ... for Tomorrow

- Diabetes and obesity research represents a worthy investment within the AFMS research community
- DORWG has made significant progress in terms of defining research priorities, establishing a charter, annual plan, strategic plan, initiating and tracking projects within established priorities
 - DORWG model can serve as example for other research focus areas
- Continued support and guidance from AFMS research leadership is needed to continue this work

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Comments/Questions?

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Delivering a Diabetes Prevention Program in a Military Setting

59 MDOS/SGO5E

Maj Lisa Strickland

OBJECTIVE: Diabetes prevention is an important consideration for the military. Lifestyle coaches were trained by the University of Pittsburgh Diabetes Prevention Support Center to implement the Group Lifestyle Balance (GLB), an adaptation of the Diabetes Prevention Program intervention, in two US Air Force settings. Our objective was to determine if GLB delivered to military healthcare beneficiaries resulted in reduction of risk factors and program satisfaction.

METHODS: The GLB intervention was delivered by face to face group classes or through the GLB DVD over 12 weeks. Program goals are to achieve/maintain weight loss and increase activity. Anthropometric (height, weight, blood pressure, and waist circumference) and laboratory (fasting glucose, triglycerides, and HDL) were collected at baseline and 12 weeks. Satisfaction surveys were administered at 12 weeks.

RESULTS: Thirty-two participated in the face to face GLB; 55 in the GLB DVD interventions. Program attendance rates declined over time. Participants in the face to face lost a median 4.4 lbs; had an average BMI decrease 0.75 kg/m², both statistically significant. Participants in the GLB DVD intervention lost a median 8.9 lbs, had a decrease of BMI 1.5 kg/m², and median reduction in waist circumference by 3.81 cm, all statistically significant. There was high program satisfaction.

CONCLUSIONS: Albeit a limited time frame and sustained program attendance, GLB can be considered a viable evidence-based risk reduction program for eligible military beneficiaries. The GLB program is an effective tool to implement lifestyle change for diabetes prevention. Further research is needed to explore motivational tools to improve adherence.

**Type 2 Diabetes Prevention
in the Military**

Lisa Strickland, M.D.
 Maj, USAF, Medical Corps
 Director Diabetes Prevention
 Diabetes Center of Excellence
 Wilford Hall Medical Center

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**Obesity Trends* Among U.S. Adults
BRFSS, 1990, 1999, 2008**

(*BMI ≥30, or about 30 lbs. overweight for 5'4" person)

No Data
<10%
10%–14%
15%–19%
20%–24%
25%–29%
≥30%

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**County-level Estimates of Diagnosed Diabetes
for Adults aged ≥ 20 years: United States 2007**

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Diabetes Statistics

- 25.8 million diabetics in US
- 79 million pre-diabetics (35% of US population)
- Heart disease → 2-4x more likely
- Stroke → 2-4x more likely
- Blindness → 12-14k new cases each year
- Kidney failure/dialysis → 48k new cases yearly
- Nervous system disease → amputations → 65k/yr

• If diabetes is prevented, these problems are avoided!

CDC: National Diabetes Fact Sheet, 2011.

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Importance to Military

Develop America's Medical Airmen Today ... for Tomorrow

- Military must have a fit active duty force in order to maintain its readiness capability
 - Active duty population must meet fitness standards
 - Diabetes prevention in this population is necessary to preserve fighting strength of our force


- Military health system (MHS) provides lifelong care for retirees and spouses
 - Majority of personnel retire in their 40's and 50's
 - Majority of diabetes cases occur during this time juncture, after fitness standards are no longer imposed
 - Preventing diabetes in retirees leads to healthier lives and it also reduces long-term costs

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The New England
Journal of Medicine

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VOLUME 346 FEBRUARY 7, 2002 NUMBER 8



REDUCTION IN THE INCIDENCE OF TYPE 2 DIABETES WITH LIFESTYLE INTERVENTION OR METFORMIN

DIABETES PREVENTION PROGRAM RESEARCH GROUP*

Conclusions Lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk. The lifestyle intervention was more effective than metformin. (N Engl J Med 2002; 346:393-403.)



American Diabetes Association Position Statement


Develop America's Medical Airmen Today ... for Tomorrow

Primary prevention of diabetes

- Among individuals at high risk for developing type 2 diabetes, structured programs emphasizing lifestyle changes that include moderate weight loss (7% body weight) and regular physical activity (150 min/week) with dietary strategies including reduced calories and reduced intake of dietary fat can reduce the risk for developing diabetes and are therefore recommended. (A)

ADA Position Statement, Standards of Medical Care in Diabetes, 2011

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American Diabetes Association Position Statement

Develop America's Medical Airmen Today ... for Tomorrow

Follow-up of all three large studies of lifestyle intervention has shown sustained reduction in the rate of conversion to type 2 diabetes, with 43% reduction at 20 years in the Da Qing study (30), 43% reduction at 7 years in the Finnish Diabetes Prevention Study (DPS) (31) and 34% reduction at 10 years in the U.S. Diabetes Prevention Program Outcomes Study (DPPOS) (32). A cost-effectiveness analysis suggested that lifestyle interventions as delivered in the DPP are cost-effective (33). Group delivery of the DPP intervention in community settings has the potential to be significantly less expensive while still achieving similar weight loss (34).

ADA Position Statement, Standards of Medical Care in Diabetes, 2011

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 **Group Lifestyle Balance Program**  Develop America's Medical Airmen Today ... for Tomorrow

- The DPP was a great success!
- GLB is an adaptation of the successful DPP lifestyle intervention
- Developed in 2004 by the Diabetes Prevention Support Center faculty of the University of Pittsburgh Diabetes Institute

 **AF Multimedia Tools**  Develop America's Medical Airmen Today ... for Tomorrow



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 **How To Enroll Patients**  Develop America's Medical Airmen Today ... for Tomorrow

- BMI \geq 25
- Pre-diabetic
- CHCS consult:
 - "SAMMC Diabetes Prevention"
 - List patient contact information
 - Note if there are barriers to brisk walking

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 **Staffing Options**  Develop America's Medical Airmen Today ... for Tomorrow

- | | |
|--|---|
| <ul style="list-style-type: none"> • PREFERRED • Nurse • Dietitian • Exercise Physiologist • Diabetes educator • Behaviorist • Physician | <ul style="list-style-type: none"> • ACCEPTABLE
(limited staffing option) • Physical Training Leaders (PTL) (Commander permission/letter of commitment) • Air Force Fitness Facility Center Trainers, Certified Personal Trainer (CPT) • Licensed Vocational Nurse • Medical Technician |
|--|---|

Lifestyle coach must complete training

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ARE YOU TRYING TO LOSE WEIGHT?
 Introducing Group Lifestyle Balance (GLB) Program
Start Date: Week of April 12, 2010
Start Time: 11:30–12:30 PM
Location: Wilford Hall Medical Center



Group Lifestyle Balance (GLB) is a proven lifestyle intervention program. It aims to promote long-term weight loss through healthy eating and physical activity.

You may be eligible to participate in this program if you are:

- Adult over the age of 18
- Overweight (BMI greater than 25 kg/m²)
- Not diagnosed with diabetes
- Women ONLY**

If you would like to participate in the GLB program, you can enroll in a 12-week intervention program to learn healthy eating techniques and how to develop and maintain a physical activity routine.

There is no cost for the program.

For more information, contact:

Call: 214-948-4444
 Email: glb@wilfordhall.af.mil
 Wilford Hall Medical Center
 1601 1st St
 Ft. Belvoir, TX 76205-5000



One Year Data

	Mean Baseline	Mean 3 Month	Difference	N	P-value
Weight (lbs)	198.89	189.46	-9.43	64	<0.001
Waist Circum (in)	41.33	39.91	-1.42	84	<0.001
Fasting Glucose (mg/dL)	101.74	96.48	-5.26	73	<0.001
A1c (%)	5.94	5.8	-0.14	70	.002
Total Cholesterol (mg/dL)	182.7	172.61	-10.09	74	.004
Triglycerides (mg/dL)	124.74	105.55	-19.19	74	.011

Summary

Develop America's Medical Airmen Today ... for Tomorrow

- Diabetes CAN be prevented or delayed
- The GLB DVD program is a cost-effective means to implement evidence-based practice
- With this tool, you can build a diabetes prevention program at YOUR base to help our airmen live healthier lives *now* and into retirement

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Summary

Develop America's Medical Airmen Today ... for Tomorrow

- Currently up and running at six bases and counting
- Formal follow-up in the process of being developed in collaboration with UPMC
- Training for lifestyle coaches will be available on-line in the fall

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Develop America's Medical Airman Today ... for Tomorrow

Questions?

POC: Lisa.Strickland.1@us.af.mil

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USAF Obesity Educator Program

MDOS (Hurlburt AFB, FL)

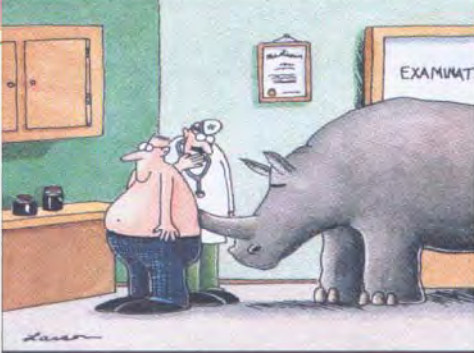
Dr. Thomas McKnight

Obesity is an epidemic that cost Americans more than \$168 billion dollars per year. The TOBESAHOL Study estimates the DoD 's annual medical cost of obesity and overweight at \$1.1 billion. In 2007, 12.4 percent Air Force personnel had a body mass index 30 or greater. Active duty members are at risk for administrative discharge for being over body fat. In 1999, 600 airmen and women were discharged for being over body fat. The Diabetes Prevention Program and the Look Ahead Study show 7 to 10 percent sustained weight loss greatly improves health. The National Weight Control Registry (NWCR), with over 5,000 registrants, has shown long-term weight management is achievable. The average NWCR registrant lost 66 lbs and kept it off >5 years. Less than 5 percent used medication. In 2006, the Certification Board of Obesity Educators (CBOE) was established to promote continuing commitment to best practices, standards of care, and knowledge of obesity counseling and education techniques. Curriculum for the certification exam is under development. During this session I propose a pilot study where Air Force healthcare professionals (physicians, nurses, dieticians, social workers, and psychologists) are trained as obesity educators to assist Air Force personnel to lose weight and maintain a healthful weight.

**The Air Force Obesity
Educator
A Prototype for the Future**

Thomas L. McKnight, MD, MPH
Colonel, AFR
AFMS Scientific Symposium
3 August 2011

Don't Miss The Obvious



A cartoon illustration of a doctor in a white coat and stethoscope examining a large rhinoceros in a medical office. The doctor is looking at the rhino's head. In the background, there is a cabinet, a framed picture, and a sign that says "EXAMINATION".

"Wait a minute here, Mr. Crumbley... Maybe it
Wait a minute Mr. Crumbly, "Maybe it isn't kidney
stones after all."

**The war against the obesity
epidemic is...**

NOT BEING WON!

“Only 3.5% of the obese population has been impacted by current initiatives.”

Dr Lee Kaplan, MD

Professor of Medicine, Harvard Med School and Director of the MGH Weight Center and the Obesity Research Center
Conference on Practical Approaches to Obesity Treatment
18 June 2011

CDC REPORT: 22 July 2011

Behavioral Risk Factor Surveillance System
2009 versus 2010

1. >30% prevalence rate: 9 states now 12 states
2. 16 states increased rate in one year
3. No state now <20% prevalence rate

OBESITY IN AIR FORCE: 2007

Overweight (BMI 25-29.9):

Air Force - 44.4%
AFSOC - 46.3% (highest in AF)


Obese (BMI 30 or higher):

Air Force - 12.4%
AFSOC - 12.6% (PACAF 13.4%)

AD DOUBLE JEOPARDY

Health cost: >\$1.1 billion/DoD/2006

Career cost: Administrative discharge




UNPUBLISHED AFPC DATA

1999: 600 airmen/women discharged
for over-body fat = failed PT

Enlisted: 96% (89% active force)

Female to male: 2:1




OVER BODY FAT = FAILED PT

22 y/o airman: WC 51 in/BMI 41

29 y/o airwoman: 45 lbs preg > WC 36 in

42 y/o MSgt (15 yrs AD); s/p back surgery
- WC 42 in




THE AF OBESITY EDUCATOR PROGRAM

Strategic:

- Obesity: A Chronic Disease
- Focus on Obesity Prevalence

Tactical: Weight Management Wheel

- The Process Wheel
- The Program Wheel



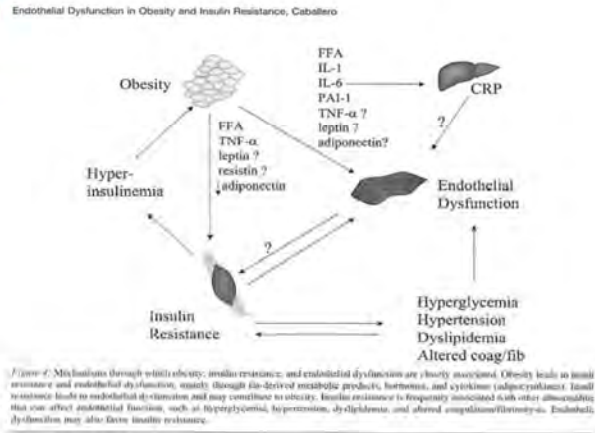
STRATEGIC PRINCIPLE #1

Obesity is a Chronic Disease

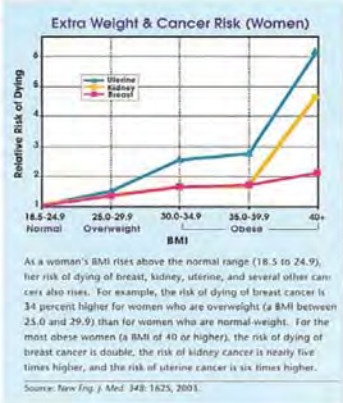
It can be controlled, not cured!

ADIPOSE TISSUE: ENDOCRINE GLAND

- (-) Adiponectin: -Atherogenic, -Inflam, -DM
- (+) Interleukin 6: +Inflammation, +DM
- (+) PAI-1: +Atherogenic, +Coagulant
- (+) TNF-alpha: +Inflam, +Insulin Resistance
- (+) Angiotensinogen: +HTN
- (+) Endocannabinoid Recep: +Lipogenesis



Obesity's impact on female cancers



Obesity's impact on male cancers



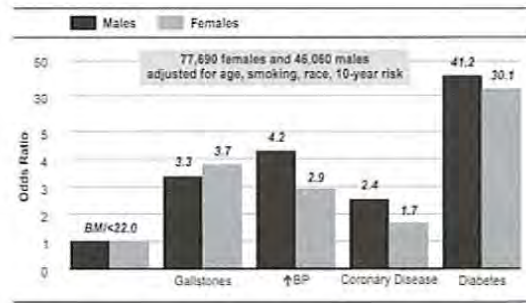


Figure 1 Impact of obesity on risk of developing chronic diseases. Adapted from: Field et al.¹

Field, Arch Intern Med 2001; 161: 1581-1586

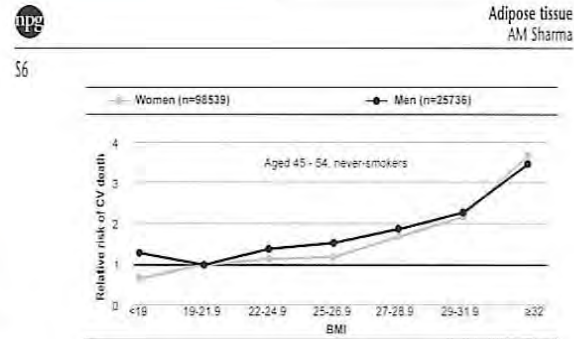


Figure 1 Cardiovascular mortality at different levels of body mass index. Source: Stevens et al.¹

AM Sharma, International J. of Obesity, 2002, Suppl 4

OBSESITY STEALS LIFE YEARS

Framingham Heart Study – 3457

40 y/o overweight:

- Non-smoker: M – lost 3.1 years
- F – lost 3.3 years

40 y/o obese:

- Non-smoker: M – lost 5.8 years
- F – lost 7.1 years

40 y/o obese:

- Smokers: M – lost 13.7 years
- F – lost 13.1 years

(compared to normal weight/predicted after age 50 to 69)
 Annals of Internal Medicine, 7 Jan 03

STRATEGIC PRINCIPLE #2

Outcome Focus: Prevalence Rate

Must attack wherever the disease is!

CHRONIC DISEASES TREATED ALIKE

Therapeutic Lifestyle Changes > Lip Service

Primary treatment most diseases is medication:

- HTN: 10 categories of medications
- Over 60 choices of single/combo meds

THE CALVARY AIN'T COMING

Redux: Pulled in 1997 – heart valve and pulmonary HTN
- 21 billion dollar compensation fund

Rimonabant: 2009 – endocannabinoid receptor blocker
> effective in weight loss. Studied 18,000 over 13 months > Reduction in MI/CVA/death. Increase: psychotic/suicide

Lorcaserin: 2010 – BLOOM study: 47.5% vs 20% lost 5%
Concern: breast/brain tumors in rats. Re-evaluated?

CONTINUED

Qnexa (topiramate + phentermine)

- Effective: 3,700 sub -14.7% (52 weeks)
- FDA rejected: psychiatric, liver, birth defects

Sibutramine: On market 13 years > effective

- SCOUT study: 9,800 over 3.4 years
- 14% increase non-fatal MI and CVA

SURGERY NOT REDUCE PREVALENCE

Bariatric surgeries: >200,000 in 2008
- average cost: \$10,000 = \$200,000,000

Obese Americans: 72 million Americans

Surgery cannot slow, stop, reverse obesity

POSITIVE LIFETYLE IMPACT

Therapeutic Lifestyle Changes: TLC

Hyperlipidemia: first line of treatment

(Conn's Current Therapy, 2003, p 649)

HTN: 1600 mg Na + DASH diet = single therapy

(JNC VII, JAMA, 14 May 2003)

Type II DM: Diabetes Prevention Program

- 6 Aug 01 HHS Thompson: 58% v 31% RR reduced

WE MUST THINK DIFFERENTLY

(Personal Responsibility)

STUDY WINNERS, NOT RUNNERS

- 1954: Roger Bannister > John Lundy
- 2008: Hicham el Guerouj > 3:43:13

NATIONAL WEIGHT CONTROL REGISTRY

Am. J. of Cl. Nutrition 1997; 66: 239-246

- Study the 'winners, not just the runners' of the race
- 1954: Roger Banister > John Lundy
- NWCR:
 - Over 5,000 registrants
 - Average member: 60 lbs / 5.5 years
 - Characteristics: self-monitor (weigh at least weekly)
 - eat low-fat/high carbohydrate diet
 - eat breakfast (78% daily, 91% - 4/7)
 - exercise 60 minutes/day (91%)

STRATEGIC SUMMARY

Common language = chronic disease

United vision = attack wherever found



TACTICAL: TWO SIDES OF WHEEL

The Process: Inclusiveness

The Program: Personal Responsibility
with assistance



TACTICAL #1: INCLUSIVENESS

Empowerment:

Each healthcare specialty



CERTIFICATION BOARD OF
OBESITY EDUCATORS

VISION

Reduce the prevalence of obesity across
all social and economic settings in
America.

-Inclusive approach!-

(www.obesityeducator.org)



OBESITY EDUCATOR

Licensed/Certified Healthcare Professional

Physicians, Nurses, Social Workers,
Psychologists, Health Educators,
Nutritionists, Exercise Physiologist



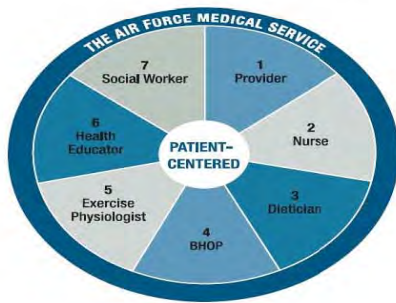
AIR FORCE OBESITY EDUCATOR

A new beginning...



PATIENT-CENTERED MEDICAL HOME FOCUS

The Process of Weight Management



TACTICAL #2: SELF-SELECTION

Bariatric surgeon:
"Looking for a few good patients."



ENHANCE SELF-EFFICACY

- Patient decides: "I'm In"
- Selects therapeutic spokes
- Referred to specialty with skill in that spoke
- Clinic 'obesity educator' coordinates

The Program of Weight Management Wheel



AF OBESITY EDUCATOR RESEARCH PROPOSAL

- Target population: AF who failed PT test
- Phase I: Specialty consultants/IRB/training
- Phase II: 6-month wgt loss phase with
18 month maintenance
- Phase: III: Begin 2nd 6-month wgt loss phase



VALUE TO AIR FORCE

1. Healthcare cost savings
2. Retention of qualified airman
3. Become DoD/national leader in effective weight management science



Discussion/Questions

Intraosseous Infusion Rates Under High Pressure: A Cadaver Study of Anatomical Site Comparisons

711 HPW/USAFSAM-ETS

Maj Joe Dubose

BACKGROUND: Modern combat injuries often involve injuries to the extremities and torso, limiting the ability of medics to obtain intravenous access for resuscitation. Therefore, combat medics are trained in the use of intraosseous (IO) devices for the delivery of resuscitative fluids after combat injury. However, the optimal site of insertion for these devices (tibia, humerus, or sternum) has not been well established.

HYPOTHESIS: The optimal site or sites for IO vascular access in humans, using devices and sites currently being employed in theater, can be objectively determined using a fresh cadaver model. **METHODS:** “Fresh” cadavers, flushed with intravascular detergent solution immediately after arrival to the morgue and stored in a holding area at 34-36 degrees Celsius until use within 24 to 48 hr, will be utilized for study. IO infusion devices will be sited in the proximal tibia, proximal humerus, and sternum. The FAST-1 (Pyng Medical Corp., Richmond, British Columbia, Canada) and EZ-IO (VidaCare Corp., San Antonio, TX), which are U.S. Federal Drug Administration approved for sternal (FAST-1) and humeral or tibial site (EZ-IO) and commonly employed in combat theaters by field medics, will be utilized. A 0.9% saline solution will be infused at each site in turn, where the volume infused over 5 min using a pressure infuser inflated to 300 mmHg will be measured. Mean flow rates for each site will be calculated and used to compare mean rates of flow achievable using the three sites of access in this model. This study will be completed in 8 months.



A Comparison of Infusion Rates Using Intraosseous Devices on Adult Fresh Cadavers

Major Joe DuBose, USAF, MC, EACS
 Clinical Assistant Professor of Surgery
 University of Maryland/R Adams
 Cowley Shock Trauma Center
 Baltimore C-STARS, USAFSAM

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Background

- Acute hemorrhage remains the leading cause of combat death
- Resuscitation
 - Blood products
 - Fluid
- Administration requires access

Sebesta JA. Surg Clin N Am, 2006

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Peripheral Intravenous

- Extremity injuries prevalent after combat injury
- Difficult in setting of hypotension



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Central Venous Access

- Advanced skill set
- Time dependent





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 **Venous Cut-Down** 

- Surgical skill required
- Time/equipment dependent



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 **Intraosseous (IO) Infusion** 

- Safe
- Effective
- Rapid



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 Distribution Statement A. Approved for public release; distribution is unlimited. Case Number: 88AW-2011-0001, 01 Jul 2011

 **IO Access** 

- American Heart Association – Resuscitation Guidelines, 2005
 - The intraosseous route should be the first alternative to difficult or delayed intravenous access.

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 **IO Site Options** 

- Tibia
- Humerus
- Sternum
- Distal Femur



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Military Relevance

- IO devices presently being utilized in theaters of conflict
 - Prevalence of extremity injuries
 - Prehospital environment challenges

- Tactical Combat Casualty Care Committee
 - Policy oversight in prehospital setting

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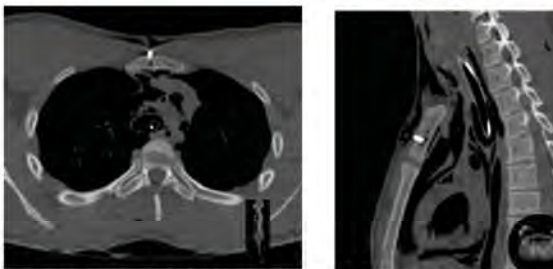
FAST-1



Pyng Medical Corp., Richmond,
 British Columbia, Canada

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FAST-1 Sternal Placement



Source: Armed Forces Medical Examiner System and Defense Medical Material Program Office

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EZ-IO

EZ-IO

1. EZ-IO® 19mm (3-19 KG), EZ-IO® 25mm (40 KG AND GREATER) AND EZ-IO® 45mm (EXCESSIVE TISSUE)

DEVICE DESCRIPTION: EZ-IO Needle Sets are comprised of a Safety Case, a Hub and a Catheter. When the Safety is removed a standard Jam Lock is exposed. Needle Sets are made of 50% Stainless and Catheters are 10 gauge. Needle Sets are provided sterile, non-sterile and in protective packaging. Needle Sets are intended for use with the EZ-IO Power Driver (Figure 1).

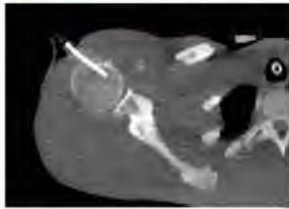
EZ-IO 19mm
 EZ-IO 25mm
 EZ-IO 45mm

EZ-IO Power Driver and Needle Sets (DS/MS 1)

VidaCare Corp., San Antonio, TX

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EZ-IO
 Humeral/Tibial Sites



Source: Armed Forces Medical Examiner System and Defense Medical Material Program Office

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Best Site?

- Ease of placement
 - Equivalent?
- Availability in face of injury
- Size of bone likely important
 - Larger = faster flow rates?

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Best Site?

- Objective = rapid administration of resuscitative fluids/critical medications for combat casualties who critically need them
- By this definition, optimal site = unknown

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Available Data

- Animal models
 - Lairet J - U.S. Army Institute of Surgical Research (USA ISR)
 - Humerus better infusion rates than tibia in rabbits
 - Larger animal studies ongoing
 - Limited human skeletal correlation
 - Particularly sternum
- Small human case series
 - No comparison of sites

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How Do We Study?



- Animals not ideal correlate
- Risks associated with human volunteers
- Randomization in theater problematic

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Cadavers?



- Fresh cadavers (<24-48 h) utilized in trauma training at specialized civilian centers
 - UMM/R Adams Cowley Shock Trauma Center
- Osseous structure preserved
- Correlates with anatomy
- Capable of sustaining flow through central lines after vascular flushing with mild detergent solution

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Study Design



- Prospective, observational study
- “Fresh cadavers”
 - Intravascular detergent solution flush on arrival
 - Stored 34-36 C
 - Utilized within 24-48 h post-mortem
 - Decedent age 18-65

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Exclusions



- Bony or myeloproliferative malignancy
- History of median sternotomy
- Known fracture or orthopedic operation at planned extremity site

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Protocol



- Protocol refinement – 4 cadavers
- Study conduct – 38 cadavers
- Surgical cut-down of Internal Jugular for measurement of central venous pressure (CVP) monitoring
 - To prevent bias due to overfilling, intravascular volume will be removed to maintain CVP < 10 cm H₂O or < 5 cm H₂O above initial baseline

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Protocol



- Randomized order of IO placement/infusion
 - Initial confirmation via marrow aspiration
 - Infusion 0.9% normal saline (NS) X 5 min
 - Pressure infuser inflated to 300 mmHg
- Appropriate insertion confirmed by cut-down upon completion of all sites

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Measurements



- Mean flow rate calculation
- Total infusion delivered determined by weight comparisons before/after infusion of bags of NS

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Data Analysis



- Primary outcome variable:
 - Mean flow rate of 0.9% NS at 300 mmHG through each of three access sites in a fresh cadaver model
 - Sternal
 - Proximal Humeral
 - Proximal Tibial

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Deliverables



- Prioritize site choice

- Standardization?
 - Training / supply simplification

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Collaborators



- Baltimore C-STARS
 - Lt Col (sel) Joe DuBose, USAF, MC
 - Maj Jon Casey, USAF, MC
- Cincinnati C-STARS
 - Maj Mike Petro, USAF, MC
 - Col Warren Dorlac, USAF, MC
- St. Louis C-STARS
 - Maj Brian Holt, USAF, MC
- USA ISR
 - Maj Julio Lairet, USAF, MC

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Questions?



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Intraosseous hydroxocobalamin versus intramuscular hydroxylamine in a validated swine model of acute cyanide toxicity and shock

59 EMDS

Lt Col Vikhyat Bebartha

Background: Non-intravenous routes of cyanide (CN) antidotes are needed as an easily administered antidote for first responders and military troops. **Objective:** To compare the return to baseline of mean arterial blood pressure (MAP) between 2 groups of swine in acute CN toxicity and treated with IO HOC or IM HAM. **Methods:** 24 swine (48-52 kg) were intubated, anesthetized, and instrumented. CN was infused until severe hypotension. Animals were randomly assigned to IO HOC or IM HAM and monitored for 60 min.

Results: Baseline mean weights, time to hypotension, and CN dose at hypotension were similar between groups. At hypotension mean MAP (42, 42 mg Hg), blood CN (3.2, 2.9 mcg/ml) and lactate levels (7.4, 7.8 mmol/L) were similar. 12/12 animals in the IO HOC group and 9/12 in IM HAM group survived ($p=0.11$). IO HOC resulted in a faster return to baseline ($p < 0.001$). Bicarbonate, pH, and lactate, levels were similar. Methemoglobin (1.2% IO HOC, 12.8% IM HAM) and CN levels (0 in IO HOC, 15.5 mcg/ml in IM HAM) were greater in the IM HAM group ($p < 0.001$). Cerebral NIRS oxygenation decreased was similar in both groups after antidote ($p=0.78$). Serum nitrotyrosine rose during CN infusion in all animals, but was lower in the IO HOC group at 60 min ($p=0.03$). TNF-a, IL-1b, IL-6 and IL-10 were similar.

Conclusions: Intraosseous hydroxocobalamin led to a faster return to baseline mean arterial blood pressure compared to intramuscular hydroxylamine. Mortality with the intramuscular hydroxylamine group was greater..

Intraosseous hydroxocobalamin vs. intramuscular hydroxylamine for severe cyanide toxicity and shock



Lt Col Vik Bebart, MD FACEP, FACMT
Chief, Medical Toxicology
Wilford Hall Med Center/Brooke Army Med Ctr
San Antonio, TX



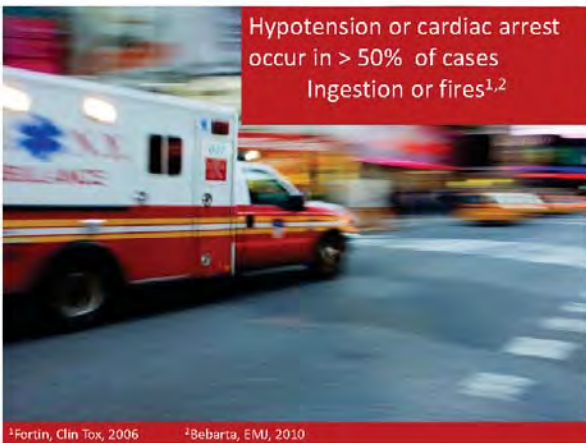
Disclosure

- My opinions and comments do not reflect the official policy or position of the Department of the Air Force or Navy, Department of Defense, US Government
- Funding - USAF Office of the Surgeon General, NIH, US Army, Univ of Texas Health Science Center
- No other financial disclosures
No industry support

Project title

Intraosseous hydroxocobalamin versus intramuscular hydroxylamine in a validated swine model of acute cyanide toxicity and shock – a randomized trial







TOXICOLOGY/ORIGINAL RESEARCH

Hydroxocobalamin and Sodium Thiosulfate Versus Sodium Nitrite and Sodium Thiosulfate in the Treatment of Acute Cyanide Toxicity in a Swine (*Sus scrofa*) Model

Vijayal S. Bebarba, MD, Maj, MC, USAF
 David A. Tanen, MD, CDR, MC, USN
 Julio Lainef, DO, Maj, MC, USAF
 Patricia S. Dixon, MS
 Sandra Valter, PhD
 Anneke Bush, SCD, MHS

From Medical Toxicology (Bebarba), the Department of Emergency Medicine (Lainef), and the Clinical Research Division (Dixon, Valter, Bush), Wilford Hall Medical Center, University of Texas Health Sciences Center, San Antonio, TX (Bebarba); and the Department of Emergency Medicine, Naval Medical Center, San Diego, CA (Tanen).

The views expressed in this article are those of the authors and do not reflect the official policy or position of the Department of the US Air Force, Department of Defense, or the US government.

Similar survival and blood pressure
 Hydroxocobalamin - Improved lactate, pH, cyanide levels

2009 National Best Basic Science Award – SAEM

Is sodium thiosulfate alone effective?

Recommended as single agent¹
 Sodium thiosulfate failed to reverse cyanide induced shock – 100% mortality
 Hydroxocobalamin alone was effective

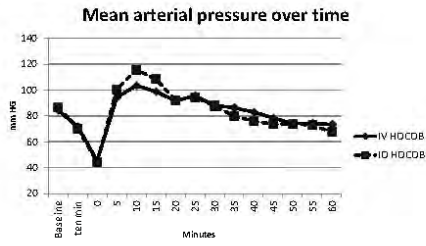
2011 National Best Basic Science Award – SAEM

NATIONAL INSTITUTES OF HEALTH CounterACT – NINDS

USAMRIID

Non intravenous route of cyanide antidotes are needed
 Hypotension may not allow absorption for IM in shock

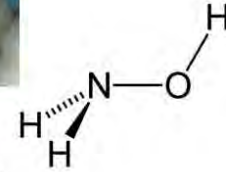
Cyanide antidote kit – IV only
 Hydroxocobalamin – cannot be given intramuscularly
 We found IO HOC as effective as IV for cyanide shock¹



¹VS Bebarta, AFMS 2011 poster, ACEP 2011

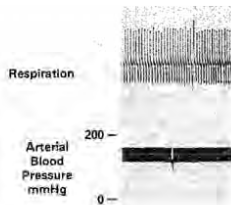


Hydroxylamine



Induces methemoglobinemia
 Intramuscular route is effective against cyanide
 Only 1 study reported

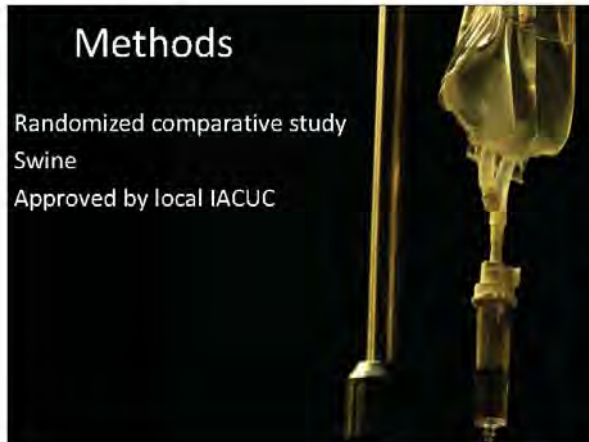
JA Vick, *Mil Med*, 1991



JA Vick, *Mil Med*, 1991

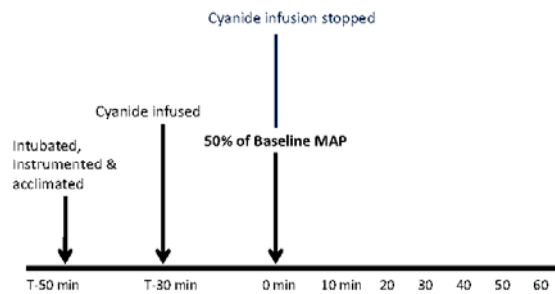
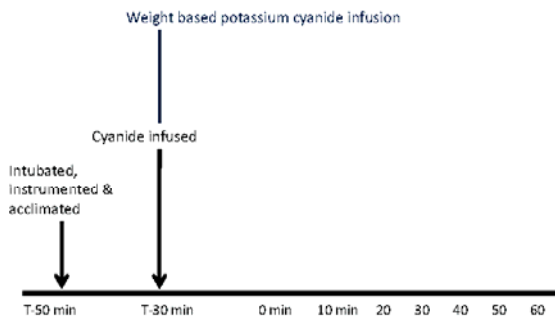
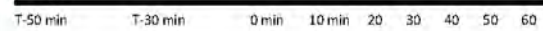
Study Objective

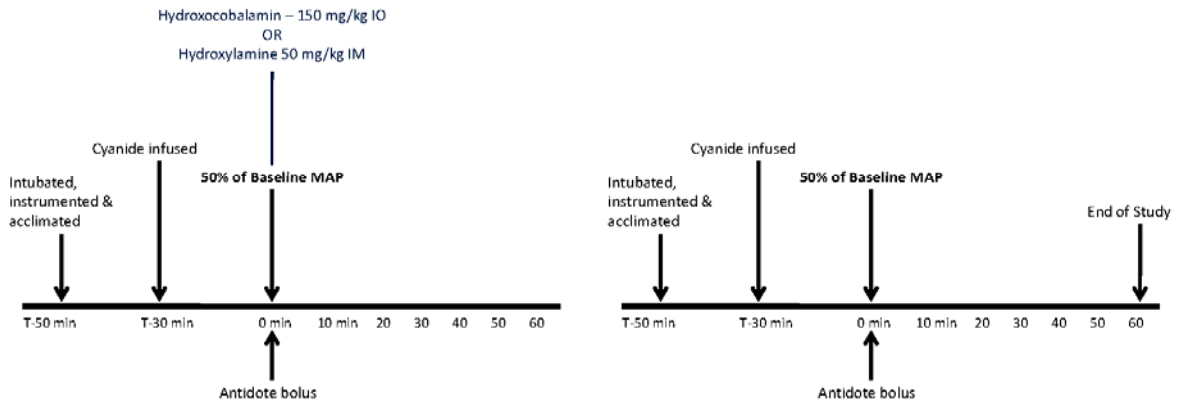
To compare the return to baseline of mean arterial blood pressure between 2 groups of swine in acute cyanide toxicity and treated with IO HOC or IM HA



24 swine (48-52 kg)
 Pulmonary artery catheter with continuous cardiac output
 Continuous central arterial monitoring

Intubated,
 instrumented &
 acclimated





Key outcome measurements

Primary

Change in mean MAP after antidote until 60 min

Secondary

HR, CO, SVR, SVO₂ over time

pH, lactate, bicarbonate, cyanide blood levels

Nitrotyrosine^{1,2}

NIRS – near infrared spectrometry on brain, kidney

Inflammatory markers

Brain tissue microdialysis

¹Gerth K, *Clin Toxicol*, 2006 ²Kan WH, *J Appl Physiol*, 2008

Data analysis

50% increase in MAP after induced hypotension
 Clinically significant

Based on our previous data

12 animals per group for power of 0.8

Two tailed alpha of 0.05

24 animals

Repeated measures ANOVA

Hemodynamic and biochemical measurements

Post hoc t-tests if differences found



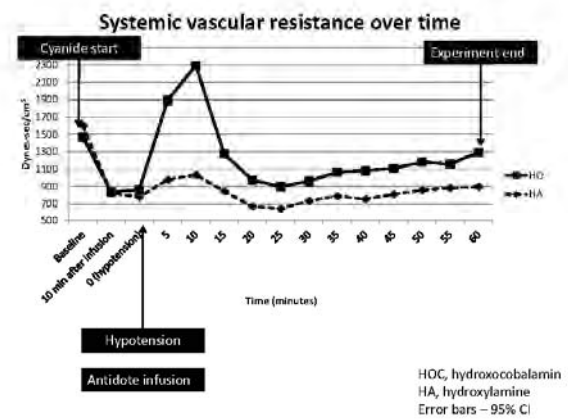
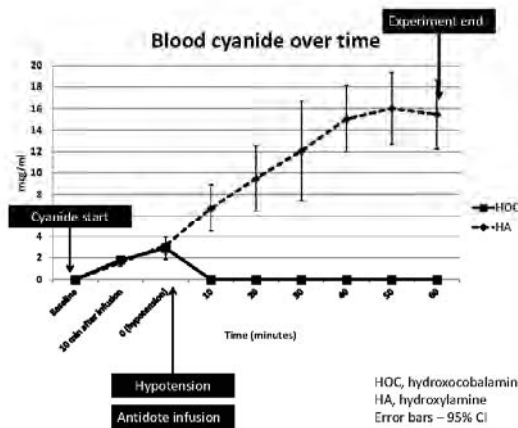
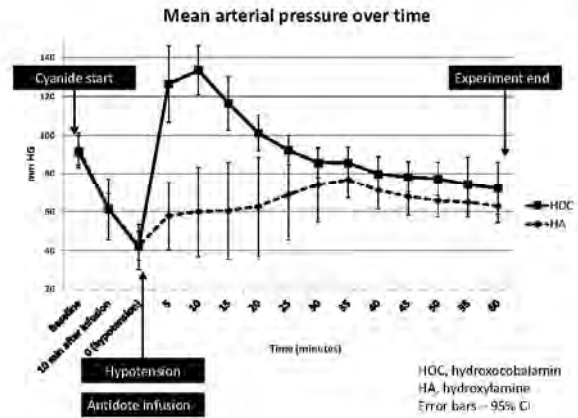
Baseline Characteristics	Hydroxocobalamin	Hydroxylamine
Weight, kg	49±3	50±2
Heart rate, beats/min	83±21	92±29
Mean art pressure, mm Hg	91±8	93±8
Cardiac output, L/min	5±1	5±1

Characteristics at hypotension (MAP < 50% of baseline)	Hydroxocobalamin	Hydroxylamine
Cyanide dose, mg/kg	5±1	4.6±1

Deaths

Antidote	Hydroxocobalamin
Deaths	0/12
Survival	100%*

*p=0.11



Results

At 60 min

Cyanide level great in HA – 15.5 vs 0 mcg/ml

Methemoglobin greater in HA – 13% vs 1%

Results

Systolic and mean arterial blood pressure, SVR, SVO2 – greater in HOC group

Cardiac output – greater in HOC group early and in HA later (p=0.003)

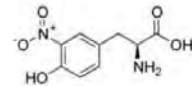
Lactate, bicarb, pH – similar

Results – NIRS



Brain NIRS was similar (p = 0.78)
Kidney NIRS was greater in HA group (p = 0.01)
Paralleled hypotension

Nitrotyrosine



Results pending

In our previous studies

Similar at baseline in all 3 arms

Increased by 60% in all arms at hypotension

Discussion

IO HOC – 100% survival

Reduced cyanide levels – neuro effects

HA – 75% survival

High cyanide and methemoglobin levels

Had improved cardiac output and NIRS kidney at study end

HA mechanism unclear – improved MAP before methemoglobin levels rose

Nitrotyrosine may suggest mechanism¹

¹Gerth K, Clin Toxicol, 2006

Limitations

Animal model

Intravenous vs. inhaled cyanide model

Short duration of observation

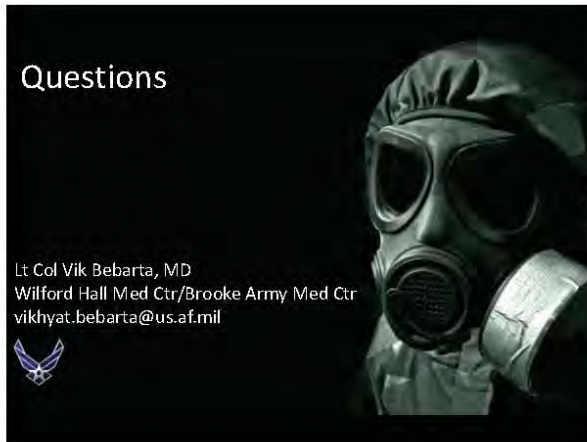
Neurological outcomes not measured

Conclusion

- Intraosseous hydroxocobalamin – faster return to baseline MAP compared to intramuscular hydroxylamine
- Methemoglobin and serum cyanide levels – greater in hydroxylamine arm
- Mortality, acidosis, and lactate – similar
- IM antidotes for cyanide shock may be effective

Acknowledgements

- Research team
 - Vik Bebarta, MD (PI)
 - Dave Tanen, MD (US Navy; Captain)
 - Rebecca Pitotti, RN, MSN
 - Susan Boudreau, RN
 - Patricia Dixon, MS
 - Julio Lairet, DO
 - Sandra Valtier, PhD
 - Anneke Bush, ScD, MHS
- USAF Office of the Surgeon General



Slides for questions

- Call for no IV routes (NIH and USAMRIC)
- Complicated, failure, higher skill level
- Cold CAK – no IO or IM
- HOC – no IO
- We conducted a study to IO vs IV is effective similarly
- What is hydroxylamine? Can state given IM
- Look at an IM route is as effective as IO HOC

Antidote dose

- Hydroxocobalamin
150 mg/kg IV^{1,2}
Package insert – 10 grams (150 mg/kg)
- Sodium thiosulfate
1.65 ml/kg of 25% solution IV – 413 mg/kg^{3,4}
Adult dose – 12.5 grams and repeat – 360 mg/kg

¹Borron S, *Clin Toxicol*, 2006
³Erdman A, *Medical Toxicology*, 2004

²Bebarta, *Ann Emerg Med*, 2010
⁴Kerns R, *GoldFrank's Toxic Emergencies*, 2002



Lab interference

- No known interference for our labs
- Colormetric and co-oximetry mostly¹
- ALT, AST, amylase, bilirubin¹⁻³
- creatinine, magnesium, iron, CK^{1,3}

Beckerman, *Semin Diagn Pathol*, 2009
Curry SC, *Ann Emerg Med*, 1994

Carlsson CJ, *Scand J Clin Lab Invest*, 2011



Antidote infusion

- Volume – 200 ml for each arm¹
Hydroxocobalamin 180 ml
Sodium thiosulfate 20 ml
- Rate based on previous studies – 5 minutes¹
- 10 ml saline flush before and after each drug

¹Bebarta, *Ann Emerg Med*, 2010



Cyanide method

- Whole-blood cyanide levels were measured with spectrophotometry^{1,2}
Diagnostic Center for Population and Animal Health,
Michigan State University, Lansing, MI
- Generates hydrogen cyanide gas, converts it to a cyanogen chloride, and uses spectrophotometric determination of the barbituric acid complex¹
- Does not measure cyanide as cyanmethemoglobin or cyanocobalamin

¹Hughes CL, *Toxicol Mechanisms Methods*, 2003 ²Bebarta VS, *Ann Emerg Med*, 2010



Ongoing or future studies

- Completed – non intravenous routes
 - Intraosseous vs intravenous hydroxocobalamin
 - Intraosseous vs intramuscular methemoglobin inducer
- Ongoing
 - Intramuscular cobalt formulation for cyanide toxicity
- Future
 - Hydroxocobalamin for other toxins and shock states
- All studies are federally funded



Circulation

Resuscitation Science: Biomarkers and Mechanisms

Hydroxocobalamin and Epinephrine Improve Survival in a Swine Model of Cyanide-Induced Cardiac Arrest: A Randomized Trial

Vikhyat S Bebar¹; Rebecca L Pitotti¹; Patricia Dixon¹; Sandra Valtier¹; Charles M Little²

Similar survival with Epi or Hydroxo (73%)
0% survival with no IV treatment
Improved lactate, pH, cyanide level in hydroxo.



Color interference with PA catheter

- Edwards Lifesciences
Engineer
- Possibly SVO2
- SVO2 correlated well with clinical parameters
Mean arterial pressure, cardiac output



Nitric oxide and nitrotyrosine

- Nitric oxide directly
Colormetric chemiluminescent analyzer (Sievers Nitric Oxide Analyzer, GE, Boulder CO)
- Nitrotyrosine
ELISA (Northwest Life Science Specialities, Vancouver, WA)

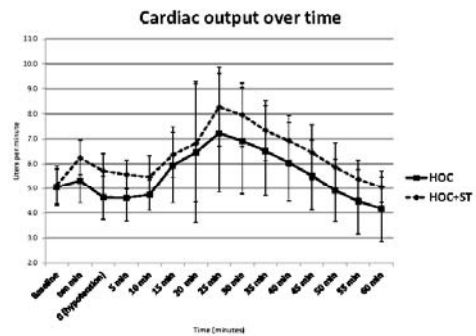
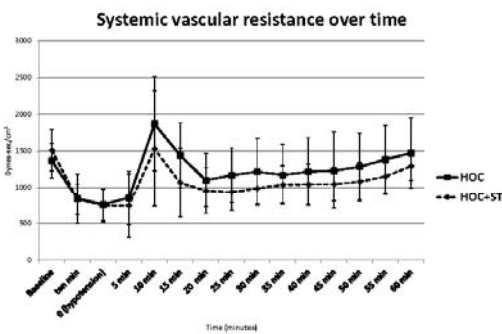
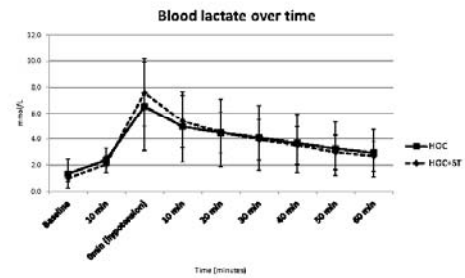


Nitrotyrosine

- Nitric oxide relaxes vascular tone – hypotension^{1,2}
- Nitrotyrosine – downstream NO byproduct²
- Cyanide decreased MAP, increased nitrotyrosine
- HOC increased MAP, and decreased nitrotyrosine
- Previous reports
 Cyanide not used in model and NO not measured³

¹Dembo, Crit Care Med, 2001
³Gerth, Clin Toxicol, 2006

²Kain, J Appl Physiol, 2008



Neurological outcomes

- No measurements in this study
- In our other studies
 NIRS – brain and renal



Cerebral microdialysis



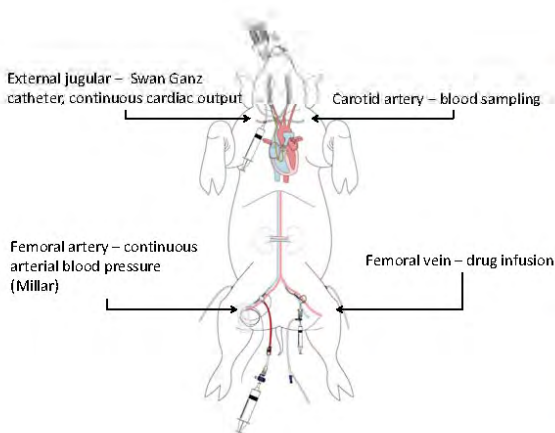
Cerebral Licox – Partial PO₂



Hypotension as primary outcome

- Apnea used as outcome^{1,2}
- Oxygen/ventilation reverses cyanide toxicity³
- Hypotension is common and predictor of death
- 50% MAP used in several swine studies⁴

¹Borron, Clin Toxicol, 2006 ²Vick, Mil Med, 2000 ³Burrow, Am J Vet Res, 1977
⁴Tanenr, Ann Emerg Med, 2000



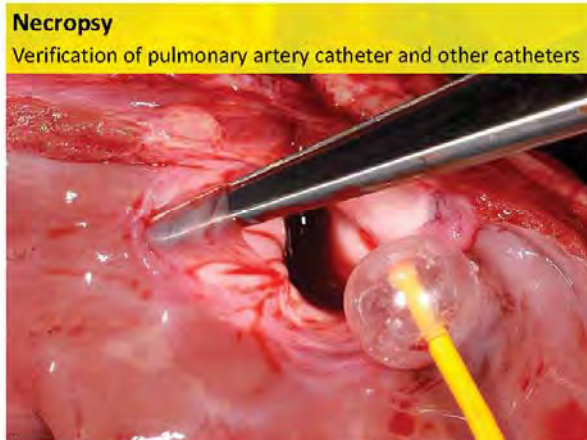
Other slides

Universal antidote

EMS use

- nucleophile and electrophiles
- Work in future studies and universal antidote
- Practice

- Cyanide is a nucleophile (neg charge)
 - Chloride, ammonia, azide, organochlorines, organophosphates?
- Cobalamin is a electrophile (pos charge)



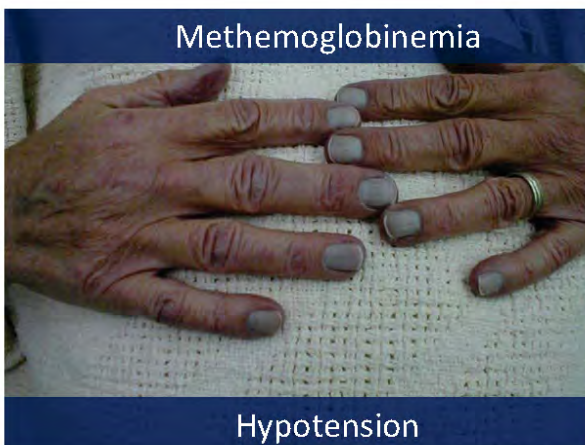
Non IV route

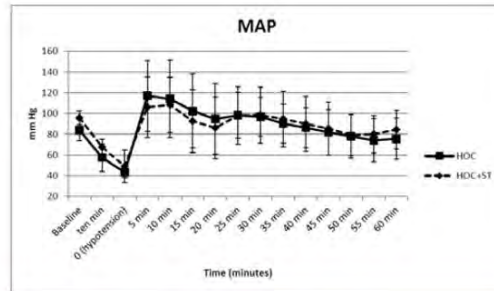
- Non IV route is important - cannot use for HOC
- Need route that requires less skill, simple
- Recommended by other agencies (NIH, USAMRIC)
- Intraosseous route
- Other antidotes

Characteristics	Hydroxo-cobalamin	Cyanide antidote kit
Few serious adverse effects	✓	
Simplicity of use	✓	
Number of drugs used	✓	

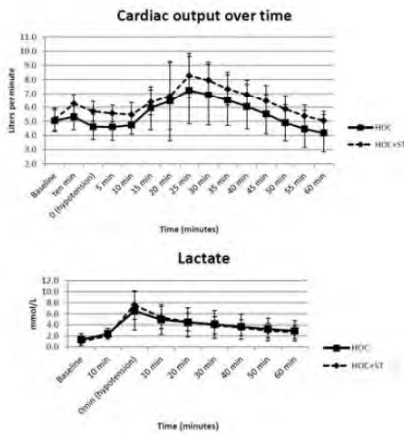
Characteristics	Hydroxocobalamin	Cyanide antidote kit
Few serious adverse effects	✓	
Simplicity of use	✓	
Number of drugs used	✓	
Cost		✓

Characteristics	Hydroxocobalamin	Cyanide antidote kit
Few serious adverse effects	✓	
Simplicity of use	✓	
Number of drugs used	✓	
Cost		✓
Efficacy	?	?





100% mortality in sodium thiosulfate alone



COMBINED EXPOSURES

TO HYDROGEN CYANIDE AND CARBON MONOXIDE
 IN ARMY OPERATIONS: FINAL REPORT

Nov 2008 – NRC of the National Academies of Sciences

Committee on Combined Exposures to Hydrogen Cyanide and
 Carbon Monoxide in Army Operations

Committee on Toxicology

Board on Environmental Studies and Toxicology

Hydroxocobalamin adverse effects

Table 1 Baseline characteristics of the animals

Characteristics	Hydroxocobalamin	Hydroxocobalamin+ Sodium thiosulfate	Sodium Thiosulfate
Weight, kg	49±2	51±2	49±2
Heart rate, beats/min	92±14	81±6	87±13
Systolic blood pressure, mm Hg	107±13	122±11	104±7
Mean arterial pressure, mm Hg	84±10	94±9	80±3
Cardiac output, L/min	5.0±0.8	5.1±0.8	4.8±0.9
Systemic vascular resistance, Dynes-sec/cm ⁵	1366±234	1511±282	1448±340
pH	7.46±0.05	7.47±0.04	7.48±0.05
Bicarbonate, mEq/L	28±2	29±2.3	28±1.9
Lactate, mmol/L	1.4±1.1	1.0±0.2	1.2±0.5

Dynes-sec/cm⁵, dynes-seconds per centimeter⁵; Kg, kilograms; L/min, liter per minute; mEq/L, milliequivalents per liter; mm, millimeters; mmol/L, millimoles per liter. Data presented as means ± standard deviation

Elevated blood pressure, red color, rash, allergic²
 Simple, single, and few adverse effects

Characteristics at hypotension (MAP < 50% of baseline)	Hydroxocobalamin	Hydroxocobalamin + Sodium thiosulfate	Sodium Thiosulfate
Cyanide dose, mg/kg	4.8±2	5.7±2	5±0.8
Time to hypotension, min:sec	27:40±14:21	33:59±13:40	24:56±4:02
MAP at hypotension, mm Hg	43±5	49±6	41±2
Lactate, mmol/L	6.5±1	7.6±0.2	8±0.5
Cyanide level, mcg/ml	3.4±0.7	3.4±0.9	3.9±1
pH	7.42±0.1	7.41±0.1	7.4±0.1



Sodium thiosulfate

- Used and recommended as single agent¹
- As effective as hydroxocobalamin as prophylaxis²
- Few side effects
- However
 - Small or uncontrolled studies³
 - Indirect outcomes⁴



“modern study...[comparing all 3] is needed”³

¹Velez LJ, *Emergency Medicine*, 6th ed
²Kerns R, *Ann Emerg Med*, 2008
³Mengel K, *Toxicology*, 1989 Kerns R
⁴Bebarta VS, *Ann Emerg Med*, 2010

“modern study...[comparing all 3] is needed”

- Hydroxocobalamin
- Hydroxocobalamin
- Hydroxocobalamin and sodium thiosulfate
- Sodium thiosulfate
- Hydroxocobalamin and sodium thiosulfate

³Kerns R, *Ann Emerg Med*, 2008

Is sodium thiosulfate alone effective?

- Recommended as single agent¹
- Effective as hydroxocobalamin as prophylaxis²
- However
 - Small or uncontrolled studies³
 - Indirect outcomes⁴

¹Velez LJ, *Emergency Medicine*, 6th ed
²Kerns R, *Ann Emerg Med*, 2008
³Mengel K, *Toxicology*, 1989
⁴Bebarta VS, *Ann Emerg Med*, 2010

“modern study...[comparing all 3] is needed”

Hydroxocobalamin Hydroxocobalamin and sodium thiosulfate Sodium thiosulfate

¹Kerns R, *Ann Emerg Med*, 2008

Is hydroxocobalamin alone effective?

HOC and sodium thiosulfate used together^{1,2}

Potentially synergistic²

Europe

However¹

Case reports and small studies

No direct comparison reported³




¹Hall AH, *J Emerg Med*, 1987 ²Hall AH, *Crit Rev Toxicol*, 2009 ³Kerns, *Ann Emerg Med*, 2008

Resuscitation with Hextend Leads to Diminished Inflammation as Compared to Hespan in Hemorrhagic Shock

711 HPW/USAFSAM-ETS

Dr. Timothy Pritts

PURPOSE: Hemorrhagic shock is the leading preventable cause of traumatic death. Recent studies have shown that hemorrhagic shock is associated with a dysfunctional inflammatory response and that this response can be affected by resuscitation strategy. CCR1 is a chemokine receptor that is important in inflammatory cell activation and recruitment. It is activated by both CCL3 (MIP-1 α) and CCL5 (RANTES). Hetastarch (6%) is a colloid resuscitation fluid and is available dissolved in normal saline as Hespan or in Lactated Ringer's as Hextend. We hypothesized that resuscitation with Hextend would lessen the inflammatory response to hemorrhagic shock as compared to Hespan. **METHODS:** Mice underwent femoral arterial cannulation and hemorrhage using a pressure-clamp model to a mean arterial pressure of 25 mmHg. After 1 hr of hemorrhagic shock, mice were resuscitated with normal saline, Lactated Ringer's, Hespan, or Hextend. The mice were then sacrificed at intervals to collect serum. Serum was analyzed by multiplex ELISA for cytokine analysis. **RESULTS:** Mice resuscitated with Hextend had a lower level of CCL3 than mice resuscitated with Hespan at 30 min (112.3 vs. 606.3 pg/mL, $p < 0.05$). At 4 hr, mice resuscitated with Hextend had a lower level of CCL5 compared to Hespan (54.6 vs. 203.8 pg/mL, $p < 0.05$). In further investigation, this did not appear to be simply the result of carrier solution alone. **CONCLUSION:** Mice resuscitated with Hextend had a diminished inflammatory response among the activators of CCR1 as compared to Hespan at both early and late time points. Resuscitation with Hextend in place of Hespan may decrease the inflammatory response to hemorrhagic shock.




Resuscitation with Hextend Leads to Diminished Inflammation as Compared to Hespan in Hemorrhagic Shock

Timothy A. Pritts, MD, PhD
 University of Cincinnati


Every Airman a Force Multiplier
 August 2011 AFMS Research Symposium

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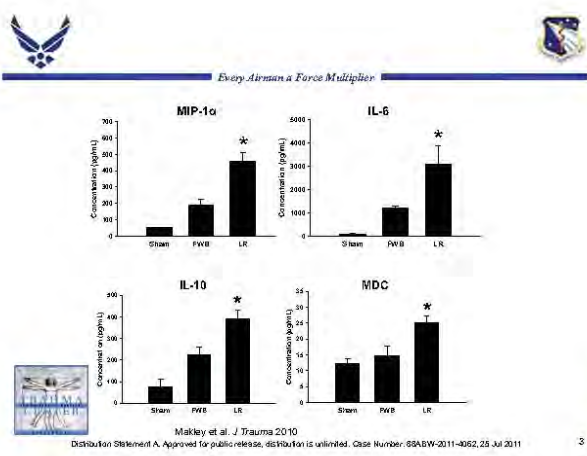



Hemorrhagic Shock

- ✓ 2nd leading cause of lethal traumatic injury
 - ✓ Leading cause of preventable mortality
 - ✓ 10,000-24,000 potentially preventable deaths annually in U.S.
- ✓ Global ischemia-reperfusion injury
 - ✓ Dysfunctional systemic inflammatory response
 - ✓ Infection, sepsis, organ failure, and late mortality




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Background

- ✓ Hespan
 - ✓ 6% hetastarch in normal saline
- ✓ Hextend
 - ✓ 6% hetastarch in lactated Ringers
- ✓ Effect of either fluid on inflammation after resuscitation is unknown

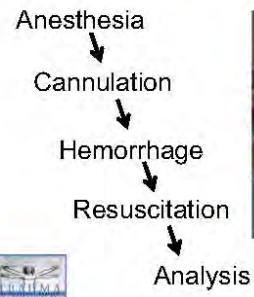


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Hypothesis **Methods**

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Resuscitation with Hespan vs. Hextend will differentially affect the systemic inflammatory profile.



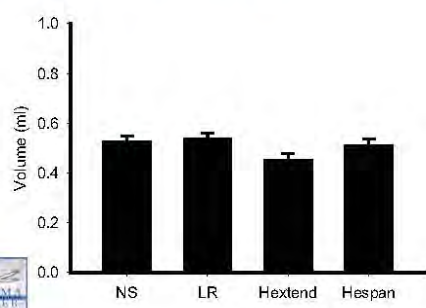
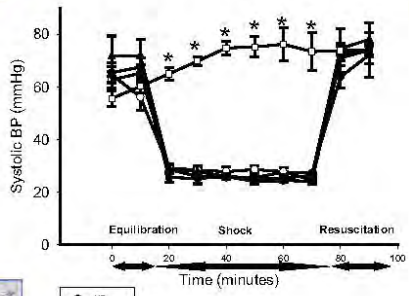
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Shed Blood

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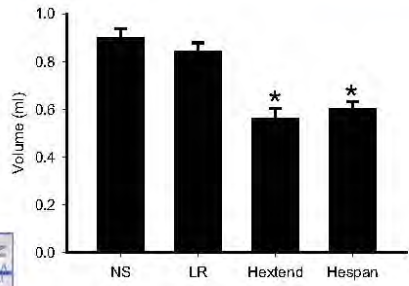


● NS
 ○ Hextend
 ■ Hespan
 □ Sham
 ▲ LR



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Volume of Resuscitation
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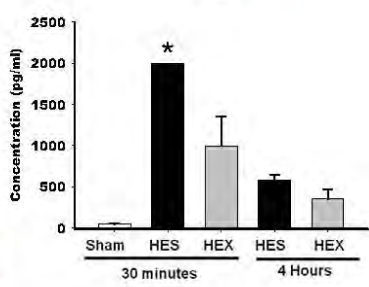
Metabolic Data
Every Airman a Force Multiplier

	pH	CO ₂	HCO ₃	BE	Cl	Hgb	Lac
Sham	7.40	46	28	3.25	110	12.9*	1.31
NS	7.29*	60	29	2	112	9.4	1.90
LR	7.35	49	27	1	111	9.2	1.17
Hespan	7.30*	59	29	2.6	113	7.9	1.38
Hextend	7.32	59	31	4.75	111	8.1	1.15



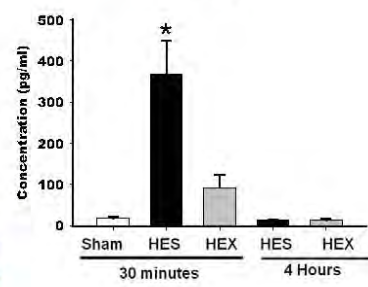
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IL-6
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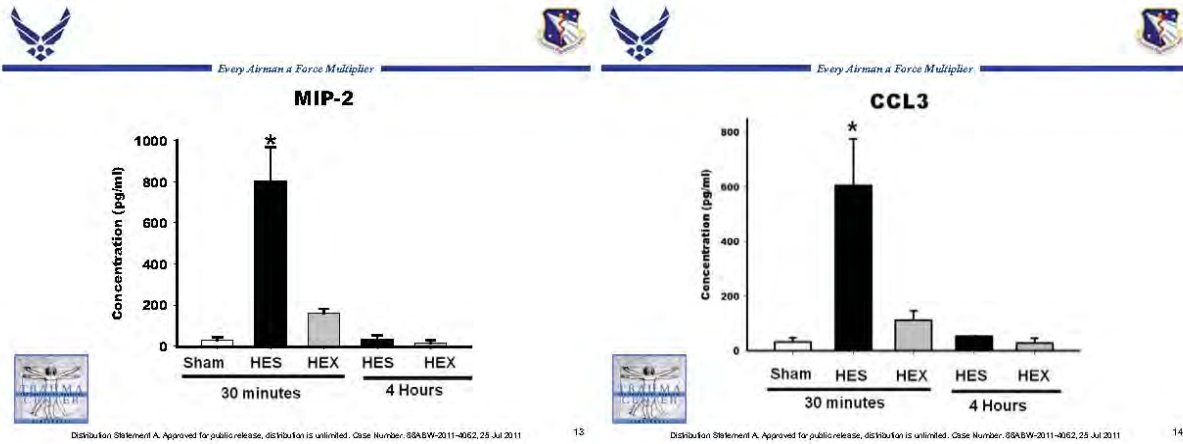


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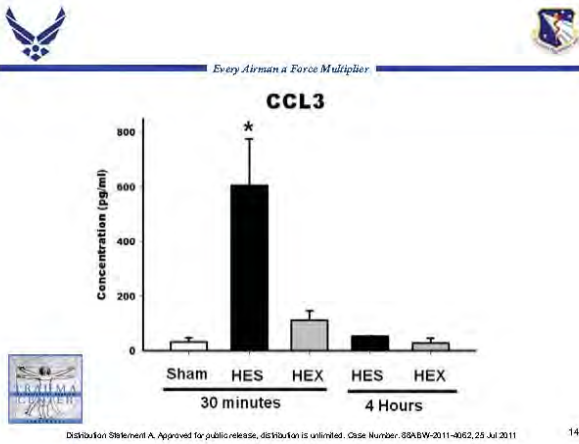
IL-10
Every Airman a Force Multiplier



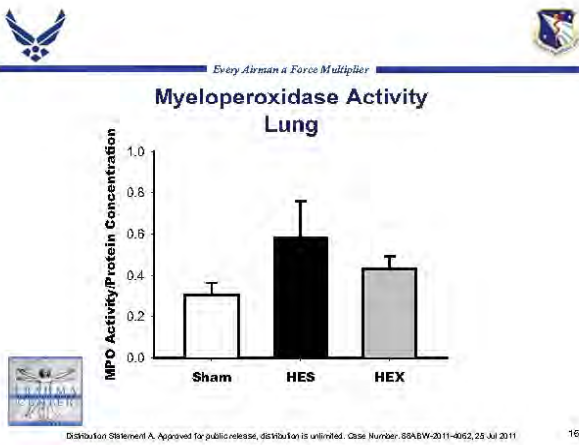
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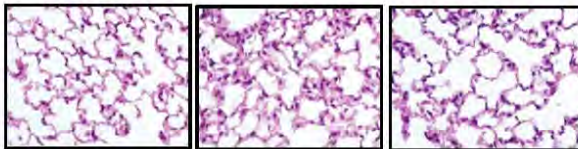
Histology

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Conclusions

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Sham

Hespan

Hextend

- Resuscitation with Hespan leads to greater systemic inflammation as compared to Hextend.
- This increase in inflammation may lead to increased end organ inflammation and complications.



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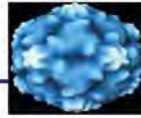
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**Epidemiology of Respiratory Illness During Basic Cadet Training at the U.S. Air Force Academy:
Implications for Future Research and Prevention**

U.S. Air Force Academy

Lt Col Catherine Witkop

BACKGROUND: Respiratory symptoms are responsible for over half of all medical visits during Basic Cadet Training (BCT) at the U.S. Air Force Academy (USAFA) each year and can impact training and duty availability. Cough is the predominant symptom. Environmental conditions and infection have been proposed as possible etiologies. Our objective was to determine if a pathogen was associated with respiratory symptoms during BCT. **METHODS:** This cross-sectional study compared cadets in three groups: (1) FRI (febrile respiratory illness); (2) ARI (afebrile respiratory illness); (3) control (presenting with other than respiratory chief complaint). Each subject completed a questionnaire including demographics, pre-existing medical history, and current symptoms. Nasal wash and throat swab specimens were evaluated by PCR for detection of adenovirus, influenza, rhinoviruses, and other pathogens. Clinical information was abstracted from the medical record. Infection rates were calculated and compared between groups. **RESULTS:** 129 cadets were included. Cough was reported as a symptom in 115/129 cadets, including 10/12 FRI, 88/99 ARI, and 17/18 controls. Rhinovirus was detected in 56/129 (43.4%) of subjects, including 51/115 (44.3%) of those with cough and 5/14 (35.7%) of those without cough. Adenovirus was only detected in one cadet at levels consistent with possible infection. **CONCLUSIONS:** Rhinovirus was identified in almost half of cadets studied. It was not significantly associated with cough, although there were very few cadets without cough in this study. Further study is warranted to test for factors such as altitude, environment, and immune status and to evaluate possible preventive measures, with implications for deployed troops.



**Epidemiology of Respiratory Illness
during Basic Cadet Training at the
U.S. Air Force Academy:
A Molecular Approach**

**Lt Col Catherine Witkop
Preventive Medicine
US Air Force Academy**

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Disclaimer

- *The opinions expressed in this brief are solely those of the authors and do not represent an endorsement by or the views of the United States Air Force Academy, the United States Air Force, the Department of Defense, or the United States Government.*

- *I have no financial disclaimers to disclose.*

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U.S. Air Force Academy

- Undergraduate military academy with over 4000 students (cadets)
- Four year institution of higher learning
- Successful cadets graduate as 2nd Lt with a Bachelor of Science Degree
- Cadets live in dorms with 2-3 to a room



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Basic Cadet Training (BCT)

- Six week rigorous training
- BCT 1:
 - In dorms (sleep 2-3 to a room)
 - Academic, physical, military training
- BCT 2:
 - 14 days in Jacks' Valley
 - Field training
 - Sleep 12-15 to a tent
 - Obstacle, assault, confidence courses
 - Support operations also move to Jacks' Valley



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What is "Jacks' Hack"?

- Lay term for the cough and other respiratory symptoms that occur during BCT at USAFA
- Most Basics get it and it can last for weeks
- Etiology is currently unknown but thought to be some combination of:
 - Environment (dry, dusty conditions in Jacks' Valley)
 - Altitude
 - Depressed immune system/stress
 - Respiratory pathogen

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Background

- Respiratory symptoms are responsible for over half of all medical visits during BCT at USAFA each year and can impact training and duty availability



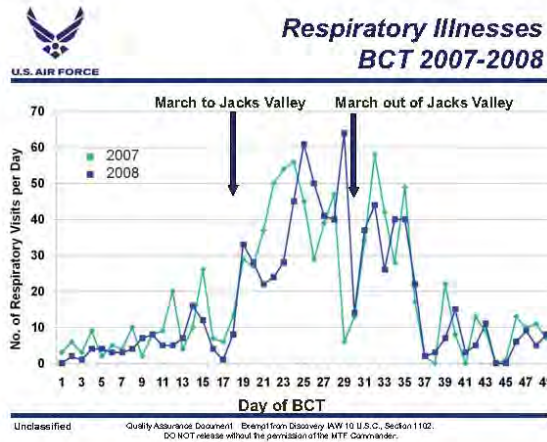
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Respiratory Illnesses BCT 2007-2008

Year	No. Total Visits for Resp. Illnesses	% of Visits Occurring During Field Training	No Cadets with Resp. Illnesses	Total No. Cadets	% Cadets with Resp. Illnesses
2007	871	48%	551	1296	42.5%
2008	802	55%	540	1356	39.8%

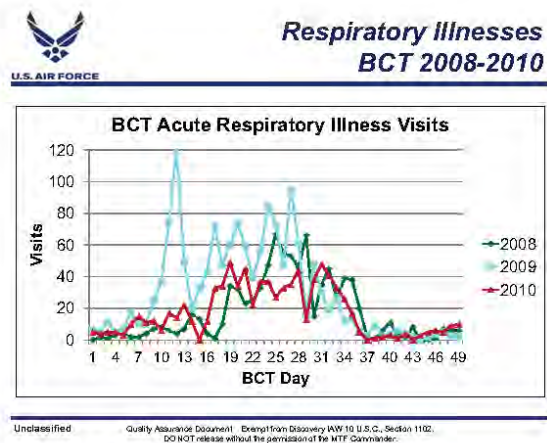
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Background

- Adenovirus has been implicated in respiratory illnesses among recruits at training bases
- Adenovirus generally peaks in weeks' 3-5
- A study performed at USAFA in summer 2009 showed no positive results for adenovirus
- An nH1N1 outbreak during the study period precluded definitive conclusions about infectious etiologies
- Rhinovirus, however, was identified in a large subset of cadets

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Objective

- The objective of this study was to determine if adenovirus, rhinovirus or another pathogen was associated with respiratory symptoms in Basic Cadets during BCT.

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U.S. AIR FORCE

Methods

- Cross sectional, descriptive design
- Participants: Male and female cadets aged 17 and above who presented for medical care at the USAFA cadet clinic or infirmary tent at Jacks' Valley
- Time period: 24 Jun-6 Aug 2010

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U.S. AIR FORCE

Groups

- Group 1 (FRI): Cadets with temperature of 100.5 or greater and any upper respiratory symptom such as cough, sore throat, rhinorrhea
- Group 2 (ARI): Cadets with respiratory illnesses, but without fever
- Group 3 (Control): Cadets who present to the clinic/tent for care for symptoms other than respiratory symptoms (e.g. musculoskeletal injuries)

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U.S. AIR FORCE

Questionnaire

- The purpose of the study and the protocol were explained to each eligible cadet
- Signed informed consent (approved by USAFA and USUHS IRBs) was obtained
- Each subject completed a questionnaire:
 - Information regarding gender, race, region/state of residence, squadron, dorm room/tent, smoking history, pre-existing medical history, symptoms, previous visits, and missed training

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U.S. AIR FORCE

Specimen Collection

- Nasal wash and throat swabs were performed per standard protocol
- Clinical information about the encounter was abstracted from the subject's medical record
- Specimens were shipped overnight to the Advanced Diagnostic Laboratory (ADL) at Lackland AFB
- Samples were processed at the ADL for detection and characterization of a variety of pathogenic and commensal organisms

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Pathogens Tested by PCR

- Adenovirus (3,4,7, 11, 14, and 21)
- Influenza A (H1, H3, H5A, H5B)
- Influenza B
- Parainfluenza viruses (types 1, 2, and 3)
- Rhinovirus
- Respiratory Syncytial Virus (RSV)
- Human Metapneumovirus (HMPV)
- Bocavirus (NS1 and NP1)
- Epstein-Barr Virus (EBV)
- Coronaviruses
- Streptococcus pneumonia
- Streptococcus pyogenes
- Mycoplasma pneumoniae
- Chlamydia pneumoniae
- Bordetella pertussis I
- Bordetella pertussis II
- Legionella pneumoniae
- Haemophilus influenza and subtyping

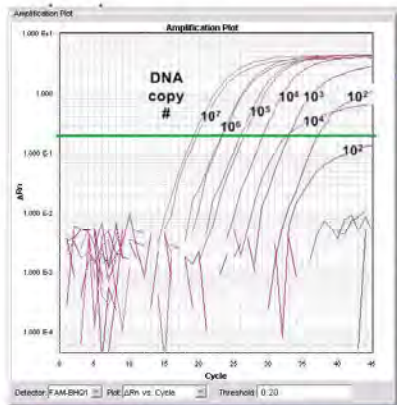
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Real-time PCR Technology

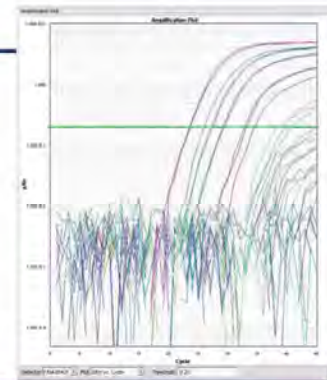
- Each time a target DNA sequence is replicated, a fluorescent molecule is released
- The amount of fluorescence correlates to the amount of DNA

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Cycle threshold value (Ct):
 The replication cycle number at which the fluorescence level (shown as an amplification curve for each sample) crosses a set threshold line (green)

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•The left-most purple curve is the positive control. The 3 right-most greenish curves are samples with Ct values greater than 35, and are considered negative.

•The blue/purple lines in between are samples that are considered positive for rhinovirus, with Ct values ranging from 26 to 34

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U.S. AIR FORCE *Validation of USAFA Biology Laboratory Techniques*

- If nasal wash specimens contained >3 cc of washing, 0.5 cc was provided to the USAFA Department of Biology laboratory
- Analyzed for the presence of influenza A, swine influenza H1, swine influenza A (as a confirmatory test to swine influenza H1), adenovirus, and rhinovirus
- Analytical results were compared with results from ADL

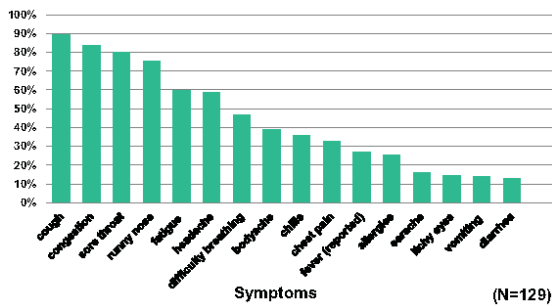
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U.S. AIR FORCE *Results*

- 129 cadets were included in the study
 - 37 females
 - 92 males
- Mean temperatures among the ARI and control groups were not significantly different
 - 97.86 ARI vs. 97.84 among controls
- Mean temperature among those in the FRI group was 101.3 (p<0.05)
- Cough was reported as a symptom in 115/129
 - 10/12 FRI, 88/99 ARI, and 17/18 controls

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U.S. AIR FORCE *Proportion of self reported symptoms of study participants*



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U.S. AIR FORCE *Adenovirus*

- The pan-screen for adenovirus was positive (Ct < 35) in only one subject
- If a more liberal cut-off of Ct <40 is used, adenovirus was detected in 3/12 (25%) of FRI and 8/88 (9.1%) of ARI

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Rhinovirus

Outcome (n)	Rhinovirus (Ct ≤40)		Rhinovirus (Ct ≤35)	
	n	%	n	%
ARI (99)	61	61.6	43	43.4
FRI (12)	6	50	5	41.7
Control (18)	11	61.1	8	44.4
Cough as a symptom (115)	71	61.7	51	44.3

*Lab confirmed Nasal Wash or Throat Swab

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Rhinovirus

Outcome (n)	Rhinovirus (Ct ≤40)		Rhinovirus (Ct ≤35)	
	n	%	n	%
ARI (99)	61	61.6	43	43.4
FRI (12)	6	50	5	41.7
Control (18)	11	61.1	8	44.4
Cough as a symptom (115)	71	61.7	51	44.3
No Cough (14)			5	35.7

*Lab confirmed Nasal Wash or Throat Swab

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Bordetella Pertussis

- Several specimens positive for Bordetella species but negative for Pertussis
- One positive for Pertussis; had been treated when results detected
 - Cadet left the Academy during the first week of training; no further cases

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Conclusions

- Respiratory symptoms were common among cadets during BCT, including in those who presented with a non-respiratory complaint
- Rhinovirus was identified in almost half of cadets studied
- It was not significantly associated with cough, although there was a very small number of cadets without cough in this study

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U.S. AIR FORCE

Conclusions

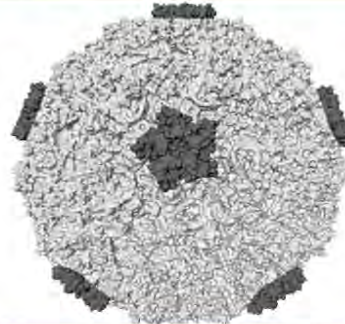
- Adenovirus may be a contributing factor in patients with FRI, but not in those with ARI
 - This finding was useful in helping determine policy for adenovirus vaccine administration at USAFA
- The use of real-time PCR technology can assist in the detection of pathogens in a particular population and potentially aid in the development of preventive measures

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Rhinovirus



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U.S. AIR FORCE

Rhinovirus

- RNA virus in the picornavirus family
- Symptoms: rhinorrhea, nasal congestion, sore throat, non-productive cough, sneezing, facial pressure and headache
- Direct contact (e.g. sneezing or coughing of aerosolized particles) seems to be the most efficient mode of transmission
- Can persist on door knobs, silverware, masks, etc

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Rhinovirus

- Symptoms typically occur within 16 hours of inoculation and last for a median of 9.5 to 11 days
- The symptoms of "Jacks' Hack" are similar to findings in patients with rhinovirus infection

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Future Directions

- Further study is warranted to test for other factors such as altitude, environment, and immune status in this USAFA population.



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Future Directions

- Further study should also focus on potential preventive measures, such as education and supplements to help reduce the spread of rhinovirus
- We began to investigate that this year and, to give a sneak preview of our study from this year.

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BCT 2011 Study Protocol

- Add educational brief for all Basic Cadets on Day 1 of BCT
 - Focused on basic public health messages
 - Hand-washing, covering cough
 - Discussing possible role of an infectious agent in Jacks' Hack
- Educational campaign (signs) in the dormitories of half of the squadrons
- Compare rates of respiratory illness diagnoses between 2010 and 2011
- Compare incidence of rhinovirus in Squadrons A-E and F-J

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Status of 2011 Study

- Study was in process when norovirus outbreak among Basic Cadets struck on 21 Jul
- The experiences at USAFA in BCT 2009 and 2011 highlight the need for field-deployable rapid diagnostic tests
 - In both cases, earlier identification of H1N1 and norovirus might have prevented lost training time
- In deployed locations, such technology can be a force-multiplier

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U.S. AIR FORCE

Acknowledgements

- **Advanced Diagnostic Laboratory**
 - Lisa Lott, Matt McDonald and Team
- **USAFA Department of Biology**
 - Mel Grogger, Michelle Wickersheim
- **USUHS Preventive Medicine Residency Program**
 - Shane Steiner
- **Biostatistical Support**
 - Katie Tastad

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U.S. AIR FORCE

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- Anzueto A and Niederman MS. Diagnosis and treatment of rhinovirus respiratory infections. *Chest*. 2003;123: 1664-1672.

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Virulence and Resistance Trends of Staphylococcus aureus in an Outpatient Military Population

59 MCCS SGOBV


Capt Corey Falcon

Skin and soft tissue infections due to community-associated methicillin resistant Staphylococcus aureus (CA-MRSA) pose a clinical challenge due to their increasing incidence and virulence. This epidemiologic study was undertaken to determine the occurrence of virulence and resistance factors in *S. aureus* isolated from an outpatient population in San Antonio, TX. A total of 200 *S. aureus* isolates from samples submitted for culture from outpatient clinics over 5 months in 2009 were tested for the presence of *mecA*, *mupA*, TSST-1, and PVL genes using EVIGENE qualitative nucleic acid hybridization assays. Antibiotic susceptibility profiles for each of the isolates were obtained. Results show that 50% of the isolates were MRSA. The prevalence of PVL was 56%. 84% of the MRSA isolates were positive for PVL while 29% of the MSSA isolates demonstrated PVL. Only 4% and 7% of the isolates carried the *mupA* and *tsst-1* genes respectively. The MRSA burden in our community is significant. The data suggests that Mupirocin remains an option for the elimination of *S. aureus* nasal carriage. There appears to be an increasing incidence of Panton-Valentine leukocidin in *S. aureus* strains, especially MRSA. Interestingly, the majority of isolates with toxic shock syndrome toxin were methicillin sensitive *S. aureus*. Ciprofloxacin, Levofloxacin, and Erythromycin should not be used to treat *S. aureus* infections in this population. There is a significant occurrence of inducible Clindamycin resistance in the MRSA strains. Bactrim and Tetracycline are viable antimicrobial options for treating *S. aureus* in our community.

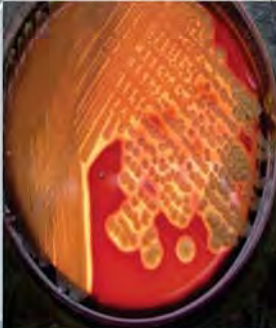
**Virulence and Resistance Trends of
Staphylococcus aureus in an
outpatient military population**

COREY FALCON MD, CAPT,
USAF, MC
2011 GRADUATE OF SAUSHEC
PEDIATRIC RESIDENCY




Background 

- Community-associated methicillin resistant *Staphylococcus aureus* (CA-MRSA)
- *mecA*
 - PBP-2a
- *Panton-Valentin leukocidin (PVL)*
 - lukS-PV & lukF-PV



Background 

- *TSST-1*
- *mupA*
 - 2006 study from Madigan Army Medical Center
 - Broth microdilution
 - E-test

Objectives of Study 

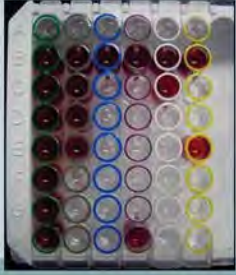
- Determine occurrence of virulence and resistance factors in *S. aureus* infections
- Discover prevalence of Methicillin-resistant *S. aureus*
- Determine USA typing for MSSA and MRSA strains using pulse field gel electrophoresis (PFGE)
- Determine effective outpatient treatment options for MRSA
- Evaluate for significant differences between isolates from children and adults

Materials & Methods

Evigene®:

- qualitative nucleic acid hybridization assay
- Results in 3 hours

Photo 1. Example of positive test (red) and negative test (clear)



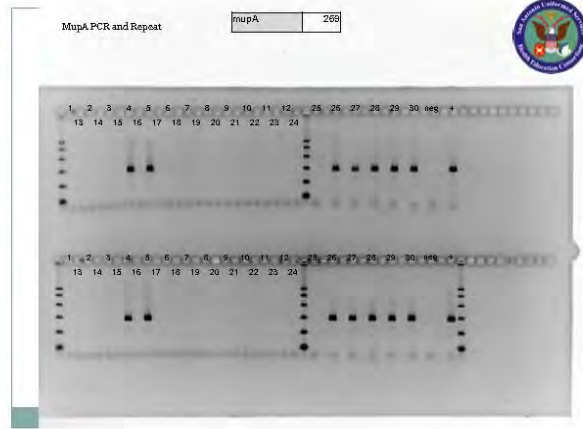
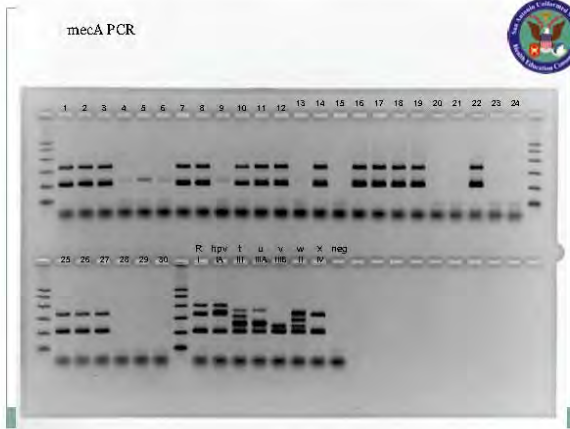
Materials & Methods

- 200 *S. aureus* isolates
- Tested each isolate for *mecA*, *mupA*, *Tsst-1*, and *lukS-lukF-PV* (PVL) genes
- Positive and negative controls

Results

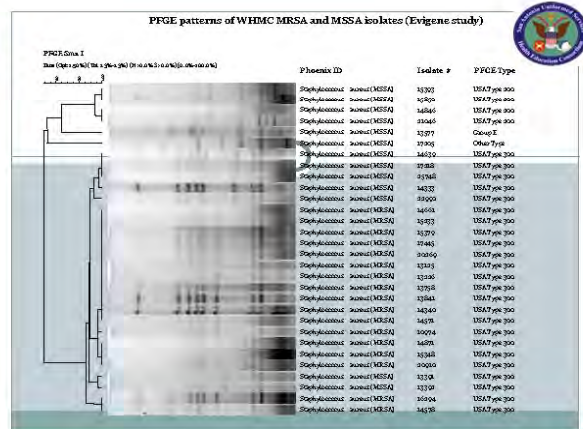
Materials & Methods Part #2

- *mecA*, *tsst-1*, *mupA*, and PVL PCR confirmatory test
- Broth microdilution and E-test for Mupirocin resistance
 - 8 *mupA* + and 22 controls
- Pulse field gel electrophoresis for SA typing




Results #2


- *mecA* and *tst-1* PCR and Evigene correlate
- 7 of 8 *mupA* Evigene isolates positive for *mupA* on PCR
- 1 PVL + Evigene isolate negative for PVL on PCR and vice versa
- Majority of MSSA & MRSA type USA 300




Results



- 5/7 *mupA* + PCR demonstrate mupirocin resistance on broth microdilution and E-test




Results

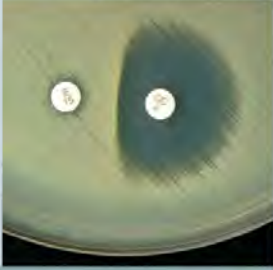


- **Pediatric isolates vs. adult isolates**
 - *mecA*
 - 48% (29/60) vs. 49% (69/140)
 - Similar results for PVL, *tsst-I*, and *mupA*


Results



- **Antibiotic susceptibility profiles**
 - Constitutive Clindamycin Resistance
 - Inducible Clindamycin resistance
 - Bactrim 98%, Tetracycline 96%
 - Fluoroquinolones: 49%
- Photo 2. D-test for Inducible Clindamycin resistance



Discussion



- CA-MRSA burden
- Evigene provides reliable, rapid detection of *mecA* and other virulence factors
- Pediatric isolates similar to adults

Discussion



- Mupirocin resistance
- USA type 300
- Bactrim and Tetracycline
- Clindamycin ???

Future Projects



- Possible utility of Evigene® in deployed settings and basic training
- Correlate laboratory markers of virulence with severity of disease

Contributors



- Ms. Donna Hensley, Civilian, 59th MDW Clinical Research Division
- Lt Col Deena Sutter MD, SAUSHEC Staff, Pediatric Infectious Disease
- Ms. Katrin Mende Ph.D, Civilian Microbiologist, BAMC
- Laboratory Support
 - Yadira Encina and Hermosilla Atamosa

- **QUESTIONS?**



Automation and Assessment of a Whole Blood Interferon Gamma Release Assay (IGRA) for LTBI Screening: The USAF-CDC TB Collaboration

711HPW/USAFSAM-PHR

Dr. Donald Goodwin

BACKGROUND: In 2006, a USAF-CDC TB Collaboration set out to enhance TB diagnostics. By April 2010 it had automated an IGRA (the QFT-GIT); completed three clinical trials to comparatively assess performance of the QFT-GIT with the TST; and, completed enabling SBIR software development efforts.

METHODS: The USAF led, multiple-sector, multiple-site, multiple-partner collaboration established laboratories at USAFSAM and at CDC's Division of TB Elimination. Private sector partners were engaged with CRADAs and contracts. Three IRB approved clinical trials were subsequently completed. Centralized IT support enabled coordinated quality assurance monitoring which optimized data quality and analytic efficiencies. Use of on-site coordinators, weekly conference calls, periodic site visits, and data/specimen exchanges enabled synchronization of efforts, validation of observations, and timely problem solving.

RESULTS: Trial #1 automated the QFT-GIT and produced an experience-refined testing protocol used to support mass LTBI screening among 2,367 USAF basic military trainees. Problems identified in Trial #1 were addressed in Trials #2 and #3.

Trial #2 assessed reproducibility of the TST and QFT-GIT (automated and manual) and measured impacts attributable to: specimen collection; antigen mixing; processing variability; diurnal variation of IFN γ concentrations; serial testing; and, inter-laboratory variability (USAF, CDC, and Tripler AMC). Test concordance/discordance was described; and, boosting with serial testing assessed.

Trial #3 documented specimen volume variability impacts on clinical results, and a work-around assessed.


DISCUSSION: Assessments considered both statistical and clinical significance. The SBIR effort yielded a 21 CFR Part 11 compliant, automation-facilitating software usable on any automated ELISA platform for producing validated, electronically reportable QFT-GIT results.





Automation and Assessment of a Whole Blood Interferon Gamma Release Assay (IGRA) for LTBI Screening: The USAF-CDC TB Collaboration

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QuantIFERON®-TB Gold In-Tube (QFT-GIT): MANUAL METHOD




Stage-1: Whole Blood Culture



Mtb**
PHA




Incubate at 37 °C for 16-24 h: sensitized lymphs produce IFN-γ



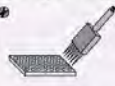
Centrifuge to separate plasma above gel plug

Collect 1 mL of heparinized whole blood in 3 tubes


Stage 2: Measure [IFN-γ] & Interpret




Add 50 μL of working conjugate to each well. Add 50 μL of plasma to standard. Incubate for 150 minutes at room temperature.



Wash plate 4 times. Add 50 μL of substrate. Incubate 30 minutes at room temperature.



Add 50 μL of stop solution. Read absorbance at 450nm (500-650 nm ref).



Software calculates results and produces a report

*FDA Approved Oct 2007. **TB Antigens: ESAT 6, CFP 10, & TB 1.7

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MEASUREMENTS FOR 1 QFT-GIT: MANUAL DETERMINATION



#	Description of Measurement
1	Time blood was collected
3	Collect 0.8 to 1 mL of blood into 3 tubes
2	Time of onset and end of incubation
1	Incubator temperature
1	300 μL of H2O to reconstitute conjugate
1	Volume of H2O to reconstitute IFN-γ standard
7	300 μL of green diluent for 7 standards
1	300 μL of stock standards for 1 st standard
6	300 μL of standards transferred for serial dilution
1	Volume of green diluent for conjugate solution
1	Volume of conjugate concentrate for conjugate solution
19	50 μL of conjugate solution to control wells (19) & samples (3)
2	Time of onset and end of 2-h ELISA incubation
1	Volume of wash concentrate for wash solution
1	Volume of H2O for wash solution
19	100 μL of substrate to each control and sample well
2	Time of onset and end of 30-min incubation with substrate
19	50 μL of stop solution to each control and sample well
38	Optical density of control and sample wells at 450 & 650 nm
121	TOTAL # of Measurements




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MEASUREMENTS FOR 1 QFT-GIT: AUTOMATED DETERMINATION



#	Description of Measurement
1	Time blood was collected
3	Collect 0.8 to 1 mL of blood into 3 tubes
2	Time of onset and end of incubation
1	Incubator temperature
1	300 μL of H2O to reconstitute conjugate
1	Volume of H2O to reconstitute IFN-γ standard
1	300 μL of stock standards for 1 st standard
1	Volume of green diluent for conjugate solution
1	Volume of conjugate concentrate for conjugate solution
1	Volume of wash concentrate for wash solution
1	Volume of H2O for wash solution
14	Total measurement not automatable
7	300 μL of green diluent for 7 standards
6	300 μL of standards transferred for serial dilution
19	50 μL of conjugate solution to control wells (19) & samples (3)
2	Time of onset and end of 2-h ELISA incubation
19	100 μL of substrate to each control and sample well
2	Time of onset and end of 30-min incubation with substrate
19	50 μL of stop solution to each control and sample well
38	Optical density of control and sample wells at 450 & 650 nm
107	Total measurement automatable




Distribution Statement A: Approved for public release; distribution is unlimited. Case Number: 28ABW-2011-094, 28 Jun 2011



USAF-CDC TB TRIAL #1: QFT-GIT AUTOMATION - Methods Overview

(FWH20060120H, Pls: Dr. D. Goodwin, Dr. G. Mazurek)



OBJECTIVE: To automate the ELISA reading using a Triturus analyzer; to compare the TST versus the QFT-GIT in a mass screening setting.

STUDY SUBJECTS: 2,374 Basic Military Trainees (BMT) at Lackland AFB.

METHOD: Used both TST & QFT-GIT to screen BMTs for LTB; included completion of an epidemiological questionnaire. IRB-approved protocol.



Triturus ELISA Analyzer
(GRIFOLS)

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USAF-CDC TB TRIAL #1: ELISA ANALYZER



Triturus ELISA Analyzer
(Grifols)

Distribution Statement A. Approved for public release, distribution is unlimited. Case Number: 85ABW-2011-3694, 28 Jun 2011



QFT-GIT: RESULTS INTERPRETATION



Interpretation	Nil	TB Response*	Mitogen - Nil
Positive	≤ 8.0	≥ 0.35 IU ⁹ /mL and ≥ 25% of Nil	Any
Negative	≤ 8.0	< 0.35 IU ⁹ /mL or < 25% of Nil	≥ 0.5
Indeterminate	≤ 8.0	< 0.35 IU ⁹ /mL or < 25% of Nil	< 0.5 Low Mitogen
	>8.0 High Nil	Any	Any

TB Response* is the IFN-γ concentration in plasma from blood stimulated with ESAT-6, CFP-10, & TB7.7, minus the IFN-γ concentration in plasma from unstimulated blood.

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USAF-CDC TB TRIAL-1: MANUAL DATA ENTRY



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**USAF-CDC TB TRIAL-1: RESULTS
 TST & QFT-GIT SPECIFICITY**



Limited to low-risk BMTs (Assumed not to have been infected)

TST < 10 mm for 1,617 of 1,626 = **99.4%*** (specificity)
 TST > 10 mm = 9/1,626 = 0.55%

QFT-GIT < 0.35 IU for 1,585 of 1,590** = **99.7%*** (specificity)
 QFT-GIT ≥ 0.35 IU = 5/1,590 = 0.31%

*Difference is not statistically significant
 **Excluding 36 indeterminates

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**USAF-CDC TB TRIAL-1: RESULTS
 TST & QFT-GIT Concordance/Discordance**



Evaluated: 2,076 (includes those with out-of-range volume and those with increased TB risk)

	TST -pos	TST -neg	Total
Concordance*			
TST-pos/QFT-GIT-pos:	1 (0.05%)		
TST-neg/QFT-GIT-neg:	2,057 (99.08%)		
Discordance*			
TST-pos/QFT-GIT-neg:	13 (0.63%)		
TST-neg/QFT-GIT-pos:	5 (0.24%)		
Total	14	2,062	2,076

QFT-GIT/TST OR_{LTBI} = 0.427 (95% CI: 0.164 - 1.114)
57% fewer screen-positives with the QFT-GIT.

*Does not include indeterminates

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**USAF-CDC TB TRIAL-1: RESULTS
 QFT-GIT Volume Problem Documented**



BLOOD COLLECTION VOLUMES

In-Range Volumes (0.8 to 1.2 mL)	1,488 (62.3%)
Out-of-Range Volumes* (<0.8 mL or >1.2 mL)	886 (37.3%)
TOTAL	2,374

*INDETERMINATE tests (n=50) associated with out-of-range volumes.

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**USAF-CDC TB TRIAL-2: Reproducibility
 Objective & Methods Overview**



(FWH20080002H, PI: Dr. K. West, Dr. G. Mazurek)

OBJECTIVE: To compare QFT-GIT & TST performance under conditions that might impact test results.

STUDY SUBJECTS: 159 persons with a history of a positive TST.

METHOD: 6 visits; 12 QFT-GIT tests (36 tubes) & 3 TSTs; IRB approved.

	Sat	Sun	Mon	Tues	Wed	Thurs	Fri
Week-1				6:30 a.m. Consent & HIPAA Blood			
Week-2			6:30 a.m. Blood	6:30 a.m. Blood 2 TSTs (L & R)		6 a.m. Read TSTs	9 a.m. Read TSTs
Week-3				6:30 a.m. Blood 1 TST		6 a.m. Read TSTs	9 a.m. Read TSTs

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METHODS



- QFT-GIT performed as follows unless stated otherwise:**
- 1 mL of blood collected 6 a.m. to 9 a.m.
 - Mixed on "Rock & Roll" mixer and incubated w/in 1 h.
 - Incubated for 23 to 24 h at 37.0 ± 1.0 °C.
 - Centrifuged and stored at 6.0 °C.
 - ELISAs performed with automated ELISA analyzer w/in 24 h.
 - Interpreted as per CDC guidelines.
- TST performed with Tubersol PPD:**
- Induration at 48 to 72 h.
 - Interpreted as + if ≥ 10 mm.
 - Different people placed and read TST on left and right.
 - Same person placed and read 1st and 2nd TST.

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METHODS

- "Rolling Rocker" mixer (Stuart).
- "Triturus" ELISA analyzer (Grifols).
- Interpreted with CDC, Cellestis, Inc. & Celedon Labs, Inc. software.
- Barcode labels used to ID blood samples and type of QFT-GIT tube (Nii, TB-Ag, Mitogen)



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Research Questions & Results

- 1) What is the **interassay** QFT-GIT variability when performed with an **automated ELISA analyzer**?
 # Discordant = 7 Interpretive agreement = 95.9% (Kappa = 0.85)
 Bias = 0.017 IU/mL Within-subject standard deviation = ± 0.492 IU/mL
No significant difference between TB response from 2 ELISA runs (p = 0.46)
- 2) What is the **interassay** QFT-GIT variability when performed **manually**?
 # Discordant = 10 Interpretive agreement = 93.1% (Kappa = 0.80)
 Bias = -0.002 IU/mL Within-subject standard deviation = ± 0.409 IU/mL
No significant difference between TB response from 2 ELISA runs (p = 0.21)
- 3) What is the **interassay** QFT-GIT variability between **automated vs. manual methods**?
 # Discordant = 8 Interpretive agreement = 94.5% (Kappa = 0.84)
 Bias = 0.064 IU/mL Within-subject standard deviation = ± 0.502 IU/mL
No significant difference between TB response from auto & manual ELISAs (p = 0.06)

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Research Questions & Results

- 4) What is QFT-GIT variability using **blood collected 1 wk apart**?
 # Discordant = 9 Interpretive agreement = 94.0% (Kappa = 0.81)
 Bias = 0.083 IU/mL Within-subject standard deviation = ± 1.407 IU/mL
No significant difference between blood collected 1 wk apart, p = 0.27
- 5) What is QFT-GIT variability using **blood collected in morning vs. evening**?
 # Discordant = 13 Interpretive agreement = 91.1% (Kappa = 0.75)
 Bias = -0.259 IU/mL Within-subject standard deviation = ± 0.836 IU/mL
Significantly greater TB response if blood collected 6-9 p.m. vs. 6-9 a.m., p = 0.006
- 6) What is QFT-GIT variability using **blood incubated at 37.0 °C vs. 35.0 °C**?
 # Discordant = 8 Interpretive agreement = 92.2% (Kappa = 0.76)
 Bias = -0.023 IU/mL Within-subject standard deviation = ± 1.372 IU/mL
No significant difference in blood incubated at 37 °C vs. 35 °C, p = 0.08

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Research Questions & Results

- 7) What is the effect of **delaying blood incubation** on QFT-GIT results?
 # Discordant = 10 Interpretive agreement = 93.2% (Kappa = 0.81)
 Bias = 0.205 IU/mL Within-subject standard deviation = ± 0.890 IU/mL
Significantly lower TB response if blood incubation is delayed for 11-12 h than if incubated within 1 h, p = 0.0009
- 8) What is the effect of **shorter blood incubation** on QFT-GIT results?
 # Discordant = 8 Interpretive agreement = 94.7% (Kappa = 0.86)
 Bias = 0.218 IU/mL Within-subject standard deviation = ± 0.809 IU/mL
Significantly lower TB response if blood is incubated 16-17 h than if incubated for 23-24 h, p = 0.002

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Research Questions & Results

- 9) What is the **interassay** variability in **simultaneous TSTs** on right vs. left arms?
 # Discordant = 21 Interpretive agreement = 86.4% (Kappa = 0.73)
 Bias = 0.49 mm Within-subject standard deviation = ± 3.8 mm
No significant difference in TSTs on right and left arm, p = 0.10
- 10) What is the **interest** variability when **TSTs are performed 1 wk apart**?
 # Discordant = 37 Interpretive agreement = 69.3% (Kappa = 0.42)
 Bias = -4.81 mm Within-subject standard deviation = ± 6.32 mm
Highly significant increase in TST induration, p = 2.8*10⁻⁹
 Demonstrates boosting of 2nd TST by 1st TST; 41% of those with negative initial TST became positive.
- 11) What is the effect of **injecting PPD** for TST on QFT-GIT performed 1 wk later?
 # Discordant = 40 Interpretive agreement = 72.6% (Kappa = 0.43)
 Bias = -3.376 IU/mL Within-subject standard deviation = ± 5.19 IU/mL
Highly significant increase in TB response, p < 10⁻⁹
 Demonstrates boosting of QFT-GIT by TST; 34% of those with negative initial QFT-GIT became positive.

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USAF-CDC TB TRIAL-2: Reproducibility
 Research Questions & Results



What is the effect of injecting PPD for TST on subsequent QFT-GIT results?
Significant "boosting" of QFT-GIT results.

Concordance* (72.6%)		Post-TST	QFT-GIT pos	QFT-GIT neg	Total
Pre-pos/Post-pos:	30 (20.5%)	Pre-TST	30	1	
Pre-neg/Post-neg:	76 (52.1%)	QFT-GIT pos	30	1	31
Discordance* (27.4%)		QFT-GIT neg	39	76	115
Pre-pos/Post-neg:	1 (0.7%)	Total	69	77	146
Pre-neg/Post-pos:	39 (26.7%)	Kappa = 0.43 (0.31-0.56)			
McNemar's p = <0.0001					

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USAF-CDC TB TRIAL-3: Volume Study
 (FWR20090033H, Pls: LTCol K-W Ma, Dr. D. Goodwin, Dr. G. Mazurek)



OBJECTIVES:

- To assess the implications of out-of-range specimen volumes.
- To assess the effects (if any) of antigen: blood mixing methods.

STUDY SUBJECTS: 104 Wilford Hall Medical Center healthcare workers with a documented history of a positive TST.

METHOD: (next slide); IRB-approved research protocol.

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USAF-CDC TB TRIAL-3: Volume Study Methods Overview

The flowchart illustrates the following steps:

- Rolling-Rocker mixer**: Mixing blood in heparin tubes.
- Shake until frothy**: Manual shaking of the tubes.
- Rolling-Rocker mixer**: Further mixing of the tubes.
- HEPARIN**: The type of tubes used.
- Incubate for 18-24 h at 37±1 °C**: Incubation of the tubes.
- 3,000 g x 10 min @ 22 ± 5 °C**: Centrifugation of the tubes.
- Plasma with IFN-γ**: The resulting plasma sample.
- Refrigerate 2-8 °C**: Storage of the plasma sample.

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USAF-CDC TB TRIAL-3: Volume Study Methods Overview (FWR20090033H)

The flowchart illustrates the following steps:

- Draw 30 mL of whole blood**: Blood collection from a participant.
- Paperwork: Consent, HIPAA release.**: Administrative steps.
- Refrigerate 2-8 °C**: Storage of the blood sample.

(continued on next slide)

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USAF-CDC TB TRIAL-3: Volume Study Methods Overview (FWR20090033H)

The flowchart illustrates the following steps:

- Transfer to QFT-GIT tubes**: Moving blood from the collection site to the test tubes.
- Mix**: Two methods are compared:
 - 1 set shaken until frothy**: Manual shaking.
 - Rolling-Rocker mixer; 20 RPM x 5 min**: Mechanical mixing.

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Research Questions & Preliminary Results

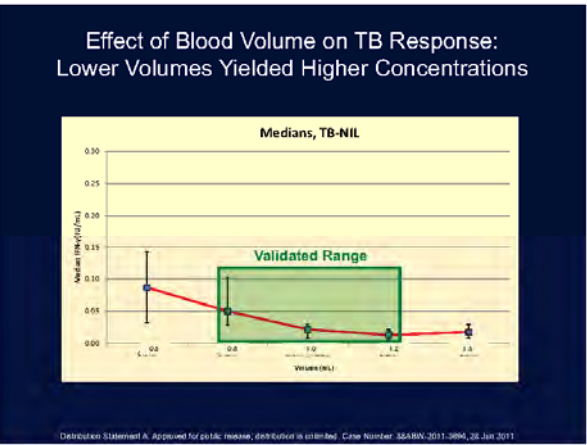
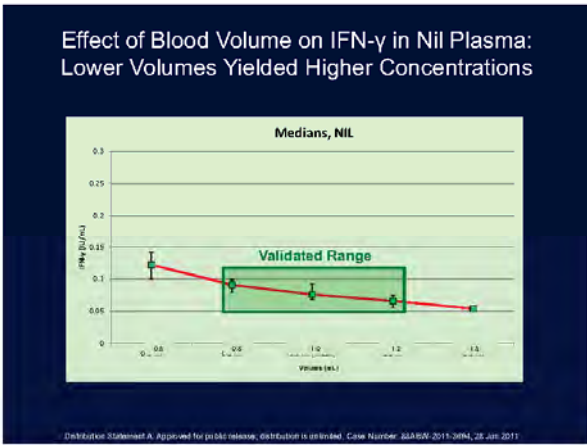
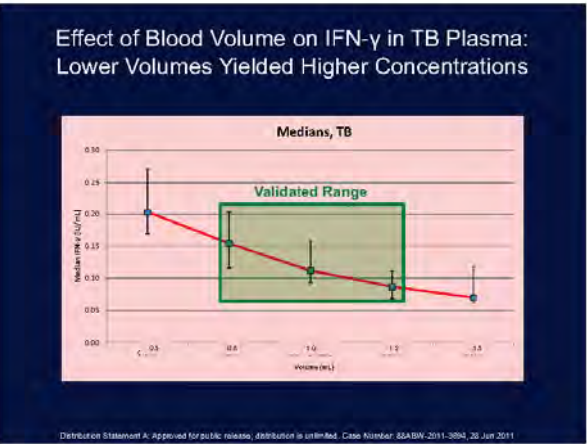
- 1) What is the effect of mixing by shaking vs. rolling on QFT-GIT?**
 # Discordant = 4 Interpretive agreement = 95.8% (Kappa = 0.88)
 Bias = -0.005 IU/mL Within-subject standard deviation = ± 0.294 IU/mL
No significant difference if blood shaken or mixed by "Rock & Roll" mixer, p = 0.36
- 2) What is the effect of transferring blood from a heparin tube on QFT-GIT?**
 # Discordant = 9 Interpretive agreement = 87.3% (Kappa = 0.63)
 Bias = 0.068 IU/mL Within-subject standard deviation = ± 0.426 IU/mL
No significant difference if blood is transferred from heparin tube, p = 0.59

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Research Questions & Preliminary Results

- 3) What is the effect of **blood volume** on IFN- γ in TB tube of QFT-GIT?
 Bias = -0.197 IU/mL Within-subject standard deviation = \pm 0.600 IU/mL
Significantly higher IFN- γ in TB tube if blood volume is 0.8 mL vs. 1.2 mL,
 $p = 1.2 \times 10^{-18}$
- 4) What is the effect of **blood volume** on IFN- γ in Nil tube of QFT-GIT?
 Bias = -0.018 IU/mL Within-subject standard deviation = \pm 0.107 IU/mL
Significantly higher IFN- γ in Nil tube if blood volume is 0.8 mL vs. 1.2 mL,
 $p = 7.0 \times 10^{-2}$
- 5) What is the effect of **blood volume** on TB response of QFT-GIT?
 Bias = -0.179 IU/mL Within-subject standard deviation = \pm 0.624 IU/mL
Significantly higher IFN- γ in Nil tube if blood volume is 0.8 mL vs. 1.2 mL and
 both TB and Nil tubes contain the same volume, $p = 7.0 \times 10^{-2}$

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USAF-CDC TB TRIAL-3: Volume Study Research Questions & Preliminary Results

What is the effect of volume on QFT-GIT results when comparing 0.5 to 1.5 mL?

Concordance* (84.0%) 0.5 Pos/1.5 Pos: 10 (13.3%) 0.5 Neg/1.5 Neg: 53 (70.7%)	1.5 mL	QFT-GIT - pos	QFT-GIT - neg	Total
	0.5 mL	QFT-GIT - pos	QFT-GIT - neg	
Discordance* (16.0%) 0.5 Pos/1.5 Neg: 9 (12.0%) 0.5 Neg/1.5 Pos: 3 (4.0%)	QFT-GIT - pos	10	9	19
	QFT-GIT - neg	3	53	56
Kappa = 0.53 (0.30-0.76) Fisher's Exact p = <0.001	Total	13	62	75

Answer: The clinical result changed 16% of the time; the lower the specimen volume, the greater the probability the result will be positive.

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USAF-CDC TB TRIAL-3: Volume Study Volume Problem Mitigation

VOLUME PROBLEM VERIFIED: QFT-GIT results may change as an artifact of the volume of blood used.

MITIGATION: Control volume by using an indirect collection method.

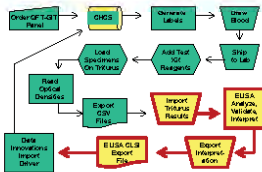


MIXING - NO PROBLEM: QFT-GIT results did not vary by mixing method, so either method is acceptable.

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USAF SBIR: Automation Enabling Software Development

(FA8850-08-C-6871, SBIR Mgr: Dr. D. Goodwin)



Phase I (N=3): Software concept

- Convert ELISA outputs into clinically interpretable results.
- Verification standards and QA performance.
- Model decision curve options.

Phase II (Celadon Laboratories, Hyattville, MD; completed 10 Jan 2010)*:

- Software developed, models built and tested, refinements made.
- Collaboration facilitated reporting of clinical results to medical record.
- Will work on any automated ELISA platform.
- 21 CFR Part 11 Compliant (FDA requirement for electronic records).

* IMMUNO-FIT – http://www.celadonlabs.com/products_immuno-fit.htm

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INTERLABORATORY VARIABILITY

(PIs: Dr. G. Mazurek, LTC L. Hamilton, & Dr. D. Goodwin)

OBJECTIVE: To assess interlaboratory variability of the QFT-GIT.

STUDY SUBJECTS: 97 previously TST positive subjects at 2 sites.

METHODS:

- Blood drawn into 3 sets of QFT-GIT and incubated together.
- 1 set held at site, 2 sent to other labs (Brooks C-B; Tripler AMC; CDC)
- Automated ELISA performed 13-15 days later in 3 labs.
- 12 (12%) subjects found to have discordant results:
 - 5 due to data entry errors (Tripler used manual reporting)
 - TB response for 6 within 0.25 IU/mL of cutoff (Tripler: 4 std vs CDC & USAF 8 std calibration curve, and within-subject variation near assay cutoff).
 - Variability increased with increasing mean IFN- γ



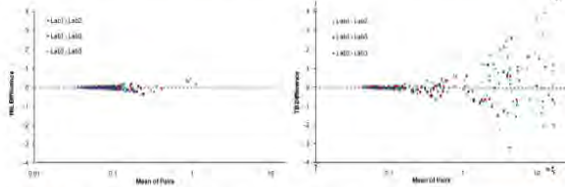
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USAF-ARMY-CDC INTERLAB VARIABILITY



Variability increased with increasing mean IFN- γ for both Nil and TB. Differences in Nil and TB were frequently in different directions.*



*Whitworth, Hamilton, Goodwin, Campbell, Barrera, Racster, Daniels, Chuke, & Mazurek. (2011). Within Subject Inter-Lab Variability of QFT-GIT Test Results.



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**USAF-CDC TB COLLABORATION:
 Summary of Accomplishments**



- ✓ Successfully automated the QFT-GIT & produced a standard protocol.
- ✓ Compared performance of TST & QFT-GIT in a mass screening setting.
- ✓ Documented degree of TST & QFT-GIT concordance/discordance.
- ✓ Documented high specificity for both TST & QFT-GIT (BMT screening).
- ✓ Documented reproducibility under a variety of scenarios.
- ✓ Documented impact of specimen volume on clinical results.
- ✓ Recommended a mitigation method for volume problems (2-step).
- ✓ Documented similarity of results using two antigen mixing methods.
- ✓ Documented interlab variability and identified sources of variation.
- ✓ Delivered automation-enabling software for electronic validation & report.
- ✓ Enabled USUHS-Army-CDC-USAF IGRA-TST assessment.
- ✓ Shared results with JPMPG to inform DoD TB screen & testing policies.

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SBIR OSD11-H05 (OSD/DHP): Development of an Alternative Screening Method for Detecting Evidence of *M. tuberculosis* Infections

Thank you!

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How to Get Your Survey Approved

Lou Datko/Panel

Air Force Survey Office

No Abstract

For decisional/internal Air Force use only

Headquarters U.S. Air Force

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Air Force Survey Program



Lou Datko
AFMA/MAPP

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AF Survey Program Mission

- Monitor and conduct attitude and opinion surveys
- IAW AFI 38-501, AF Survey Program
- AF representative IAW DoDI 100.13, Surveys of DoD Personnel
- In CY 2010, reviewed 187 AF-wide survey requests
- Disapproved 51 – cost avoidance \$500K, 13K man-hours
- Only Air Force agency with authority to manage and control surveys of Total Force members
- One of few survey hosting sites with DoD Certification and Accreditation (dot mil servers)



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What is Attitude and Opinion Research?

- Any methodology investigating, but not limited to, an individual's thoughts, feelings, impressions, agreement, satisfaction or interpretation of an event, policy, or phenomenon obtained through...
- Climate assessments
- Polls
- Focus Groups
- Telephone Interviews
- Questionnaires and surveys
- Program Evaluations (Active Duty Military/Civilians)

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Targeted Population

- Use appropriate sample size
- Minimum number to represent population
- No contract employees
- Spouses, dependents, retirees are included
- Surveys to non-mil members require OMB coordination

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Survey Questions/Topics

- Should not be sensitive in nature, objectionable, or in bad taste
- Should not require a lot of time and effort to respond
- Should be grammatically correct and easily understood by respondents
- Likert-type response scales should be balanced – equal number on both sides of neutral point

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Exemptions

- AF/A1P
 - Psychological/character assessments
- Installation Commander (base-level or below)
 - If issues are within their control/purview
- AF/IG
 - Surveys in conjunction with inspections
- HQ AETC Occupational Measurement Division
 - Task Inventories and SKT Construction
- Base-level customer satisfaction

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Survey Control Number Process

Any type of research/questions to investigate attitudes and/or opinions of any AF member must go through SCN process

- Fill out SCN form
 - Important! How will results be used?
- Submit questions for review
- Proof of Pentagon sponsorship
 - Must include all HAF sponsors if “crossing lanes”
- AF IRB submission, if required
- OPSEC, FOIA, Privacy Act, and non dot mil administration are sponsor’s responsibility
- 20 working days to review requests
- No student research

1.5M Targeted Annually

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AF IRB Process

- IRB vs. AF Survey Review
 - Purpose of the IRB is to protect the individual involved in human research
 - Purpose of AF Survey Review is to protect the Air Force agencies involved in organizational research

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Sample AF Survey Topics
 Approved CY 2011

Diabetes in the Military	Immunization
Professional Development	Golf Loyalty
Performance Feedback	Uniform
Enlisted Aide Utilization Training	First Sergeant Utilization
Gallup Q12	Indeterminate TDY
Officer/Enlisted New Directions	IDEA Program
Smokeless Tobacco Use	Airman Resiliency Training
Field Evaluation Questionnaires	Where Airmen Get Information
Boston Globe	Alumni & Student Supervisor
Post Event/Implementation	Combat Shield Assessment

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Survey Projects

Title	Purpose	Target Population	End User	Frequency	Take Time (Minutes)
Air Force Climate Survey (POC: AF/AM)	Assesses organizational climate factors to help commanders improve their units	Total Force 600K	SECAF, CSAF, CNAF, Unit Leaders	Biennially	30
Caring for People Survey (POC: AF/ALS)	Feedback on how Services addresses impact America's quality of life perceptions	Total Force 600K	CSAF, Senior Leaders	Biennially	25
Community Assessment (POC: HAF CANS, AF/CAASG, AI Retention)	Facilitates planning, programming, and resourcing of human service efforts	350K	HAF 3 Base-level CANS	Biennially	25
EO Unit Climate Assessment (POC: AF/ALQ)	Diversity and Equal Opportunity	Units >200K	Unit Commanders	Biennially or 6 months after change of command	15
Career Decisions Survey (Retention) (POC: AF/AIP)	Reasons influencing decision to remain on active duty, or undecided	30K	AIP	Biennially	35
New Directions (Exit) Survey (POC: AF/AIP)	Reasons influencing decision to separate	Based on separation & retirement rates	AIP	Continuous	30
Air Expeditionary Force (AEF) and Joint Expeditionary Tasking (JET) Survey (POC: AF/AIP)	Insight into the deployment process and the level of support Airmen receive during their deployment	22K	AIP & AEF Steering Group	Quarterly	12

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Survey Projects

Title	Purpose	Target Population	End User	Frequency	Take Time (Minutes)
2010 Air Force Personal Safety Survey (POC: AF/AID)	Risk of occurrence of sexual assault	100K	AF Senior Leadership	One administration in 2010	20
AFMOC Checkmate Q12 Engagement Survey & (POC: AF/MC)	Production, safety, health of the workforce, services as point of reference in gauging the level of employee engagement & the health of an organization	14K	AFMOC, participating Centers/CCs, all squadrons & bases/units	3rd administration	10
Performance Feedback Survey (POC: AF/AIP)	Assesses effectiveness of Air Force performance feedback system	30K	AF/AIP	One administration in May 2011	5
USAF A Climate Surveys (POC: SA/AMR)	Assesses organizational climate factors to help commanders improve their units	CSAF's (AEK) & Permanent Party (2.5K)	USAF/AMR	Biennially	30
AF Uniform Survey (POC: AF/UC)	Verify standards that Airmen are exposed to when uniforms are required and determine how well garments/case performing	17K	AF/UC	One administration in May 2011	30

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Sample DoD Survey Topics

Active in CY 2011

MIL/Civ/Travel Pay Satisfaction	Customer Service Feedback
Tricare Inpatient/Outpatient	Recruit Oral Health
Post Deployment Health	Wounded, Ill and Injured Support
Employee Exit	Emergency Room Utilization
Recruiter Quality of Life	Federal Voting Assistance Program
Organizational Climate	Commissary Customer Service
Entertainment Preferences	Survivor Family Member
MWR Customer Satisfaction	Service Member Healthcare
Status of Forces	Influenza-Like Illness
Health Related Behaviors	Life After Deployment

<http://www.dmdc.osd.mil/surveys>

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Issues

- Survey research conducted without approval
- Lack of appropriate AF level sponsor
- Repeated survey questions on same topic and/or subject
- Survey overload is reducing participation rates for legitimate and needed surveys
- Contracts awarded and funded before surveys are approved
- Surveys hosted on non dot mil domain
- Requirement for digital signature on email invitation
- Protection of data
- Samples too large

Survey demand continues to grow dramatically!

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AF Senior Leader Guidance

- SECAF
 - Initiative to reduce airmen's time spent on non-mission related workload
- CSAF
 - AF members experiencing survey fatigue/overload
 - Reduce number of surveys

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AF Survey Summit

- SECAF/CSAF requested AFMA lead effort to reduce surveys
- Conducted Survey Summit in Jul 11 to reduce survey footprint
 - Met with survey principles from SAF/GCM, SAF/PAX, SAF/A6ON, AF/A1, AF/SE, USAFA and AFIT
- Summit Purpose
 - Eliminate non-value added surveys
 - Encourage survey approval prior to contract/grant
 - Reduce outside entities (contracts, grants, etc.)
 - Encourage agencies to share existing survey results
 - Explore alternatives for collecting information and solving problems
 - Avoid duplication of topics thru improved coordination of HAF level functional managers; schedule large-scale surveys to avoid overlap
- Working follow-on action items
 - Policy, communication, exemptions, consolidation, cost savings
- Recommendations will be provided to AF senior leadership Sep/Oct

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Survey Office Contact Info

Air Force Manpower Agency
Performance Management Division
Performance Planning Branch
Air Force Survey Office
Randolph AFB, TX
af_surveys@us.af.mil
DSN 487-4773

Commercial 210-652-4773

Air Force AF Portal Web Link:

<https://www.my.af.mil/gcss-af/USAF/ep/globalTab.do?channelPagelId=s5FDEA9F02134FFA70121351677C80048>

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Pre-decisional/Internal Air Force use only



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