CLINICAL INVESTIGATION PROGRAM REPORT
CONTROL SYMBOL: RCS MED-300 (R1)

Department of Clinical Investigation
Womack Army Medical Center
Fort Bragg, North Carolina 28307

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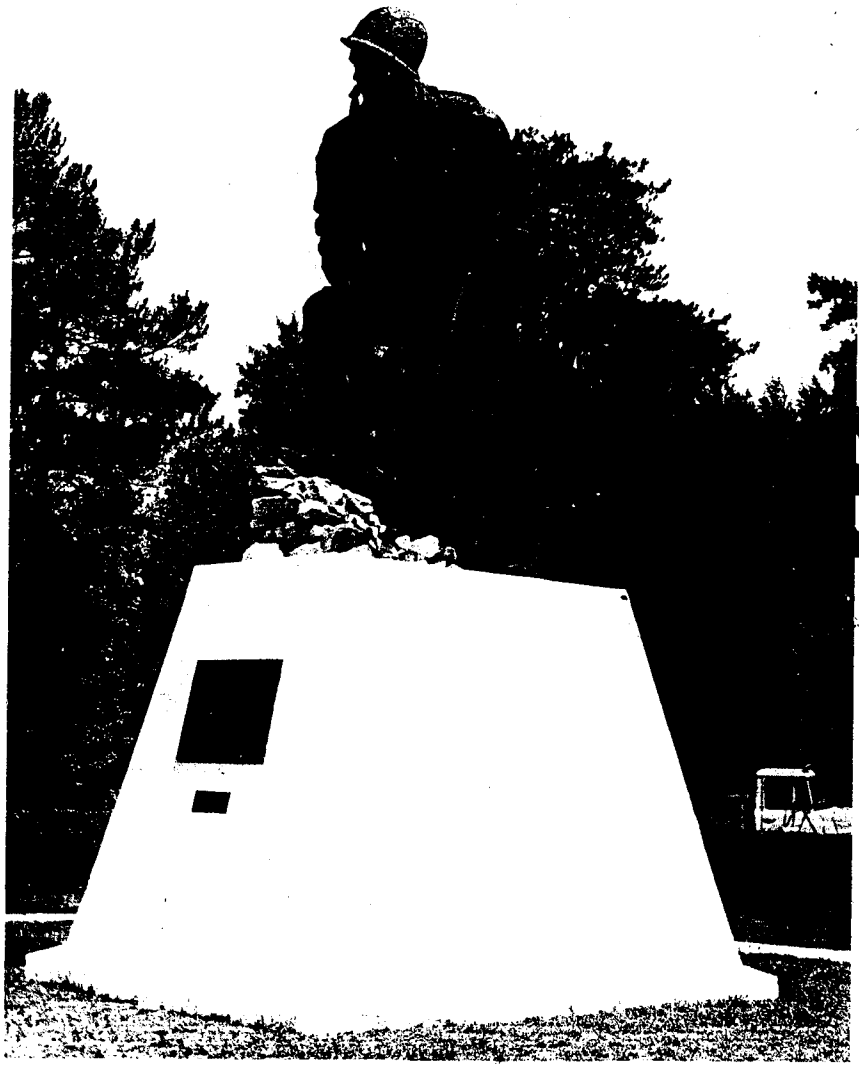
Annual Progress Report
FY94



Clinical Investigation Service
Womack Army Medical Center
Fort Bragg, North Carolina
28307-5000

REPORT DOCUMENTATION PAGE

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	1 October 1994	Annual - 1 Oct 93 to 30 Sept 94

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Director, Clinical Investigation

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Fort Bragg, North Carolina 28307-5000

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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 and Human Use Committee/Institutional Review Board. This report includes a Detail Summary Sheet outlining the progress of each protocol during Fiscal Year 94. 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
59

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Foreword

The Clinical Investigation Service (CIS) was approved as a modified mission for the Womack Army Community Hospital in May 1990. The first protocols were reviewed and approved in the fall of 1991, coinciding with the designation of Womack as a medical center. This third annual report documents the progress of clinical investigation at Womack and the continued development of the CIS at a growing medical center.

More fertile ground for patient-oriented, clinically-based scholarly activity than the Fort Bragg community could hardly be imagined. With approximately 50,000 active duty members and over 200,000 beneficiaries in our catchment area, the clinical material is indeed ample. Certainly, this fact is recognized by the Walter Reed Army Institute of Research and the US Army Medical Research Institute for Infectious Disease, who among others periodically conduct studies at Fort Bragg. Unfortunately, the involvement of Womack clinicians in research has traditionally been low, in part due to the high patient care load. I hope, as did my predecessor MAJ Vic McGlaughlin, that the potential at Fort Bragg for clinical investigation of military medical significance is fully recognized in the years ahead. Furthermore, as scare personnel resources are re-aligned in the Army medical community, it is hoped that interested and capable individuals are appropriately committed toward the realization of this immense potential.

The CIS 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 Joe FitzHarris, as Chief of the Department of Family Medicine, commits a physician and a secretary 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

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 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, CIS	04	61H	MC	Smucny, John
Protocol Coord	04	0679	GS	Collazo, Karen

Clinical Investigation Committee Members

COL Tony Carter	Chairman & Deputy Commander for Clinical Services
MAJ John Smucny	Director, Clinical Investigation Service
COL Kelly McKee	Chief, Communicable Disease Unit
COL Sharon Cooper	Chief, Pediatrics
COL Joseph FitzHarris	Chief, Department of Family Medicine
COL W.L. Lumpkin	Chief, Veterinary Care
LTC Marjorie Mitchell	Center Judge Advocate
LTC Guy Stong	Chief, Pathology
LTC Gail McClelland	Representing Chief, Nursing
LTC David Schneck	Chief, Dental Activities
LTC Nathan Erteschik	Chief, Medicine
LTC William Eggebroten	Chief, Surgery
LTC Mark Siletchnik	Chief, OB/GYN
MAJ David Kishbaugh	Representing Chief, Psychiatry & Neurology
MAJ Rob Saunders	Representing Chief, Social Work Service
MAJ Richard Rosin	Chief, Radiology
CPT Thomas Dudley	Chief, Ministry & Pastoral Care
CSM Henry Spear	Lay/Non-Affiliated Representative
Dr. Carlos DeCamara	Representing Chief, Pharmacy Service
Ms. Judy Kerr	Representing, Veterans Administration Hospital

Human Use Committee Members

COL Tony Carter, MC	Chairman & Deputy Commander for Clinical Services
MAJ John Smucny, MC	Director, Clinical Investigation Service
LTC Gail McClelland, AN	Representing Chief, Nursing
LTC Marjorie Mitchell, JA	Center Judge Advocate
CPT Thomas Dudley, CH	Chief, Ministry & Pastoral Care
CSM Henry Spear	Lay/Non-Affiliated Representative

Research Award Recipients

Recipient of

The Uniformed Services Academy of Family Physicians Resident Research Award

was Captain Daniel Schissel for his poster

"Chronic Compartment Syndrome: A Case Report"

This poster was presented in Norfolk, Virginia winning First Place, 13-18 Mar 94.

Recipient of

The Uniformed Services Academy of Family Physicians Resident Research Award

was Captain Benjamin Thompson for his poster

"Tuberculosis Peritonitis with elevated CA-125 levels: A Case Report"

This poster was presented in Norfolk, Virginia winning Second Place, 13-18 Mar 94.

Recipient of

The Uniformed Services Academy of Family Physicians Staff Research Award

was Lieutenant Colonel Glenn C. Griffiths for his poster

"Junior High School Health Education:
Community Service and Adolescent Medicine Training"

This poster was presented in Norfolk, Virginia winning Second Place, 13-18 Mar 94.

Research Award Recipients

Recipient of

The Southern Medical Association Resident Research Award was

Captain Michael Schooff for his poster

"Neurosarcoidosis: An unusual etiology of Headache"

This poster was presented in New Orleans, Louisiana winning First Place, 28-31 Oct 93.

Recipient of

The Southern Medical Association Resident Research Award was

Captain Bryan Smith for his poster

"Acute Appendicitis in the Puerperium: A Case Report and Literature Review"

This poster was presented in New Orleans, Louisiana winning Second Place, 28-31 Oct 93.

Code: C = Complete, T = Terminated, O = Ongoing
IND- drug, IDE - device, EXP - expedited, MR - minimal risk, GR - greater risk

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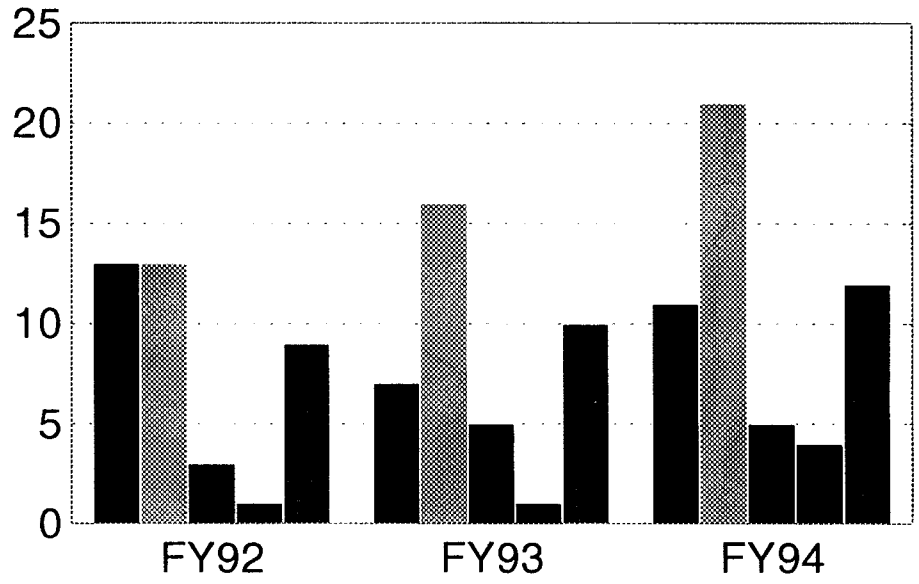
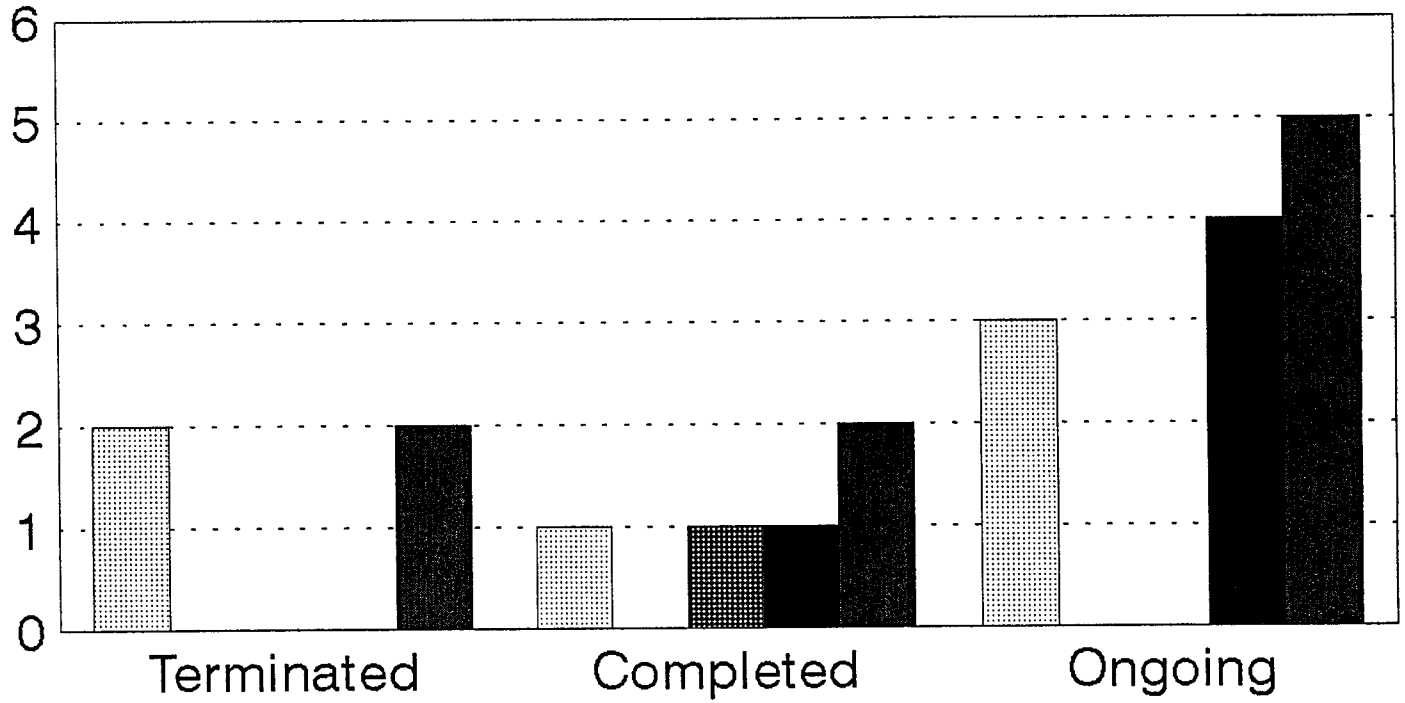
FY92-FY94 Protocol Activity



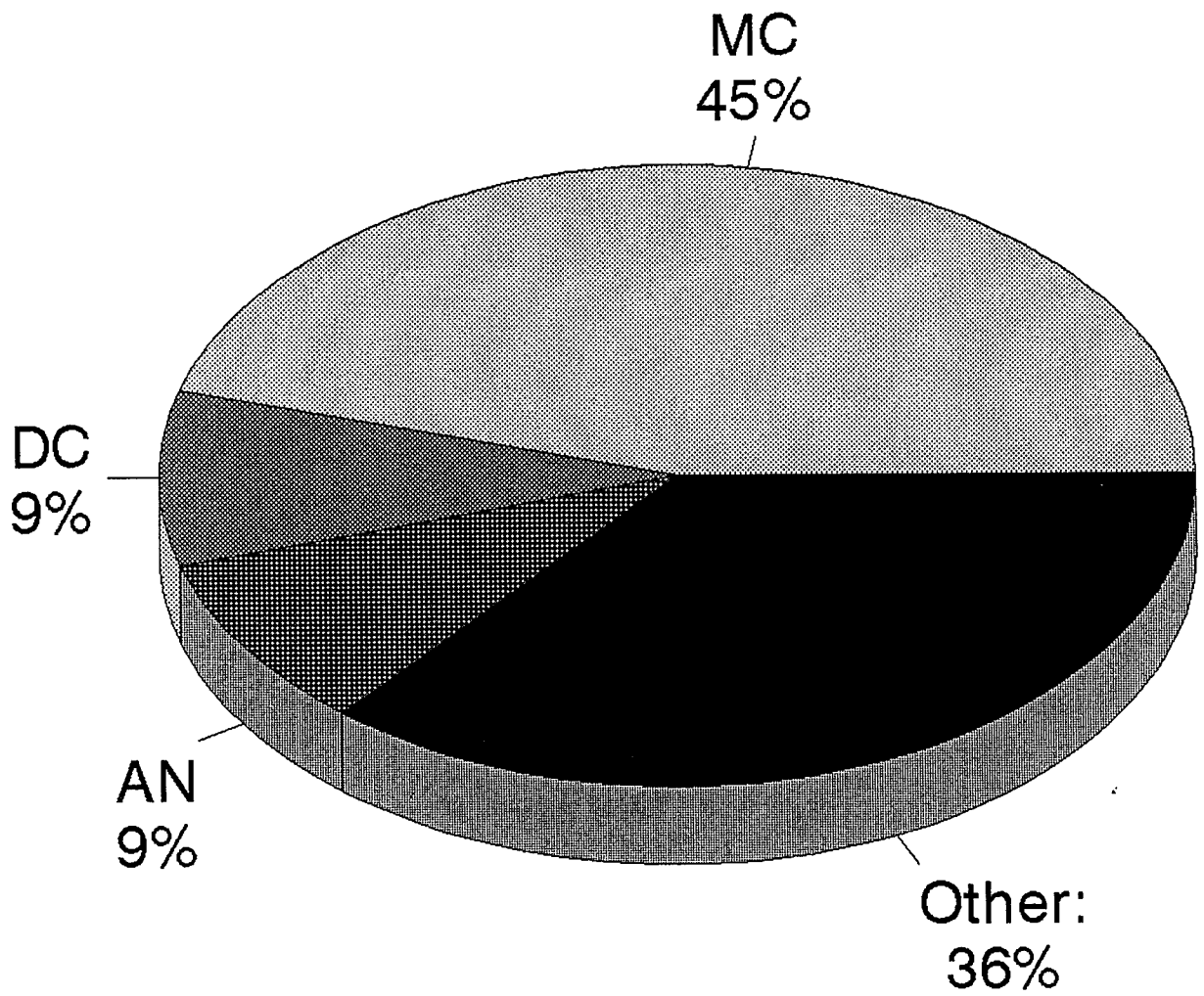
	FY92	FY93	FY94
Approved FY	13	7	11
Total Ongoing FY	13	16	21
Completed FY	3	5	5
Terminated FY	1	1	4
Ongoing conclusion FY	9	10	12

FY 94 Protocols by Subject



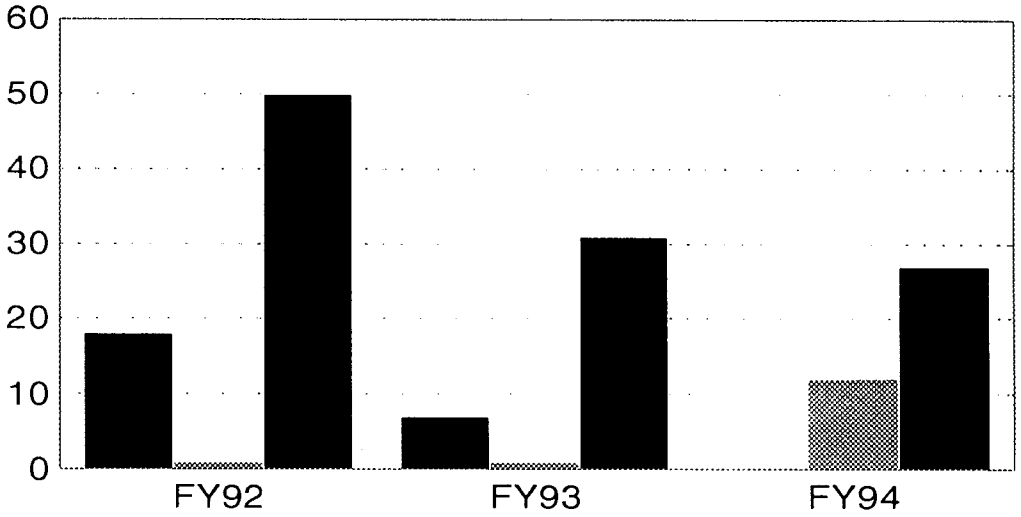
	Terminated	Completed	Ongoing
IND	2	1	3
IDE	0	0	0
Expedited	0	1	0
Minimal Risk	0	1	4
Greater Risk	2	2	5

FY94 Protocols by AMEDD Officer Corps



Other: indicates civilian (HMJF)

FY92-94 Publications & Presentations*



	FY92	FY93	FY94
Articles	18	7	0
Abstracts	1	1	12
Presentations	50	31	27

*based upon response to survey sent to all Department Chiefs at WAMC

FY 94 Publications & Presentations

Department of Family Medicine

Lang, WL., Goforth G. Optimal Panel Sizes for Military Family Physicians. USAFP, 13-18 Mar 94. Norfolk, VA. (Pr)

Snoddy, RO., Henderson JM. Medical Consequences of Basic Infantry Training and Predictors of Training Success. USAFP, 13-18 Mar 94. Norfolk, VA. (Pr)

Schissel, D. Chronic Compartment Syndrome: A Case Report. USAFP, 13-18 Mar 94. Norfolk, VA. (Pr)

Thomspon, B. Tuberculosis Peritonitis with elevated CA-125 levels: A Case Report. USAFP, 13-18 Mar 94. Norfolk, VA. (Pr)

Vogelman, L. Sleep Apnea Syndrome: A Case Report. USAFP, 13-18 Mar 94. Norfolk, VA. (Pr)

Griffiths, G. Junior High School Health Education: Community Service and Adolescent TRaining. USAFP, 13-18 Mar 94. Norfolk, VA. (Pr)

Schooff, M. Intussception: An uncommon presentation of a common disease. SMA, 28-31 Oct 93. New Orleans, LA. (Pr)

Keehn, M. Thrombotic Thrombocytopenic Purpura in the Puerperium. SMA, 28-31 Oct 93. New Orleans, LA. (Pr)

Lawrence, W. Nephrolithiasis during Pregnancy: A Case Report and Literature Review. SMA, 28-31 Oct 93. New Orleans, LA. (Pr)

Light, D. Do Zung Self-Rating Depression scores vary with duration of Pregnancy? SMA, 28-31 Oct 93. New Orleans, LA. (Pr)

Smith B. Acute Appendicitis in the Puerperium: A Case Report and Literature Review. SMA, 28-31 Oct 93. New Orleans, LA. (Pr)

Thompson, B. Mycobacterial Cellulitis: A Case Report and Literature Review. SMA, 28-31 Oct 93. New Orleans, LA. (Pr)

Schooff, M. Neurosarcoidosis: An unususal etiology of headache. SMA, 28-31 Oct 93. New Orleans, LA. (Pr)

Code: Pr=presentation, P=publication, A=abstract

FY 94 Publications & Presentations

Department of Family Medicine

Wise, S. Nephrogenic Diabetes Insipidus Secondary to Posterior Urethral Valves. Submitted to Southern Medical Association. (A)

Smith, B. Neonatal Hypoglycemia for the Primary Care Physician. Submitted to Southern Medical Association (A)

Hannapel, A. Congestive Heart Failure in the Puerperium. Submitted to Southern Medical Association. (A)

Smith, R. Pectoralis Major Rupture: A unique cause of Chest Pain. Submitted to Southern Medical Association. (A)

Thompson, B. Postpartum ruptured Subcapsular Hematoma: A Case Report. Submitted to Southern Medical Association (A)

McGlaughlin, V. Introducing new residents to the specialty of family practice: A curriculum approach. Submitted to Southern Medical Association (A)

McGlaughlin, V. HELLP Syndrome in Pregnancy: A case report and literature review. Submitted to Southern Medical Association (A)

Schooff, M. Chronic Diarrhea: An unusal presenting symptom of diabetes mellitus. Submitted to Southern Medical Association (A)

Schooff, M. Left-sided inferior vena cava presenting as a right peritracheal mass on chest rajdiograph. Submitted to Southern Medical Association. (A)

Griffiths, G. Junior High School Health Education: Community Service and Adolescent Training. Submitted to Southern Medical Association (A)

Snoddy, RO. Medical Consequences of Basic Infantry Training and Predictors of Training Success. Submitted to Southern Medical Association (A)

Thompson, B. Tuberculous Peritonitis with elevated CA-125 levels. Submitted to Southern Medical Association. (A)

Code: Pr=presentation, P=publication, A=abstract

FY 94 Publications & Presentations

Pharmacy Service

Williford, S. Impact of Patient Counseling. 28th Annual ASHP Midyear Clinical Meeting, 5-9 Dec 93. Atlanta, GA. (Pr)

Masaracchia, J. Pharmacy as an Integral Part of the Code Blue Team. American Society of Hospital Pharmacy, Annual Clinical Meeting, 5-9 Jun 94. Reno, NE. (Pr)

Preventive Medicine Service
Henry M. Jackson Foundation for the Advancement
of Military Medicine

Jenkins, P. Transmission Risk Relevant Behaviors in HIV-Seronegative Individuals. Implications for Interventions. Army HIV Conference, 16 Jun 94. Washington, DC. (Pr)

Jenkins, P. Summary of HIV Risk-Relevant Behaviors. Regional HIV Conference, 8 Mar 94. Fort Campbell, KY. (Pr)

Community Health Nursing

Fraser, C. Somalia: Lessons learned and Patient Information. ACHN Regional Conference, 19 May 94. WRAMC, Washington, DC. (Pr)

Franchak, M. Disability Awareness Education. 17th Annual Community/Public Health Nursing Conference, 22 May 94. Chapel Hill, NC. (Pr)

Franchak, M. Preventive Breast Cancer Screening and Education for Active Duty Soldiers and Dependents. Preventive Medicine Officer's Symposium, 15 Jun 94. Falls Church, VA. (Pr)

Franchak, M. Drinking and Driving Behaviors. Clinical Nurse Specialist Conference, 1 Oct 93. Asheville, NC. (Pr)

Code: Pr=presenation, P=publication, A=abstract

FY 94 Publications & Presentations

Department of Surgery
Podiatry Service

Spitalny, AD. Cuboid Fractures. Tri-Service Military Podiatry Seminar, 25-27 Mar 94. Tucson, AZ. (Pr)

Spitalny, AD. Stress Fractures of the Lower Extremity. National Military Physicians Assistant's Conference, Apr 94. Fayetteville, NC. (Pr)

Spitalny, AD. Fractures of the Lower Extremity, Fractures of the Foot and Ankle, Tarsal Coalitions, and Pediatric Trauma of the Foot. University of Osteopathic Medicine and Health Sciences, 5 Dec 93. Des Moines, IA. (Pr)

Urology Service

Quinones, D. Erectile Dysfunction. National Military Physician Assistant's Conference, Apr 94. Fayetteville, NC. (Pr)

Code: Pr=presentation, P=publication, A=abstract

Detail Summary Sheets

REPORT DATE: 12/27/94 PROTOCOL: 92001 STATUS: Terminated

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

APPROVAL DATE: Oct 1991

PRINCIPAL INVESTIGATOR: Victor McGlaughlin, MAJ, MC

DEPARTMENT/SERVICE: Department of Family Medicine

KEYWORDS: asthma, asthma treatment

Accumulative MEDCASE Cost: $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 investigational site, and no patients were enrolled. Protocol Terminated - 30 Sept 92.

CONCLUSIONS: None.

REPORT DATE: 12/27/94 PROTOCOL: 92002 STATUS: Completed

Detail Summary Sheet

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

APPROVAL DATE: Oct 91

PRINCIPAL INVESTIGATOR: Randy Swackhammer, MAJ, MC

DEPARTMENT/SERVICE: Department of Medicine
Internal Medicine

KEYWORDS: hypertension, elderly, enzyme inhibition use

Accumulative MEDCASE cost: $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: 12/27/94 PROTOCOL: 92003 STATUS: Terminated

Detail Summary Sheet

TITLE: A comparison of the efficacy, safety and tolerance of Ceftibuten 300mg and Augmentin 500mg given TID in the treatment of Community Acquired Pneumonia.

APPROVAL DATE: Jan 92

PRINCIPAL INVESTIGATOR: Victor G. McGlaughlin, MAJ, MC

DEPARTMENT/SERVICE: Department of Family Medicine

KEYWORDS: Pneumonia, Augmentin, Ceftibuten

Accumulative MEDCASE cost: $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 Nov 93, 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: 12/27/94 PROTOCOL: 92004 STATUS: Terminated

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.

APPROVAL DATE: Jan 92

PRINCIPAL INVESTIGATOR: Victor G. McGlaughlin, MAJ, MC

DEPARTMENT/SERVICE: Department of Family Medicine

KEYWORDS: Bronchitis, Augmentin, Ceftibuten

Accumulative MEDCASE cost: $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 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 insufficient 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.

REPORT DATE: 12/27/94 PROTOCOL: 92005 STATUS: Completed

Detail Summary Sheet

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

APPROVAL DATE: Jan 92

PRINCIPAL INVESTIGATOR: Victor G. McGlaughlin, MAJ, MC

DEPARTMENT/SERVICE: Department of Family Medicine

KEYWORDS: Pregnancy outcome, work, pregnancy complications

Accumulative MEDCASE cost: $ 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 pregnancy 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 greater 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: 12/27/94 PROTOCOL: 92006 STATUS: Completed

Detail Summary Sheet

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

APPROVAL DATE: Feb 92

PRINCIPAL INVESTIGATOR: Victor G. McGlaughlin, MAJ, MC

DEPARTMENT/SERVICE: Department of Family Medicine

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

Accumulative MEDCASE cost: $ 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: 12/27/94 PROTOCOL: 92007 STATUS: Completed

Detail Summary Sheet

TITLE: Fluoride Concentration in Human Bone

APPROVAL DATE: Mar 92

PRINCIPAL INVESTIGATOR: Randy Davis, MAJ, DC

DEPARTMENT/SERVICE: WAMC Dental Activitiy

KEYWORDS: fluoride, bone fluoride concentrations

Accumulative MEDCASE cost: $ 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 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: 12/27/94 PROTOCOL: 92008 STATUS: Completed

Detail Summary Sheet

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

APPROVAL DATE: Mar 92

PRINCIPAL INVESTIGATOR: Gary Goforth, LTC, MC

DEPARTMENT/SERVICE: Department of Family Medicine

KEYWORDS: Tick-borne disease, Ehrlichiosis, Lyme Disease

Accumulative MEDCASE cost: $ 0

STUDY OBJECTIVE: To determien 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 data. Manpower consists of the Principal Investigator, Associate Investigators, WAMC laboratory personnel and shipping technician, and Family Practice nurses.

PRIOR AND CURRENT PROGRESS: There have been 25 subjects enrolled from 10 Mar 92 - 30 Sep 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 acqurie 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: 12/27/94 PROTOCOL: 92009 STATUS: Completed

Detail Summary Sheet

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

APPROVAL DATE: Mar 92

PRINCIPAL INVESTIGATOR: Ellen O'Keefe, CPT, SP

DEPARTMENT/SERVICE: Department of Surgery
Physical Therapy Section
Department of Orthopedics

KEYWORDS: ankle sprain, compression, functional tests

Accumulative MEDCASE cost: $ 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 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 patietns 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.

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

REPORT DATE: 12/27/94 PROTOCOL: 92010 STATUS: Terminated

Detail Summary Sheet

TITLE: Ultrasound guided percutaneous needle core biopsy

APPROVAL DATE: Mar 92

PRINCIPAL INVESTIGATOR: Brian Burke, CPT, MC

DEPARTMENT/SERVICE: Department of Radiology

KEYWORDS: breast mass, breast cancer, breast biopsy

Accumulative MEDCASE cost: $ 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 ETD of the Principal Investigator. No study subjects were enrolled.

CONCLUSIONS: None.

REPORT DATE: 12/28/94 PROTOCOL: 92011 STATUS: Ongoing

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

APPROVAL DATE: May 92

PRINCIPAL INVESTIGATOR: Kelly McKee, COL, MC

DEPARTMENT/SERVICE: Department of Medicine
Preventive Medicine
Internal Medicine

KEYWORDS: HIV, Mycobacterium Avium Complex, Azithromycin

Accumulative MEDCASE cost: $ 0

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

TECHNICAL APPROACH: This study will enroll all patients with CD4 counts <100/ul who have negative MAC cultures. Screening and baseline evaluations will include a full medical history and physical exam. Blood tests, stool cultures, CXR, and baseline audiometry will be performed. Patients will then be randomized in double-blind fashion to receive Azithromycin 1200mg or placebo as a single dose once a week. Patients will be evaluated clinically once a month and at three months lab and MAC culture will be obtained.

PRIOR AND CURRENT PROGRESS: There were a total of 6 patients enrolled in the study to date. 3 patients remain on the protocol, 1 death unrelated to the protocol, 1 patient disenrolled for non compliance, and 1 patient disenrolled self prior to medication being given in order to get involved with another research project.

No adverse effects of the medication has been noted.

CONCLUSIONS: None. Active recruitment of more patients continues.

REPORT DATE: 12/27/94 PROTOCOL: 92012 STATUS: Completed

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

APPROVAL DATE: Feb 92

PRINCIPAL INVESTIGATOR: Stephen Craig, MAJ, MC

DEPARTMENT/SERVICE: Preventive Medicine Service
WRAIR

KEYWORDS: degenerative joint disease, spine

Accumulative MEDCASE cost: $ 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 Advisory Committee at WRAIR in June 92. Part II has been completed. Radiographic data has been read. Awaiting data from Part II in order to compare parts I and II for conclusions.

CONCLUSIONS: None as of this report. Data due to be completed on Parts I and II in the next month (Feb 95).

REPORT DATE: 12/27/94 PROTOCOL: 93013 STATUS: Completed

Detail Summary Sheet

TITLE: Immunization of Military Personnel with Hepatitis A Vaccine

APPROVAL DATE: Sep 92

PRINCIPAL INVESTIGATOR: Phillip Pittman, LTC, MC

DEPARTMENT/SERVICE: USAMRIID Medicine, WRAIR

KEYWORDS: Hepatitis A, immunization

Accumulative MEDCASE cost: $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: A total of 1051 volunteers were enrolled in this study. 526 were randomized to group A and 525 were randomized to group B. Group A received a double dose of vaccine (a dose of vacicne into each deltoid) of day 0; group B received one dose of vaccine and one dose of placebo on day 0. Approximately 11% of each group were immune. On study day 30, group A (494 volunteers returned) received a dose of placebo; and group B (492 volunteers) received its second dose of vaccine. On study day 365, both groups received a dose of vaccine (N=390 for group A and 384 gor group B). A cohort from each group returned for titers on day 395 (group A = 72 and 57 for group B).

Detail Summary Sheet (continued)

Preliminary evaluation of a cohort with respect to symptoms and immune response has been conducted. Results suggest that at one year 55% and 62% of group A and group B recipients, respectively, will have >20IU/ml (p=0.13). After boosting, all recipients responded with high titers, GMT > 1:2005 and 2553 for groups A and B respectively, (p=0.053).

CONCLUSIONS: Based on these preliminary results, Hepatitis A vaccine is safe and immunogenic when administered as a double dose. The immune response to the booster dose was robust. A booster dose is strongly recommended. Indeed, perhaps it would be prudent to boost at 6 or 9 months in order to avoid the decrement in antibody level observed in the preliminary analysis of this study. The final analyses of all results is pending and should be part of the final report next year.

REPORT DATE: 12/27/94 PROTOCOL: 93014 STATUS: Ongoing

Detail Summary Sheet

TITLE: Safety and Immunogenicity of a Hepatitis A vaccine

APPROVAL DATE: Feb 93

PRINCIPAL INVESTIGATOR: Robert Kuschner, MAJ, MC

DEPARTMENT/SERVICE: WRAIR
Preventive Medicine Service, WAMC

KEYWORDS: Hepatitis A, immunization, vaccine

Accumulative MEDCASE cost: $ 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 Thailand. 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. Those subjects who met the includion 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, and (d) Group 4: Low potency, vaccination at time 0 and day 30 (standard immunization regimen). In addition, each soldier received a booster dose at 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. 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).

Detail Summary Sheet (continued)

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 assess 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 is planned for March 95. Serology results for the first year following the initial immunization will be available soon. Formal analysis of adverse experiences for the different groups is ongoing. Study ongoing.

REPORT DATE: 12/27/94 PROTOCOL: 93015 STATUS: Terminated

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).

APPROVAL DATE: Mar 93

PRINCIPAL INVESTIGATOR: James I. Meyer, MAJ, MC

DEPARTMENT/SERVICE: Internal Medicine

KEYWORDS: Sepsis, SIRS, CP-0127

Accumulative MEDCASE cost: $ 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 parallel dose ranging study. This study totaling 500 patients will be conducted in 20-40 investigational sites. Patients will be doses 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.

14 potential patietns 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.

REPORT DATE: 12/28/94 PROTOCOL: 93016 STATUS: Completed

Detail Summary Sheet

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

APPROVAL DATE: Mar 93

PRINCIPAL INVESTIGATOR: David Belyea, MAJ, MC

DEPARTMENT/SERVICE: Ophthalmology

KEYWORDS: cricoid pressure, intraocular pressure

Accumulative MEDCASE cost: $ 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 30 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 an without manually applied cricoid pressure. The procedure should be complete within ten minutes.

PRIOR AND CURRENT PROGRESS: Study completed June 93. Attempt to contact investigators have been unsuccessful.

CONCLUSIONS: Unknown.

REPORT DATE: 12/28/94 PROTOCOL: 93017 STATUS: Completed

Detail Summary Sheet

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

APPROVAL DATE: Mar 93

PRINCIPAL INVESTIGATOR: Michael Humphrey, MAJ, MC

DEPARTMENT/SERVICE: Department of Medicine
Internal Medicine

KEYWORDS: Diabetes Mellitus, sustacal stimulation testing

Accumulative MEDCASE cost: $ 0

STUDY OBJECTIVE: To differentiate between Type I and Type II diabetes in younger patients 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, patietns will present to the medical clinic and will be given instructions to hold their AM oral hypoglycemic agent/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-peptite. 50 patients are required for the study to include all active duty and dependent patients which meet criteria.

CURRENT AND PRIOR PROGRESS: 52 patients 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 processess. No complications have occured with testing.

CONCLUSIONS: The results have been predicted: patients with blunted insulin and C-peptide 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: 12/28/94 PROTOCOL: 93018 STATUS: Completed

Detail Summary Sheet

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

APPROVAL DATE: Jun 93

PRINCIPAL INVESTIGATOR: Phillip Pittman, LTC, MC

DEPARTMENT/SERVICE: USAMRIID
Preventive Medicine

KEYWORDS: tickborne encephalitis, FSME-IMMUN inject

Accumulative MEDCASE cost: $ 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 week, 4 weeks) immunization schedule to define the antibody response in 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.

Detail Summary Sheet (continued)

PRIOR AND CURRENT PROGRESS: A total of 99 persons were enrolled in Part I of this protocol at USAMRIID, Ft Detrick MD. Volunteers were randomized to receive the accelerated dose schedule at week 0, 1 and 4 or the standard schedule at 0 and 4 weeks. Both groups received a booster dose at 9 months. Blood was drawn for titer determination at set intervals during the study period. Analysis 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: 12/28/94 PROTOCOL: 93019 STATUS: Ongoing

Detail Summary Sheet

TITLE: Treatment of Adults Patients with Varicella with short course oral Acyclovir

APPROVAL DATE: Sep 93

PRINCIPAL INVESTIGATOR: Ted Epperly, LTC, MC

DEPARTMENT/SERVICE: USUHS
Department of Family Medicine, WAMC

KEYWORDS: Varicella, Acyclovir

Accumulative MEDCASE cost: $ 0

STUDY OBJECTIVE: The objective of this study is to determine if the shourt 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 randomzied 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 the Fall 95.

CONCLUSIONS: None. Study ongoing.

REPORT DATE: 12/28/94 PROTOCOL: 93020 STATUS: Completed

Detail Summary Sheet

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

APPROVAL DATE: Mar 93

PRINCIPAL INVESTIGATOR: Kathleen Mauro, LTC, MC

DEPARTMENT/SERVICE: Department of Obstetrics & Gynecology

KEYWORDS: pre-natal, post-natal, birth

Accumulative MEDCASE cost: $ 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 pre-natal factors which signficantly influence and predict women's preceptions of birthing experiences, explore relationships between the selected prenatal factors, and communicate results to the miltiary nursing community, military health care providers, and military leaders.

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

CONCLUSIONS: None as of this report.

REPORT DATE: 12/28/94 PROTOCOL: 94001 STATUS: Ongoing

Detail Summary Sheet

TITLE: Assessment of Risk Factors for HIV infection among active duty U.S. Military Personnel with documented recent HIV-antibody Seroconversion

APPROVAL DATE: May 94

PRINCIPAL INVESTIGATOR: Lynn Levin, MPH (WRAIR)
Pamela Jenkins, HMJ

DEPARTMENT/SERVICE: Preventive Medicine, WRAIR
Henry M. Jackson Foundation, FT Bragg, NC
Preventive Medicine, WAMC

KEYWORDS: HIV infection, Seroconversion, HIV risk factors

Accumulative MEDCASE cost: $ 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: The study will be conducted using a anonymous self-report questionnaire, via talking computer, in a case-control design. A case will be defined on the basis of seroconversion to antibody to HIV using ELISA with duplicate Western Blot confirmation. Control will be selected at random from the group of all uninfected active duty personnel at the same installation and matched on key demographic elements, gender, ethnicity, rank, and length of service. Two male controls will be recruited for each male case and three female controls for each female case. Upon enrollment, a study ID number will be assigned to each participant. The log will be mailed to WRAIR after interviews have been completed.

PRIOR AND CURRENT PROGRESS: Awaiting equipment in order to initiate study.

CONCLUSIONS: None. Study Ongoing.

REPORT DATE: 12/28/94 PROTOCOL: 94002 STATUS: Terminated

Detail Summary Sheet

TITLE: Needle Core Breast Biopsy

APPROVAL DATE: Dec 93

PRINCIPAL INVESTIGATOR: Mary Phillips, MAJ, MC

DEPARTMENT/SERVICE: Mammography
Department of Radiology

KEYWORDS: breast, biopsy

Accumulative MEDCASE cost: $ 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 stereotactic 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 nedessitating surgical intervention.

PRIOR AND CURRENT PROGRESS: Study terminated due to PI PCS.

CONCLUSIONS: None. No patients were enrolled.

REPORT DATE: 12/28/94 PROTOCOL: 94003 STATUS: Ongoing

Detail Summary Sheet

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

APPROVAL DATE: Jun 94

PRINCIPAL INVESTIGATOR: Maryanne Franchak, LT, AN

DEPARTMENT/SERVICE: Community Health
Department of Radiology
One Stop In-Processing, Ft Bragg
Womack Classrooms/conference rooms

KEYWORDS: breast care, preventive care

Accumulative MEDCASE cost: FY94 $108,505 (HMJ)
FY95 $101,988
FY96 $108,742
FY97 $113,410
TOTAL: 432,645

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, o1C'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: No progress to date. Study initiated Oct 94.

CONCLUSIONS: None.

REPORT DATE: 12/28/94 PROTOCOL: 94004 STATUS: Ongoing

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

APPROVAL DATE: Jun 94

PRINCIPAL INVESTIGATOR: Kelly McKee, COL, MC

DEPARTMENT/SERVICE: Communicable Disease Unit
Preventive Medicine Service

KEYWORDS: Herpes Simplex 2 vaccine, Herpes, STD

Accumulative MEDCASE cost: FY94 $1190.00

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.

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 cards 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.

REPORT DATE: 12/28/94 PROTOCOL: 94004 STATUS: Ongoing

Detail Summary Sheet (Continued)

PRIOR AND CURRENT PROGRESS: This study was initiated 1 Sep 94. There is one patient enrolled in the study to date. This patient had a febrile response after vaccination.

CONCLUSIONS: Study ongoing. Data collection continues.

REPORT DATE: 12/20/94 PROTOCOL: 94005 STATUS: Ongoing

Detail Summary Sheet

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

APPROVAL DATE: Nov 93

PRINCIPAL INVESTIGATOR: Kelly McKee, COL, MC

DEPARTMENT/SERVICE: Preventive Medicine Service
Communicable Disease Unit

KEYWORDS: STDs, HIV, Epidemiology

Accumulative MEDCASE cost: $ 0

STUDY OBJECTIVE: To determine incidence of specific sexually transmitted diseases at Fort Bragg, NC 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 questionnairs and behavior interventions in future protocols.

TECHNICAL APPROACH: Existing EDC Data Analysis. Propose to carefully evaulate sex, age, race, deployment status and other relevant characteristics in our 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 provided 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 these 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 Mar 91 for a period of 15 months. After many on-site delays, data collection actually started in Mar 92. 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 97. Study is ongoing.

REPORT DATE: 12/28/94 PROTOCOL: 94006 STATUS: Ongoing

Detail Summary Sheet

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

APPROVAL DATE: May 94

PRINCIPAL INVESTIGATOR: Pamela Jenkins, Henry M. Jackson Foundation

DEPARTMENT/SERVICE: Preventive Medicine Service
Communicable Disease Unit

KEYWORDS: HIV, STD, prevention

Accumulative MEDCASE cost: $ 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. To evaluate the feasibility and safety of delivering the proposed HIV/STD intervention programs to a high-risk military population (STD patients). To evaluate the immediate impace of interventions on compliance with standard STD recommendations (e.g., return for test of cure, partner notification), as well as risk-related knowledge, attitudes, perceptions of risk, and readiness for change. To determine if the efficacy of various interventions in reducing the rates of risk-relevant behaviors and related factors. To evaluate the effectiveness of the interventions in lowering STD incidence and recidivism rates. To describe demographic, attitudinal and behavioral characteristics of individuals resistant and/or responsive to behavior change, in order to design more effective programs.

TECHNICAL APPROACH: Three types of interventions are planned: (1) Interactive Video Disc (IAVD), (2) Health Risk Appraisal for STDs/HIV and (3) Targeted Behavioral Intervention. These interventions were chosen because they represent the most feasible interventions currently available and build on technologies already available in the U.S. Army. The intervention content will remain similar across interventions, while the format and strategies used to motivate and reinforce change will vary. All interventions are designed to limit their imposition on soldier's duty time and are consistent with the military's goal of keeping personnel healthy and combat ready.

PRIOR AND CURRENT PROGRESS: 25 focus groups have been conducted. 49 individuals participated in Pilot testing.

Detail Summary Sheet

CONCLUSIONS: Results from pilot tests and focus groups has demonstrated that STD patients are not concerned with the ethnicity or gender of their counselor in the clinic. What they are concerned with is that the individual be honest and knowledgable. This aspect was addressed to ascertain whether the Euro-American HMJF staff would be able to reach the predominantly minority STD client. Results from pilot tests have demonstrated that the IAVD is well recieved and soldiers have no problems using it. Study continues.

REPORT DATE: 12/28/94 PROTOCOL: 94007 STATUS: Ongoing

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

APPROVAL DATE: Jun 94

PRINCIPAL INVESTIGATOR: Dr. Sammy Y. Choi

DEPARTMENT/SERVICE: Department of Pediatrics

KEYWORDS: RDW, anemic infants, iron-deficiency

Accumulative MEDCASE cost: $ 0

STUDY OBJECTIVE: To determine whether automated CBC assessment is accurately predictive or 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 explaiend, 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 Jan 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 requried 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 significance could be reach 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: None. Study ongoing.

REPORT DATE: 12/28/94 PROTOCOL: 94008 STATUS: Completed

Detail Summary Sheet

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

APPROVAL DATE: May 94

PRINCIPAL INVESTIGATOR: Eric Adrian, LTC, DC

DEPARTMENT/SERVICE: One Stop Dental Clinica, USA DENTAC

KEYWORDS: dental caries, fiber optic transillumination

Accumulative MEDCASE cost: $ 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 Fort 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 UNC, Chapel Hill, NC.

CONCLUSIONS: Awaiting results.

REPORT DATE: 12/28/94 PROTOCOL: 94009 STATUS: Ongoing

Detail Summary Sheet

TITLE: The effect of pregnancy on the performance, health and nutritional status of postpartum soldiers

APPROVAL DATE: Sep 94

PRINCIPAL INVESTIGATOR: Terri Vanderlinde, CPT, MC

DEPARTMENT/SERVICE: Department of Obstetrics & Gynecology

KEYWORDS: pregnancy, postpartum soldiers, nutrition

Accumulative MEDCASE cost: $ 0

STUDY OBJECTIVE: To determine the proportion of soldiers who return to their preconception fitness level at theirfirst 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 pregnancy and postpartum soldiers and family members. And, to comapre iron and folate status among late pregnancy and postpartum soldiers, late pregnancy and postpartum family members, and nonpregnancy, non-postpartum soldiers.

TECHNICAL APPROACH: Beginning Sep 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 initiated Oct 94. No progress to date.

CONCLUSIONS: None.

REPORT DATE: 12/28/94 PROTOCOL: 94010 STATUS: Ongoing

Detail Summary Sheet

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

APPROVAL DATE: Sep 94

PRINCIPAL INVESTIGATOR: Pamela Jenkins, HMJF

DEPARTMENT/SERVICE: Preventive Medicine Service
Communicable Disease Unit

KEYWORDS: STD, HIV, Behavioral Interventions

Accumulative MEDCASE cost: $ 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: Awaiting funding from DoD Women's Health Care Initiatives.

CONCLUSIONS: None.

REPORT DATE: 12/28/94 PROTOCOL: 94011 STATUS: Ongoing

Detail Summary Sheet

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

APPROVAL DATE: Sep 94

PRINCIPAL INVESTIGATOR: Kelly McKee, COL, MC

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

KEYWORDS: Chlamydia trachomatis

Accumulative MEDCASE cost: $ 0 (Defense Women's Health Program)

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 development of a chlamydia control program will be developed.

PRIOR AND CURRENT PROGRESS: None. Awaiting funding from Defense Women's Health Program.

CONCLUSIONS: None.

Investigator Index

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