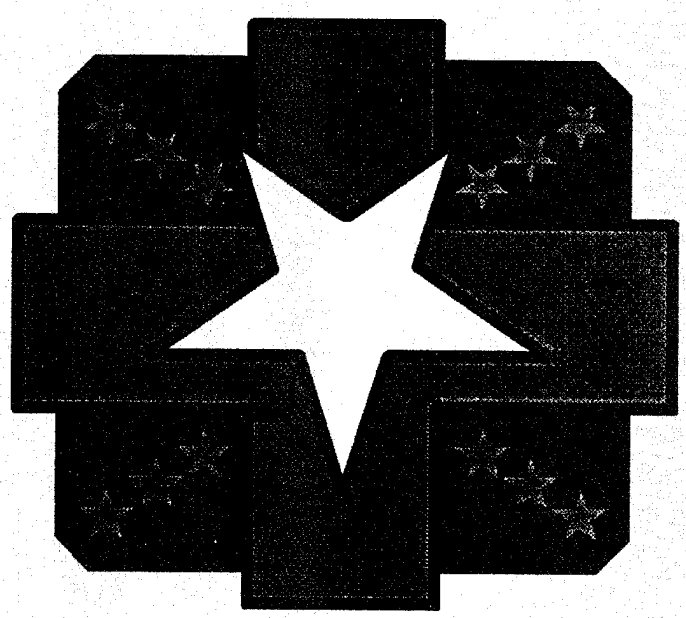
Clinical Investigation Service



Annual Research Progress Report Fiscal Year 1995

Department of Family Medicine
Womack Army Medical Center
Fort Bragg, NC 28307-5000

CLINICAL INVESTIGATION

PROGRAM REPORT

1 October 1995

CONTROL SYMBOL: RCS MED-300 (R1)

Clinical Investigation Service
Department of Family Medicine
Womack Army Medical Center
Fort Bragg, North Carolina 28307-5000

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Foreword

Clinical Investigation was approved as a modified mission for Womack Army Community Hospital in May 1990. Due to the deployments in support of Operation Desert Shield/Desert Storm, our first efforts at the research review and approval process did not take place until the Fall of 1991. Significantly, Womack was designated a medical center that same autumn.

Over the course of the last few years there has been a slow but steady increase in the amount of research activity at Womack Army Medical Center. In the first year after approval 13 protocols were approved. In FY95, 24 protocols were approved and 20 were still active at the end of the year.

The Clinical Investigation Service is indebted to the leadership, past and present, of Womack Army Medical Center for their commitment to a new and growing clinical investigation program. The service could not continue without the ongoing support of the Commander, COL Michael Brennan, and the DCCS, COL Tony Carter. COL Joseph FitzHarris, as Chief of the Department of Family Medicine, commits a physician and a protocol coordinator to CIS and continues to strongly support scholarly activity. I am also indebted to MAJ Vic McGlaughlin, who was the driving force behind the establishment of the CIS and directed it in its infancy.

JOHN J. SMUCNY, M.D.
MAJ, MC
Director, Clinical Investigation Service

REPORT DOCUMENTATION PAGE

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JOHN J. SMUCNY, M.D.
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The findings in this report are not to be considered as an official Department of the Army position unless so designated by other authorized documents.

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13. ABSTRACT *(Maximum 200 words)*

This report identifies approved clinical research activities conducted at Womack Army Medical Center through protocols approved by the Clinical Investigation Committee and Human Use Committee/Institutional Review Board. This report includes a Detail Summary Sheet outlining the progress of each protocol during Fiscal Year 95. Also included is a list of all known presentations and publications by Womack Army Medical Center professional staff. All research was conducted under the provisions of AR 40-38 (Clinical Investigation Program), AR 40-7 (Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances), AR 70-25 (Use of Volunteers as Subjects of Research) and HSC Reg 40-23 (Management of Clinical Investigations, Protocols and Reports).

14. SUBJECT TERMS
APR - Annual Progress Report, PI - principal investigator, protocol, study objective, technical approach, prior and current progress, conclusions, status, publications

15. NUMBER OF PAGES
81

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Unit Summary

A. Objective

To implement and manage the Clinical Investigation Service at Womack Army Medical Center (WAMC), Fort Bragg, North Carolina by promoting, supporting, coordinating, and providing the atmosphere of inquiry necessary to stimulate clinical medical investigation.

B. Technical Approach

The Clinical Investigation Service at WAMC is conducted by careful monitoring of all approved protocols to assure strict compliance with the following applicable regulations:

AR 40-7	Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances
AR 40-38	Clinical Investigation Program
AR 70-25	Research and Development Use of Volunteers as Subjects of Research
AR 40-37	Licensing and Control of Radioactive Materials for Medical Purposes
HSC 40-23	Management of Clinical Investigation Protocols and Reports

C. Staffing

Description	Rank	MOS	Branch	Name
Director	04	61H	MC	Smucny, J
Protocol Coord	04	0679	GS	Collazo, K
FACT Study Nurse	-	-	-	Jones, B

D. Funding

Civilian Salaries	10,000.
Military Salaries	3,000.
Consumable Supplies	1,000.
Total:	14,000.

Extraumural Funding:	Protocol #	Amount
Federal Sources:		
Defense Womens Health Initiative (DWHI):		
multicenter studies	95014	131,848. (all sites)
	95002	65,500. (all sites)
	95015	90,025. (all sites)
Total:		287,373.
National Cancer Institute Grant (NCI):		
multicenter study	95010	649,625. (all sites)
US Army Center for Health Promotion & Preventive Medicine (CHPPM):		
multicenter study	95020	89,000. (all sites)
Total all Federal Sources:		1,025,998.
Non-Federal Sources:		
Facilitators of Applied Clinical Trials (FACT):		
multicenter total (WAMC budget 23,395.)	95003	152,150. (all sites)
Henry M. Jackson Foundation (HMJF)		
single center (WAMC)	95006	24,750. (WAMC only)
single center (WAMC)	94004	19,000. (WAMC only)
single center (WAMC)	95011	85,542. (WAMC only)
multicenter study	94005	101,900. (all sites)
Total all Non-Federal Sources:		254,587.
GRAND TOTAL: (from all protocols)		1,280,585.
Sum total (protocols, salaries & supplies)		1,294,585.

E. Progress

During FY 95, there were 24 newly approved protocols. Of those, 8 were completed (1 Investigational New Drug (IND), 5 Expedited (EXP), and 2 More than Minimal Risk (MTMR) studies). Eight protocols were terminated: 1 IND, 1 EXP, 2 MR and 4 MTMR. 20 protocols remain active at the conclusion of FY 95. These studies include 3 INDs, 2 EXP, 7 MR, and 8 MTMR.

Institutional Review Board

Clinical Investigation Committee

Tony Carter, COL, MC	Chairman & DCCS
John Smucny, MAJ, MC	Director, Clinical Investigation
William Eggebroten, COL, MC	C, Surgery
Nathan Erteschik, LTC, MC	C, Medicine
Mark Siletchnik, LTC, MC	C, OB/GYN
Sharon Cooper, COL, MC	C, Pediatrics
Kelly McKee, COL, MC	C, Communicable Disease Unit
Joseph FitzHarris, COL, MC	C, Family Practice
David Schneck, LTC, MC	C, Oral Surgery
Guy Stong, LTC, MC	C, Pathology
Robert Saunders, MAJ, MS	C, Social Work Service
Gordon McDevitt, MAJ, MC	C, Radiology
Carlos DaCamara, Pharm.D.	Rep, Pharmacy Service

Human Use Committee

Tony Carter, COL, MC	Chairman & DCCS
John Smucny, MAJ, MC	Director, Clinical Investigation
Marjorie Mitchell, LTC, JA	Center Judge Advocate
J.P. Foley, LTC, CH	C, Ministry & Pastoral Care
Gail McClelland, LTC, AN	Rep, Nursing
David Jaffee, MAJ, MC	Rep, Psychiatry & Neurology
Judy Kerr, RN	Non-affiliated Lay Rep/VA Hospital
Donald Spear, CSM	Non-affiliated Lay Rep/307th Med Bn

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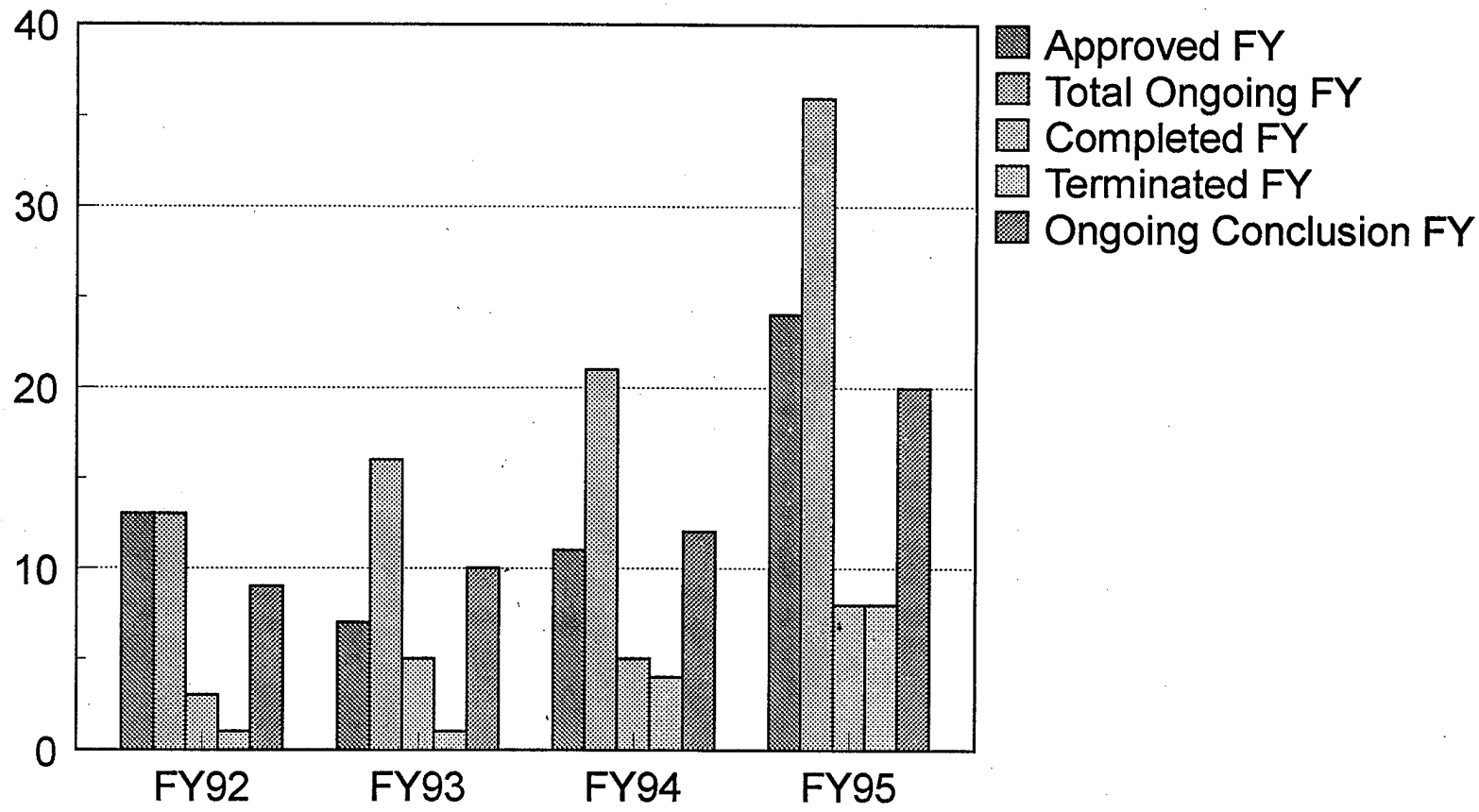
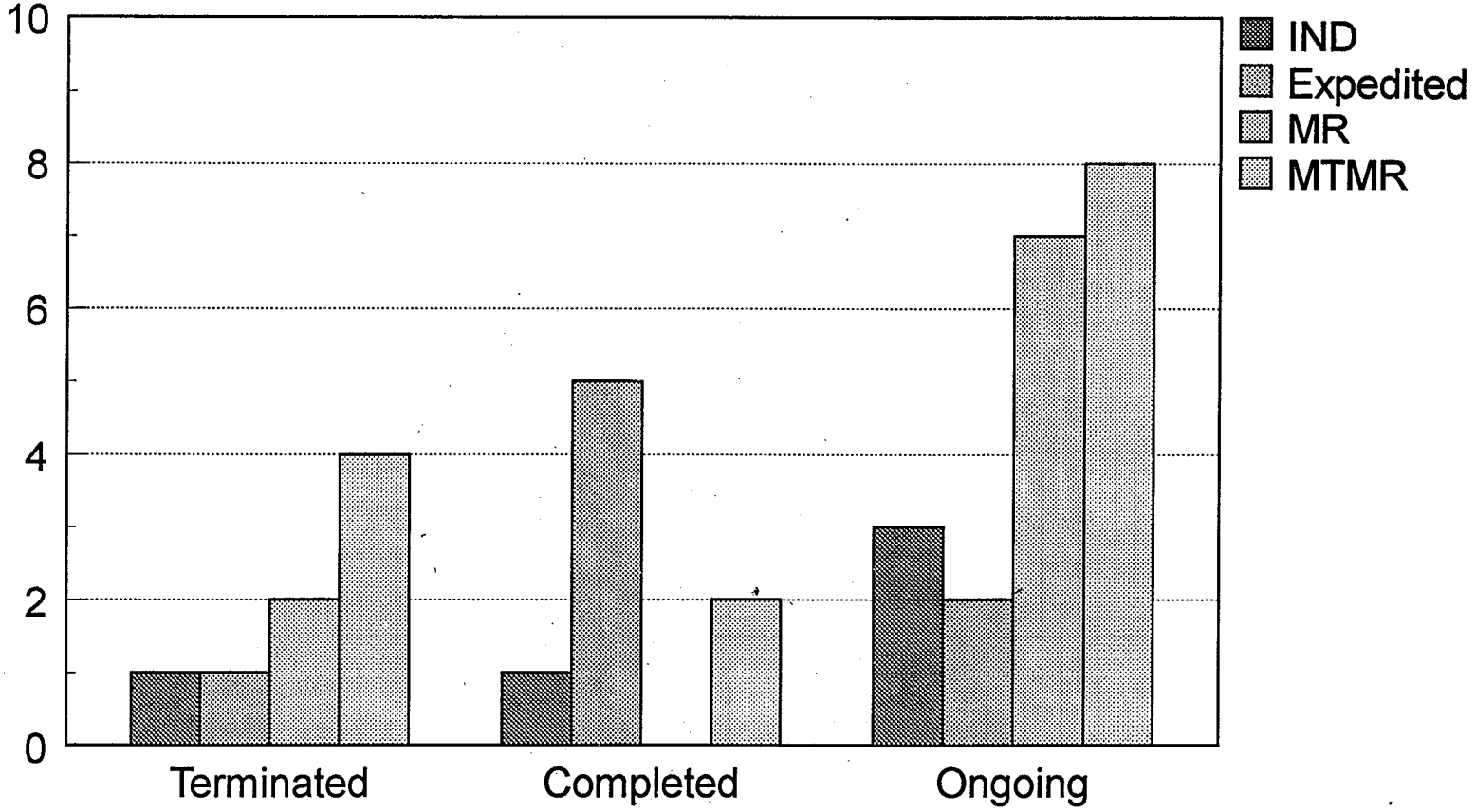
CODE: C = COMPLETE, T = TERMINATED, O = ONGOING
IND = INVESTIGATIONAL NEW DRUG, IDE = INVESTIGATION DEVICE, MR = MINIMAL RISK, MTMR = MORE THAN MINIMAL RISK, EXP = EXPEDITED

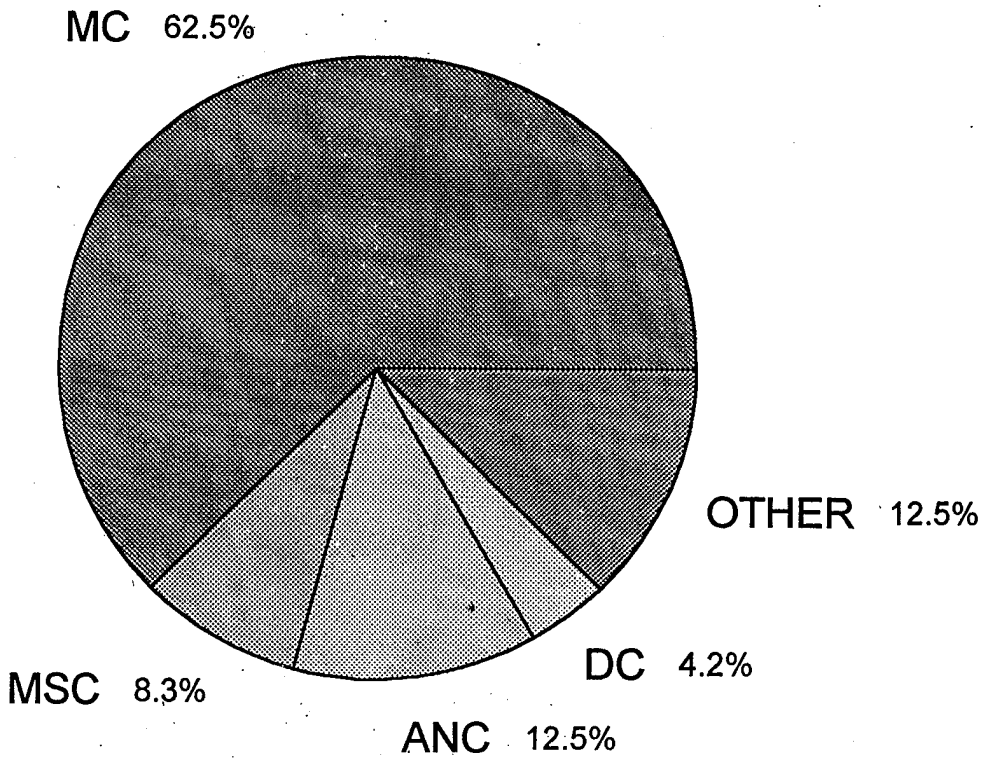
FY92-FY95 Protocol Activity



FY95 Protocols by Subject

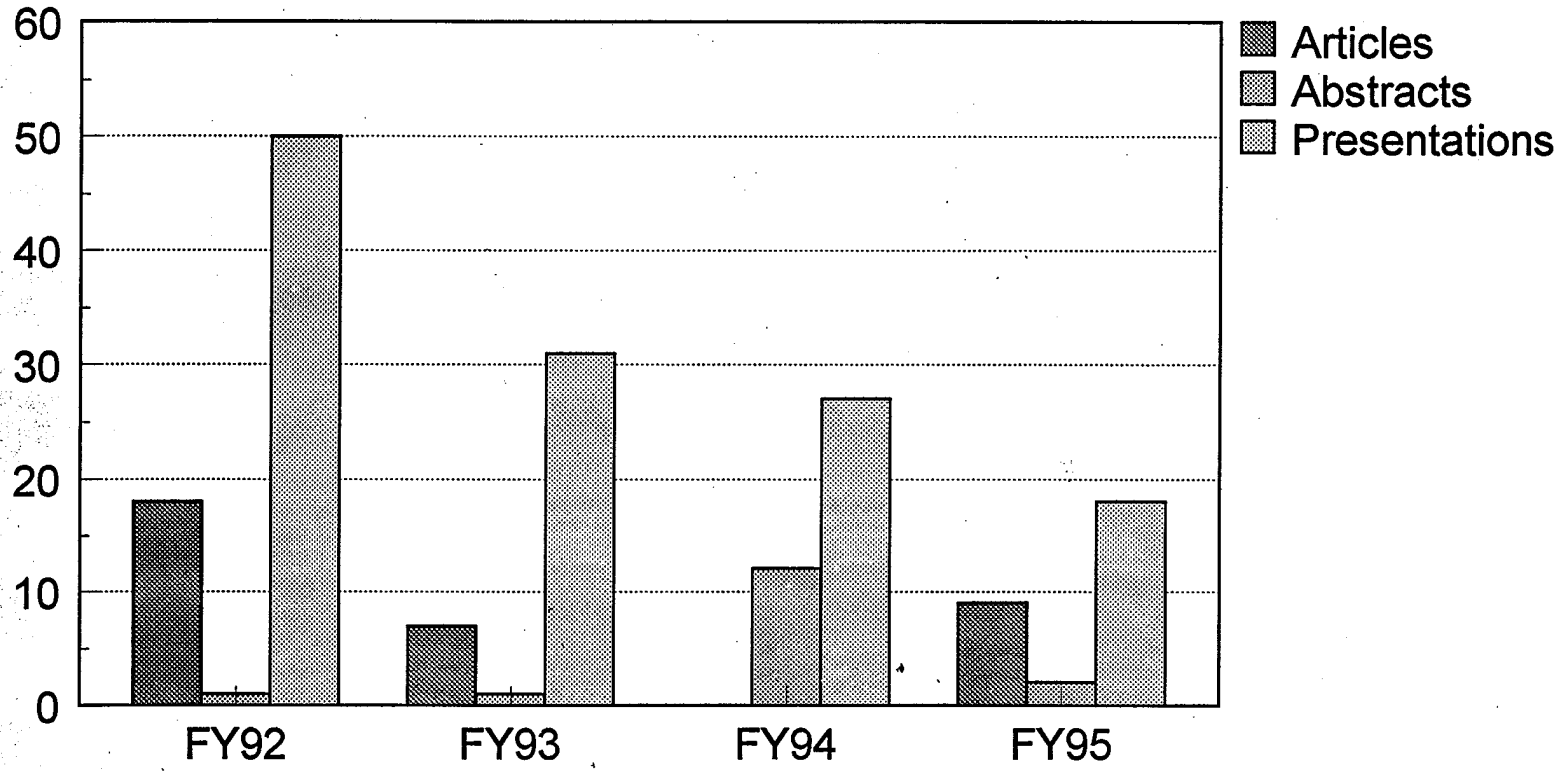


Protocols by AMEDD Officer Corps



Other indicates civilian, HMJF, Fact, etc.

FY92-FY95 Publications & Presentations



*These numbers indicate what was reported to CIS.

FY 95 Publications & Presentations
By Department/Service & Author

Department of Family Medicine	*Type
Bernstein S: "Intranasal Desmopressin Associated Hyponatremia," American Academy of Family Physicians 47th Annual Meeting, 21-24 Sept 94.	Ab
Bernstein S: "Intranasal Desmopressin Associated Hyponatremia," USAFP, San Diego, CA, Apr 1995.	Pr
Fewell H: "Coxsackieviral Encephalitis - A Case Report," USAFP, San Diego, CA, Apr 1995.	Pr
FitzHarris J: "Cardiac Sarcoidosis: An Unusual Etiology for Ventricular Techcardia," USAFP, San Diego, CA, Apr 1995.	Pr
Griffiths G: "Head Pain: An Unusual Presentation for Metastasis," USAFP, San Diego, CA, Apr 1995.	Pr
Hannapel A: "Antiphospholipid Syndrome in Pregnancy," USAFP, San Diego, CA, Apr 1995.	Pr
Johnston J: "Asymptomatic Coarctation of the Aorta Detected Due to Routine Vital Signs," USAFP, San Diego, CA, Apr 1995.	Pr
McGlaughlin V: "Introducing New Residents to the Specialty of Family Practice: A Curriculum Apporach," SMA, Orlando, FL, Nov 1994.	Pr
McGlaughlin V: "HELLP Syndrome in Pregnancy: Case Report and Literature Review," SMA, Orlando, FL, Nov 1994.	Pr
Morton E: "Treatment of Primary Hypokalemic Periodic Paralysis with Potassium," USAFP, San Diego, CA, Apr 1995.	Pr
Schooff M: "Intussusception" in Rakel, et al. Manual of Medical Therapy, to be published 1995.	P
Schooff M: "Chronic Diarrhea: An Unusual Presenting Symptom of Diabetes Mellitus," Annual Scientific Assembly of the Southern Medical Association, November 1994.	Pr
Smith B: "Neonatal Hypoglycemia for the Primary Care Physician," SMA, Orlando, FL, Nov 1994.	Pr

* P = publication, Pr = presentation, Ab = abstract

Department of Family Medicine	*Type
Smith R: "Pectoralis Major Rupture: A Unique Cause of Chest Pain," SMA, Orlando, FL, Nov 1994.	Pr
Smucny J: "Calcitonin as Symptomatic Treatment for Painful Osteoporosis," USAFP, San Diego, CA, Apr 1995.	Pr
Snoddy R: "Medical Consequences of Basic Infantry Training and Predictors of Training Success," SMA, Orlando, FL, Nov 1994.	Pr
Thompson B: "Post Partum Ruptured Subcapsular Hematoma: A Case Report," SMA, Orlando, FL, Nov 1994.	Pr
Wise S, Williford S: "Rocky Moutain Spotted Fever and the Use of Sulfonamides: A Case Report and Literature Review," American Academy of Family Physicians 47th Annual Meeting, 21-24 Sept 94.	Ab
Wise S, Williford S: "Rocky Mountain Spotted Fever and the Use of Sulfonamides: A Case Report and Literature Review," USAFP, San Diego, CA, Apr 1995.	Pr
Department of Medicine	
Creticos P., Burk J., Smith L., et al.: "The use of twice daily nedocromil sodium in the treatment of asthma," J Allergy Clin Immunol, April 1995, 4:829-836.	P
Department of Pediatrics	
Kahn C: "Lead Screening in Children with Attention Deficit Hyperactivity Disorder and Developmental Delay," Clinical Pediatrics, Sept 1995, 498-501.	P
Preventive Medicine Service	
Devlin C: "Pregnant Soldier Wellness Program," Seventh Annual Health Promotion Conference, 14-18 Aug 1995, Herndon, VA.	Pr
Department of Psychiatry & Neurology	
Lavigne K: "Survey of Lead Levels in Patients Presenting to Child and Adolescent Psychiatry," Hawaii Medical Journal, July 1995, 54:671-672.	P

* P = publication, Pr = presentation, Ab = abstract

Department of Surgery	*Type
McNeill JJ, Quinones D, Modesto VL, et al., "Battlefield Technologies and the Forward Surgical Team," Poster Exhibit with Video, American College of Surgeons Annual Meeting, October 1995, New Orleans, LA.	Pr
Modesto VL, Gottesman L: "Sexually Transmitted Diseases." In: Wexner SD, Vernava AM (eds), Clinical Decision Making in Colorectal Surgery, IGAKU-Shoin Medical publishers, Inc., 1995, Chapter 37.	P
Modesto VL, Gold RP, Gottesman L: "Pelvic Floor Abnormalities." In: Mazier WP, Levien DH, Lutchfield MA, and Senagove AJ (eds), Surgery of the Colon, Rectum, and Anus: WB Saunders, 1995; 1075-1090	P
Modesto VL, Gottesman L: "Sexually Transmitted Diseases and Anal Manifestations of AIDS." The Surgical Clinics of North America, Vol 74, No 6; December 1994, 1433-1464.	P
Modesto VL: "Feed Me Seymour!" Feeding the Colonocytes. (Colonic Mucosal Metabolism). In: Robertston WG, Selected Topics in Colon and Rectal Surgery, Vol VII, 1994. United States Surgical Corporation Manual.	P
Modesto VL, Harkins MB, Carlton WC, Martindale RG: "Laparascopic Gastrostomy Using Four Point Fixation," The American J of Surgery, 1994, Vol 167:273-276.	P

* P = publication, Pr = presentation, Ab = abstract

Detail Summary Sheets

REPORT DATE: 12/27/95 PROTOCOL: #92001

Detail Summary Sheet

TITLE: The Nedocromil Sodium Inhalation Aerosol Clinical Experience Study: An Evaluation of Nedocromil Sodium Inhalation Aerosol in Symptomatic Patients with Mild to Moderate Asthma

KEYWORDS: asthma, asthma treatment

PRINCIPAL INVESTIGATOR: McGlaughlin, Victor, MAJ, MC

DEPARTMENT: Department of Family Medicine

STATUS: Terminated

APPROVAL DATE: Oct 1991

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To demonstrate improvements in symptoms and global indices of lifestyle in symptomatic patients with mild-moderate asthma after four weeks of treatment with Nedocromil Sodium.

TECHNICAL APPROACH: Multicenter, open label trial. Weekly symptom assessment, pulmonary function testing, and lifestyle indices assessment.

PRIOR AND CURRENT PROGRESS: Womack Army Medical Center was not selected as an investigation site, and no patients were enrolled. Protocol closed - 30 Sept 92.

CONCLUSIONS: None. Study Terminated.

REPORT DATE: 12/27/95 PROTOCOL: # 92002

Detail Summary Sheet

TITLE: Long-Acting Converting Enzyme Inhibition Use in Elderly, Hypertensive Patients: A Nationwide Study.

KEYWORDS: hypertension, elderly, enzyme inhibition use

PRINCIPAL INVESTIGATOR: Swackhammer, Randy, MAJ, MC

DEPARTMENT: Department of Medicine
Internal Medicine

STATUS: Completed

APPROVAL DATE: Oct 1991

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: This trial proposed to examine a national database of elderly, hypertensive patients managed with long-acting converting enzyme inhibitors to assess clinical usage and effects.

TECHNICAL APPROACH: This study was a retrospective, multi-center drug use evaluation of the clinical usage and effects in the elderly (age over 60 years) of ACE inhibitors. Outpatient charts of identified patients were reviewed and case forms completed. Patient, Medication, Safety, and Clinical Response Data was collected.

PRIOR AND CURRENT PROGRESS: This study was completed in May 92 with a total of thirty (30) subjects entered into the study.

CONCLUSIONS: Many of the patients are not controlled despite Combination Therapy. I suspect compliance may be a factor.

REPORT DATE: 12/27/95 PROTOCOL: #92003

Detail Summary Sheet

TITLE: A comparison of the efficacy, safety and tolerance of Ceftibuten 300 mg and Augmentin 500 mg given TID in the treatment of community acquired pneumonia.

KEYWORDS: Pneumonia, Augmentin, Ceftibuten

PRINCIPAL INVESTIGATOR: McGlaughlin, Victor G., MAJ, MC

DEPARTMENT: Department of Family Medicine

STATUS: Terminated, Nov 93

APPROVAL DATE: Jan 1992

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To compare the efficacy, safety, and tolerance of high dose Ceftibuten (300mg BID) with that of Augmentin (500mg TID) in the treatment of pneumonia in up to thirty adults with culture confirmed pneumonia.

TECHNICAL APPROACH: A randomized, single blind comparison drug study. Data collected via subjective and objective assessment by the physician in the pre-treatment, during treatment and post treatment phase. Data reported via standardized forms. Statistical analyses will be provided by the sponsor and is ongoing.

PRIOR AND CURRENT PROGRESS: As of 19 November 1993 the trial was terminated. Patient enrollment was discontinued 11 Nov 93. A total of +25 potential candidates have been screened with a subsequent enrollment of 11. A total of 5 of the 11 have been rated evaluable by the sponsor.

No serious adverse events reported.

Manpower consisted of the principal investigator and a part time study coordinator provided by the sponsor. Additional technical support is provided by the Womack Army Medical Center Department(s) of Microbiology, Radiology and Outpatient Pharmacy.

CONCLUSIONS: Study enrollment did not reach anticipated levels. Pooled results from the multicenter trial sites are pending.

REPORT DATE: 12/27/95 PROTOCOL: #92004

Detail Summary Sheet

TITLE: A comparison of the efficacy, safety and tolerance of Ceftibuten 400mg in the fed and fasted state and Augmentin 1.5gm in the fed state in the treatment of acute exacerbations of chronic bronchitis.

KEYWORDS: Bronchitis, Augmentin, Ceftibuten

PRINCIPAL INVESTIGATOR: McGlaughlin, Victor G., MAJ, MC

DEPARTMENT: Department of Family Medicine

STATUS: Terminated, 11 Nov 93

APPROVAL DATE: Jan 1992

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To compare the efficacy, safety, and primarily the GI tolerance of once daily Ceftibuten in both the fed and fasted state with that of Augmentin (500mg TID) in the fed state in the treatment of acute exacerbations of chronic bronchitis.

TECHNICAL APPROACH: A randomized, single blind comparison drug study. Data is collected via subjective and objective assessment by the physician in the pre-treatment, during treatment and post treatment phase. Data is reported via standardized forms. Statistical analyses will be provided by the sponsor.

PRIOR AND CURRENT PROGRESS: As of 19 Nov 93 the trial was terminated due to sufficient participant enrollment. Patient enrollment was discontinued 11 Nov 93. A total of +35 potential candidates have been screened with a subsequent enrollment of 6. Evaluability of the participants is not available at present.

There have been no serious adverse events reported.

Manpower consists of the principal investigator and a part time study coordinator provided by the sponsor. Additional technical support is provided by the Womack Army Medical Center Department(s) of Microbiology, Radiology and Outpatient Pharmacy.

CONCLUSIONS: Study enrollment did not reach anticipated levels. Pooled results from the multicenter trial sites are pending.

REPORT DATE: 12/27/95 PROTOCOL: #92005

Detail Summary Sheet

TITLE: The influence of work on the outcome of pregnancy in military and non-military nulliparous women

KEYWORDS: Pregnancy outcome, work, pregnancy complications

PRINCIPAL INVESTIGATOR: McGlaughlin, Victor G., MAJ, MC

DEPARTMENT: Department of Family Medicine

STATUS: Completed

APPROVAL DATE: Jan 1992

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To determine (1) if pregnant soldiers have different work and experiences than pregnant civilian workers, (2) if soldiers have a higher rate of complicated pregnancy than civilian workers.

TECHNICAL APPROACH: A prospective cohort study. Each woman consenting to participate completed a questionnaire at 28 weeks gestation, seeking information about work activity and exposures, sources of stress and support at home and in the work place, wellness behaviors and demographics. The responses of pregnant soldiers and pregnant women who reported working outside the home were compared.

PRIOR AND CURRENT PROGRESS: The responses of 25 soldiers and 13 civilian workers were reviewed. Soldiers reported more hours worked per week during pregnancy, and were more likely to have a lower total household income, to be single and to be black. No significant differences in work activity or exposure were evident from this small sample.

Previous retrospective studies indicated a greatly increased risk of pregnancy complications for soldiers over their civilian counterparts. However, no comparison of the actual work performed was made between the groups. While soldiers and civilian workers are similar in several important work dimensions, they are very different in hours worked per week, and may also be demographically different. Data for specific complications of pregnancy are pending but, together with this antepartum information, may help to better define the risks for the pregnant soldier.

CONCLUSIONS: None.

REPORT DATE: 12/27/95 PROTOCOL: #92006

Detail Summary Sheet

TITLE: Tick-Borne Disease Surveillance in febrile, hospitalized patients

KEYWORDS: tick-borne disease, Lyme disease, Rocky Mountain Spotted Fever

PRINCIPAL INVESTIGATOR: McGlaughlin, Victor G., MAJ, MC

DEPARTMENT: Department of Family Medicine

STATUS: Completed

APPROVAL DATE: Feb 1992

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: A prospective study to determine the relative frequencies of several common tick-borne diseases such as Lyme disease, Ehrlichiosis, Q fever, and Rocky Mountain Spotted Fever in the patients admitted to Womack Army Medical Center.

TECHNICAL APPROACH: The study population consists of all consenting patients, 18 years and older, admitted to Womack. Patients will be enrolled if they have a history of tick exposure within the preceding two weeks. PCR, CBC and liver function tests will be performed. A convalescent titer will be determined from all participating patients 21-28 days after the acute titer is drawn.

PRIOR AND CURRENT PROGRESS: A total of 22 patients have been included into the inpatient study. LFT's and CBC's have been followed every 3 days while in-house. Acute titers have been obtained at that time as well. Convalescent titers have been extremely difficult to obtain and when obtained are often later than four weeks.

CONCLUSIONS: A small number of inpatients had evidence of tickborne disease, but are insufficient to generalize results to the Fort Bragg population.

REPORT DATE: 12/27/95 PROTOCOL: #92007

Detail Summary Sheet

TITLE: Fluoride Concentrations in Human Bone

KEYWORDS: fluoride, bone fluoride concentrations

PRINCIPAL INVESTIGATOR: Davis, Randy MAJ, DC

DEPARTMENT: WAMC Dental Activity

STATUS: Completed

APPROVAL DATE: March 1992

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To determine current bone fluoride concentrations of subjects with a known history of systemic fluoride exposure.

TECHNICAL APPROACH: Bone samples were obtained through cooperation of the Operating Room staff and Orthopedic Surgery. Surgical procedures were identified in which it was anticipated that bone would be removed from patients and discarded. No additional bone was removed for this study. Prior to surgery, the patients were interviewed, a summary of medical history recorded and the best possible fluoride exposure history obtained. Bone specimens from the Operating Room at Womack are assayed at UNC Chapel Hill for bone fluoride concentration.

PRIOR AND CURRENT PROGRESS: 13 samples were collected and all had normal fluoride concentrations. The principal investigator was unable, however, to correlate these bone levels with the water supply fluoride level at the subject's home of record (no response from the various utility departments). The rough draft of the research project has been submitted. An ongoing effort to secure this data is being made.

CONCLUSIONS: None.

REPORT DATE: 12/27/95 PROTOCOL: #92008

Detail Summary Sheet

TITLE: Fort Bragg Tick-Borne Disease Study: Womack Family Practice Clinic (Non-Active Duty Outpatients)

KEYWORDS: Tick-borne disease, Ehrlichiosis, Lyme disease

PRINCIPAL INVESTIGATOR: Goforth, Gary, LTC, MC

DEPARTMENT: Department of Family Medicine

STATUS: Completed

APPROVAL DATE: March 1992

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To determine the relative frequency of several common tick-borne diseases such as Lyme disease, Ehrlichiosis, Q fever, and Rocky Mountain Spotted Fever (RMSF) in a non-active duty military population.

TECHNICAL APPROACH: A prospective study utilizing serological and questionnaire date. Manpower consists of the Principal Investigator, Associate Investigators, WAMC laboratory personnel and shipping technician, and Family Practice Clinic Nurses.

PRIOR AND CURRENT PROGRESS: There have been 25 subjects enrolled from 10 Mar 92 - 30 Sept 92.

No serious adverse events noted.

All acute serologic specimens have been collected for the study. 5 convalescent specimens and questionnaires have been received and forwarded to the CDC. The study investigators have completed multiple follow-up attempts to acquire the remainder of the convalescent sera and questionnaires including phone calls and letters to the study subjects. Final results are based on both acute and convalescent sera results.

CONCLUSIONS: None.

REPORT DATE: 12/27/95 PROTOCOL: #92009

Detail Summary Sheet

TITLE: A comparison of functional recovery rates using circumferential, collateral and focal continuous compression following grade II ankle inversion injuries

KEYWORDS: ankle sprain, compression, functional tests

PRINCIPAL INVESTIGATOR: O'Keefe, Ellen, CPT, SP

DEPARTMENT: Department of Surgery
Physical Therapy Section
Department of Orthopedics

STATUS: Completed

APPROVAL DATE: March 1992

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To compare the rates of functional recovery using different modes of continuous compression following grade II ankle inversion injuries in a healthy male active duty military population.

TECHNICAL APPROACH: This study will examine 300 male active duty personnel with a diagnosis of acute grade II ankle inversion injury by clinical examination. After informed consent, the patient will be randomly assigned to one of three continuous compression groups: circumferential, collateral or focal. Each of the patients will receive standard physical therapy treatment on an outpatient basis. The rate of functional recovery will be measured through the use of an eleven level post-sprain function scale. Clinical measurements will also be used to assess progress in the areas of range of motion, swelling, subjective pain, strength and proprioception.

PRIOR AND CURRENT PROGRESS: As of the last reporting, 65 patients had been screened for enrollment with a subsequent participation of 38.

No serious adverse events were noted.

Manpower consists of the principal investigator, the associate investigator, a physical therapy technician and an orthopedic technician. WAMC Department of Radiology provides technical support.

CONCLUSION: None. The principal investigator was not available to respond to the conclusions of this study due to a PCS.

REPORT DATE: 12/27/95 PROTOCOL: #92010

Detail Summary Sheet

TITLE: Ultrasound guided percutaneous needle core biopsy

KEYWORDS: breast mass, breast cancer, breast biopsy

PRINCIPAL INVESTIGATOR: Burke, Brian, CPT, MC

DEPARTMENT: Department of Radiology

STATUS: Terminated

APPROVAL DATE: March 1992

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: This study seeks to evaluate radiologic aspects of core biopsy and to discern if the method can effectively diagnose breast carcinoma pre-operatively.

TECHNICAL APPROACH: Prospective, blinded study of fifty (50) patients who would undergo ultrasound-guided needle core breast biopsy, followed by surgical excisional biopsy, and have independent pathologic correlation of their biopsy results. Subjects are those women with suspicious lesions who would undergo surgical biopsy anyway.

PRIOR AND CURRENT PROGRESS: Study was terminated due to ETS of the Principal Investigator. No study subjects were enrolled.

CONCLUSIONS: None.

REPORT DATE: 10/16/95 PROTOCOL: #92011

Detail Summary Sheet

TITLE: A double-blind, placebo controlled, parallel group, multicenter study of the use of weekly Azithromycin against the development of Mycobacterium Avium Complex Disease in HIV infected people

KEYWORDS: HIV, Mycobacterium Avium Complex, Azithromycin

PRINCIPAL INVESTIGATOR: McKee, Kelly, COL, MC

DEPARTMENT: Department of Medicine
Preventive Medicine
Internal Medicine

STATUS: Terminated Sept 95

APPROVAL DATE: May 1992

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To study the efficacy of Azithromycin in prophylaxis of MAC infection in patients with HIV infection and low CD4 counts.

TECHNICAL APPROACH: This study enrolled patients with CD4 counts <100/ul who had negative MAC cultures. Screening and baseline evaluations included a full history and physical examination. Blood tests, stool cultures, CXR, and baseline audiometry were performed. Patients were then randomized in a double-blind fashion to receive Azithromycin 1200 mg or placebo as a single dose once a week. Patients were evaluated clinically once a month.

PRIOR AND CURRENT PROGRESS: There were a total of 6 patients enrolled in the study to date. Two patients are still alive and appear to be doing relatively well. There have been four deaths unrelated to the protocol. No adverse effects of the medication were noted.

CONCLUSIONS: Final analysis of data by Pfizer is proceeding.

REPORT DATE: 12/27/95 PROTOCOL: #92012

Detail Summary Sheet

TITLE: The Prevalence of Degenerative Joint Disease of the Spine in Airborne Infantry, Non-Airborne Infantry, and Non-Airborne Combat Service Support Personnel

KEYWORDS: degenerative joint disease, spine, chronic back injury

PRINCIPAL INVESTIGATOR: Craig, Stephen, MAJ, MC

DEPARTMENT: Preventive Medicine
WRAIR

STATUS: Completed

APPROVAL DATE: Feb 1992

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To determine the prevalence of chronic back injury and degenerative joint disease in the study population.

TECHNICAL APPROACH: This cross-sectional study was conducted in two parts: Part I consisted of a questionnaire and medical records review and Part II consisted of 3 lateral radiographs of the spine. All investigative personnel were from WRAIR and WRAMC. Radiology assets from Womack and BACH, Ft Campbell, KY. were utilized. Troops from the 82nd, 101st, and 18th COSCOM comprised the study population.

PRIOR AND CURRENT PROGRESS: Part I was completed, analyzed and formally presented at the end of the year Residency Advirosy Committee at WRAIR in June 1992. Part II is still currently being analyzed.

CONCLUSIONS: Blacks are less likely to have chronic back pain than whites whether they jump or not. Only night jumping increased the likelihood that a troop would have chronic back pain. Marching or running with a ruck did not increase the odds that a soldier would have chronic back pain.

Part II which consisted of the 3 lateral radiographs of the spine is currently being analyzed. No conclusions were reported as of the time of this report.

REPORT DATE: 12/27/95 PROTOCOL: #92013

Detail Summary Sheet

TITLE: Immunization of Military Personnel with Hepatitis A Vaccine

KEYWORDS: Hepatitis A, immunization

PRINCIPAL INVESTIGATOR: Pittman, Phillip, LTC, MC

DEPARTMENT: USAMRIID Medicine
WRAIR

STATUS: Completed

APPROVAL DATE: Sept 1992

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To make the hepatitis A vaccine available to DOD beneficiaries who may be at risk of contracting hepatitis A as a result of training in or deployment to areas where hepatitis A is endemic and to establish the immunogenicity and reactogenicity of this vaccine when it is given as a double dose compared with two single doses administered one month apart.

TECHNICAL APPROACH: The vaccine will be made available in single-blind fashion to members of the Joint Special Operations Command, according to one of two regiments: approximately half of the individuals will receive a double vaccine dose on day 0, and a saline placebo on day 30; the remainder will receive a single vaccine dose in one arm and saline placebo in the other on day 0, and a single vaccine dose on day 30. Both groups will be boosted at one year with vaccine to anchor the antibody response. Blood samples for serologic analysis will be obtained prior to the first dose (day 0), prior to the booster dose (1 year), and at the conclusion of the project (2 years).

No use of WAMC facilities is anticipated. All clinical work will be conducted within the confines of the JSOC.

PRIOR AND CURRENT PROGRESS: This study was completed March 95. No progress has been reported to date.

CONCLUSIONS: Study complete. Report not available.

REPORT DATE: 12/27/95 PROTOCOL #92014

Detail Summary Sheet

TITLE: Safety and Immunogenicity of a Hepatitis A vaccine

KEYWORDS: Hepatitis A, immunization, vaccine

PRINCIPAL INVESTIGATOR: Kuschner, Robert, MAJ, MC
McKee, Kelly, COL, MC

DEPARTMENT: WRAIR
Preventive Medicine, Ft Bragg

STATUS: Complete

APPROVAL DATE: February 1993

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: The Hepatitis A vaccine evaluated in this protocol was previously found to be extremely effective (>90%) in preventing infection from Hepatitis A virus in Thai children. The objective of this study was to determine if a single vaccination with a higher potency vaccine (1440 ELISA units) would include protective antibodies more rapidly than the standard (720 ELISA units) two dose regimen used in the study in Thailan. A second objective was to test variation in antibody response between two consecutively manufactured lots.

TECHNICAL APPROACH: This is a prospective, open label, randomized study. Volunteers were recruited from the 3rd and 7th Special Forces Group, 528th Special Operations Support Battalion, 112th Signal Battalion, and 96th Civil Affairs Battalion. Soldiers were given an oral briefing on the protocol and then asked to read the informed consent form. Informed written consent was indicated by signing the consent form. Those subjects who met the inclusion criteria were then randomly assigned to one of the four vaccine groups:

a. Group 1: High potency, vaccination at time 0.

b. Group 2: High potency (different lot), vaccination at time 0.

c. Group 3: Low potency, vaccination at time 0.

d. Group 4: Low potency, vaccination at time 0 and day 30 (standard immunization regimen).

In addition, each soldier received a booster dose a month 6. After each immunization, each subject was questioned for possible adverse reactions. Blood was drawn to determine anti-HAV antibodies by

ELISA at time 0, days 14, 30, 60, months 6, 8, 12, and month 24 (March 95).

Manpower consisted of military personnel and civilians. Civilians were employed directed by SmithKline Beecham. Military personnel originated from the WRAIR and from the Special Forces units involved in the study.

Funding for the study was provided by SmithKline Beecham by means of a Cooperative Research and Development Agreement (CRDA).

PRIOR AND CURRENT PROGRESS: A total of 823 volunteers were enrolled in the study and received the first vaccination. There have been no serious adverse experiences related to the vaccine. One subject developed HIV-associated renal failure approximately one month after the initial vaccination. Subsequent analysis of the baseline sera revealed the subject was HIV Positive on entry into the study. In a separate study performed by SKB, this vaccine was given to subjects known to be HIV positive to access safety and immunogenicity. The vaccine was felt to be safe in the population and NOT associated with renal dysfunction. Two subjects died during the study due to motor vehicle injuries sustained during training accidents. Serology results are not available at this time. Sera for the first year of the study was "batched" and is currently being assayed.

CONCLUSIONS: A final blood draw was accomplished March 95. Serology results for the first year following the initial immunization will be available soon. Formal analysis is ongoing.

REPORT DATE: 12/27/95 PROTOCOL: #93015

Detail Summary Sheet

TITLE: Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of Three Doses of CP-0127 and Placebo in Patients with Presumed Sepsis and the Systemic Inflammatory Response Syndrome (SIRS).

KEYWORDS: Sepsis, SIRS, CP-0127

PRINCIPAL INVESTIGATOR: Meyer, James I, MAJ, MC

DEPARTMENT: Internal Medicine

STATUS: Terminated

APPROVAL DATE: 19 March 1993

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To assess the safety, efficacy and dose response characteristics of a 72-hour infusion of three doses of CP-0127 or placebo in the treatment of patients with presumed sepsis and SIRS.

TECHNICAL APPROACH: A double-blind, placebo-controlled prospective, randomized and parallel dose ranging study. This study totaling 500 patients will be conducted in 20-40 investigational sites. Patients will be dosed for three days with a continuous IV infusion and then followed for a 28 day period. Subjective and objective data will be collected and reported for analyses.

PRIOR AND CURRENT PROGRESS: Progress of the clinical trial includes: organization of the research team, orientation to the protocol, participant awareness and recruitment.

Fourteen potential patients had been screened in the MICU and 26 pre-surgical patients were screened. No patients were enrolled.

CONCLUSIONS: None. Study terminated due to no patients being enrolled in the study.

REPORT DATE: 12/27/95 PROTOCOL: #93015

Detail Summary Sheet

TITLE: Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of Three Doses of CP-0127 and Placebo in Patients with Presumed Sepsis and the Systemic Inflammatory Response Syndrome (SIRS).

KEYWORDS: Sepsis, SIRS, CP-0127

PRINCIPAL INVESTIGATOR: Meyer, James I, MAJ, MC

DEPARTMENT: Internal Medicine

STATUS: Terminated

APPROVAL DATE: 19 March 1993

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To assess the safety, efficacy and dose response characteristics of a 72-hour infusion of three doses of CP-0127 or placebo in the treatment of patients with presumed sepsis and SIRS.

TECHNICAL APPROACH: A double-blind, placebo-controlled prospective, randomized and parallel dose ranging study. This study totaling 500 patients will be conducted in 20-40 investigational sites. Patients will be dosed for three days with a continuous IV infusion and then followed for a 28 day period. Subjective and objective data will be collected and reported for analyses.

PRIOR AND CURRENT PROGRESS: Progress of the clinical trial includes: organization of the research team, orientation to the protocol, participant awareness and recruitment.

Fourteen potential patients had been screened in the MICU and 26 pre-surgical patients were screened. No patients were enrolled.

CONCLUSIONS: None. Study terminated due to no patients being enrolled in the study.

REPORT DATE: 12/28/95 PROTOCOL: # 93016

Detail Summary Sheet

TITLE: The effect of cricoid pressure on intraocular pressure in supine human subjects.

KEYWORDS: cricoid pressure, intraocular pressure

PRINCIPAL INVESTIGATOR: Belyea, David, MAJ, MC

DEPARTMENT: Ophthalmology

STATUS: Completed

APPROVAL DATE: March 1993

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: A pilot study to investigate the effect of Cricoid pressure on intraocular pressure in supine human subjects using a small volunteer sample. Subjects will be thirty adult volunteers with no history of increased intraocular pressure, cardiovascular disease or breathing difficulty.

TECHNICAL APPROACH: Subjects will be placed in the supine position and the cornea of one eye will be anesthetized using a topical lidocaine solution. A tonometer, supplied by the Department of Ophthalmology, will be used to record ocular pressure with and without manually applied cricoid pressure. The procedure should be complete within ten minutes.

PRIOR AND CURRENT PROGRESS: Study completed June 1993. Attempt to contact investigators unsuccessful (all have PCS'd or ETS'd).

CONCLUSIONS: Unknown.

REPORT DATE: 12/28/95 PROTOCOL: #93017

Detail Summary Sheet

TITLE: Use of sustacal stimulation testing to differentiate between early onset type I and type II diabetes mellitus.

KEYWORDS: Diabetes Mellitus, sustacal stimulation testing

PRINCIPAL INVESTIGATOR: Humphrey, Michael, MAJ, MC

DEPARTMENT: Department of Medicine
Internal Medicine

STATUS: Completed

APPROVAL DATE: March 1993

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To differentiate between Type I and Type II diabetes in younger patients by measuring insulin and C-Peptide response after a complex caloric meal. In new onset diabetics it is often difficult to characterize them as either type I or type II.

TECHNICAL APPROACH: After an overnight fast, patients will present to the medical clinic and will be given instructions to hold their AM oral hypoglycemic agent and/or insulin the morning of testing. They will be instructed to eat and utilize their medications in the usual fashion the night prior to testing. After informed consent, baseline blood samples will be obtained for glucose, insulin and c-peptide levels. Patients will then be given a meal of Sustacal HC at 2cc/kg not to exceed 236cc's. Samples will be obtained at 30 and 60 minutes after completion of Sustacal for glucose, insulin and c-peptide. 50 patients are required for the study to include all active duty and dependent patients which meet criteria.

CURRENT AND PRIOR PROGRESS: 52 subjects have been enrolled in the study at a rate of approximately 4 patients per month. All have completed sustacal stimulation and all data has been returned. Preliminary evaluation indicates that peak insulin response after sustacal stimulation is useful in differentiating between type I and type II DM. We continue to track participants to determine the natural history of their disease processes. No complications have occurred with testing.

CONCLUSIONS: The results have been predicted: patients with blunted insulin and CPeptide responses are being treated as having Type I Diabetes Mellitus. Only 2 patients enrolled have had anti-insulin antibodies present in serum. Data is being collected and analyzed and results will be made available.

REPORT DATE: 12/28/95 PROTOCOL: #93018

Detail Summary Sheet

TITLE: Immunization with a highly purified vaccine (FSME-IMMUN inject) against tickborne encephalitis: comparison of an accelerated versus standard schedule

KEYWORDS: tickborne encephalitis, FSME-IMMUN inject

PRINCIPAL INVESTIGATOR: Pittman, Phillip, LTC, MC

SITE INVESTIGATOR: Kelly McKee, COL, MC

DEPARTMENT: USAMRIID
Preventive Medicine
Communicable Disease Unit

STATUS: Completed

APPROVAL DATE: June 1993

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To make available a thoroughly tested and apparently safe TBE vaccine (FSME-IMMUN inject, IND 1836), currently unlicensed in the U.S., to personnel authorized immunization at Department of Defense affiliated medical treatment facilities or by DOD immunization teams to provide protection against potentially lethal strains of TBE. Intensive observation and specimen collection are impractical in this group. To provide an accelerated vaccination schedule that requires one month instead of 10 months to obtain optimal protection for troops on alert for deployment or already deployed to TBE endemic areas. To compare, in a small group of volunteers under controlled conditions in which more intensive observation and specimen collection can occur, the current (0, 1 month, 9 months) and accelerated (0, 1 weeks, 4 weeks) immunization schedule to define the antibody response to multiple strains of TBE representing predominant strains in different geographic areas.

TECHNICAL APPROACH: This study will have two Parts. Part I will be a small study conducted to compare the standard immunization schedule (0, 1 month, 9 months) with the accelerated schedule (0, 1 week, 4 weeks) in 50 volunteer subjects per group. This will begin as soon as possible to obtain information about kinetics of immune response (seroconversion rate, neutralization and ELISA titer against CEE and RSSE). Part II of the study will vaccinate large numbers of personnel with an accelerated schedule (0, 1, 4 weeks) prior to or during rapid deployment to TBE endemic areas. This arm will be conducted, as required, independent of the immunization schedule comparison arm.

CURRENT AND PRIOR PROGRESS: A total of 99 persons were enrolled in Part I of this protocol at USAMRIID, Ft Detrick, Maryland. Volunteers were randomized to receive the accelerated dose schedule at week 0,1,4 or the standard schedule at 0 and 4 weeks. Both groups received a booster dose a 9 months. Blood was drawn for titer determination at set intervals during the study period. Analaysis of symptoms and titer determination are pending and should be a part of the final report next year. The contingency did not occur, therefore, large schedule vaccination of deploying troops did not occur.

CONCLUSIONS: Pending titer determination and analysis of symptoms and titers.

REPORT DATE: 12/28/95 PROTOCOL: #93019

Detail Summary Sheet

TITLE: Treatment of Adult Patients with Varicella with short course oral Acyclovir.

KEYWORDS: Varicella, Acyclovir

PRINCIPAL INVESTIGATOR: Epperly, Ted, LTC, MC

DEPARTMENT: USUHS
Department of Family Medicine

STATUS: Complete

APPROVAL DATE: Sept 93

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: The objective of this study is to determine if the short course (5 day) oral administration of acyclovir reduces the duration of skin lesions and symptoms of varicella infection in adults. In addition, acyclovir usage will be analyzed to determine if it reduces the length of hospitalization of adult patients, and if it hastens the return to health and duty in a cost effective manner.

TECHNICAL APPROACH: Patients will be randomized into one of two treatment groups. The one group will receive oral acyclovir (800mg five times a day) for 5 days. The other group will receive an identical look-alike placebo given 5 times a day for 5 days. The patients will be followed daily from admission to discharge, and will have all skin lesions counted on a daily basis. 45-50 patients from Fort Bragg and 45-50 patients from Fort Benning will be required to complete the study.

PRIOR AND CURRENT PROGRESS: As of Dec 94, about twenty-five (25) patients have taken part in this study at Fort Bragg. The study will continue through Fall 1995.

CONCLUSIONS: Study recently completed. Report will be made available.

REPORT DATE: 12/28/95 PROTOCOL: #93020

Detail Summary Sheet

TITLE: Relationships among selected pre- and post-natal factors and preception of pain

KEYWORDS: pre-natal, post-natal, birth

PRINCIPAL INVESTIGATOR: Mauro, Kathleen B., LTC

DEPARTMENT: Department of Obstetrics/Gynecology

STATUS: Completed

APPROVAL DATE: Mar 93

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To examine the birth experiences of civilian women who are married to active duty soldiers. The immediate and short range study aims will be to identify preinatal factors which significantly influence and predict women's preceptions of birthing experiences, explore relationships between the selected prenatal factors, and communicate results to the military nursing community, military health care providers, and military leaders.

TECHNICAL APPROACH: A non-probability sample of 250 expectant mothers, planning to deliver and receive 6 week postpartum care at William Beaumont Army Medical Center or Womack Army Medical Center will be obtained. Subjects will meet the following criteria: civilian, married to an active duty army soldier, able to read and understand English, 32-38 weeks pregnant, experiencing an uncomplicated pregnancy, and anticipating her first delivery. Data will be obtained prenatally and postnatally using mailed questionnaires and chart audits. One questionnaire will be sent to all eligibile women and a second questionnaire will be sent to each subject approximately 6 weeks after her delivery.

PRIOR AND CURRENT PROGRESS: Unknown. Attempts to contact the Principal Investigator were unsuccessful. She has PCS'd or ETS'd from Womack Army Medical Center, Fort Bragg.

CONCLUSIONS: None.

REPORT DATE: 12/20/95 PROTOCOL: #94005

Detail Summary Sheet

TITLE: Analysis of Sexually Transmitted Disease Patterns at Fort Bragg, NC: Preparation for Human Immunodeficiency Virus Behavioral Interventions

KEYWORDS: STDs, Surveillance

PRINCIPAL INVESTIGATOR: McKee, Kelly, COL, MC
Pamela Jenkins, RN, HMJF

DEPARTMENT: Preventive Medicine
Communicable Disease Unit

STATUS: Ongoing

APPROVAL DATE: November 1993

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To determine incidence of specific sexually transmitted diseases at Fort Bragg, N.C. between 1983 and 1990. To describe the epidemiological characteristics of individuals who acquire STD's. To identify demographically determined groups which would be the targets of sexual history questionnaires and behavior interventions in future protocols. Ongoing surveillance and analysis of STD trends at Fort Bragg.

TECHNICAL APPROACH: Existing EDC Data Analysis. Propose to carefully evaluate sex, age, race, deployment status and other relevant characteristics in out STD surveillance data from 1983 to present. This analysis will form the foundation for future behavioral interventions to be performed, such as Phase II protocol "Assessing Behavioral Correlates of HIV", and in particular will provide the basis for identifying sub-groups whose pattern of STD incidence makes them a logical target for a behavioral intervention protocol.

PRIOR AND CURRENT PROGRESS: Since 1983, the EDC clinic has collected data on almost 13,000 patients who were diagnosed and treated for a STD. During FY94, a total of 6,545 patients were seen in the EDC Clinic. A subset of thse patients have STDs from which epidemiologic data is extracted.

CONCLUSIONS: As of 13 Jan 93 a five year extension to this protocol was approved. Initially, this study was approved by WRAMC on 26 March 91 for a period of 15 months. After many on-site delays, data collection actually started in March 1992. Monthly data has been sent to WRAIR and to the PI at Henry M. Jackson Foundation. Data will continue to be collected. The expiration date of this protocol is June 1997. Study ongoing and continued review of analysis.

REPORT DATE: 12/28/95 PROTOCOL: # 94002

Detail Summary Sheet

TITLE: Needle Core Breast Biopsy

KEYWORDS: breast, biopsy

PRINCIPAL INVESTIGATOR: Phillips, Mary, MAJ, MC

DAPARTMENT: Mammography
Department of Radiology

STATUS: Terminated

APPROVAL DATE: December 1993

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: Implement use of stereotactic guided percutaneous needle biopsies of nonpalpable breast lesions as a diagnostic alternative to surgical excisional biopsies. To insure the accuracy of large core needle breast biopsies at Womack prior to implementation of the procedure in lieu of diagnostic surgical excisions of nonpalpable breast lesions.

TECHNICAL APPROACH: The study design includes a series of fifty (50) patients who would undergo sterotactic guided needle core breast biopsy followed by hook wire localization and surgical excisional biopsy. Subsequent independent pathologic correlation of the biopsy results will be performed. If the technique proves accurate at this institution, it would be a potential diagnostic option available to render a histologic diagnosis without necessitating surgical intervention.

PRIOR AND CURRENT PROGRESS: Study terminated due to Principal Investigator's PCS.

CONCLUSIONS: None.

REPORT DATE: 12/28/95 PROTOCOL: # 94003

Detail Summary Sheet

TITLE: Preventive Breast Care and screening program for Active Duty Military Women and Dependents.

KEYWORDS: breast care, preventive care

PRINCIPAL INVESTIGATOR: Franchak, Maryanne, CPT, AN

DEPARTMENT: Community Health
Department of Radiology
One-Stop In-Processing, Ft Bragg
Womack Classrooms/Conference Rooms

STATUS: Terminated

APPROVAL DATE: Jun 94

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To evaluate active duty female military members and dependents, including minorities, for breast cancer at Fort Bragg. To reach this goal, there will be screening clinics and educational workshops taught by Army Community Health Nurses and staff. These classes include breast self-exam instruction, clinical demonstration, risk appraisal, and follow-up mammography for high risk patients.

TECHNICAL APPROACH: There are several phases to this project. Phase I involves development of curriculum to train staff, 91C's, community nurses, and military unit personnel. During this stage, equipment is procured and units are assessed. In Phase II classes are implemented through community centers, women's groups, family support group meetings, and in-processing areas. These clinics will be taught by trained personnel using models, videos, brochures, and demonstrations. Phase III will include data collection and evaluation. Care for soldiers at risk will include follow up with health care providers, clinical palpation and mammography.

PRIOR AND CURRENT PROGRESS: Study was never funded. It was accepted only.

CONCLUSIONS: None. Study was not initiated.

DATE: 12/28/95 PROTOCOL: #94001

Detail Summary Sheet

TITLE: Assessment of Risk Factors for HIV Infection Among Active Duty U.S. Military Personnel with Documented Recent HIV-Antibody Seroconversion

KEYWORDS: HIV infection, Seroconversion, HIV Risk Factors

PRINCIPAL INVESTIGATOR: Pamela Jenkins, RN, HMJF
Levin, Lynn, MPH

DEPARTMENT: Preventive Medicine, WRAIR
Henry M. Jackson Foundation, Preventive Medicine

STATUS: Terminated

APPROVAL DATE: May 94

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To evaluate biologic and behavioral determinants of HIV seroconversion by comparing medical, demographic, and behavioral histories of active study personnel recently infected with HIV to histories of individuals who have not seroconverted over a similar time.

TECHNICAL APPROACH: This study was to enroll 2 HIV seronegative active duty men and three seronegative active duty women for each HIV positive man or woman respectively. The participant would then complete a detailed questionnaire using a talking computer. The coded information would be downloaded and sent to WRAIR for analysis. This study was to be done at several sites.

PRIOR AND CURRENT PROGRESS: There were no participants enrolled.

CONCLUSIONS: None.

REPORT DATE: 12/28/95 PROTOCOL: #94004

Detail Summary Sheet

TITLE: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of the Efficacy of an HSV Vaccine Composed of Recombinant Herpes Simplex Virus Type 2 (HSV-2) Subunit Antigens Combined with MF59 Adjuvant Emulsion When Given to HSV-2 Seronegative Adults at High Risk for Acquisition of a Sexually Transmitted Disease

KEYWORDS: Herpes Simplex 2 Vaccine, Herpes, STD

PRINCIPAL INVESTIGATOR: McKee, Kelly, COL, MC

DEPARTMENT: Communicable Disease Unit

STATUS: Ongoing

APPROVAL DATE: June 94

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To evaluate the efficacy of a vaccine containing recombinant glycoprotein HSV gD2 and gB2 antigens combined with MF59 adjuvant emulsion versus placebo in protecting HSV-2 seronegative subjects at high risk for acquisition of a sexually transmitted disease from acquiring HSV-2 infection. In this study, "high risk" is defined as at least one documented STD or >4 partners in the past 12 months. Efficacy will be assessed by comparing HSV-2 infection rates (as determined by positive HSV-2 viral culture or Western Blot) between vaccinated and placebo groups. Fort Bragg is one of 22 sites enrolling volunteers to assess vaccine efficacy.

TECHNICAL APPROACH: Subjects will be randomized into two equal groups for this 18 month study. One group will receive the antigen-containing vaccine at 0, 1, and 6 months. The second group will receive placebo vaccine at 0, 1, and 6 months. A twelve-month follow-up interval after the third immunization will allow for evaluation of immunogenicity and efficacy. Subjects will be screened confidentially for HIV at study screening and at study termination. Following each immunization, all subjects will be observed for 30 minutes for evidence of immediate local and systemic reactions. Subjects will be instructed to complete diary carts to describe local and systemic reactions. Subjects will also report on their sexual activity and, will be evaluated in clinic for every symptomatic possible genital HSV episode.

PRIOR AND CURRENT PROGRESS: This study was initiated 1 Sept 94. Of the 51 volunteers enrolled in the study: (1) one transferred to another site, (2) 3 were dropped from the study and (3) one terminated due to inappropriate enrollment. 46 remaining subjects actively participate.

CONCLUSIONS: Study ongoing. Data collection continues.

REPORT DATE: 12/28/95 PROTOCOL: #94006

Detail Summary Sheet

TITLE: Prevention of Exposure to HIV and other Sexually Transmitted Diseases in a Sero-negative Military Population

KEYWORDS: HIV, STD, prevention

PRINCIPAL INVESTIGATOR: Jenkins, Pamela, HMJF

DEPARTMENT: Preventive Medicine Service
Communicable Disease Unit

STATUS: Ongoing

APPROVAL DATE: May 94

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: The primary objective is to examine the relative safety, feasibility and effectiveness of several interventions designed to reduce exposure to human immunodeficiency virus (HIV) and other sexually transitted diseases (STDs) in a population at high risk for HIV infection (active duty military STD patients).

TECHNICAL APPROACH: This study is enrolling active duty male patients with symptoms of a STD, but who are HIV seronegative. The participants complete baseline questionnaires and they then receive standard clinic care. After the health care provider sees them, they receive one of three interventions (interactive video, target situational behavior, or health risk appraisal). One group serves a a control. Participants are seen at 2 weeks and 2 months for further follow-up. State of the art microbiologicals are taken at the initial visit, the 2 month follow-up, and on any other visit.

PROGRESS: A total of 326 active duty males from the STD clinic have been enrolled to date.

CONCLUSIONS: Final analysis of data by HMJF is pending completion of the study.

REPORT DATE: 12/28/95 PROTOCOL: #94007

Detail Summary Sheet

TITLE: Use of Red Cell Distribution Width (RDW) and Mean Corpuscular Volume (MCV) to Predict Iron-Deficiency Anemia in One Year Old Infants

KEYWORDS: RDW, anemic infants, iron-deficiency

PRINCIPAL INVESTIGATOR: Choi, Sammy Y.,

DEPARTMENT: Department of Pediatrics

STATUS: Complete

APPROVAL DATE: June 94

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To determine whether automated CBC assessment is accurately predictive of iron-deficiency when used as a routine twelve month anemia screening.

TECHNICAL APPROACH: All infants already receive a spun hematocrit at the twelve month well baby visit. All infants with a HCT of <33% will have a heel stick complete blood count performed. If the Hb is <11.0%, the patient will be contacted for follow-up appointment with the study team. The protocol is explained, and the patient will be started on empiric iron therapy at 3mg/kg/day of elemental iron. Follow-up CBC will be obtained at one month.

PRIOR AND CURRENT PROGRESS: As of 17 January 95, total study population is 514 patients. Only 7 patients or 1.4% were anemic which is below the national average. Of those patients that required empiric iron therapy, a normal mcv and rdw was predictive of non-iron deficiency anemia. Unfortunately, at the present rate, approximately 7300 patients would have to be enrolled before statistical signficance could be reached which would take 7 years. If other clinics were enrolled, this number could be reached much sooner. Preliminary findings (pilot study) could be determined after perhaps 30 patients have required iron therapy.

CONCLUSIONS: As of 24 Oct 95 there have been a total of 961 patients. The results were as follows: 62/970 abnls, 31/62 nl by cbc. 31 abnls; 7 incomplete f/u, 2 PCS'd, 1 ETS'd, 1 pending studies. 20 have had full follow up of these. 6 improved-all high high rdw and 4 had low mcv. 14 did not improve. 9 had nl rdw and mcv; 3 had nl mcv/ hi rdw; and 2 had low mcv/hi rdw. In summary, 6 patients had iron deficiency anemia and all had high RDWs. A normal RDW excluded iron deficiency anemia. hb electrophoresis is pending on many patients

REPORT DATE: 12/28/95 PROTOCOL: #94008

Detail Summary Sheet

TITLE: A Comparison of fiber optic transillumination and radiographic technologies for the diagnosis of interproximal dental caries

KEYWORDS: dental caries, fiber optic transillumination

PRINCIPAL INVESTIGATOR: Adrian, Eric, LTC

DEPARTMENT: One-Stop Dental Clinic, USA DENTAC

STATUS: Completed

APPROVAL DATE: May 94

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: The objective is to compare the caries detection ability of the fiber optic transillumination technique (FOTI) to that of conventional dental diagnostic practice in the USA.

TECHNICAL APPROACH: The subjects will be from a normal population seen at the One-Stop screening center at the Fort Bragg Dental Activity. 1200 records will be tagged by the One-Stop dentist for screening. These records will be collected from the various Ft Bragg dental clinics by carrier and screened to obtain (1) 100 patients with interproximal caries to or beyond the dento-enamel junction as seen on bite wing radiographs (2) 25 patients with incipient interproximal lesions and (3) 25 patients who are caries free.

PRIOR AND CURRENT PROGRESS: Data collection has been completed. Awaiting results from University of North Carolina.

CONCLUSIONS: Awaiting results from UNC, Chapel Hill.

REPORT DATE: 12/28/95 Protocol: #94009

Detail Summary Sheet

TITLE: The Effect of Pregnancy on the Performance, Health and Nutritional Status of Postpartum Soldiers

KEYWORDS: pregnancy, postpartum soldiers, nutrition

PRINCIPAL INVESTIGATOR: Vanderlinde, Terri, CPT, MC

DEPARTMENT: Department of Obstetrics & Gynecology

STATUS: Terminated

APPROVAL DATE: Sept 94

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To determine the proportion of soldiers who return to their preconception fitness level at their first postpartum APFT. To compare the distribution, incidence and risk of injury and illness between postpartum soldiers and nonpregnant, non-postpartum soldiers. To compare changes in weight and body composition between soldiers and family members in the postpartum period. To compare bone mineral status between late pregnancy and postpartum soldiers and family members. To compare nutritional status between late pregnant and postpartum soldiers and family members. And, to compare iron and folate status among late pregnant and postpartum soldiers, late pregnancy and postpartum family members, and nonpregnancy, non-postpartum soldiers.

TECHNICAL APPROACH: Beginning Sept 94, women in their third trimester of pregnancy will be identified through the OB/GYN clinic and asked to volunteer for the study. Non-pregnant soldiers will be solicited through the unit chain of command. Those who meet the criteria will receive written and verbal explanations as to the nature, duration, purposes, risks and benefits of the study. Subjects will be compensated for blood draws. The procedures for reimbursement for the blood samples will follow USAMRIID Regulation 40-2 and the payment will be $20.00 per draw. These blood draws will assess iron, folate and calcium status; anthropometric measurements to determine body composition IAW AR 600-9; dual energy x-ray absorptiometry to measure bone mineral density and to validate body fat percentages; and low back and hamstring flexibility evaluations.

PRIOR AND CURRENT PROGRESS: This study was not initiated due to too many logistical problems.

CONCLUSIONS: None. Study Terminated.

REPORT DATE: 12/28/95 Protocol: #94010

Detail Summary Sheet

TITLE: Development of STD/HIV Risk-Reductional Behavioral Interventions for Active Duty Women in the US Army

KEYWORDS: STD, HIV, Behavioral Interventions

PRINCIPAL INVESTIGATOR: Jenkins, Pamela, HMJF

DEPARTMENT: Preventive Medicine Service
Communicable Disease Unit

STATUS: Terminated

APPROVAL DATE: Sept 94

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To develop empirically-based HIV/STD prevention interventions to motivate and maintain individual behavior change consistent with preventing exposure to HIV and other STDs.

TECHNICAL APPROACH: To conduct qualitative in-depth, open-ended interviews with active duty women diagnosed with a STD to determine the specific demographic, attitudinal, situational and behavioral factors that place a woman at risk for STDs/HIV. Based on the results from these interviews, as well as the results from Army Wide AIDS Survey (AWAS), modify/develop 2 behavioral interventions to be evaluated in a quasi-experimental, case control fashion with active duty women over a 12 month period.

PRIOR AND CURRENT PROGRESS: No patients enrolled due to lack of funding.

CONCLUSIONS: None. Study Terminated.

REPORT DATE: 12/28/95 Protocol: #94011

Detail Summary Sheet

TITLE: Study of Chlamydia trachomatis in military women: prevalence, risk factors, and a cost benefit analysis of early diagnosis and treatment

KEYWORDS: Chlamydia trachomatis, STDs, ligase chain reaction

PRINCIPAL INVESTIGATOR: Dr. Charlotte Gaydos, John Hopkins Univ

SITE INVESTIGATOR: Kelly McKee, COL, MC

DEPARTMENT: Preventive Medicine Service
Troop Medical Clinics, Ft Bragg
Fort Jackson Physical Exam and TMC
John Hopkins University, Baltimore

STATUS: Ongoing

APPROVAL DATE: Sept 94

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: The purpose of this study is to test a new diagnostic method to determine if a woman is infected with chlamydia by examining urine.

TECHNICAL APPROACH: 1,000 active duty asymptomatic females at Fort Bragg will be given a questionnaire to establish prevalence, determine risk factors, and to do a comparison of LCR to culture by testing urine by LCR and performing chlamydial cultures. Selective screening criteria will be developed from risk factors by regression analysis. A course of action for the development of a chlamydia control program will be developed.

PRIOR AND CURRENT PROGRESS: Study was to be initiated at the end of Jan 96.

REPORT DATE: 12/27/95 PROTOCOL: #95001

Detail Summary Sheet

TITLE: Promotion of Quality of Life in Stage T2 and T3 Prostate Cancer

KEYWORDS: prostate cancer, quality of life, cancer

PRINCIPAL INVESTIGATOR: Quinones, Deogracia, LTC, MC

DEPARTMENT: Urology Service
Department of Surgery

STATUS: Ongoing

APPROVAL DATE: January 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To determine the effectiveness of an uncertainty management nursing intervention delivered by a nurse client manager via telephone in increasing cancer knowledge, enhancing self care, promoting self help response and improving quality of life; and to estimate cost effectiveness of the intervention.

TECHNICAL APPROACH: Subjects who have been diagnosed with stage T2 and T3 prostate cancer are being recruiting from the Urology Clinic. Subjects are randomized into one of three study groups using a randomization table. The three study groups include: (a) uncertainty management intervention to the patient, (b) uncertainty management directly to the patient plus supplemented by a family care provider, (c) natural controls (no exposure to the intervention) crossed with two levels of ethnicity creating a six cell design.

PRIOR AND CURRENT PROGRESS: This study is ongoing. Nursing personnel from Chapel Hill are involved in the interview and randomization of the patients. Very good feed back from the patients involved as per last recent conversation with Chapel Hill. 30 percent of referrals from Womack have been enrolled in the study.

CONCLUSIONS: None to date. Study ongoing.

REPORT DATE: 12/27/95 PROTOCOL: # 95002

Detail Summary Sheet

TITLE: Social environment and stress factors that relate to the well-being, satisfaction and attitudes toward retention and deployability in married and single parent female soldiers.

KEYWORDS: environmental, stress, satisfaction

PRINCIPAL INVESTIGATOR: Lavigne, Kathleen, MAJ, MC

DEPARTMENT: Psychiatry & Neurology
82nd York Theater & WAM
COSCOM lecture rooms

STATUS: Ongoing

APPROVAL DATE: Jan 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: The objective is to determine the degree which social environment and stress variables such as work environment, family environment, and role conflict are related to various outcome variables for married and single parent female soldiers.

TECHNICAL APPROACH: To have soldiers attend a mandatory briefing and then voluntarily consent to fill out a series of questionnaires, and subsuquent interviews.

PRIOR AND CURRENT PROGRESS: Twelve subjects were recruited from the 82nd division. An additional briefing is scheduled for 30 Nov using COSCOM soldiers.

CONCLUSIONS: None. Study ongoing.

REPORT DATE: 12/27/95 PROTOCOL: # 95003

Detail Summary Sheet

TITLE: Relationships between a female soldier's Military Occupational Specialty (MOS) and Birth Outcomes

KEYWORDS: Birth outcomes, MOS, female soldier

PRINICPAL INVESTIGATOR: Costley, Scott, CPT, MC

DEPARTMENT: Department of Family Medicine
Troop Medical Clinics

STATUS: Ongoing

APPROVAL DATE: Apr 1995

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: Birth outcomes based on female soldiers MOS.

TECHNICAL APPROACH: Prospective study on birth outcomes with civilian (dependent wives) as study controls.

PRIOR AND CURRENT PROGRESS: Presently enrolled 625 individuals with at least 10 deliveries to date. No outcome analysis available at this time.

CONCLUSIONS: None. Study ongoing.

REPORT DATE: 12/27/95 PROTOCOL: # 95004

Detail Summary Sheet

TITLE: Testicular Volume in Children and Adolescents

KEYWORDS: testicular volume, Tanner stage, children, adolescents

PRINCIPAL INVESTIGATOR: Smucny, John, MAJ, MC

DEPARTMENT: Department of Family Medicine

STATUS: Ongoing

APPROVAL DATE: Jan 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To determine standards for testicular growth in American children and adolescents adjusted for age, race, and Tanner stage.

TECHNICAL APPROACH: Use template orchidometers to estimate testicular volume in male children and adolescents who present for school or sports physicals.

PRIOR AND CURRENT PROGRESS: Have submitted 194 data forms to WRAMC for inclusion in the multicenter database. Statistical analysis not yet completed.

CONCLUSIONS: None. Study ongoing.

REPORT DATE: 12/27/95 PROTOCOL: # 95005

Detail Summary Sheet

TITLE: The Adequacy of Oral Sodium Phosphate Vs. Bisacodyl and Sodium Phosphate Enemas for Flexible Sigmoidoscopy

KEYWORDS: Flexible Sigmoidoscopy, Fleet Phospho-Soda, Fleet Enema

PRINCIPAL INVESTIGATOR: Perry, Cassandra, CPT, MC

DEPARTMENT: Department of Family Medicine

STATUS: Ongoing

APPROVAL DATE: Jan 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To assess the more superior preparation in relation to cleansing performance, occurence of adverse effects, patient satisfaction, and ultimately, the one which proves to be more cost effective.

TECHNICAL APPROACH: A randomized assignment of patients to 2 preparation groups with the physician performing the examination blinded to the type of preparation, then grading the degree of cleansing. Patients are surveyed for adverse effects and satisfaction with method.

PRIOR AND CURRENT PROGRESS: Since 1 Feb 95, 25 eligible patietns have been enrolled in the study. No adverse drug reactions occurred. Study is onoing. Continue to recruit patients and collect data. A final progress report will be submitted at the completion of this study scheduled for Feb 96.

CONCLUSIONS: None. Study ongoing.

REPORT DATE: 12/27/95 PROTOCOL: # 95006

Detail Summary Sheet

TITLE: Staged Based Smoking Cessation

KEYWORDS: Smoking, Cessation, Longitudinal Study

PRINCIPAL INVESTIGATOR: Dolly Metasakis, RN

DEPARTMENT: CORFIT Health Promotion
Community Health

STATUS: Ongoing

APPROVAL DATE: April 1995

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To devise a method to integrate inprocessing and health risk appraisal systems to determine the prevalence ofsmoking among newly-arrived soldiers, to analyze smoking prevalence by demographic categories, and to identify a cohort for longitudinal study of smoking behavior and smoking cessation. Among soldiers who are identified as smokers to develop a method to assess intention to quit, attempts to quit, and long-term success rates. To evaluate the impact of an adaptive smoking cessation strategy on smoking rates in the identified population.

TECHNICAL APPROACH: Soldiers inprocessing through the medical one stop will complete the health risk appraisal (HRA). In addition they will be asked to complete a smoking cessation activity for each cycle. The survey in subsequent cycles will be tailored to the individual respondents. On basis of their initial and 6 month self report, participants will be classified by their stage of quitting activity. A computer managed decision support system will be developed to monitor and select recommended smoking cessation services specific to each participant. Computer generated letters will provide advice matched to respondent.

PRIOR AND CURRENT PROGRESS: 385 individuals have been enrolled from One Stop. There have been 22 smoking cessation classes held.

CONCLUSIONS: None. Study ongoing.

REPORT DATE: 12/27/95 PROTOCOL: #95007

Detail Summary Sheet

TITLE: The Impact of Metronidazole on Nifedipine-induced gingival hyperplasia: A Pilot Study

KEYWORDS: gingival hyperplasia, Metronidazole, Nifedipine

PRINCIPAL INVESTIGATOR: Dr. Carlos daCamara, Pharm.D., Ph.d.

DEPARTMENT: Pharmacy Service

STATUS: Ongoing

APPROVAL DATE: March 1995

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To determine the effects of a 7 day course of metronidazole on nifedipine-induced hyperplasia.

TECHNICAL APPROACH: Patients will be recruiting from the Internal Medicine, Family Medicine, and Periodontics Clinics. After an initial evaluation by one of the asociate investigators the patient will be offered and opportunity to enroll in the study. Patients wil be enrolled if they do not meet any exclusion criteria, and if they agree to participate. Volunteers will receive a 7 day course of metronidazole (250mg/day), and then be followed at periodic visits in the Periodontics Clinic for a total of nine weeks. At the follow-up visits, volunteers will have clinical assessments and photographic measurements of their gingival tissue, and be asked about any side effects from metronidazole.

PRIOR AND CURRENT PROGRESS: This study has not been initiated yet due to revisions recommended to be completed before initiation. No subjects have been enrolled in the study.

CONCLUSIONS. None. Study Ongoing.

REPORT DATE: 12/27/95 PROTOCOL: # 95007E

Detail Summary Sheet

TITLE: Creation of a Prostate Cancer Data Base for the Center of Prostate Disease Research (CPDR)

KEYWORDS: Prostate Cancer, Data Base

PRINCIPAL INVESTIGATOR: Quinones, Deogracia, LTC, MC

DEPARTMENT: Urology Service
Department of Surgery

STATUS: Ongoing

APPROVAL DATE: August 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: Prepare data base for future research in prostate cancer.

TECHNICAL APPROACH: All patients diagnosed with prostate cancer as of 1 Jan 95 will be included in thisstudy. A standard form developed by the CPDR will be utilized. All data will be kept on a computer data base and forwarded to the CPDR. If time permits, retrospective analysis will be made on patients diagnosed with prostate cancer since 1980.

PRIOR AND CURRENT PROGRESS: Due to other obligations and recent accident, I have not been able to call in patients for initial interview. There are 10-15 potential patients that will be called in for interview in Nov/Dec 95.

CONCLUSIONS: None. Study Onogoing.

REPORT DATE: 12/27/95 PROTOCOL: # 95008

Detail Summary Sheet

TITLE: Use of Mechanical Ventilation with the Ohmeda Univeral Portable Anesthesia Complete (UPAC) Draw-over Anesthesia System

KEYWORDS: mechanical ventilation, portable anesthesia

PRINCIPAL INVESTIGATOR: Hawkins, Mark, MAJ, AN

DEPARTMENT: OR/Anesthesia Service

STATUS: Complete

APPROVAL DATE: March 1995

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To evalaute the use of the portable LIFECARE ventilator (PLV-100) with the Ohmeda Universal Portable Anesthesia Complete (UPAC) System.

TECHNICAL APPROACH: This study is purely descriptive in nature in that only the performance of the vaporizer when used with the ventilator will be evaluated. Thirty active duty ASA status I and II patients schedueld to undergo general anesthesia for elective surgical procedures will be utilized for the study. All ventilatory parameters, oxygen delivery, vaporizer settings, and inspiratory/expiratory agent concentrations will be recorded spearately.

PRIOR AND CURRENT PROGRESS: 18 patients were used on the protocol. The original plan called for a total of 30 patients but due to time constraints on borrowing the necessary equipment has made this difficult.

CONCLUSIONS: Vaporizer performance with the ventilator and vaporizer configured in a "push-over" mode has been consistant and predictable. There have been no equipment failures or malfunction requiring the removal of the patient from the system. Four breathing valve systems have been evaluated and modified for use with the system. The issue of pressurization of the breathing circuit due to the nonbreathing valves and the vaporizer one-way valve has been resolved with the modifications. Clinician user friendliness with regard to set-up and use of the equipment has been acceptable.

REPORT DATE: 12/27/95 PROTOCOL: # 95009

Detail Summary Sheet

TITLE: Low intensity Ultrasound for Tibial Stress Fractures

KEYWORDS: ultrasound, tibial stress fractures

PRINCIPAL INVESTIGATOR: Allgood, Brian, MAJ, MC

DEPARTMENT: Department of Orthopedics
Troop Medical Clinics

STATUS: Ongoing

APPROVAL DATE: March 1995

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: Compare healing times of tibial stress fractures treated with low intentisty ultrasound and non interventional treatment (rest).

TECHNICAL APPROACH: Potential patients will be identified by WAMC clinics, outlying clinics and the department of Radiology with referral to the orthopedic clinic via 72 hour consult upon new diagnosis of a tibial stress fracture by Technetium-99 bone scan. Patients will be randomized and treatments begun not later than 2 weeks from the diagnostic bone scan. Treatments will be performed on a daily basis with each treatment lasting approximately 20 minutes. Patients, therapy technicians and investigators will be blinded to the sham and ultrasound group. During this phase (phase II) patients will be restricted from performing weight bearing athletic activities and airborne operations as well as strenuous field duties. After completion of the treatments, patients will enter phase III and be allowed to perform limited graduated running for another 5 weeks with weekly subjective assessment of function. Patients will undergo examination weekly during the first two weeks and every other week thereafter. A repeat plain film A-P & LAT x-ray will be performed at 6 weeks. The study will be terminated after the 10th week and patients that are still sympomatic will be treated with standard treatment regimes of altered activity until resolution of the symptoms. At the completion of Phase III, data on the functional outcome will be evaluated for statistical significance.

PRIOR AND CURRENT PROGRESS: 22 patients have been through or are presently completing the protocol. All patients are followed for 10 weeks.

CONCLUSIONS: None. Study ongoing.

REPORT DATE: 12/27/95 PROTOCOL: # 95010

Detail Summary Sheet

TITLE: Managing Uncertainty: Self Help in Breast Cancer

KEYWORDS: psychosocial intervention, quality of life, uncertainty

PRINCIPAL INVESTIGATOR: Merle Mishel, UNC-CH, School of Nursing

SITE INVESTIGATOR: Quinones, Deogracia, LTC, MC

DEPARTMENT: Urology Service
Department of Surgery

STATUS: Ongoing

APPROVAL DATE: July 1995

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: A chance for women to learn skills for managing side effects of treatment and for living with cancer. An attempt to improve quality of life issues, family support, stress, etc.

TECHNICAL APPROACH: None. Telephone intervention.

PRIOR AND CURRENT PROGRESS: As of Dec 31, 1995, 174 women were enrolled in the breast cancer study, 50 African-Americans, 95 white, and 29 Mexican American. Eight women have enrolled from Womack. Only nine women have withdrawn from the study, none were from Womack. No changes have been made in the breast study or the consent form.

CONCLUSIONS: None. Study ongoing.

REPORT DATE: 12/27/95 PROTOCOL: # 95011

Detail Summary Sheet

TITLE: Using interactive media to promote responsible sexual behavior in HIV-positive personnel

KEYWORDS: HIV Seropositive, Interactive Media

PRINCIPAL INVESTIGATOR: Pamela Jenkins, RN, HMJF

DEPARTMENT: Henry M. Jackson Foundation
Preventive Medicine Service

STATUS: Terminated Sept 95

APPROVAL DATE: May 92

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To evalaute the safety of video material, in terms of its ability to transmit accurate HIV behavior change messages in a highly motivating manner. To evaluate the immediate impact of the video in terms of change in knowledge, attitudes, and behavioral interventions.

TECHNICAL APPROACH: This study enrolled HIV seropositive paitents. The participants completed a pre-video questionnaire and then viewed a selected portion of the interactive video "Living with HIV Challenges". After the video, the participants were interviewed by a HMJF staff member.

PRIOR AND CURRENT PROGRESS: A total of 20 HIV seropositive active duty or retired individuals participated in the study.

CONCLUSIONS: Final analysis of data by HMJF is proceeding.

REPORT DATE: 12/27/95 PROTOCOL: # 95011E

Detail Summary Sheet

TITLE: Job Satisfaction Among Army Nurses

KEYWORDS: job satisfaction, army nurses

PRINCIPAL INVESTIGATOR: McCollum, Alexine, MAJ, AN

DEPARTMENT: Nursing

STATUS: Complete

APPROVAL DATE: March 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To determine if military nurses are satisfied with nursing; to examine the relationship between continued enlistment in the military and job satisfaction; and to determine if there is a difference between job satisfaction in clinical staff nurses and clinical administrators.

TECHNICAL APPROACH: Non-experimental descriptive study is based on a survey design.

PRIOR AND CURRENT PROGRESS: 132 questionnaires were mailed 15 Oct 1995. Project will be complete 8 December 95.

CONCLUSIONS: None. Awaiting final report.

REPORT DATE: 12/27/95 PROTOCOL: # 95012

Detail Summary Sheet

TITLE: Prevalence of Snuff Dippers Keratotis in a Military Population of Smokeless Tobacco Users

KEYWORDS: smokeless tobacco, snuff, leukoplakia

PRINCIPAL INVESTIGATOR: Grasser, Jeff, MAJ, DC

DEPARTMENT: Dental Clinic #5

STATUS: Complete

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To determine the prevalence of snuff dippers Keratosis in a specific military population.

TECHNICAL APPROACH: Random, self-reported questionnaire followed by dental examination to determine prevalence of snuff dippers Keratosis.

PRIOR AND CURRENT PROGRESS: 220 examinations performed at one stop - in and out processing center with rough draft paper written. Final draft awaiting additional data and results.

CONCLUSIONS: 220 examinations performed. Awaiting final data and results. Study complete.

REPORT DATE: 12/27/95 PROTOCOL: # 95013

Detail Summary Sheet

TITLE: A Comparison of open vs. laparoscopic Inguinal Hernia Repair of soldiers in contingency units.

KEYWORDS: hernia repair, laparoscopic

PRINCIPAL INVESTIGATOR: Cuthbertson, Louis, LTC, AN

DEPARTMENT: OR/CMS

STATUS: Completed

APPROVAL DATE: Aug 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: Retrospective study comparing the length of convalescent leave and profile length of the two types of hernia repair. General Surgeons will be interviewed on the average amount of convalescent leave and the length of profile they give their patients in regards to the two types of hernia procedures.

TECHNICAL APPROACH: To review the inpatient records on patients that have had a laparoscopic hernia repair and collect data on their convalescent and profile lengths. I will then review the same number of records on patients that have had an open hernia repair.

PRIOR AND CURRENT PROGRESS: Data collection continues.

CONCLUSIONS: Awaiting final report.

REPORT DATE: 12/27/95 PROTOCOL: # 95014

Detail Summary Sheet

TITLE: Women in the Military: Pregnancy, Command Climate Organization Behavior and Outcomes

KEYWORDS: pregnancy, AD women, birth outcomes

PRINCIPAL INVESTIGATOR: McNulty, Kristin, MAJ, MC

STATUS: Ongoing

APPROVAL DATE: Aug 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To examine the role of supportive/nonsupportive command climate in pregnant servicewomen's attitudes about the military, performance, morale, career intentions, and delivery outcomes. To examine the extent to which pregnant women experience/perceive positive/negative feedback from commanders and coworkers. To investigate career choices, intentions, and planning before, during and after pregnancy. To investigate the effects of social support on delivery outcomes, morale, attitudes about the military, performance, and retention. To assess the relationship between the timing of pregnancy; planned and unplanned; TO&E or TDA assignment, leadership or staff position; and positive/negative experiences, performance, and retention, morale, and attitudes about the military.

TECHNICAL APPROACH: Questionnaires will be administered to new and existing active duty obstetric patients at WRAMC, NNMC, and Womack. New patients will be briefed about the purpose of the study, confidentiality, and voluntary nature of the study during their initial orientation to obstetrics by a member of the research team and receive a follow-up questionnaire during their last trimester.

PRIOR AND CURRENT PROGRESS: Data collection is complete. Data analysis is being done by Dr. Evans at Fort Sam Houston. Preliminary findings to come.

CONCLUSIONS: Awaiting findings from Ft Sam Houston.

REPORT DATE: 12/27/95 PROTOCOL: # 95015

Detail Summary Sheet

TITLE: Influence of Parenteral Progesterone administration on the Prevalence and severity of Mastodynia in Active Duty Servicewomen: A multi-institutional cross sectional study

KEYWORDS: Progesterone, Mastodynia

PRINICPAL INVESTIGATOR: Vanderlinde, Terri MAJ, MC

DEPARTMENT: OB/GYN

STATUS: Complete

APPROVAL DATE: Aug 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To see if Depoprovera influences breast tenderness.

TECHNICAL APPROACH: Questionnaire.

PRIOR AND CURRENT PROGRESS: Completion of patient enrollment. Data being assessed and compiled by principal investigators at Tripler Army Medical Center, Hawaii.

CONCLUSIONS: Awaiting results.

REPORT DATE: 1/5/96 PROTOCOL: 95016

Detail Summary Sheet

TITLE: Center for Prostate Disease Research, Prostate Cancer Radical Prostatectomy Follow-up Questionnaire

KEYWORDS: Prostate Cancer, Prostate Disease Research

PRINCIPAL INVESTIGATOR: Quinones, Deogracia, LTC, MC

STATUS: Ongoing

APPROVAL DATE: Aug 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To conduct a comprehensive survey of men who have undergone a radical prostatectomy (RP) to assess long-term quality of life regarding impotence, incontinence and surgical complications.

TECHNICAL APPROACH: Subjects are recruited from a database of all RP patients treated at Womack Army Medical Center between 1980-1994. The CPDR Prostate Cancer Radical Prostatectomy Follow-Up Questionnaire will be mailed to all potential subjects, along with a cover letter from the PI. All mailings will take place from USUHS and a prepaid return envelope will be included for the subject's use.

PRIOR AND CURRENT PROGRESS: Due to other obligations and recent accident there has been no progress to date on this study.

CONCLUSIONS: None. Study ongoing.

REPORT DATE: 12/29/95 PROTOCOL: 95017

Detail Summary Sheet

TITLE: Characteristics of military personnel complaining of multiple medical problems following deploying during the Persian Gulf War

KEYWORDS: Persian Gulf Illness, Psychosomatic illness, Comprehensive Clinical Evaluation Program (CCEP)

PRINCIPAL INVESTIGATOR: Hazlett, Gary, CPT, MS

ASSOCIATE INVESTIGATOR: Dr. David Mullen

DEPARTMENT: Department of Psychiatry & Neurology
Psychology Service

STATUS: Complete (Aug 95)

APPROVAL DATE: July 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To identify demographic and personality characteristics, and patterns of pscyhological dysfunction in soldiers presenting unsubstantiated somatic complaints attributed to Persian Gulf service.

TECHNICAL APPROACH: Record Review. Participants in the Comprehensive Clinical Evaluation Program referred for psychological testing were evaluated using several commonly used psychological tests and a set of history questionnaires. All subjects referred for evaluation were Persian Gulf veterans in which general medical evaluation had failed to substantiate their somatic complaints. The results of the assessment allowed for assignment of subjects into primary diagnostic groups (depressive disorder, somatization disorder, normal, post-traumatic stress disorder, substance abuse). Differences between diagnostic groups along with demographic and testing variables were analyzed.

PRIOR AND CURRENT PROGRESS: Completed. 206 CCEP subject records were analyzed for the study, representing all the CCEP participants seen by the Psychology Service from March 1995 to the end of July 1995. There are no adverse reactions/consequences to report. The evaluation method was record review at no risk to the subjects.

CONCLUSIONS: The results of the study were presented at the Behavioral Sciences Short Course in Miami. Overall, the results of the study indicated a fairly high rate of subtle and more obvious depressive disorders that were likely to account for the subject's somatic complaints and meriting treatment. Rates of PTSD and other

anxiety disorders were considered to be very low. Regardless, among the 80% of the sample subjects considered to be demonstrating a likely psychological disturbance, somatic complaints were common across diagnostic groups, and there was a direct relationship between severity of psychological complaints and extent of somatic complaints. The overall findings were considered to be highly similar to other samples reported in the literature from previous conflicts. The results were considered to be representative of commonly seen patterns of complaints among war veterans and unlikely to be reflective of some new syndrome of illness. The findings suggest that a substantial proportion of soldiers seeking evaluation through the CCEP program are likely to merit a primary diagnosis involving a pscyhiatric condition vs. a general medical condition.

REPORT DATE: 1/5/96 PROTOCOL: 95018

Detail Summary Sheet

TITLE: Treatment of Gemzar (Gemcitabine) for patients with Pancreatic Cancer

KEYWORDS: Gemzar, Gemcitabine, Pancreatic Cancer

PRINCIPAL INVESTIGATOR: Corso, Steven, MAJ, MC

STATUS: Ongoing

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To provide the treatment of patients with locally advanced (Stage IIC or III) metastic (Stage IV) pancreatic cancer. Patient access to Gemzar through the treatment IND will occur while the FDA reviews the safety and efficacy. The secondary objective is to collect further basic safety and efficacy data.

TECHNICAL APPROACH: Patients must have advanced, progressive pancreatic cancer. Gemzar will be administered intravenously at a dose of 1000mg/m2 for 30 minutes once weekly for up to 7 weeks followed by a week of rest, then once weekly for 3 weeks out of every 4 weeks. The first series of weekly doses up to 7 weeks plus the initial weekly doses given over a period of 4 weeks with the fourth week as a week of rest. No other chemotherapy, immunotherapy, hormonal therapy, radiation therapy or experimental medications will be permitted while the patients are on the study.

PRIOR AND CURRENT PROGRESS: Study not yet initiated. No progress to date.

CONCLUSIONS: None.

REPORT DATE: 1/5/96 PROTOCOL: 95019

Detail Summary Sheet

TITLE: A Phase II Study of Fludarabine Phosphate in Mantle Cell Lymphoma

KEYWORDS: Lymphoma, Fludarabine Phosphate

PRINCIPAL INVESTIGATOR: Corso, Steven, MAJ, MC

STATUS: Ongoing

APPROVAL DATE: Aug 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: To evaluate the response rate and response duration of patients with mantle cell lymphoma when treated with fludarabine and to assess the toxicity of fludarabine in patients with mantle cell lymphoma.

TECHNICAL APPROACH: Patients will undergo a series of tests before the study to determine the extent of the disease. All tests are routinely performed before beginning any treatment for mantle cell lymphoma. These include blood tests, CT scans, and a bone marrow examination. Therapy must be initiated within 2 weeks of completion of pre-study questionnaire. Allopurinol 300 mg po Qd from day 1 to day 8 will be given for the first 3 months. Fludarabine phosphate 25mg/m2/d IV, days 1-5 will be given with cycles repeating every 28 days.

PRIOR AND CURRENT PROGRESS: No progress to date.

CONCLUSIONS: None to report.

REPORT DATE: 1/5/96 PROTOCOL: 95020

Detail Summary Sheet

TITLE: Fracture & Stress Fracture Sentinel Injury Surveillance Project

KEYWORDS: Fracture, Stress Fracture, Injury Surveillance

PRINCIPAL INVESTIGATOR: Craig, Steven, LTC, MC

STATUS: Ongoing

APROVAL DATE: Aug 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: This study is designed to conduct surveillance of the active duty population at Fort Bragg for fractures and stress fractures via capture and verification of personal and medical data and diangosis of all soldiers referred to the Dept of Radiology at WAMC for fracture or stress fracture. In addition, a sample data reflecting the demographic and medical care needs of the total soldier population will be acquired to calculate incidence rates and to validate fracture/stress fracture surveillance data. Descriptive and statistical analyses of the obtained data will be prepared to describe the correlation between the incidence of stress fractures and the incidence of overuse and acute traumatic injuries.

TECHNICAL APPROACH: Initiation of surveillance for fractures and stress fractures will require careful review of records of soldiers within a designed Division (82nd ABN) who were referred to the Dept of Radiology for diagnosis of a fracture and stress fracture. This review will be conducted once to twice weekly, and a list of all potential cases will be prepared. In particular age, race, gender, unit of the soldier, location and type of injury, days of limited duty, physical fitness scores, height, weight, precent body fat, and the results of other diagnostic tests performed to confirm the diagnosis will be gathered. These data will constitute the primary Sentinel Injury Surveillance Database.

PRIOR AND CURRENT PROGRESS: Preliminary site visit to set up the study will be on 25 Jan 96.

CONCLUSIONS: None. Study ongoing.

REPORT DATE: 12/27/95 PROTOCOL: 95021

Detail Summary Sheet

TITLE: Evaluation of a Nurse-Administered Cognitive Therapy Program on a Military Inpatient Psychiatric Unit

KEYWORDS: cognitive therapy program, inpatient psychiatry

PRINCIPAL INVESTIGATOR: McClelland, Gail, LTC, AN

DEPARTMENT: Nursing

STATUS: Terminated

APPROVAL DATE: August 95

CUMULATIVE MEDCASE AND OMA COSTS: $ 0

STUDY OBJECTIVE: The goal of Cognitive Therapy (CT) is to help patients identify and alter distorted cognitions that underlie their psychiatric disturbance. The goal of the proposed research is to examine the effects of a CT program administered by nursing personnel on an inpatient military psychiatric unit.

TECHNICAL APPROACH: The design of the study will be a program evaluation design. The specific aims are to: (1) Evaluate the efficacy of a CT treatment program administered by nursing staff on a military inpatient unit by comparing admission and discharge patients' adaptive functioning on several psychological instruments; (2) Evaluate patient's learning and retention of CT skills; (3) Ascertain the patient's subjective assessments of the usefulness of their exposure to the CT treatment program; (4) Explore which patient diagnostic groups are responsive to the CT treatment program; (5) Explore the cost-effectiveness pre-and post-implementation of the CT program on lengths of stay, readmissions; (6) Determine the nursing staff's perceived level of professional growth and development of tratment skills as a result of their participation in the CT program.

PRIOR AND CURRENT PROGRESS: This study was not accepted for funding therefore it is terminated.

CONCLUSIONS: None.

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