

# ANNUAL PROGRESS REPORT

Fiscal Year 1988

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REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER 23	2. GOVT ACCESSION NO.	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) Clinical Investigation Program RCS-MED-300 (R1)		5. TYPE OF REPORT & PERIOD COVERED ANNUAL - FY 88
		6. PERFORMING ORG. REPORT NUMBER
7. AUTHOR(s)  STEPHEN R. STEPHENSON, COL, MC		8. CONTRACT OR GRANT NUMBER(s)
9. PERFORMING ORGANIZATION NAME AND ADDRESS Department of Clinical Investigation William Beaumont Army Medical Center (HSHM-DCI)		10. PROGRAM ELEMENT PROJECT, TASK AREA & WORK UNIT NUMBERS  3A062110A826 00
11. CONTROLLING OFFICE NAME AND ADDRESS Human Use and Clinical Investigation SGRD-HR, Ft Detrick, Frederick MD 21701		12. REPORT DATE 30 Sep 88
		13. NUMBER OF PAGES 192
14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office)  SGRD-HR, Ft Detrick, Frederick, MD 21701		15. SECURITY CLASS. (of this report)  UNCLASSIFIED
		15a. DECLASSIFICATION DOWNGRADING SCHEDULE
16. DISTRIBUTION STATEMENT (of this Report) This document has been approved for public circulation. Distribution is unlimited. Copies may be obtained from the Defense Documentation Center.		
17. DISTRIBUTION STATEMENT (of the abstract: entered in Block 20, if different from Report)		
18. SUPPLEMENTARY NOTES		
19. KEY WORDS (Continue on reverse side if necessary and identify by block number)  See Key Word Index.		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) This report serves to detail the progress, status, and funding of approved projects conducted under protocol by staff members, interns, and residents at William Beaumont Army Medical Center. The varying projects as reported are classified according to the service or department to which the principal investigator belongs.		

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## **FY 88 ANNUAL PROGRESS REPORT**

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**HEADQUARTERS  
WILLIAM BEAUMONT ARMY  
MEDICAL CENTER  
EL PASO, TEXAS 79920-5001**

**CLINICAL INVESTIGATION  
PROGRAM  
RCS MED-300 (R1)**

*This report was prepared under the direction of Colonel Stephen R. Stephenson,  
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**1988 brought about continued expansion and change in the Department of Clinical Investigation at William Beaumont Army Medical Center. The Human Performance and Physiology Laboratory was transferred wholly to DCI management from the U.S. Army Medical Research and Development command. Due to the support of the WBAMC command and the cooperation of USAMRDC, the lab will continue to produce outstanding research. The arrival of Captain David Smith has led to the development of a new molecular genetics lab to complement the basic science already being done in protein chemistry, genetics and microbiology.**

**There has also been increased emphasis on research that will directly benefit our soldiers and their families. I would specifically like to thank the leadership at Fort Bliss for their enthusiastic support and cooperation in these projects. This partnership will continue to benefit all of us in the military and our families.**

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**Unit Summary**  
**Fiscal Year 1988**

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## **Objectives**

The Department of Clinical Investigation is responsible for providing the facilities and atmosphere of inquiry necessary to support and stimulate basic and clinical medical investigation within William Beaumont Army Medical Center.

## **Technical Approach**

The Department of Clinical Investigation provides support for staff, fellows and housestaff research projects under the guidelines of the Declaration of Helsinki, the Clinical Investigation Program (as described in AR 40-38 and HSC Reg 40-23), and the Use of Investigational Drugs in Humans and the Use of Scheduled Controlled Drug Substances (as described in AR 40-7). Research is conducted under protocols approved by the Research Committee (WBAMC HR 15-1), the Human Use Committee (WBAMC HR 15-1), and the Radioisotope Committee (WBAMC HR 15-1) where applicable. For research protocols utilizing laboratory animals, the Animal Use Committee (WBAMC HR 15-1) ensures that the investigators follow guidelines set forth in the "Guide for Laboratory Animal Facilities and Care", published by the National Academy of Sciences-National Research Council, and the criteria established by the American Association for Accreditation of Laboratory Animal Care.



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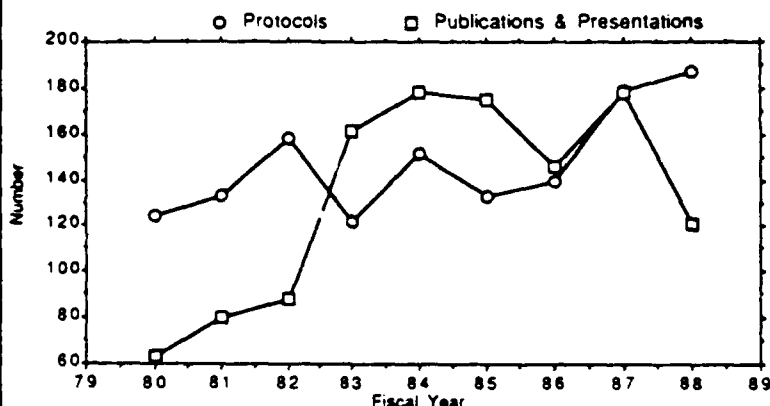
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## FUNDING

EXPENDITURES	FY 85	FY86	FY87	FY88
Personnel (Civ)	167,242	307,120	363,094	325,197
Consumable Supplies	104,666	138,737	236,662	141,175
MEDCASE Equipment	132,342	161,839	89,105	434,064
Capital Equipment	12,935	43,988	8,743	34,726
IDY	4,289	3,888	5,272	3,092
Contract Services				
Printing & Reproduction	9,287	28,613	28,821	26,338
TOTAL:	430,761	684,185	731,697	964,592
Military Pay	272,695	237,754	457,879	417,265
	703,456	921,939	1,189,576	1,381,857

## PROTOCOLS & PUBLICATIONS/PRESENTATIONS FY88



	Protocols Ongoing 1 Oct	New Protocols Submitted During FY	Total Protocols	Protocols Completed During FY	Protocols Terminated During FY	Publications and Presentations	OMA Supply Budget
FY80	83	41	124	25	25	63	\$60,134
FY81	74	59	133	16	17	80	\$86,351
FY82	100	58	158	42	45	88	\$122,189
FY83	71	51	122	24	19	161	\$120,660
FY84	76	76	152	30	43	178	\$108,370
FY85	79	54	133	30	28	175	\$104,666
FY86	75	65	140	43	11	146	\$138,737
FY87	86	93	179	31	48	178	\$236,662
FY88	100	88	188	25	30	121	\$141,175



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## **PUBLICATIONS - FY 88**

### **DEPARTMENT OF CLINICAL INVESTIGATION**

Bhattacharyya SN, Walker MP, Klapper DG. Partial characterization of core protein of human bronchial mucin. Abstract, Socety for Complex Carbohydrates, 48, 1988

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Keniston RC, Campbell RA, Weir MR: Polyamine and drug-induced vitamin B6 deficiency: A common feature of serious illness. Submitted to *Am J Clin Nutr*

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Keniston RC, Weir MR, Enriquez JI, Duncan F: Decreased plasma pyridoxal 5'-phosphate levels in healthy adult cigarette smokers: Dose effect and decreased increment in plasma PLP with supplementation. Submitted to *JAMA*, March, 1988

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### **DEPARTMENT OF MEDICINE**

Burkhalter E: Incidence of gastrectomy in United States Army hospitals world-wide from 1975 to 1985. *Am J*

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Burkhalter E: Medical professional liability lawsuit. *The El Paso Physician*, February 1988, p 4

Burkhalter E: Endoscopic neodymium:YAG laser palliative therapy of esophagogastric cancer. *Lasers in Surgery and Medicine* 8:165, 1988

Burkhalter E: The William Beaumont Army Medical Center experience with endoscopic laser palliative therapy for esophagogastric cancer. *J Clin Gastroenterol*, in press

Burkhalter E: Procedures performed by gastroenterology fellows during a two-year training program. Submitted to *J Med Educ*

Burkhalter E: Occurrence screening and an effective risk management program. Submitted to *Health Care Management Review*

Burkhalter E: Predicting a positive technetium-99m labeled red blood cell scintigraph in the diagnosis of lower gastrointestinal bleeding. Submitted to *J Nucl Med*

Charya RV, McNamee GA, Keniston RC: Effects of nicotine and cigarette smoke on theophylline kinetics in healthy rabbits. *J Allerg Clin Path* 90:501, 1988

Cuetter AC, Bartoszek DM: The thoracic outlet syndrome: Controversies, overdiagnosis, overtreatment, and recommendations for management. *Muscle and Nerve*, in press

Duran L, Ramirez L, et al: Esophageal perforation in a patient with pemphigus vulgaris. Submitted to *J Clin Gastroenterol*

Ellis RB, McGregor M: Group VE-2 pneumonia and septicemia: A case report and review of the literature. Submitted to *J Clin Microbiol*

McNerney J, Ramirez L, Cannady P: Hepatocellular dysfunction complicating streptococcus mitis endocarditis. *Am J Gastroenterol*, in press

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Ramirez LA, Oliver GA: Esophageal motility disorders in patients with significant gastroesophageal reflux. *Gastroenterol* 94:A367, 1988

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## DEPARTMENT OF NURSING

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## DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

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Lyons JV, Brown JE: Transvaginal sonographic assessment of cervical length in pregnancy)Is there correlation with maternal history? Submitted to *Obstet Gynecol*

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Mayer AR, Hill PS, Rosa C, McNamee GA, Morgenstern LL: Extended surgical training in an obstetrics/gynecology residency program. Submitted to *Obstet Gynecol*, May 1988

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## DEPARTMENT OF PATHOLOGY

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Choi YS, Pearl W: Chest pain and cardiac effects of drug abuse in adolescents. Submitted to *J Adolesc Med*

Getts AG: Diagnosing *Chlamydia Trachomatis* Urethritis by First-Catch Urine Enzyme Immunoassay in Adolescent Males. Submitted to *J Adolesc Health Care*

Getts AG: The influence of a one-week breast-feeding clinic visit on breast-feeding mothers and infants. *South Med J*, in press

Humphrey M, McGivney R, Perkins C, Harris R, Rowe J: *Yersinia pestis*: A case of mistaken identity. Submitted to *Pediatr Infect Dis J*

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## **DEPARTMENT OF PRIMARY CARE AND COMMUNITY MEDICINE**

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Aponte, JE, Ghiatas A: Acute plastic bowing deformity, a review of the literature. *Ann Emerg Med*, in press

Emery A, Simm B, Jensen-Wilzewski, Aldridge RG: Experiential process in hospital staff education on HIV/AIDS. Submitted

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# **PRESENTATIONS - FY 88**

## **DEPARTMENT OF CLINICAL INVESTIGATION**

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Bhattacharyya SN, Walker MP, Klapper DG. Partial characterization of core protein of human bronchial mucin. Presented to the Society for Complex Carbohydrates, Bethesda, MD, Nov 5-7, 1987

Enriquez JI, Keniston RC, Becker W: Prognostic value of direct and total plasma pyridoxal 5'-phosphate. Presented to the American Association of Clinical Chemistry, New Orleans LA, July, 1988

Keniston RC, Weir MR, Enriquez JI, Duncan F: The sergeant major study: Health risk assessment by clinical laboratory parameters. Presented to the Federation of American Societies for Experimental Biology, Las Vegas, NV, May, 1988

Stewart DA: Granulocyte-macrophage colony forming cell and lymphocyte mitogenesis in mice after thermal injury. Presented to the SAFM<sup>1</sup> S Annual Meeting in Reno, Nevada, March, 1988

## **DEPARTMENT OF MEDICINE**

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Burkhalter E: Incidence of gastrectomy in United States Army hospitals world-wide from 1975 to 1985. Presented at the 17th William Beaumont Gastrointestinal Symposium in San Francisco, CA, October 1987

Charya RV, McNamee GA, Keniston RC: Effects of nicotine and cigarette smoke on theophylline kinetics in healthy rabbits. Presented to the 44th annual meeting of the American Academy of Allergy and Immunology, Anaheim, CA, March, 1988

Graham DI, Ozyurt E, Park CK, Nehls DG, Woodruff JN, McCulloch J, Teasdale GM: Protective effects of the NMDA antagonist, MK-801, on focal ischemic brain damage. Presented to the 16th Princeton Conference on Cerebral Ischemia, Miami, FL, March, 1988

Kurumaji A, Nehls D, Park C, McCulloch J: Comparative study of competitive and non-competitive N-methyl-D-aspartate receptor antagonists and cerebral glucose utilisation. Presented to the British Pharmacological Society, London, England, January, 1988

McNerney J, Ramirez L, Cannady P: Hepatocellular dysfunction complicating *Streptococcus mitis* (viridans group) endocarditis: A case report with William Beaumont Army Medical Center (WBAMC) experience (1982-1987)

and review of the literature. Presented to the American College of Physicians 69th Annual Session, New York City, NY, March, 1988

Nehls DG, Mendelow AD, Graham DI, Teasdale GM: Experimental intracerebral hemorrhage: Early removal of a spontaneous mass lesion improves late outcome. Presented to the American Association of Neurological Surgeons Annual Meeting, Toronto, Canada, April, 1988

Nehls DG, Park CK, Graham DI, McCulloch J: Pre- or post-treatment with the glutamate antagonist MK-801 reduces ischemic damage after MCA occlusion in the rat. Presented to the American Association of Neurological Surgeons Annual Meeting, Toronto, Canada, April, 1988

Nehls DG, Park CK, McCulloch J: The effects of N-Methyl-D-Aspartate (NMDA) receptor blockade upon local cerebral glucose utilisation and local cerebral blood flow. Presented to the Society for Neuroscience, New Orleans, LA, November, 1987

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Ramirez L, Burkhalter E, Lindell T: Evaluation of asymptomatic volunteer blood donors with hepatitis B surface antigen (HBsAg) positivity or elevated transaminases: A pilot study. Presented to the American College of Physicians 69th Annual Session, New York City, NY, March, 1988

Ramirez LA, Oliver GA: Relationship between hiatus hernia and esophageal motility disorders in patients without significant gastroesophageal reflux. Presented to the American College of Physicians 69th Annual Session, New York City, NY, March, 1988

Ramirez LA, Oliver GA: Esophageal motility disorders in patients with significant gastroesophageal reflux. Presented to the 89th Annual Meeting of The American Gastroenterological Association in New Orleans, Louisiana, May, 1988

## **DEPARTMENT OF NURSING**

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Duli, L: Problems associated with needs fulfillment of colostomy clients Presented to First Annual Research Day of Sigma Theta Tau, El Paso, TX, November 1987

Duli L: ANA certification review: Medical surgical nursing - orthopedics. Presented at UTEP, El Paso, TX, September 1988

Duli L, Pieniadz C, Prince P: Trying it all together: Nursing diagnosis, nursing process, nursing documentation. Presented at WBAMC, El Paso, TX, September 1988

Kessler D: Incisional sequelae in post coronary bypass graft surgery Patients. Presented at First Annual Research Day of Sigma Theta Tau, October 1987.

McNicol LB, Hadersbeck RE, Dickens D: AIDS and pregnancy, a survey of knowledge, Attitudes, Beliefs and Self-Identification of Risks. Presented at the Armed Forces District American College of Obstetrics and Gynecology-Nursing American College of Obstetrics and Gynecology (ACOG-NAACOG), Denver, CO, Oct 87. Presented the 1987 Admiral Duerke Award by the Armed Forces District NAACOG.

## DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

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Bayliss PM, Eckberg D: Is the active duty soldier a high risk pregnancy? Presented to the Armed Forces District Meeting (ACOG), Denver, Colorado, October 1987

Bayliss PM, Hodge GM: Extragenital cancer presenting as vaginal bleeding. Presented to the Armed Forces District Meeting (ACOG), Denver, Colorado, October 1987

Beaton S, Rosa C: Comparison of chlamydia and gonorrhea infection rates. Presented to the Armed Forces District Meeting (ACOG), Denver, Colorado, October 1987

Brown JE, SanMiguel G, Morgenstern LL: The antepartum diagnostic center: Its development, implementation, and preliminary results. Presented to the Armed Forces District Meeting (ACOG), Denver, Colorado, October 1987

Cavazos R, Gehlbach DL, Morgenstern LL: Comparison of preoperative hematocrits in autologous donors and non-donors undergoing major gynecologic surgery. Presented to the Armed Forces District Meeting (ACOG), Denver, Colorado, October 1987

Eckberg DJ, Hodge GM: Does bacteremia occur during labor and delivery? Presented to the Armed Forces District Meeting (ACOG), Denver, Colorado, October 1987

Greenberg H, Patsner B, Mann WJ: Radical vulvectomy and bilateral "sneak" superficial inguinal lymphadenectomy utilizing a single elliptical incision: a preliminary report. Presented to the Armed Forces District Meeting (ACOG), Denver, Colorado, October 1987. (Winner of the Ortho Pharmaceutical Corporation Award for outstanding contribution to knowledge of obstetrics and gynecology)

Habib N, Brown JE, Morgenstern LL: Umbilical cord stricture as a possible cause of fetal death. Presented to the Armed Forces District Meeting (ACOG), Denver, Colorado, October 1987

Hill PS, Miles PA, Penney LL: Ovarian dysgerminoma with syncytiotrophoblastic giant cells and stromal luteinization presenting in a 4 1/2-year-old female with precocious puberty. Presented to the Armed Forces District Meeting (ACOG), Denver, Colorado, October 1987

Lyons JV, Brown JE: Transvaginal sonographic assessment of cervical length in pregnancy: Correlation with maternal history. Presented to the Basic and Clinical Investigation Program of the American College of Obstetricians and Gynecologists 36th Annual Clinical Meeting in Boston, Massachusetts, May, 1988 (Winner of an Upjohn Award for Excellence in Scientific Presentation)

Lyons JV, Brown JE: Transvaginal sonographic assessment of cervical length in pregnancy) Is there correlation with maternal history? Presented to the Armed Forces District Meeting (ACOG), Denver, Colorado, October 1987 (Winner of the third Upjohn Award for excellence in scientific presentation)

Mayer AR: Diagnostic management of ectopic pregnancy. Mayer AR, Hill PS, Rosa C, McNamee GA, Morgenstern LL: Extended surgical training in an obstetrics/gynecology residency program. Scientific exhibit presentation at the American College of Obstetricians and Gynecologists 36th Annual Clinical Meeting in Boston, Massachusetts, May, 1988 (Prize award for outstanding exhibit)

Mayer AR: Anal incontinence: Three methods of repair. Scientific exhibit presentation at the American College of Obstetricians and Gynecologists 36th Annual Clinical Meeting in Boston, Massachusetts, May, 1988 (Prize award for outstanding exhibit)

Mayer AR, Hill PS, Rosa C, McNamee GA, Morgenstern LL: Extended surgical training in an obstetrics/gynecology residency program. Presented to the Armed Forces District Meeting (ACOG), Denver, Colorado, October 1987 (Prize award for outstanding exhibit)

Mayer AR, Hill PS, Rosa C, McNamee GA, Morgenstern LL: Extended surgical training in an obstetrics/gynecology residency program. Scientific exhibit presentation at the American College of Obstetricians and Gynecologists 36th Annual Clinical Meeting in Boston, Massachusetts, May, 1988 (Prize award for outstanding exhibit)

Robertson AW, Duff P: The nitrite and leukocyte esterase tests for the evaluation of asymptomatic bacteriuria in obstetric patients. Presented to the Armed Forces District Meeting (ACOG), Denver, Colorado, October 1987

Robertson AW, Duff P: Treatment of lower urinary tract infections in obstetric patients utilizing three different dosage regimens of amoxicillin-clavulanic acid. Presented to the Armed Forces District Meeting (ACOG), Denver, Colorado, October 1987

Robertson AW, Kopelman JN, Read JA, et al: External cephalic version at term: Is a tocolytic necessary? Presented to the Armed Forces District Meeting (ACOG),



Denver, Colorado, October 1987 (Received outstanding scientific paper award)

## **DEPARTMENT OF PATHOLOGY**

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Lieoerman MM: Bactericidal proteins from *Pseudomonas aeruginosa* with activity against autologous but not homogenous serotype strains. Presented to the Annual Meeting of the American Society for Microbiology, May, 1988

## **DEPARTMENT OF PEDIATRICS**

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Atkinson AW: The usefulness of three instruments in diagnosis and management of attention deficit disorder. Presented to the 6th Annual Meeting of the Society for Behavioral Pediatrics, Washington, DC, May, 1988

Getts AG: Urinary sediment chlamydia enzyme immunoassay (EIA) in sexually active adolescent males. Presented at the 23rd Annual Uniformed Services Pediatric Seminar, San Diego, CA, March, 1988

Smith GF, Spector J: Down syndrome and Alzheimer's disease. Presented in Switzerland, August

Svec RL: Dehydroepiandrosterone activation of brown adipose tissue. Presented to the American Pediatric Society and the Society for Pediatric Research meeting in Washington, D.C.

## **DEPARTMENT OF PRIMARY CARE AND COMMUNITY MEDICINE**

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Giberson TP, Kern J, Pettigrew DW III, Eaves CC Jr, Haynes J: Near Fatal hydrogen peroxide ingestion. Presented to American Association of Poison Control, American Board of Medical Toxicology, Baltimore, MD, September, 1988.

## **DEPARTMENT OF SURGERY**

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Graham DI, Ozyurt E, Park CK, Nehls DG, Woodruff JN, McCulloch J, Teasdale GM: Protective effects of the NMDA antagonist, MK-801, on focal ischemic brain damage. Sixteenth Princeton Conference on Cerebral Ischemia, Miami, March, 1988

Kurumaji A, Nehls D, Park C, McCulloch J: Comparative study of competitive and non-competitive N-methyl-D-aspartate receptor antagonists and cerebral glucos utilisation. British Pharmacological Society, London, January, 1988

Nehls DG, Mandelow AD, Graham DI, Teasdale GM: Experimental intracerebral hemorrhage: Early removal of a spontaneous mass lesion improves late outcome. American Association of Neurological Surgeons Annual Meeting, Toronto, April, 1988

Nehls DG, Park CK, Graham DI, McCulloch J: Pre or post-treatment with the glutamate antagonist MK-801 reduces ischemic damage after MCA occlusion in the rat. American Association of Neurological surgeons Annual Meeting, Toronto, April, 1988

Nehls DG, Park CK, McCulloch J: The effects of N-Methyl-D-Aspartate (NMDA) receptor blockade upon local cerebral glucose utilisation and local cerebral blood flow. Society for Neuroscience, New Orleans, November, 1987

Park CK, Nehls DG, Ozyurt E, McCulloch J: Ischemic brain damage is reduced by systemic administration of the N-Methyl-D-Aspartate (NMDA) antagonist, MK-801. Society for Neuroscience, New Orleans, November, 1987

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/17

STATUS: Ongoing

TITLE: Human Tracheal Mucin: Biochemical, Physical and Rheological Studies

START DATE: March 1986

ESTIMATED COMPLETION DATE: October 1989

PRINCIPAL INVESTIGATOR: PhD Sam Bhattacharya

DEPARTMENT: DCI

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Brigitta Manna, John Enriquez

KEY WORDS: Tracheal Mucin

**Study Objective:** This proposal is concerned with isolation, purification and characterization of mucin glycoprotein components (mucins) from tracheal secretion of patients with asthma, chronic bronchitis and cystic fibrosis. The glycosylated and nonglycosylated peptides will be isolated, purified and sequenced (peptide portion) after subjecting the purified mucins with different proteolytic enzymes. Antibodies will be developed in rabbits against the nonglycosylated peptides which, in turn, will be used to follow the synthesis and secretion of these macromolecules in a tracheal (or bronchial) culture system. Finally, the viscoelastic properties of purified mucins will be investigated.

**Technical Approach:** The following proposal will be undertaken in the Department of Clinical Investigation, WBAMC, regarding respiratory mucins:

- (1) Collect sputum from patients (either male or female, any age) with asthma, chronic bronchitis and cystic fibrosis.
- (2) Solubilize mucins with water and buffer.
- (3) Establish the homogeneity of mucin glycoproteins isolated from sputum of patients with asthma, chronic bronchitis, and cystic fibrosis by molecular sieve and ion-exchange chromatography.
- (4) Isolation and characterization of peptides (or glycopeptides) derived from digestion of mucins with different proteolytic enzymes (Column and HPLC);
- (5) Amino acid sequence analysis of these peptides by sequenator and cDNA cloning procedure;
- (6) Raise antibodies in rabbits against these peptides (preferably against nonglycosylated peptides); and finally,
- (7) Establish a tracheal (or bronchial) culture system to examine the synthesis and control in secretion of these macromolecules by ELISA or radioimmunoassay (RIA) procedures using these antibodies.

In addition to the proposals cited above, the physical properties of mucins, particularly their interaction (in terms of viscosity) with other serum proteins (such as albumin, immunoglobulin, and fibronectin) will be studied.

**Progress:** Two peptides of  $M_r$  97KD<sub>0</sub> have been isolated by high pressure liquid chromatography from diglycosylated mucin. the first peptide has a blocked N-terminus and the other has a sequence of Ser-Ala-Pro-Leu-. Further sequence analysis could not be done on these peptides because of degradation of these materials in acids. Experiments are now underway to raise antibody against the peptides. The antibody will be used to sequence these peptides by cDNA procedures. Also, we are on our way to establishing the tracheal epithelial culture system to study the regulation of mucin protein.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/14

STATUS: Ongoing

TITLE: Biochemical Properties of Colonic Mucin in Health and Disease

START DATE: December 1987

ESTIMATED COMPLETION DATE: October 1989

PRINCIPAL INVESTIGATOR: PhD Sam Bhattacharya

DEPARTMENT: DCI

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Dr. J.S. Ramirez, Ms. Brigitta Manna, Ms. Maxine Lund

KEY WORDS: Colonic Mucin

**Study Objective:** This proposal is concerned with isolation, purification, and characterization of mucin glycoproteins from the human colon. The protein core of these mucins will be isolated by high pressure liquid chromatography after chemical deglycosylation procedure and amino acid sequence of these peptides will be determined either by sequanator or cDNA cloning procedure. Antibodies will be raised against these deglycosylated peptides which, in turn, will be used to follow the synthesis and secretion of these macromolecules in a colonic culture system.

**Technical Approach:**

1. Collect surgery specimens of colon from patients (either male or female of any age) with different bowel diseases with written permission from patients that these specimens will be used for research purposes only.
2. Solubilize mucins with water and buffer.
3. Establish purity of the preparation by molecular sieve and ion-exchange chromatography.
4. Deglycosylation of these mucins by chemical deglycosylation procedure (phenylmethylsulfonyl fluoride method) and isolate the peptide(s) by high pressure liquid chromatography method.
5. Amino acid sequence analyses by sequanator and cDNA cloning procedure, and establish the homology of amino acid sequence of the colonic mucin peptides with those from respiratory sources.
6. Raise antibodies against these deglycosylated peptides and establish a clonic epithelium culture system to follow the synthesis of these macromolecules.

**Progress:** Colonic mucin has been extracted from human colonic mucosa by phenol-water extraction procedures and further purified by Sepharose 2B column chromatography. The mucin has been deglycosylated and the protein core was purified by high pressure liquid chromatography. The protein has a molecular weight of 97kDa and has similar amino acid compositions to that of tracheal mucin apoprotein. Amino acid sequence analysis indicated serine as NH<sub>2</sub>termini. Attempts are being made now to raise antibody against this protein. this antibody will be utilized to sequence this protein by cDNA cloning procedure.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 82/60

STATUS: Ongoing

TITLE: Interactions Between Aminoglycoside Antibiotics and Vitamin B6 in Vitro and In Vivo

START DATE: Oct 82

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: MAJ R.C. Keniston

DEPARTMENT: DCI

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: John Enriquez, PFC Ismael Delgado

KEY WORDS: Pathology Aminoglycosides, Vitamin B6

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**Study Objective:** To develop a method for isolating and quantitating aminoglycoside pyridoxal-5'-phosphate complexes. To isolate these complexes from the urine of patients receiving the aminoglycoside antibiotics. To determine if depletion of vitamin B6 occurs in patients receiving aminoglycoside antibiotics, and if so, how this depletion correlates with morbidity and mortality.

**Technical Approach:** Subjects will be patients who are to be given aminoglycoside antibiotics for clinical indications (sepsis, serious gram-negative infections, etc). These patients should also have SMAC 20 chemistry screens and monitoring of their aminoglycoside levels (procedures already routinely performed). The blood and urine samples from at least 30 patients will be examined.

**Progress:** Complexes have not been isolated, except those made up in vitro due to the departure of the chemist who was working on this project. Will be able to isolate complexes with the new mass spectrophotometer on order for the Department of Clinical Investigation. Vitamin B6 levels have been measured in 72 aminoglycoside patients; an article entitled "Factors Influencing Survival in Aminoglycoside Patients' Role of Vitamin B6", plus one letter to the editor, and one article published (1986 and 1987).

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 85/52

STATUS: Ongoing

TITLE: Pyruoxine Effect in Aminophylline Toxicity in Rabbits

START DATE: Sep 85

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: MAJ Richard C. Keniston

DEPARTMENT: DCI

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: LTC Raghav Charya, John Enriques, Ismael Delgado

KEY WORDS: Pyridoxine, Vitamin B6, Aminophylline toxicity

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**Study Objective:** To determine the response of unsupplemented normal rabbits and B6 supplemented rabbits to theophylline administration.

**Technical Approach:** New Zealand rabbits were given single daily intraperitoneal injections of aminophylline in a dose of 17 mg/kg/day or increasing daily doses of theophylline for five days. Serum PLP levels were done every one to two days.

**Progress:** I.P. aminophylline causes a rapid decrease in plasma PLP levels; supplemental vitamin B6 can initially counter this drop in plasma PLP levels, but after prolonged treatment with aminophylline, even this supplemental vitamin B6 is unable to restore plasma PLP levels to normal. PLP levels correlate inversely with severity of  
Principal investigator plans to continue this project, and intends to include other drugs and animals (Digoxin, histamine, nicotine, etc.).

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/28

STATUS: Ongoing

TITLE: Measurement of Plasma Pyridoxal 5'-Phosphate in Seriously Ill Patients and Effect of Supplementation of Pyridoxine HCL on Laboratory Tests (Monitor: COL Stephenson)

START DATE: July 1988

ESTIMATED COMPLETION DATE: July 1989

PRINCIPAL INVESTIGATOR: MAJ R.C. Keniston

DEPARTMENT: DCI

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Stephen Carey, MC., John Enriquez, PFC Ismael Delgado

KEY WORDS: PLP

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**Study Objective:** Gather evidence of vitamin B6 deficiency in hospitalized patients and determine if plasma pyridoxal 5' phosphate levels can be restored easily to normal. Determine effect of PLP level changes on other measured parameters.

**Technical Approach:** All surgical patients will have a plasma PLP, CBC and SMAC-20 drawn on admission or, in the case of elective surgeries, as part of the pre-admission lab work. Those patients found to have a plasma PLP of greater than 20 nM will not be entered into either the B6S or the NS group. If the initial or subsequent plasma PLP goes below 20 nM, the patient will be assigned the B6S or NS group on the basis of the last digit of their social security number. Me will be given 50 mg/day or 0 mg/day of PN:HCl if his plasma PLP is between 10 and 20nM, and 100 mg/day or 50 mg/day of PN:HCl if his plasma PLP is less than 10 nM. After one week of no supplementation (for those in the NS group) or one week of supplementation (for those in the B6S group), a repeat plasma PLP, CBC and SMAC-20 will be drawn. Whenever the plasma PLP exceeds 20 nM, supplementation with PN:HCl will stop and further plasma PLP levels will be drawn weekly and at pre-discharge.

**Progress:** Two book chapters published; four abstracts, two poster presentations. After associate investigator departed there has not been much activity. I am currently attempting to reinstate this project with new personnel in Department of Surgery.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/30

STATUS: Ongoing

TITLE: Vitamin B6 Status of Sergeant Major Candidates: Effect of Smoking on Vitamin B6 Levels and of Vitamin B6 Supplementation in Vitamin B6 Deficient Individuals

START DATE: July 1986

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: MAJ R.C. Keniston

DEPARTMENT: DCI

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: John Enriquez, Ismael Delgado, Clent Aldridge, LTC Allister Morris, MC

KEY WORDS: Vitamin B6

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**Study Objective:** To see if cigarette smokers are vitamin B6 deficient, and to determine if vitamin B6 supplementation of vitamin B6 deficient individuals alters serum chemistries (SMAC-20), CBC, and HDL cholesterol.

**Technical Approach:** Smoking-induced vitamin B6 deficiency may contribute to the altered biochemical measures. Increasing the plasma PLP of vitamin B6 deficient individuals may help to normalize these values. In particular, a relationship between plasma PLP levels and HDL cholesterol will be explored: this would have implications for the prevention and treatment of atherosclerosis. A performance measure effect of serum PLP will be explored. Subjects: All subjects will be Sergeant Major candidates, already enrolled in the Over 40-Sergeants Major Study (already scheduled to have blood drawn for a CBC, SMAC-20, and HDL cholesterol). Controls: These will be the nonsmokers and B6 deficient patients randomized to receive a placebo instead of vitamin B6. Design of the Experiment: (1) Initial Blood Draw - blood will be drawn for CBC, SMAC-20, HDL cholesterol, and plasma PLP. (2) Randomization and Supplementation Phase - subjects will be classified by smoking status, and assigned to vitamin B6 sufficient (B6+), intermediate vitamin B6 status (B6I), or vitamin B6 deficient (B6-) groups on the basis of the initial plasma PLP level (20 nM or greater, 10 to 20 nM, or less than 10 nM, respectively). The B6+ group will receive no PN:HCl supplementation; the B6- group will all receive 50 mg/day of PN:HCl; and the B6I group will be randomized to receive either 50 mg/day of PN:HCl or placebo. (3) Final Blood Draw - at the end of the Sergeants Major course, blood will be drawn for CBC, SMAC-20, HDL cholesterol, and plasma PLP.

**Progress:** Additional funding has been requested to continue and expand this study. Currently looking at Residential Treatment Facility patients as well as Sergeants Major Academy candidates. Colonel Dale Block, Director of Fitness Policy, Office of the Surgeon General, is scheduled to visit 10 November 1988; he will support our request for funds from the Research and Development Command.

There have been 1400 subjects entered in this project with no withdrawals nor adverse reactions.

There has been one poster presentation, three abstracts, and one book chapter completed. Other articles and abstracts are in preparation. One U.S. Army Service Conference article (1988).

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/48

STATUS: Ongoing

TITLE: Alteration of Lymphomyelopoietic Cell Response and Treatment in Mice Following Burns and Radiation Trauma

START DATE: Jun 86

ESTIMATED COMPLETION DATE: Nov 88

PRINCIPAL INVESTIGATOR: MAJ Dennis A. Stewart

DEPARTMENT: DCI

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: G. David Ledney, PhD; Bruce Veit, PhD

KEY WORDS: Radiation trauma

**Study Objective:** The proposed study is designed to determine how the precursor stem cells are effected over a time course following injury, the initiating factors in the cellular response, and means of altering the response in vivo.

**Technical Approach:** Trauma Control - Previously established LD<sub>50/30</sub> survival curves for radiation exposure and combine radiation/burn will be verified in the B6D2 F<sub>1</sub> hybrid strain without administration of GM-CSF or other therapeutic agents except normal saline for burn trauma animals as described in the protocol.

Recombinant murine GM-CSF will be tested in both normal and in animals subjected to trauma.

In addition, CSF produced and purified utilizing high pressure liquid chromatography (HPLC) in our own laboratory will be tested in vivo in our trauma model (burn, physical skin injury, radiation, and combine radiation/burn).

**Progress:** A study of the GM-CFC in the bone marrow, spleen and peripheral blood in thermal injured mice at days 1,3,7 and 14 post burn supports the contention that mobilization or migration of clonogenic cells is occurring from one hematopoietic compartment to another. Traumatized groups of mice were either submitted to a 14 second ethanol burn to 2 cm x 3 cm portion of the back or given a circular skin wound removing 2.0 to 2.5 cm<sup>2</sup> of dorsal skin. Following trauma the mice were assayed for GM-CFC in soft agar culture. We found that stem cells proliferate rapidly in the bone marrow compartment. However, this increase is rather short lived with the GM-CFC assayed again at day 7 being markedly depressed. Clonogenic stem cells assayed following burn trauma in the spleen and peripheral blood showed a moderate increase at day 1, although by day 3 as much as a five fold increase was observed with increased levels continued out to 14 days. Colony Stimulating Factor (CSF) is closely associated with stem cell mobilization to the spleen and peripheral blood. Metcalf et al. (1) has reported a similar depletion of bone marrow stem cells in normal mice 6 days after injecting recombinant GM-CSF. In our studies we have found following injury that colony-stimulating-activity was present in peripheral blood at measurable low levels after 3 hours. Although significant levels were not measured until after 3 days. These levels continued out two weeks following trauma.

Research in granulocyte-macrophage precursor stem cell regulation coupled with the recent interest in the role of myeloid growth factors such as colony-stimulating factors (CSF's) may provide new insight into the immune response following trauma. The information presented here suggest that trauma, whether a burn or skin wound, stimulates the production of precursor stem cells (GM-CFC) in the bone marrow compartment. However, this increase in the marrow compartment is short lived with the number of GM-CFC decreasing to normal or below after the first week post trauma. While this decrease was observed in the marrow, a nearly five fold increase in GM-CFC was occurring in the spleen and peripheral blood compartments. It would appear that the increases noted in the spleen and peripheral blood resulted from a migration of stem cells from the marrow cavity.



Colony-stimulating factor's are closely associated with stem cell regulation in the organ systems. These factors have been identified as specific glycoproteins that are able to control the proliferation and differentiation of granulocytes and macrophages. We have shown in this study and a previous wound study ( ) that Colony-stimulating activity (CSA) can be measured by soft agar culture techniques in the serum of mice following trauma. The highest levels of CSA were measured after three days and correlates with the increased progenitor stem cell activity observed in the spleen and peripheral blood.

A single, mechanism of action does not adequately explain the role CSF has in the regulation of progenitor stem cells following trauma. Our data suggests that CSF is the key factor responsible for the movement of stem cells out of the bone marrow to spleen and peripheral blood. A recent study has show that six days following recombinant CSF (rCSF) injection into normal murine animals results in the marrow cavity depletion of nonerythroid progenitor stem cells and an increase of 2 to 5 fold in the spleen. These results from exogenous rCSF are consistent with the compartmental shift of stem cells seen in this study. Trauma could cause the production of endogenous CSF which was assayed as CSA in this study.

It has been shown in severely burned humans that there is an initial increase in granulocytic stem cells in the peripheral blood of survivors, whereas nonsurvivors fall significantly below normal peripheral blood stem cells levels ( ). In the absence of labeling stem cells and following their movement, the best explanation for the observed for quantitative changes in clonogenic stem cells following trauma is an initial proliferation in the marrow cavity followed by mobilization to the spleen and peripheral blood. We believe this sequence of events is mediated primarily by endogenous CSF production following trauma.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/22

STATUS: Terminated

TITLE: Allogenic Bone Marrow Transplantation (in the Rat Model)

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: PhD Bruce C. Veit

DEPARTMENT: DCI

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Bone Marrow Transplantation

**Study Objective:** This is a multi-faceted research program project which encompasses investigational studies of three aspects of contemporary interest to transplantation immunologists: (1) mechanism(s) and prevention of graft versus host disease (GVHD); (2) mechanism(s) involved in stem rejection (engraftment failures); and (3) T cell differentiation as it relates to the establishment of tolerance in allogeneic bone marrow chimeras.

**Technical Approach:** Animal Model: Female 125 - 150gm Wistar Furth rats (RT11) are infused i.v. with  $1 \times 10^8$  nucleated bone marrow cells supplemented with  $2.5 \times 10^7$  nucleated spleen cells from 125-150gm female Lewis rats (RT11). Recipient rats are conditioned with 20mg/kg cyclophosphamide i.p. on days -3 and -2 and with 1200r (90r/min) on Day -1 prior to transplant. Engraftment is monitored by RBC, WBC, and platelet counts and chimerism is determined by analyzing peripheral blood cells with fluorescein-labeled allo-antisera.

**Marrow pre-treatment:** Donor marrow suspended in RPMI 1640 medium is incubated with 20-40um deoxyadenosine in the presence of lum 2-deoxycoformycin for 14 to 20 hours. Treated cells (and non-treated control cells) are washed free of nucleoside and infused i.v. Each cell suspension is analyzed for residual T cell content by polyclonal expansion (T cell activators-pMA, CONA) and flow cytometry (reactivity with monoclonal anti-T cell antibodies). T cell subset analysis will be a critical feature of assessing selectivity in T cell depletion. Stem cell (CFU-c) activity is determined in an in vitro colony growth assay.

**Immunological analyses:** Upon confirmation of stem cell engraftment, peripheral blood cells are tested for responsiveness to T cells mitogens (CONA, PHA), T cell mitogens (PWM, LPS) and alloantigens (MLR). Natural killer cell activity is measured with a  $^{51}\text{Chromium}$  release cytotoxicity assay. Suppressor cell activity is determined by adding peripheral blood cells into an MLR consisting of stimulator and responder cells from normal (nontransplanted) rats.

**Histology:** Samples of skin, thymus, lymph nodes, spleen, liver, small and large intestine, lung and marrow will be taken from animals afflicted with GVMD at autopsy or necropsy and fixed for histological sectioning and staining (bones will be decalcified). Samples will also be frozen for cryostat sectioning in order that immunoperoxidase methodology can be applied to subset analyses of lymphocyte infiltrates in the affected tissues. Frozen sections will also be analyzed for immune complex deposition in studies of chronic GVMD.

**Progress:** No progress has been made during this reporting period.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/55

STATUS: Ongoing

TITLE: Development of a Hemophilus Influenza Anti-Idiotypic Vaccine (In the Mice and Rabbit Models)

START DATE: May 1987

ESTIMATED COMPLETION DATE: May 1989

PRINCIPAL INVESTIGATOR: PhD Bruce C. Veit

DEPARTMENT: DCI

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ George McNamee, DVM; Becky Smiley, Susan McIntyre, Cambyes Darvish

KEY WORDS: Hemophilus influenzae, vaccine

**Study Objective:** Prepare an immunogenic vaccine that will establish effective immunity to Hemophilus influenzae in children under two years of age. Since the polysaccharide antigen (Hib) itself is only weakly immunogenic at best, we will attempt to develop an internal image anti-idiotypic vaccine which, by virtue of its protein structure, should be highly immunogenic in this patient population. Although our ultimate goal is to develop such a vaccine for human use, our initial efforts will be focused on an animal model which will be used to establish the merit of this approach.

**Technical Approach:** Balb/c mice and New Zealand white rabbits will be immunized with Hemophilus influenzae type B polysaccharide (PRP). Since polysaccharides are poorly immunogenic in general, a protein conjugated form of PRP, namely polysaccharide-diphtheria toxoid, will be used in order to overcome this potential pitfall. At the time of peak, antibody synthesis, rabbits will be bled via the marginal ear vein or central artery in the ear and the anti-PRP antibodies will be affinity purified on PRP-Sepharose 4B columns. Spleens from immunized mice will be single-cell suspended and fused with the MAT-sensitive myeloma cells, SP2/0. Hybridomas secreting anti-PRP antibodies will be identified using ELISA screening techniques.

Affinity-purified rabbit anti-PRP antibodies as well as mouse monoclonal antibodies will be used to immunize Balb/c for the production of monoclonal anti-idiotypic antibodies. Appropriate hybridomas secreting the desired antibodies will be selected by ELISA screening. Those which bind to anti-PRP but not to pooled mouse immunoglobulins or to PRP antigen, will be further characterized for their ability to elicit an antibody response to PRP in rats (heterologous species with respect to the origin of the antibodies to be used).

Upon confirmation that the anti-idiotypic antibodies elicit a specific response to PRP, infant rats (1 to 2 weeks post-partum) will be immunized with the anti-idiotypic vaccine and then challenged with virulent Hemophilus influenzae intranasally. Infected animals will be housed in isolation quarters so that other animals will not become infected.

Having established the efficacy of the anti-idiotypic vaccine in protecting against infection, we will then submit an additional protocol which will describe the methodologies for generating hybrid molecules of the anti-idiotypic antibodies so that the "V" regions are mouse and the "C" regions are human.

In initial studies that will focus on the immunogenic aspects of the anti-idiotypic vaccine (immunization of rats), we will be able to ascertain whether heterologous proteins (mouse immunoglobulins into rat) will induce anti-mouse Ig and/or immune complexes. Then the hybrid immunoglobulins will be tested by comparison for elimination of any anti-mouse Ig response that may occur.

**Progress:** Rabbit anti-Hib has been prepared and IgG fraction obtained by DEAE chromatography. Mice have been immunized with this fraction in producing hybridomas which synthesize anti-anti-Hib antibodies (anti-idiotypic antibodies).

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/04

STATUS: Ongoing

TITLE: Activation of T-Cell Subsets in Bermuda Grass Allergy Patients

START DATE: Nov 1987

ESTIMATED COMPLETION DATE: Nov 1989

PRINCIPAL INVESTIGATOR: PhD Bruce C. Veit

DEPARTMENT: DCI

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Stanislaus Ting, M.D.; LTC R.V. Charya, MC; Beck Smiley, B.S.; Susan McIntyre

KEY WORDS: Bermuda grass allergy, T-cell subsets, IL-2R, VLA, 2-color flow cytometry

**Study Objective:** Samples of peripheral blood (approx. 10 ml) will be collected from 15 Bermuda grass allergy patients one month prior to the allergy season, early after onset of allergy symptoms, at the height of their allergic condition and following immunotherapy. Blood will be collected in EDTA-containing tubes and diluted 1:1 with RPMI 1640 medium containing 3% pooled human AB serum. Ficoll-Hypaque purified mononuclear cells will be analyzed either noncultured (freshly obtained) or following culture for 6 days in the presence of Bermuda allergen (specific) or Mulberry allergen (non-specific). Cells will be incubated with monoclonal antibodies reactive with T4, T8, Very Late Antigen (VLA), IL-2 receptor, and transferrin receptor (T9) that have been conjugated to either fluorescein isothiocyanate (FITC) or phycoerythrin (PE). Therefore, the T4 and T8 subsets will be identified with one color and the activation antigen-positive cells (IL-2+, VLA+, T9+) within each of these two subsets will be quantitated via the other color. A typical staining protocol will be as follows:

TUBE #:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
OKT3-FITC	+														
OKT4-FITC		+								+					
OKT4 PE			+								+			+	
OKT8-FITC				+							+				
OKT8-PE					+							+		+	
OKT9-FITC						+							+	+	
VLA-FITC							+				+	+			
IL2-PE							+	+	+						
CTRL MoAb									+						

Two-color fluorescence analysis will be carried out on an Ortho Cytofluorograph, Model 50H linked to a Data General 2151 computer which will acquire data using the FLUORCOMP program for ated two-color analysis. for comparison, mononuclear cells from normal individuals will be incubated with phytohemagglutinin (PHA) for varying periods of time ranging from - to 20 days and then varying periods of time ranging from 0 to 20 days and then analyzed by the same protocol as described above.

Mononuclear cells from these patients will also be fractionated into T4+, T9+ and B cell subsets by a "panning" process in which tissue culture dishes coated with either anti-T4 or anti-T8 monoclonal antibodies will be used to bind the respective subsets in sequential fashion. Cells remaining nonbound following this treatment will be almost entirely B cells which will be analyzed for their ability to secrete IgE or IgG antibodies in the presence of T helper/inducer cells or T suppressor cells. Percentages of activated (IL-2+, T9+ or VLA+) T4 or T8 cells will be determined using immunohistochemical staining methods. These values will be compared with those obtained by flow cytometry. T cell subsets will either be stimulated with specific allergen or an unrelated allergen and then added to cultures of B cells that have been stimulated with specific or unrelated allergen. Following a 48-72 hour incubation period, the presence of secreted IgE and IgG antibodies will be detected by ELISA. Essentially, increased or decreased synthesis of antibodies will suggest the presence of helper or suppressor cells, respectively. It is likely that helper activity will be detected in patients during an early phase of their disease while suppressor cells should be detected later on following a course of immunotherapy. Sera from these patients will be analyzed for IL-2R levels (circulating IL-2 receptor). Variations in soluble IL-2R may indicate significant alterations in helper and/or suppressor T cell functions.

T cell subsets from individual patients will be tested for activity with B cells from the same patient (autologous) or with other patients with the same allergy (or unrelated allergy for determining specificity) in order to test the possibility that such interactions between T cells and B cells may be genetically restricted. DNA, RNA and protein synthesis inhibitors will be used to determine if proliferation and/or protein synthesis are necessary for help or suppression to be expressed. IgE plaque-forming cells will be quantitated by the ELISA method of Sedgwick and Holt.

Mononuclear cells will also be cultured with Bermuda grass allergen (specific allergen) or Mulberry allergen (non-specific allergen) for 6 days and then pulsed for 24 hours with tritiated thymidine. The level of uptake of this labelled DNA precursor by antigen-stimulated cells can be attained when challenged with allergen in vitro.

**Progress:** Patient's cells have been tested by 2-color flow cytometric analysis. Samples were obtained from individuals with untreated, active allergy and from individuals undergoing immunotherapy. A subset of IL-2R (activated) CD4+ cells was detected in the former group, whereas the CD8+ subset contained no detectable IL-2R+ cells. Immunotherapy patients' cells were also analyzed and found to contain a lower percentage of IL-2R+/CD4+ cells. Activated (IL-2R+) cells were found only after 6 days of culture with antigen and the percentage of IL-2R+/CD4+ cells was significantly increased by subjecting the peripheral blood mononuclear cells to an adherence procedure (plastic adherence). It was observed that mononuclear cells from Bermuda grass allergy patients were significantly more adherent to plastic than those from normal individuals - this phenomenon is, as yet, unexplainable and requires further study.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/79

STATUS: Ongoing

TITLE: Admitting Criteria for TCA Overdose, a Prospective Look

START DATE: Oct 1988

ESTIMATED COMPLETION DATE: May 1989

PRINCIPAL INVESTIGATOR: MAJ Jose E. Aponte

DEPARTMENT: DPCCM

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: TCA, admitting criteria

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**Study Objective:** To determine if the admitting criteria previously validated by several retrospective studies can be utilized in a prospective manner in an emergency room setting.

**Technical Approach:** As each patient presents with a history of TCA ingestion, they will be logged into a book, maintained in the ED, so as to facilitate retrieving their charts for information or from our computer terminals. Those criteria outlined in the algorithm will be attached to the patient's ED chart. Criteria that are ambiguous (i.e. signs of major toxicity) will be clarified for the house officer treating each patient admitted. During the hospitalization the patient will be monitored daily for signs or symptoms of major toxicity. Significant events during the hospitalization period will be documented on the form (algorithm) attached to the patient's records. Upon discharge, each patient's form will be collected and reviewed. Those patients discharged from the ED will have documented on their ED charts the presence or absence of signs of major toxicity (i.e., QRS width, bowel sounds, etc.). The management of each patient will be the same as any patient thought to have a toxic ingestion. All patients will be lavaged via the orogastric route until bile is noted in the aspirate, at which time they will be given their first dose of charcoal and a cathartic. If prior to lavage the patient demonstrates an altered mental status then the patient will be intubated before initiating the lavage. At that time the patient will also be given thiamine, glucose and Narcan in the standard doses. A lab data base, to include an ABG, CXR, SMA-10, Calcium, PT/PTT, CBC, serum osmolality, serum/urine tox and drug screen, with TCA levels, will be obtained on all patients suspected of a TCA overdose. The method of testing will be by EIA, GLC, HPLC and TLC by the Nichols Institute. This lab data base is routinely obtained on all suspected significant ingestions. So as to allow as large a group as possible, the duration of this study should be about one year or involve 100 patients. Neither sex or age should influence the results of this study. The data will be analyzed for uncomplicated versus complicated hospital stays by the Student T method. The complication frequencies for subgroups versus the hospitalized patient population as a whole will be studied by a comparison of the binomial distribution. The method of Hanley and Lippman-Hand will be used to calculate the 95% confidence interval around the observed rate of complications. Those patients who are negative on their drug/tox screens for TCA's will be used as a control group.

**Progress:** No analysis of data has been completed yet, as TCA levels on many patients are still pending.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/71

STATUS: Ongoing

TITLE: Emergency Procedures Laboratory (Carpine Model)

START DATE: July 1988

ESTIMATED COMPLETION DATE: July 1989

PRINCIPAL INVESTIGATOR: CPT T. Giberson

DEPARTMENT: DPCCM

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ C. Eaves, MAJ J. Aponte, MAJ M. Stolpe, CPT M. Peterson

KEY WORDS: Emergency Procedures

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**Study Objective:** To train accredited physicians who are not dealing with emergencies on a day-to-day basis, but may be called upon to perform this function. The goat model will simulate the human emergency patient.

**Technical Approach:** Cricothyroidotomy, venous cutdown, chest trauma management, and peritoneal lavage procedures will be accomplished in accordance with training manuals for each procedure.

**Progress:** Training has been on hold recently. Full use of this project is anticipated to begin in January 1989.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/15

STATUS: Completed

TITLE: A Study to Determine the Appropriateness of Hospital Information System (HIS) Training Being Provided to Healthcare Professionals at WBAMC

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: CPT Grover C. Peters, III

DEPARTMENT: HDQ

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Hospital Information System, Training

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Study Objective: The study is concerned with identifying what the organizational objectives are for the HIS, determining what management's expectations are relative to the HIS, and determining if system user expectations are being met. Given that information, the study will then determine if HIS user training is properly preparing users to ensure organizational objectives and management expectations are being met.

Technical Approach:

- a. A survey questionnaire will be developed to identify management expectations of the HIS.
- b. A user survey will be developed to identify user expectations and to determine to what degree their expectations have been met.
- c. The study population will be all HIS users at WBAMC.
- d. A reliable and valid survey questionnaire will be utilized.

Progress: This protocol was completed prior to principal investigator PCS'ing. No data to report.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/49

STATUS: Ongoing

TITLE: The Natural History of HTLV-III Infection and Disease in a US Military Population

START DATE: May 86

ESTIMATED COMPLETION DATE: May 91

PRINCIPAL INVESTIGATOR: Maj Naomi Aronson

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Charles E. Davis, Jr., MAJ Eugene Etzkorn

KEY WORDS: HTLV-III

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Study Objective: Study the epidemiology of HTLV-III infection in active duty and retired military personnel and their dependents.

Technical Approach: Standard evaluation will be routine medical evaluation, immunological evaluation, laboratory tests, tests for opportunistic infections, HTLV-III viral cultures on body fluids and organs whenever possible. Completion of HTLV-III clinical evaluation form. HTLV-III tests. Counselling, education, and referral of contacts. Follow-up of individuals in the study. Data analysis: disease progression will be studied, as defined by Walter Reed Staging Classification. The effect of variables, including but not limited to age, sex, ethnic background, risk factors, length of infection, and simultaneous viral infections, will be studied.

Progress: Since inception of this protocol 86 individuals have been evaluated using the Walter Reed HIV staging system at WBAMC, 35 have subsequently been lost to followup.

Evaluating this population, during the most recent staging, 38 (44%) are Walter Reed stage 1, 9 (10%) are Walter Reed stage 2, 18 (21%) are Walter Reed stage 3, 3 (4%) are Walter Reed stage 4, 9 (10%) are Walter Reed stage 5, 5 (6%) are Walter Reed stage 6 (CDC definition AIDS) and 4 (5%) have died.

Segregating those individuals who have presented for more than one evaluation since 1986 (49 patients); 26 (53%) showed no change in stage, 6 (12%) changed 1 stage, 10 (20%) changed 2 stages, 3 (6%) changed 3 stages, 3 (6%) changed 4 stages, and 1 (2%) changed 5 stages.

Because of our relatively small HIV population, the merit of this study can best be recognized once data is centrally studied (WRAIR) and when patients have been followed for time periods greater than 2 years.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/85

STATUS: Ongoing

TITLE: Evaluation of the Effectiveness of Reglan in Involuntary Movement Disorders (Monitor: COL Cuetter)

START DATE: Sep 87

ESTIMATED COMPLETION DATE: Sep 89

PRINCIPAL INVESTIGATOR: MAJ David Bartoszek

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: COL Jabbar, WRAMC Neurology Svc

KEY WORDS: Movement disorders, Metoclopramide, Torrette syndrome

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**Study Objective:** To determine whether Metoclopramide at 120-240 mg/day in adults and up to 2 mg/kg/day in children can eliminate or significantly reduce the involuntary movements.

**Technical Approach:** Patients with involuntary movement disorders will be considered for the study. Patients will be admitted to the hospital and given increasing doses of Metoclopramide. In patients who achieve a complete remission at a lower dosage, the progressive increases will be held at the minimal effective dose. A videotape will be made of the patient before treatment is started and at the maximal effective dose. After a four-day observation period, a third videotape will be made. Those patients who improve on Metoclopramide and elect to continue the medication will be followed at four-month intervals by the investigators in the neurology clinic. The normal period of follow-up will be one year, in which the long-term effects will be monitored, including the development of adverse effects or decreased efficacy. A final tape will be made documenting the effects of the drug at the completion of the follow-up period.

**Progress:** Twelve patients (12 at WRAMC and 0 from WBAMC) are enrolled in the protocol at the present time. Two patients with Torrette Syndrome are scheduled to be enrolled in the summer of 1989. The 2 patients are in the pediatric age-group and admission (required by protocol) to hospital is planned around summer vacation.

Three patients with torrette's have been studied and 1 had a transient response and 2 had sustained responses. A single patient with Spasmodic Torticollis had a transient response.

The delay in the entry of patients from WBAMC has been due to the fact that the principal investigator had just PCS'd to WBAMC in the summer of 1987 and the protocol requires conventional therapies for movement disorder be exhausted prior to entry into the protocol. Principal investigator is in the process of therapeutic trials of accepted medications with several patients at this point.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/61

STATUS: Completed

TITLE: Review of Health Records and PAD Data for Incidence of Gastrectomy for Peptic Ulcer Disease (PUD) in Army MTF

START DATE: Jul 1986

ESTIMATED COMPLETION DATE: Jul 1988

PRINCIPAL INVESTIGATOR: COL Edward Burkhalter

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Peptic Ulcer Disease

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**Study Objective:** Review of health records and PAD will determine the incidence of gastrectomy for PUD in Army medical treatment facilities world-wide.

**Technical Approach:** The methodology used will involve an extraction of data from the computer library of the US Army Patient Administration System and Biostatistics activity, Fort Sam Houston, TX. All gastrectomy surgeries for PUD in Army medical treatment facilities world-wide will be reviewed and a correlation will be made between the years before the use of cimetidine and after cimetidine was approved for use.

This will be exclusively a chart and computer data study without direct patient contact. The number of surgeries reviewed will be approximately 2000. Limited statistical support will be required. Collection of computer data from Ft Sam Houston will take about two months. Statistical method will be Student  $t$ -test.

**Progress:** Accepted for publication, American Journal of Gastroenterology

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 85/01

STATUS: Terminated

TITLE: Skin Test Reaction Variability in Human Skin Induced by Single Strength Antigen

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Robert W. Haverly, Jr., DAC

KEY WORDS: Skin testing

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Study Objective: To determine if the incidence of variability in skin test reaction as a function of skin test site.

Technical Approach: One hundred patients from the Allergy/Immunology Clinic population at WBAMC will be asked to participate in the study. Each patient will be prick skin tested on a preselected single antigen to which they have a known hypersensitivity. The concentration of the extract will be 1:200 w/v. Skin testing to antigen, saline and histamine and DMH control will be done on the back on the upper right and left and lower left and right quadrants. The resulting wheal and flare reactions will be outlined and recorded by cellophane tape technique for later evaluation. Data will be analyzed with a SPSS package, specifically analysis of variance.

Progress: There has been a great deal of information on this subject and does not warrant any new study.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 85/47

STATUS: Ongoing

TITLE: Effect of Vitamin B-6 on Asthma

START DATE: Mar 89

ESTIMATED COMPLETION DATE: Jul 89

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Ruth Hulse, LPN

KEY WORDS: Vitamin B6, Asthma

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**Study Objective:** To investigate whether asthmatic patients will benefit from oral vitamin B6 supplementation.

**Technical Approach:** Fifty stable, asthmatic adult patients attending the Allergy Clinic will be invited to be participants in this study. Baseline spirometry, plasma histamine, B6 level and skin response to histamine DMH and allergens will be recorded. Oral vitamin B6, 50mg b.i.d., will be given for 3 weeks. The patient will be advised not to add supplemental "over-the-counter" type vitamins to their diet during the testing period. Similar laboratory testing and skin testing will be repeated. Various data points obtained pre- and post-B6 treatment will be analyzed by paired student's t-test.

**Progress:** Patients are being recruited at this time.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/07

STATUS: Ongoing

TITLE: Evaluation of Specific IgE Level, IgG Blocking Antibody Level and Skin Test Reactions with Plasma Histamine Levels in Patients with Adverse Reaction to Allergen Immunotherapy

START DATE: Jan 1987

ESTIMATED COMPLETION DATE: May 1989

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Ruth Hulse, LVN; Robert Haverly, DAC

KEY WORDS: Allergy immunotherapy

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**Study Objective:** To determine the effect of nicotine on serum theophylline in nonsmokers and in asthmatics.

**Technical Approach:** Approximately ten nonsmokers, who do not have asthma, and ten nonsmoker asthmatics will be invited to participate in this study.

The nonsmoker subjects will be given a theophylline preparation of Theo-Dur, 10mg/kg/day in divided doses, and a baseline theophylline level will be obtained on the sixth day. A baseline, four and eight hours after a dose of theophylline, blood samples will be drawn.

Nicotine chewing gum will be prescribed for a total of 10 sticks per day for three days. At the end of three days, three serum theophylline levels will be obtained, baseline, four hours and eight hours post-dose.

The asthmatic subjects will continue to take their prescribed theophylline, and serum theophylline level will be obtained, pre-dose and four hours and eight hours after the dose. The nicotine gum will be prescribed if theophylline levels are within therapeutic range. Otherwise the dose of theophylline is adjusted prior to prescribing the nicotine gum. Serum theophylline levels will be drawn three days after being on nicotine chewing gum. Blood samples will be drawn also, before and after administration of nicotine chewing gum, for the following:

- a. Vitamin B6
- b. Plasma histamine level.

**Progress:** Patients with significant adverse reaction to immunotherapy are being invited to participate in the study. Reduction of the technical staff had impact on the study.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/08

STATUS: Completed

TITLE: A Pilot Study on Effect of Nicotine and Cigarette Smoking on Theophylline Kinetics in Healthy Rabbits

START DATE: Dec 1987

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ George A. McNamey, Jr., VC; MAJ R.C. Keniston, MC

KEY WORDS: Nicotine, Theophylline kinetics

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Study Objective: To determine the effect of nicotine and cigarette smoking on plasma theophylline level in healthy rabbits.

Technical Approach: Investigate the effect of nicotine and cigarette smoke on theophylline kinetics in rabbits. Animals are justified because the risk of nicotine administration in adult volunteers is ethically problematic since nicotine is addictive. The rabbit animal model has been used previously as the best model to study theophylline kinetics.

Experimental Design: Ten healthy rabbits will be studied. Theophylline, 20 mg/kg/da, in divided doses, will be administered daily, and blood samples will be drawn for baseline, two hours, six hours, and eight hours after the dose. From these values, a half-life will be calculated on Day 5. Nicotine will be given for four days and theophylline levels will be obtained as above on Day 4. The individual dose of nicotine will be based on neonatal dosage for apnea and given tid. One week after stopping the nicotine, the rabbits will be exposed to cigarette smoke intermittently for one week, for 5-10 minutes several times daily. The theophylline levels will be repeated.

Number of animals required: Initially only three rabbits will be used. The magnitude of the effects, if noted, will determine the number of animals necessary to show significant differences.

Progress: This pilot study was completed and was presented as an abstract poster session at the Annual Meeting of the American Academy of Allergy and Clinical Immunology, Anaheim, California in March 1988.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/12

STATUS: Terminated

TITLE: Effect of Nicotine Chewing Gum on Theophylline Kinetics, Plasma Vitamin B6 Level, and Plasma Histamine Level

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Robert Haverly, DAC

KEY WORDS: Nicotine, Theophylline kinetics, Vitamin B6

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Study Objective: To determine the effect of nicotine on serum theophylline, B6 levels, and plasma histamine in smokers with asthma.

Technical Approach: Forty asthmatic smokers will be asked to participate in the study. Baseline theophylline, plasma histamine and vitamin B6 levels will be obtained prior to taking their morning dose of theophylline. Each subject will receive his morning dose of theophylline, and lab studies will be drawn at four and eight hours.

After the eighth hour lab determinations, subjects will begin the nicotine regimen, ten sticks per day for four days. Nicotine gum will be prescribed only if theophylline levels are within the therapeutic range. If not, dosages will be adjusted and levels repeated prior to prescribing the gum. The laboratory studies will be repeated after the patient has stopped smoking, but continues to use nicotine gum. The theophylline kinetics will be compared for three different stages of cigarette smoking, cigarette smoking and nicotine gum use, and when the patient is using nicotine gum alone.

Progress: Asthmatic smoker volunteers could not be recruited, as most smokers with asthma, for unspecified reasons, do not want to quit smoking at this time.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/19

STATUS: Terminated

TITLE: Effect of Topical Steroid, H1 and H2 Antagonists on Cutaneous type I Late Phase Reaction

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: H1 and H2 Antagonists

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Study Objective: To investigate whether topical application of steroid or a mixture of H1 and H2 antagonists can prevent allergy skin test-induced late phase reaction.

Technical Approach: We plan to investigate whether a single application of topical steroid spray and topical H1 and H2 antihistamine spray after the allergic skin test can prevent the development of LPR in patients undergoing routine pollen skin testing for diagnosis of hay fever. Twenty adult individuals with previous history of late phase reaction to routine skin test will be invited to participate. Prick skin tests will be placed, with the allergen that induced late phase reaction, i.e., Bermuda grass extract, at three different sites, two on the right forearm 14-15 cm apart and the third one on the left arm. The reactions will be observed at 15 minute intervals. On skin test site #1, Kenalog solution, 10 mg/ml, will be applied as a two-second spray, similar to Kenalog spray. The second skin test site will be sprayed for two seconds with a solution containing cimetidine 75mg (injectable solution) Benadryl (125 mg/ml mixed). Normal saline spray will be applied for two seconds on a third skin test site. The patient will be observed for any reaction at 1, 4, 8, and 24 hour intervals after the initial skin testing. Any reaction with induration and erythema will be measured by the investigator and recorded with clear scotch tape impression or photographed. Initially ten patients will be evaluated with normal saline spray as control. If, after ten patients, the normal saline control is read as "no change", the combination M1 and H2 spray will be split with one spray containing the M1 blocker and the other containing the H2 blocker at the same concentration as the initial mixture. An additional 20 patients may be entered on the protocol at this time. Data analysis will be by repeated measured ANOVA/MANOVA.

Progress: The necessary materials to dispense uniform dose of medication used in this study could not be procured.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/24

STATUS: Ongoing

TITLE: Effect of Auranofin on Skin Test Response to Histamine, Codeine, Dextromethorphan on 24-Hour Histamine Levels

START DATE: Apr 1987

ESTIMATED COMPLETION DATE: Mar 1989

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ D.R. Hough, MC

KEY WORDS: Auranofin, Skin test response

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**Study Objective:** Investigate in vivo effect of the oral gold preparation (auranofin) on the skin test response to histamine, codeine phosphate, and dextromethorphan and 24-hour urinary histamine levels.

**Technical Approach:** Adult patients requiring treatment with triethylphosphine gold (auranofin) as determined by their rheumatologist will be invited to participate in this study. Baseline urinary histamine levels will be measured by assay in DCI or referred to a laboratory where the assay is established. Skin tests will be performed with histamine phosphate 0.1 mg/ml, codeine phosphate 1 mg/ml, and dextromethorphan 1 mg/ml injected in a dose of 0.02 ml. The wheal and flare reaction will be measured after 15 minutes. The patient will be instructed to begin therapy with auranofin per prescribed schedule. After a two-week treatment with auranofin, and after with-holding any antihistamine drug, the urinary histamine levels will be determined. Skin testing will be repeated with histamine phosphate, codeine, and dextromethorphan as described above. Data will be analyzed by repeated measures ANOVA.

**Progress:** Few patients were studied and the results are inconclusive. Due to delay in the urine histamine assay, new patients could not be recruited, but recent progress in urine histamine assay will enable us to continue the study.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/45

STATUS: Ongoing

TITLE: Comparison of Prick and Intradermal Skin Test

START DATE: May 1987

ESTIMATED COMPLETION DATE: May 1989

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: M. Wells, Juan Cruz, Helen Villegas

KEY WORDS: Skin testing

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**Study Objective:** To investigate the correlation between prick and intradermal skin test with serial concentrations of extracts.

**Technical Approach:** Fifty patients with various allergies will be invited to participate in this study. In patients being evaluated for various allergies, routine skin testing will be performed. If the prick skin test is negative, intradermal skin testing is performed with selected antigens such as Bermuda, Mulberry, Russian Thistle, and Ragweed, starting with 1:50,000, 1:5000, 1:500 dilutions, i.e., a patient may have a positive reaction only with 1:500 extract. If the skin test is positive, the size of the reactions is marked with a ballpoint pen and a clear scotch tape impression is obtained and will be transferred to the patient's record. A blood sample will be obtained to determine RAST specific IgE for the tested antigens. The first positive reaction (the weakest positive test) for each patient for his most reactive skin test will be compared with RAST using paired t-test.

**Progress:** Thus far, 54 patients were included in the study. The results were presented in the form of an abstract at the annual meeting of the American College of Allergy and Immunology, Los Angeles, California, 11-14 November 1988.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/61

STATUS: Terminated

TITLE: Clinical Trial of Gold in Steroid Dependent Asthmatics

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Stanislaus Ting, M.D.

KEY WORDS: Asthmatics

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**Study Objective:** To determine the therapeutic potential of Auranotin oral gold in steroid dependent severe asthmatics.

**Technical Approach:** Ten severe, steroid dependent, asthmatic adults will be invited to participate in this study. The following criteria will be used to define steroid dependent asthma:

1. Asthmatics who have been receiving oral corticosteroid daily or an alternate day for more than one year.
2. Patients with asthma, who require frequent short course corticosteroid treatment to control wheezing, i.e., 5-7 day course of Prednisone/Medrol in the range of 40-50mg.
3. Patients who need TAQ (Troleandomycin - a corticosteroid sparing macrolide antibiotic) to keep the corticosteroid dose lower.

Patients will be observed for two weeks before the study with symptom scores along with daily peak expiratory flow rate measurements at home. If baseline CBC, liver function tests and urinalysis are within normal limits, oral gold is prescribed, one capsule daily for one week and if tolerated will be increased to one capsule bid. Pulmonary function test peak flows will be monitored four times a day. An asthma symptoms score card will be given to keep records of the symptoms. CBC and urinalysis will be performed every two weeks. The patient will be monitored and gold will be withheld if abnormalities are found.

Study patients will be evaluated by the investigator biweekly, which includes careful physical exam, pulmonary function testing and monitoring of CBC, urinalysis, and liver function studies. If significant improvement is noted in patient's symptoms and pulmonary functions, an attempt will be made to taper corticosteroids in those patients, but all other medications will be continued as before (i.e., theophylline).

At the end of three months pre- and post-study data will be compared and data analyzed using a paired t-test baseline. Continuously collected data, i.e., symptom scores, peakflows will be evaluated using a multivariate repeated measuring design. Therapeutic benefit of oral gold preparation will be analyzed and compared between patients receiving both corticosteroid and oral gold preparation, as well as patients on oral gold alone after steroids are tapered off.

**Progress:** Difficulty obtaining an IND number and small patient population caused termination of this project.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/62

STATUS: Ongoing

TITLE: ACTH and Beta-Endorphin Levels in Patients with Urticaria

START DATE: Feb 1988

ESTIMATED COMPLETION DATE: Mar 1989

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Arun Thyagarajan, M.B., B.S., Laboratory of Clinical Sciences, National Institute of Health, Bethesda, Maryland

KEY WORDS: Beta-endorphin, Urticaria, ACTH

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Study Objective: To investigate the levels of Beta-endorphin, histamine and ACTH in patients during acute episodes of urticaria and during asymptomatic state.

Technical Approach: Twenty adult patients with chronic urticaria without any obvious cause will be given State-Straight Anxiety Inventory, a standard questionnaire to evaluate psychological stress. ACTH and Beta-endorphin levels will be obtained at various points, baseline (asymptomatic state and on no medication), during the episode of acute urticaria and during asymptomatic phase while patients are receiving antihistamine therapy. In addition to the above, blood samples will be obtained to measure plasma histamine levels, along with ACTH and Beta-endorphin. Plasma ACTH and Beta-endorphin assays will be performed by the co-investigator in the Laboratory of Clinical Sciences, National Institutes of Health. Stress levels will be evaluated with the use of the questionnaire during different phases; i.e., asymptomatic state, urticarial phase. Patients will be instructed to avoid medications containing opioids. Statistical analysis: repeated measure ANOVA will be utilized.

Progress: A total of 24 patients were included in the study. The results were submitted as an abstract for the upcoming annual meeting of the American Academy of Allergy and Clinical Immunology.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/11

STATUS: Ongoing

TITLE: Skin Test Response to Histamine, DMH and Aeroallergen and Plasma Histamine Levels in Patients Undergoing Hemodialysis and Peritoneal Dialysis (Monitor: MAJ Grant Greely)

START DATE: Feb 1988

ESTIMATED COMPLETION DATE: Feb 1989

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Maxine Lund, John Enriques, MAJ Richard Keniston, MC; MAJ Clifford Ferguson, MC; MAJ Don Hammonds, MC

KEY WORDS: Histamine, hemodialysis, peritoneal dialysis

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**Study Objective:** Histamine levels will be determined in plasma and dialysate fluids in renal failure patients before and after peritoneal/hemodialysis. Skin test response to a panel of aeroallergen histamine and Dextromethorphan to determine the atopic nature.

**Technical Approach:** Fifteen patients who undergo hemo/peritoneal dialysis for chronic renal failure will be invited to participate in this study. History of allergic disease will be evaluated through an allergy survey questionnaire. Antihistamines will be withheld 5 days prior to allergy skin testing and prior to obtaining plasma samples for histamine level. Baseline plasma histamine levels will be collected prior to the patients' routine dialysis procedure. Throughout the dialysis period, 5 ml samples from the dialysate fluid will be collected and stored at -70 degrees. Immediately following the hemo/peritoneal dialysis, a second blood sample will be obtained. Plasma is separated from the cells by centrifugation at 4 degrees and the samples are stored at -70 degrees until assayed. In addition to the above, BUN, creatine, and creatine clearance will be obtained pre and post dialysis. Prick and intradermal skin testing will be performed with histamine (0.1mg/ml for prick and 1mg/ml for intradermal) and Dextromethorphan (0.1mg/ml prick and 1.0mg/ml intradermal) prick skin testing will also be performed with a standard panel of aeroallergens (1:20 w/v extracts) which includes grass, tree, weeds, and mold extracts. Total IgE in blood will be determined and correlated with skin tests.

**Progress:** Seven patients undergoing hemodialysis were studied. The results were submitted as an abstract to the American Academy of Allergy and Clinical Immunology annual meeting (24 Feb - 1 Mar 89)

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/25

STATUS: Ongoing

TITLE: Immediate and Delayed Hypersensitivity with Correlation of Specific IgE and IgG to Trichophyton Antigen

START DATE: Jun 1988

ESTIMATED COMPLETION DATE: Mar 1989

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Specific IgE, Trichophyton, Delayed hypersensitivity

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**Study Objective:** To determine the incidence of immediate type reaction, IgE and IgG antibodies to Trichophyton during routine delayed hypersensitivity skin testing.

**Technical Approach:** Sixty patients who require anergy screen with standard anergy panel that includes Trichophyton antigen, will be invited to participate. Any reaction that occurs at 20 minutes will be recorded. Serum samples will be obtained for specific IgE and IgG antibodies. Skin test response will be recorded at 24 and 48 hour intervals and the size of the reaction will be noted.

The data will be analyzed to find:

1. The incidence of positive reaction at 20 minutes and Trichophyton antigen.
2. Correlation between positive skin tests and specific IgE for Trichophyton.
3. Incidence of positive delayed hypersensitivity skin tests at 24 and 48 hours with Trichophyton in patients who react in 20 minutes.

**Progress:** ELISA assay is being developed for specific IgE to Trichophyton. Patients will be invited when the specific IgE assay is available.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/31

STATUS: Ongoing

TITLE: Comparison of Intradermal and Multitest (CIM) DHS Skin Tests and Correlation with CD4 Cells in HIV Patients

START DATE: May 1988

ESTIMATED COMPLETION DATE: Mar 1989

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Joan Cruz, Helen Villegas, C. Davis, M.D.

KEY WORDS: CD4 cells, Multitest-CMI<sup>®</sup>, Mantoux technique

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**Study Objective:** To compare standard intradermal (Mantoux) DHS skin tests with Multitest CMI anergy screen.

**Technical Approach:** It is planned to investigate DHS with simultaneous application of multitest CMI and a panel of antigens that are present in multitest intradermally on a different site. Multitest CMI has 8 areas loaded with various antigens and the device is applied on the forearm after cleaning with 70% alcohol to the site. Gentle pressure and side to side motion is applied to introduce the antigens into the skin. Intradermal technique (Mantoux) consists of injection of 0.1 ml of antigen intradermally. Tetanus (1:100), Trichophyton (1:30), Monila at 20 minutes, 24- and 48-hour intervals. A blood sample is obtained to determine CD4 helper-inducer cells as part of staging and follow-up of disease status.

**Progress:** Thirty-eight patients were included in the study. The results were presented at the annual meeting of the American College of Allergy and Immunology, Los Angeles, California, 11-14 November 1988.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/34

STATUS: Ongoing

TITLE: Correlation of 24- and 48-Hour Skin Test Reaction with In Vitro Lymphocyte Transformation with Spherulin

START DATE: Feb 1989

ESTIMATED COMPLETION DATE: Jun 1989

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Maurice Wells, Bruce Veit, Ph.D.

KEY WORDS: Lymphocyte transformation, Spherulin

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**Study Objective:** To evaluate the significance of 24-hour and 48-hour skin test reactions with spherulin and correlate with in vitro lymphocyte transformation in patients undergoing anergy screen.

**Technical Approach:** Forty patients referred for anergy screen as part of their medical evaluation will be invited to participate in the study. DTH skin tests will be placed with a panel of antigens including spherulin. 0.1ml of antigen will be injected intradermally after cleaning the area with 70% alcohol. Patients will be observed in the clinic for 20 minutes to record any positive reactions. The reaction size is measured at 24- and 48-hours. Dr. Veit and personnel in DCI will perform in vitro lymphocyte transformation studies per standard protocol. If any of the study patients have had serological studies for cocci, the results will be utilized in the study. Repeated measure ANOVA will be utilized.

**Progress:** In vitro lymphocyte transformation assay is being developed to obtain a dose response curve, utilizing positive and negative controls. Once the optimal concentration of Spherulin for lymphocyte transformation is established, the actual study will begin.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/37

STATUS: Ongoing

TITLE: Role of Endogenous Opioids in Acute Bronchospasm, Urticaria, and Anaphylactic Reactions

START DATE: Aug 1988

ESTIMATED COMPLETION DATE: Mar 1989

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Charles C. Eaves, Jr.; MAJ Thomas P. Giberson; Arun Thyagarajan, M.B., B.S.

KEY WORDS: Beta endorphin, acute bronchospasm, endogenous opioids

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**Study Objective:** To determine the significance of endogenous opioids in acute asthma, acute urticaria, and anaphylactic reactions where mast cell degranulation may play a key role.

**Technical Approach:** Twenty asthmatics visiting the Emergency Room for treatment of bronchospasm will be asked to participate in the study. Seven ml of blood sample will be obtained by venipuncture for beta-endorphin and ACTH level. Twenty patients with acute urticaria will be recruited for 7ml venous blood sample for determination of beta-endorphin and ACTH level. Similarly, twenty patients who are evaluated and treated for acute anaphylactic/anaphylactoid reaction will be asked for a 7ml venous blood sample for beta-endorphin and plasma ACTH level. The patients will be followed in the Allergy Clinic. A second blood sample of 7ml venous blood will be obtained during a stable/asymptomatic stage of the disease. ACTH and beta-endorphin assay will be performed by the co-investigator, Dr. Thyagarajan, at the National Institute of Health.

**Progress:** The study is a cooperative effort between WBAMC Emergency Room and Allergy Service. The study was initiated in late August 1988. Several patients were included in the study, and follow-up Beta-endorphin samples are being obtained at this time.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/75

STATUS: Ongoing

TITLE: Effect of B<sup>6</sup> Supplementation on the DHS Skin Test and T-Lymphocytes in Anergic Patients

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: LTC Raghava V. Charya

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Richard C. Keniston, M.D., Bruce Veit, Ph.D., John Enriques

KEY WORDS: Anergy-lack of reactivity, DHS-delayed hypersensitivity, PLP-Pyridoxal 5' phosphate, T-Lymphocytes, Cell Mediated Immunity, Antigen

Study Objective: To study the effect of B<sup>6</sup> supplementation on the delayed hypersensitivity skin tests in anergic patients who do not respond to a battery of standard DHS skin test antigens.

Technical Approach: We plan to investigate the effect of vitamin B<sup>6</sup> supplementation on the delayed hypersensitivity response to a battery of antigens that include mumps, monilia, tetanus, trichophyton, PPD, and spherulin. Thirty individuals, age 18 and above, both male and female, will be studied. Military active duty, retired and their dependents are included in the study. No civilians will participate in the study. Individuals who were anergic to standard anergy panel (monilia, trichophyton, tetanus, PPD, and coccidioidomycosis) will be invited to participate in the study. Patients will be asked to withhold any vitamin supplements for 3 weeks prior to the study. Baseline DHS skin tests will be performed as described below. Volar surface of both forearms will be cleaned with 70% alcohol. The individual antigens will be injected intradermally 0.1ml with tuberculin syringes with 27 gauge needle. Patients will be asked to wait for 20 minutes to record any reactions. The skin reaction will be recorded either negative or induration in 2 opposite planes in millimeters in 24- and 48-hour intervals. If the patient continues to be anergic (negative reaction to skin test antigens), pyridoxine Hcl 50mg will be given P.O. daily for 4 weeks and the anergy screen will be repeated. In addition to the above, plasma PLP levels will be measured before and after supplementation. Lymphocyte transformation with PHA will be studied by Dr. Veit in the DCI Immunology Laboratory. Briefly, lymphocytes will be obtained by density centrifugation and cultured with and without PHA. Transformation will be evaluated by tritiated thymidine uptake, before and after supplementation of vitamin B<sup>6</sup>. The blood samples will be drawn before placing the skin tests.

PROGRESS: This is a newly activated study with no results to report to this date.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/13

STATUS: Terminated

TITLE: AZT Treatment for HTLV-III Positive Patients (Monitor: LTC Parker)

START DATE: 1986

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: MAJ C.S. Davis

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: AZT, HTLV-III

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**Study Objective:** To provide for the administration of AZT to eligible patients with careful supervision, and to monitor survival, disease progression, and toxicity.

**Technical Approach:** The details are lengthy and specified in the Burroughs Wellcome Co. protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

**Progress:** Since April 1987, AZT/Zidovidine has been available for general "Open Label" prescribing for patients with T helper cell counts less than 200/mm<sup>3</sup> or post-Pneumocystis carinii pneumonia. Nine patients were entered under the Burroughs Wellcome protocol prior to April 1987. 4, have subsequently died, 2/9 moved out of the area and have become lost to follow-up. Of the remaining 3, 2/3 are transfusion dependent when taking AZT, despite receiving only half the recommended dosage (100mg Q4h). These 3 all have WR-6 HIV infection.

In addition, six other patients have been placed on Zidovidine since April 1987. 1/6 is now deceased, 2/6 have been lost to follow-up (moved out of the area) and of the 3/6 that are regularly followed at WBAMC, 1/3 has required periodic transfusion therapy.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/46

STATUS: Ongoing

TITLE: Rate of Spherulin Skin Test Conversion Among Basic Trainees Exposed to Desert Training at Fort Bliss, Texas

START DATE: Sep 1988

ESTIMATED COMPLETION DATE: Nov 1989

PRINCIPAL INVESTIGATOR: CPT R. Ellis

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: CPT B.L. Martin, MC

KEY WORDS: Spherulin, Skin test to *C. immitis*.

**Study Objective:** To establish the rate of spherulin skin test conversion among active duty basic trainees who are exposed to desert training at Fort Bliss, Texas. To attempt to define the morbidity associated with *Coccidioides immitis* in terms of time lost from basic training due to acute Coccidioidal infection.

**Technical Approach:** Basic trainees will be invited to participate in the study. Study participants will be briefed by the principal investigators about the study and given an opportunity to volunteer for the program. One basic training cycle will be tested in each month to determine if there is a seasonal peak to exposure. As basic training cycles are 8 weeks in length and encompass between 60-240 soldiers (average 180) and begin every week, except the 2 weeks prior to Christmas, 12 basic training cycles will be studied, giving an approximate total study base of 2,400 soldiers in 1 year. This has been coordinated with the S-3 (plans) of the Training Brigade.

Each participant will fill out a preformatted questionnaire which will identify each volunteer by name, age, sex and provide a brief history of areas where the participant has lived prior to basic training and the number of years he has lived in each area. This will enable the investigators to provide a *C. immitis* exposure index which will categorize each soldier as having a low, medium or high index of exposure. In a large group of people with an infinite degree of exposure this will provide relevant criteria to judge each participant's risk of prior exposure. This questionnaire will also be used to chart sensitivities and other relevant information. These will be filled in by the soldier and returned to the investigators and kept on file.

Based on the information received in this questionnaire, each participant will be assigned to a group with a low, medium, or high exposure to *C. immitis*. This grouping will be based on the historical data given by the patient concerning where he lived and amount of time spent in each state. The states have been divided into 3 groups and given a statistical score based on the expected rate of exposure to *C. immitis* based on epidemiologic studies of the regions with endemic *C. immitis*.

Each state is assigned a value:

a. 2 for high possibility of exposure to *C. immitis*

- (1) California
- (2) Arizona
- (3) New Mexico

b. 1 for moderate possibility of exposure to *C. immitis*

- (1) Texas
- (2) Utah
- (3) Nevada

c. 0 for low probability of exposure to *C. immitis*; this includes all other states.

Each participant is assigned a sum product of (State's assigned value) X (number of years lived in the state). The sum value is used to determine the life exposure index.

- a. Low: 1-10
- b. Moderate: 11-25
- c. High: 26+

The life exposure index will then be correlated with the statistical rate of skin test positivity among our tested population.

Each participant will be skin tested to spherulin. 0.1ml of antigen will be injected intradermally after cleaning the area with 70% alcohol. Patients will be observed for 20 minutes after the test placement to record any positive immediate reactions. The reaction size will then be measured at approximately 48-72 hours after placement. Induration of 5mm or greater will be considered a positive reaction. Those who react to this first test, indicating previous sensitivity, will be included in the study for statistical purposes only. They will not be further tested. Tetanus will be used as a control antigen to ensure the patient is not anergic. The identity of those soldiers who are skin test negative to both tetanus and spherulin will be recorded for appropriate followup; it is estimated that as many as 40% of patients will not react to either spherulin or to tetanus.

These same soldiers (only those who did not react to spherulin on the first testing will be retested with spherulin within 1 week of graduation from basic training, using the same technique as listed above. The results will be tabulated for statistical analysis. We will ascertain the location of AIT training for all participants who remain skin test negative and if they remain in El Paso, they will be re-enrolled in an extended study and followed with repeat skin testing at the end of their 7 weeks of Advanced Individual Training (AIT), giving a total study time of 15 weeks. Also during the repeat testing, those subjects listed above who did not initially react to either tetanus or to spherulin will further receive an anergy test utilizing a battery of injections to test for skin test reactivity to tetanus, mumps, monilia and trichophyton. Those who do not react to any of these antigens will be considered anergic and will be consulted to the Allergy Clinic for any further workup required. We estimate less than 5 percent of our subjects will fall into this classification. The results of testing on any subject who meets this definition of anergy will not be included in the database for this study.

**Progress:** Four cycles have been tested (460 soldiers). First cycle is due to be completed in November 1988. At that time will re-test to determine percent of conversion. Ten percent initial tests on soldiers signify + spherulin, indicating prior exposure to *C. immitis*; 20-40% + tetanus. Twenty five soldiers have been admitted to WBAMC with URI's; serology has been done and frozen for later submission to University of California at Davis for *C. immitis* ab titers.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/47

STATUS: Terminated

TITLE: Comparative Open Label Clinical Trial of Sulfasalazine and Auranofin in the Treatment of Rheumatoid Arthritis

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: MAJ D.R. Hough

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Rheumatoid Arthritis

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**Study Objective:** Compare therapeutic efficacy of sulfasalazine versus auranofin in the treatment of patients with definite or classical active rheumatoid arthritis in a six-month open trial. The patients will be permitted a fixed regimen of background therapy to include nonsteroidal anti-inflammatory drugs, physical therapy, and low dose prednisone. Compare the incidence and severity of side effects and complications among the treatment groups.

**Technical Approach:** A 26-week open label, randomized, single blinded, parallel trial of SASP and auranofin. Both drugs have demonstrated more efficacy than placebo and all patients will be selected for this trial based upon the need for a disease modifying drug. Randomization schedules will be created from a computer generated series at WBAMC allocating 30-60 patients within each participating rheumatology clinic to be randomized to SASP or auranofin within each clinic. Each participating clinic will select patients who qualify and send a completed data base to the coordinating center. The patients may not enter the study until the signed informed is obtained and examination by the PI finds them eligible. They will be assigned a number indicating the clinic and "order of entry into the study". The clinic will then use the designated drug to be dispensed by the toxicity surveyor.

**Progress:** This study was terminated due to the principal investigator leaving the Army.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/72

STATUS: Completed

TITLE: 131 I mIBG Compassionate One Time Use, IND #31,571

START DATE: Sep 88

ESTIMATED COMPLETION DATE: Sep 88

PRINCIPAL INVESTIGATOR: MAJ Daniel H. Knodel

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: 131 I mIBG

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**Study Objective:** To evaluate the use of <sup>131</sup>I-meta-iodobenzylguanidine sulfate (<sup>131</sup>I-mIBG) as an aid in the diagnosis, evaluation and localization of pheochromocytomas, paraganglioma, neuroblastoma and/or adrenal medullary hyperplasia.

**Technical Approach:** The details are lengthy and specified in the protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

**Progress:** The patient is a 56-year-old female with symptoms consistent with a pheochromocytoma. Her internist became concerned about this possibility in light of fluctuating blood pressures and the difficulty she was having controlling patient's blood pressure. Tests were performed that showed an elevation of the 24-hour urine catecholamines to 292 with normal being less than 108. The patient also had performed a clonidine suppression test which demonstrated an elevated and flat norepinephrine level. Because of a normal CT scan of the adrenals, an MIBG scan was performed to, hopefully, localize a pheochromocytoma. The MIBG scan was performed and showed a possible area of increased uptake under the left lobe of the liver.

Unfortunately, the patient had to leave the area. The results of the MIBG scan were given to the patient and the patient was advised to seek followup with an endocrinologist at her new location. A summary note was also given to the patient which outlines both the findings on the MIBG scan and some of the concerns of the doctor's caring for the patient while here at Beaumont.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/09

STATUS: Completed

TITLE: Sensitivity of Rapid Streptococcal Antigen Detection Versus Throat Cultures

START DATE: Dec 1987

ESTIMATED COMPLETION DATE: Jan 1988

PRINCIPAL INVESTIGATOR: CPT Scot M. Lewey

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: C.B. White, M. Lieberman, E. Morales

KEY WORDS: Rapid strep testing

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**Study Objective:** To study the accuracy of a commercially available rapid streptococcal antigen detection (RSAD) test compared to the throat culture in diagnosing Group A Beta hemolytic streptococcal (GABHS) tonsillopharyngitis.

**Technical Approach:** Three hundred subjects with clinical symptoms and signs suggestive of Group A Streptococcal pharyngitis will have their throats swabbed using Culturette II prepackaged double swabs. Throat swabs will be performed by a limited number of health care providers instructed in the proper sampling technique to ensure maximal yield and reproducibility. Each subject will have their tonsillopharyngeal tissue swabbed twice using the Culturette II. This will provide four swabs for each subject. A RSAD test will be performed on one of the swabs from the first Culturette II. This will be used by the physician caring for the subject to base decision on treatment. The second swab will be cultured overnight on selective streptococcal media (5% sheep blood agar with trimethoprim/sulfamethoxazole at 37 degrees centigrade in 5% CO<sub>2</sub>). The second Culturette II will be coded using a code known only to the principal investigator. One of the swabs will undergo a second RSAD test and one will be sent for culture on selective streptococcal media as described above. These second swabs will be blinded to the technicians performing RSAD test and the microbiologic culture, in regard to patient's identity and the other results. This will generate two RSAD results and two throat culture results for each subject. These results will be analyzed and compared. Specifically, a comparison of concordance between a RSAD test and a second RSAD test, two RSAD tests and two throat cultures, and a throat culture to a second throat culture.

**Progress:** Study results accepted for publication in Pediatric Infectious Disease Journal.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 84/15

STATUS: Completed

TITLE: Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for Remission Induction Therapy SWOG 8229/30

START DATE: Oct 1982

ESTIMATED COMPLETION DATE: Mar 1987

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Multiple Myeloma

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Study Objective: Comparison of 2 different methods of giving the 6 best chemotherapy drugs that fight cancer.

Technical Approach: The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress: Five patients were placed on this protocol. Two patients are deceased, and three patients are still alive and on chemotherapy

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 84/35

STATUS: Ongoing

TITLE: Adjuvant Chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma (SWOG 7804) (Monitor: LTC L. Sanders)

START DATE: Mar 1978

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Adenocarcinoma

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Study Objective: To determine the efficacy of adjuvant chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TNM stage-groups IB, IC, II and III gastric adenocarcinoma compared to potentially curative surgery alone.

Technical Approach: The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress: No patients have entered this protocol.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 84/36

STATUS: Terminated

TITLE: Trial of chlorozotocin and 5-FU in Metastatic Islet Cell Carcinoma (SWOG 8208)

START DATE: Dec 1982

ESTIMATED COMPLETION DATE: Dec 1987

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Carcinoma

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Study Objective: To study the response of functioning and nonfunctioning Islet Cell carcinoma chlorozotocin (CTZ) and 5-fluorouracil (5-FU). To determine the toxicity of 5-FU and CTZ when given in combination.

Technical Approach: The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress: No patients have been entered into the protocol.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 84/38

STATUS: Completed

TITLE: Combined Modality Therapy for Breast Carcinoma (SWOG 7827)

START DATE: Jul 1979

ESTIMATED COMPLETION DATE: Mar 1984

PRINCIPAL INVESTIGATOR: COL Ray O.  
Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Carcinoma

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**Study Objective:** To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus combination chemotherapy and oophorectomy.

To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, for combination chemotherapy plus tamoxifen, tamoxifen alone, and combination chemotherapy alone.

To compare the disease-free interval and recurrence rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy.

To compare the effect of these various adjunctive therapy programs upon the survival patterns of such patients.

To correlate the ER status with disease-free interval and survival.

**Technical Approach:** The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

**Progress:** One patient has been entered into the study; is still alive and well.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 85/07

STATUS: Ongoing

TITLE. Treatment of Limited Non-Small Cell Lung Ca Radiation vs Radiation & Chemotherapy (SWOG 8300) (Monitor: LTC L. Sanders)

START DATE: Jul 1984

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Lung Carcinoma

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**Study Objective:** To compare combination chemotherapy (FOMi/CAP: 5-Fluorouracil, Vincristine and Mitomycin-C alternating with Cyclophosphamide, Adriamycin and Cis-platinum) plus radiotherapy to radiotherapy alone for patients with limited, non-small cell lung cancer (NSCLC) in a randomized study with stratification for known important prognostic factors with regard to response rate, response duration and survival duration. To determine the toxicity of radiotherapy plus FOMi/CAP relative to radiotherapy alone for patients with limited NSCLC. To evaluate the responsiveness of smaller tumor burdens to FOMi/CAP (i.e., less than metastatic disease). To determine the pattern of relapsing disease in each treatment arm and in subgroups of patients determined by histology and response to FOMi/CAP. To determine if prophylactic brain irradiation will decrease the chances for brain metastases and influence toxicity of survival.

**Technical Approach:** The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

**Progress:** One patient was entered into this protocol. That patient is now deceased.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 85/10

STATUS: Ongoing

TITLE: Evaluation of Tamoxifen in Unresectable and Refractory Meningioma (SWOG 8415)  
(Monitor: LTC L. Sanders).

START DATE: Jul 1984

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Meningioma

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Study Objective: To determine the antitumor activity of Tamoxifen in meningiomas not amenable to surgery or radiotherapy. To estimate the response rate and response duration experienced by these patients.

Technical Approach: The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress: No patients have entered study.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 85/20

STATUS: Terminated

TITLE: Evaluation of Adjuvant Therapy & Biological Parameters in Node Negative Operable Female Breast Ca, Intergroup Study

START DATE: Dec 1982

ESTIMATED COMPLETION DATE: May 1987

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Breast Carcinoma

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Study Objective: Assess the impact of short-term intensive chemotherapy with CMPP to prevent disease recurrence and prolong survival in N- patients with any size ER- tumors and N- patients with ER+ tumors whose pathological size is greater than or equal to 3 cm. Assess the impact of surgical procedures, ER status, menopausal status, and tumor size. Develop guidelines referable to histopathological features of N- tumors which are reproducible and assess their prognostic impact for disease-free survival and survival. Assess the value to CEA in predicting recurrence and survival rates. Assess the natural history of a subgroup with N-, ER+ small tumors.

Technical Approach: The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress: No patients have been entered into this protocol.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/32

STATUS: Ongoing

TITLE: SWOG 8313 Multiple Drug Adjuvant Chemotherapy for Patients with ER Negative Carcinoma of the Breast (Monitor: LTC L. Sanders)

START DATE: Apr 1984

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Breast carcinoma

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Study Objective: To compare the quality of life of patients with operable breast cancer randomized to receive one year of CMFVP or a short intensive regimen of FAC-M x 4 courses. To compare a multiple item questionnaire to a single item questionnaire for assessing quality of life.

Technical Approach: The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress: No patients entered into this protocol.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/40

STATUS: Ongoing

TITLE: SWOG 8590 Effect of combining chemotherapy with Surgery and Radiotherapy for Resectable Squamous Cell Carcinoma of Head and Neck (Monitor: LTC L. Sanders)

START DATE: Feb 1985

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Squamous Cell Carcinoma

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Study Objective: Case identification and data collection.

Technical Approach: The details are lengthy and specified in the SWOG protocol. Duplicates are kept in the Department of Clinical Investigation and are available upon request.

Progress: No patients have been entered into this protocol.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/41

STATUS: Ongoing

TITLE: SWOG 8600 Randomized Investigation of High Dose vs Standard Dose Cytosine Arabinoside with Daunorubicin in Patients with Acute Nonlymphocyte Leukemia (Monitor: LTC L. Sanders)

START DATE: Nov 1986

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Nonlymphocyte leukemia

Study Objective: To compare, among patients with acute nonlymphocytic leukemia, the rate of complete remission produced by induction regimens of either standard dose cytosine arabinoside and daunorubicin or high dose cytosine arabinoside and daunorubicin. To compare the duration of complete remission and of disease-free survival among patients who each receive one of three combinations of induction and consolidation regimens: Standard dose cytosine arabinoside and daunorubicin for both induction and consolidation. Standard dose cytosine arabinoside and daunorubicin for induction followed by high dose cytosine arabinoside and daunorubicin for consolidation. High dose cytosine arabinoside and daunorubicin for both induction and consolidation.

To determine the comparative toxicities of these three programs of induction and consolidation.

To determine the feasibility of implementing a predetermined approach to supportive care within a multi-institutional cooperative group setting for patients receiving intensive chemotherapy for acute nonlymphocytic leukemia.

Technical Approach: The details are lengthy and specified in the SWOG protocol. Duplicates are kept in the Department of Clinical Investigation and are available upon request.

Progress: No patients have been placed on this protocol.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/47

STATUS: Ongoing

TITLE: SWOG 8598 Prospective Trial for Localized Cancer of the Esophagus (Monitor: LTC L. Sanders)

START DATE: Oct 1986

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Cancer, esophagus

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**Study Objective:** Determine the role of chemotherapy for a potentially curable subset of patients with squamous cell cancer of the esophagus. Specifically to determine if the combination of chemotherapy and radiation will add to the overall survival and cure of patients treated with the combination when compared to patients treated by radiation alone. Determine if the patterns of recurrence for patients treated with the combination of chemotherapy and radiation differs from those patients treated with radiation alone.

**Technical Approach:** The details are lengthy and specified in the SWOG protocol. Duplicates are kept in the Department of Clinical Investigation and are available upon request.

**Progress:** No patients have been entered into this protocol.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/48

STATUS: Ongoing

TITLE: SWOG 8691 A Randomized Comparison of Deoxycoformycin vs Alpha Interferon in Previously Treated Patients with Hairy Cell Leukemia (Monitor: LTC L. Sanders)

START DATE: Dec 1986

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Leukemia

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**Study Objective:** Compare deoxycoformycin and alpha-interferon with respect to frequency of response, time to response, and duration of relapse-free survival among unsplenectomized patients with hairy cell leukemia.

Compare deoxycoformycin and alpha-interferon with respect to improvement in specific patient characteristics including hematologic parameters, size of the spleen, performance status, frequency of documented infections, and number of red blood cell and platelet transfusions.

Estimate the rate of response for each treatment when used among patients who have failed to respond to or had unresolvable toxicity from the other treatment.

Determine the impact of a complete versus a partial remission on remission duration and survival.

Compare toxicities of administration of interferon versus deoxycoformycin to patients with hairy cell leukemia.

**Technical Approach:** The details are lengthy and specified in the SWOG protocol. Duplicates are kept in the Department of Clinical Investigation and are available upon request.

**Progress:** No patients have been entered into this protocol.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/74

STATUS: Ongoing

TITLE: SWOG 8693 Adjuvant Therapy of Primary Osteosarcoma: A Phase III Randomized Intergroup Study (Monitor: LTC L. Sanders)

START DATE: Mar 1987

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Osteosarcoma

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Study Objective: Determine whether the intensity of adjuvant chemotherapy affects its success in terms of local recurrence, disease-free survival and overall survival in patients who have primary osteosarcoma of the extremities and who are randomized to either surgery followed by adjuvant chemotherapy with three drugs or surgery followed by adjuvant chemotherapy with six drugs. Determine the influence of clinical prognostic variables on disease outcome. Determine the influence of histopathology on disease outcome. Determine the influence of clinical prognostic variables on disease-free survival and survival after resection of pulmonary metastases in patients who relapse after being treated as above.

Technical Approach: The details are lengthy and specified in the SWOG protocol. Duplicates are kept in the Department of Clinical Investigation and are available upon request.

Progress: No patients have been entered into this protocol.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/75

STATUS: Ongoing

TITLE: SWOG 8694 A Comparison of Pentostatin (NSC-218321) and Alpha-Interferon (NSC-377523) in Splenectomized Patients with Active Hairy Cell Leukemia (Monitor: LTC L. Sanders)

START DATE: Feb 1987

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Hairy Cell Leukemia

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Study Objective: To compare the frequency of response between pentostatin and a-IFN treatment in patients with hairy cell leukemia who following splenectomy manifest active or progressive disease. To compare time to response between these two treatments. To compare the response duration of these two treatments.

To determine whether pentostatin salvages nonresponders to a-IFN treatment and whether a-IFN salvages nonresponders to pentostatin treatment. To compare the toxicity of the two treatments.

Technical Approach: The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress: No patients have been entered into this protocol.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/77

STATUS: Ongoing

TITLE: SWOG 8792 Phase III Study of Alfa-nl (Wellferon) as Adjuvant Treatment for Resectable Renal Cell Carcinoma (Monitor: LTC L. Sanders)

START DATE: Jun 1987

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Ray O. Lundy

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Renal Cell Carcinoma

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Study Objective: To assess in a controlled fashion the effectiveness of interon alfa-nl (Wellferon) as a surgical adjuvant in patients with renal cell carcinoma. Study endpoints will consist of patient survival and time to recurrence.

Technical Approach: The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress: No patients have been entered into this protocol.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/53

STATUS: Ongoing

TITLE: IND - Single Patient Emergency Administration of Dipentum in Patients with Active Ulcerative Colitis Disease for whom Sulfasalazine is Contraindicated (Monitor: COL Burkhalter)

START DATE: Aug 1988

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: MAJ Robert Miller

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: CPT Greg Schlepp, MC

KEY WORDS: Dipentum, ulcerative colitis

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Study Objective: To ascertain the efficacy of Dipentum in the treatment of active ulcerative colitis in emergency instances of individual patients for whom sulfasalazine is contraindicated. To ascertain the potential of Dipentum to produce side effects in such patients.

Technical Approach: The details are lengthy and specified in the Pharmaceutical Companies' protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress: The patient has gained some mild clinical and endoscopic improvement but since she is presently at the lowest dose therapy will be continued at a higher dose. The dosage will be increased until adequate clinical response has occurred or the maximum dose is reached. If the patient has not attained a good clinical response with the maximum dose, therapy will be discontinued.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 83/51

STATUS: Terminated

TITLE: Biodistribution of Tc-99m-Folic Acid in 30 Normal Rabbits

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: MAJ Albert J. Moreno

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: CPT Gene Roth, Ph.D.

KEY WORDS: Tc-99m-Folic Acid

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**Study Objective:** To radiolabel folic acid (pteroylmonoglutamic acid) with Technetium-99m and to characterize the tag using a physical description and chromatographically; to determine qualitatively and quantitatively the biodistribution of Tc-99m-folic acid in health rabbits.

**Technical Approach:** An investigation will be conducted to determine the optimum labeling conditions of Tc-99mfolic acid. The major factors to be considered are pH. Past experience has shown that the percent of tagged material which will pass through a 0.22 u millipore filter is pH dependent. Also, folic acid appears to be labeled at either basic pH's or acidic pH's. Imaging of sheep with the apparent Tc-99mfolate demonstrated different biodistribution depending on whether the folate was labeled basic or acidic. Additionally at more physiologic pH, the Tc-99m-folate compound apparently disassociated. To isolate the tagged material at varying pH, paper chromatography will be used. The isolated material will further be characterized by U-V spectroscopy and the HPLC with the help of a chemist. The specific procedures for tagging Tc-99m as sodium pertechnetate to folic acid uses a modified stannous chloride method. After a satisfactory radiolabeled folate is achieved, biodistribution studies will be performed using a rabbit model.

**Progress:** This project requires more resources than are currently available.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/34

STATUS: Ongoing

TITLE: The Effects of Verapamil and Diltiazem on Gastric Emptying

START DATE: Dec 1987

ESTIMATED COMPLETION DATE: May 1989

PRINCIPAL INVESTIGATOR: MAJ Albert J. Moreno

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: LTC Morakinyo A. Oyewole Toney

KEY WORDS: Gastric Emptying

**Study Objective:** Calcium channel blockers are currently indicated in the treatment of several medical problems. Data on the effects of calcium channel blockers on gastric emptying currently is sparse, but potentially important. This study is to determine the effects of verapamil and diltiazem on gastric emptying in normal human volunteers.

**Technical Approach:** Selection of patients: Twenty healthy (10 male, 10 female) nonpregnant volunteers with an age range of 21-40 will be studied. Patients with any underlying medical problem, on any medication, with a known allergy history to verapamil or diltiazem, or with an abnormal gastric emptying study will be excluded from the study. Patients will also need a normal physical examination, vital signs, EKG, and SMA-20 prior to entering the study. A BHCG will be drawn on all female patients.

**Radiation doses:** Each patient will have three studies. Each study consists of 1 mCi Tc-99m SCOL and 250 uCi of In-111 DTPA. The target organs for the Tc-99m SCOL and the In-111 DTPA will be the stomach and colon. The stomach may receive approximately 340 m/rad from Tc-99m SCOL. The distal bowel may receive up to 650 m/rads from the In-111 DTPA. These are acceptable levels of radiation exposure.

Patients presenting to the Gastroenterology Service, WBAMC, will be invited to participate in the study. They will be assigned a number for identification purposes. Each subject will undergo study with each drug. A daily history and physical exam will be accomplished.

**Gastric emptying:** A modification of the technique prepared by Heading et al. will be used. Both solid and liquid phases will be studied. The solid phase will be a standard meal of beef stew impregnated with 1 mCi of 99mTechnetium labeled sulfur colloid. The liquid phase will be 150cc of water combined with 250 uCi of 111Indium labeled diethylene-triamine-pentaacetic acid (111In-DTPA). The time of ingestion of the meal is defined as the midpoint in the period of ingestion. Initial scanning is done every 15 minutes (60 sec images) for a total of three hours. During scanning the patient will be supine, but at all other times they will be seated in a chair.

**Methods:** Baseline scan: Day 1. If this is abnormal (40% retention at three hours), the patient will be excluded.

**Scan 2:** Patients on verapamil for three days or diltiazem for one dose. Last dose of the medication will be 30 minutes prior to scanning. The patient will have nothing by mouth after midnight except for medications. The patients will be randomized to receive verapamil or diltiazem first. There will be a one-week minimum of time off the initial medication prior to starting the second medication. A plasma concentration of the drug will be drawn prior to the gastric emptying study.

**Scan 3:** The patient will receive the second drug in the same format. The patient will be

examined daily by an associate investigator during the investigational period.

Statistical analysis: Student t-test

Medications: Verapamil: Dosage schedule will be 80mg by mouth every six hours. The mean elimination half-life in single dose studies ranged from 2.8 to 7.4 hours. After continuous dosing (every six hours for ten doses) the half life increases to 4.5 to 12.0 hours. Therefore, the drug will be administered for three days prior to testing. The last dose will be 30 minutes prior to testing.

Potential side effects: Cardiovascular: Hypotension - 2.9%, peripheral edema - 1.7%, AV block - 0.8%, bradycardia - 1.1%, CHF or pulmonary edema - 0.9%.

Central nervous system: Dizziness - 3.6%, headache - 1.8%, fatigue - 1.1%.

Gastrointestinal: Constipation - 6.3%, nausea - 1.6%.

Side-effects with less than 0.5% incidence and where a causal relationship is not certain: confusion, paresthesia, insomnia, somnolence, equilibrium disorders, blurred vision, syncope, muscle cramps, shakiness, claudication, hair loss, macular eruptions and spotty menstruation.

Diltiazem: Dosage schedule will be 60mg by mouth 30 minutes prior to the test. The plasma elimination half life is 3.5 hours whether single or multiple administrations are used; therefore, a single dose is sufficient.

Progress: Currently acquiring data from volunteers.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/22

STATUS: Terminated

TITLE: Fecal Odorgrams in Crohns Disease

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: MAJ Alan Parker

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS:

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Study Objective: To evaluate odorgrams of patients who have Crohns disease in search of a specific pattern which may be helpful in making a noninvasive diagnosis.

Technical Approach: Clinical patients with known Crohns disease will be asked to submit stool specimens in containers not containing preservative. Other specimens will be collected from normal subjects and from patients with other bowel diseases. The air contained above the samples will be aspirated and injected into the gas chromatograph. The resulting graphs will be searched for the presence of a spike in Crohns disease not found in the other samples.

The number of specimens tested will be decided after seeing the feasibility of finding specific odors on initial specimens.

Progress: The project was terminated due to being too cumberson.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/40

STATUS: Ongoing

TITLE: IND Janssen Pharmaceutica # R51,619 - Use of IND Cisapride (Monitor: COL Burkhalter)

START DATE: Jun 1988

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC Allan Parker

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: CPT Jesus A. Hernandez, MC

KEY WORDS: Cisapride

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**Study Objective:** To determine the effect of cisapride on the symptoms of unexplained upper abdominal pain, nausea, vomiting, early satiety, bloating/distension in patients with gastroparesis and/or gastrointestinal motor dysfunction.

**Technical Approach:** The details are lengthy and specified in the Pharmaceutical Companies' protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

**Progress:** Single patient with diagnosis of idiopathic intestinal pseudobstruction is being treated. Symptom score being followed, patient has had approximately 18 weeks of treatment.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/43

STATUS: Ongoing

TITLE: Effect of Sclerotherapy on Gastric Emptying

START DATE: Apr 1988

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC Allan L. Parker

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Albert Moreno, MD

KEY WORDS: Sclerotherapy, gastric emptying

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**Study Objective:** Sclerotherapy of esophageal varices to control upper gastrointestinal bleeding is now commonly done. This procedure has been shown to cause extensive periesophageal inflammation and eventually fibrosis which may lead to stricture formation. Since the vagus nerves are in this immediate area it is possible that they are injured as a result of the inflammatory response. A readily measurable effect of vagal activity is gastric motility. The objective of this study will be to use gastric emptying time as a measure of vagal integrity in post sclerotherapy patients.

**Technical Approach:** Patients seen in the GI Service for sclerotherapy will be asked to obtain a gastric emptying study (Nuclear Medicine). If agreed the study will be performed in the usual manner. These results will be compared with normal values (standard) as well as with other patients with cirrhosis who have not undergone sclerotherapy. The number of sclerotherapy sessions, amount of sclerosant injected, and time from last therapy will also be studied.

No equipment or special materials will be required above those used normally in the above procedures.

The number of patients to be involved will be approximately 15-20 sclerotherapy patients and as many controls as available up to a comparable number.

The only risks of the study are those associated with a minuscule dose of radiotracer for the gastric emptying study. To date, no adverse effects have been reported with this study and any risks are theoretical only. The expected survival for these patients is less than five years, further minimizing the radiation risk.

**Progress:** Five patient have entered the study so far. More data is need to determine the effect of sclerotherapy on gstric emptying. More patients will be intered into the study.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/23

STATUS: Ongoing

TITLE: Magnetocardiography in the Evaluation of Left Ventricular Hypertrophy

START DATE: Feb 86

ESTIMATED COMPLETION DATE: Sep 89

PRINCIPAL INVESTIGATOR: LTC William Pearl

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Dr. Ho, Dept of Physics, UT El Paso

KEY WORDS: Magnetocardiography

**Study Objective:** Superconducting Quantum Interface Device (SQUID) Magnetocardiography has proven a reliable noninvasive method of studying the human heart. The objective of the present study is to define changes from normal in the magnetocardiogram in left ventricular hypertrophy.

**Technical Approach:** It is anticipated that we will need 12 subjects for the protocol. Eight subjects will have left ventricular hypertrophy as defined by standard electrocardiographic and echocardiographic techniques. Four subjects will be used as controls and will be evaluated as to their normalcy by electrocardiography and echocardiography. The studied subjects will be chosen from the clinic population at WBAMC utilizing a computerized electrocardiography data base as well as the presently developing Cardiology Clinic data base. All studied subjects will have left ventricular hypertrophy on the electrocardiogram as defined by Estes criteria to include ST and T-wave changes giving the so-called "strain pattern". The status of their hypertrophy will be confirmed by echocardiography, which will demonstrate increased wall thickness both in the septum and free wall on M-mode echocardiography. Additionally, the patients will have no evidence of atherosclerotic heart disease or specifically previous myocardial infarction. The particular subjects to be studied meeting the above criteria will be chosen because of their willingness to participate in the project after the appropriate informed consent. The actual magnetocardiography will be carried out at the University of Texas El Paso, using the SQUID magnetometer. This technique involves the patient lying supine on a wooden bed directly underneath a superinsulated fiberglass Dewar which contains a liquid helium bath. This bath cools an appropriate coil system to within a few degrees of absolute 0. At this point, resistance approaches 0. The eventually acquired analog data is then transferred to a wave form analyzer which has a capability of signal averaging multiple complexes to produce a wave form free of major artifact. The wave forms are then stored on an appropriate magnetic disc. Records then can be transferred to a second computer and plotted appropriately. The resulting wave form can be analyzed both in terms of time as well as magnitude of the magnetic field. All the techniques listed above to include echocardiography and magnetocardiography are all perfected. The acquired data will be analyzed in terms of comparing the studied subjects to control in terms of their magnetocardiography wave forms. More specifically, the wave forms will be compared in terms of duration, direction, and concordance versus discordance of the QRS and the T wave and magnitude of the deflection of the signal. The echo and electrocardiography will be used to determine a normalcy or left ventricular hypertrophy for the studied subjects. Since echocardiography offers some hope of a quantitative assessment of the left ventricular hypertrophy, it is hoped that we will be able to prepare the degree of magnetocardiography changes to the degree of left ventricular hypertrophy present in the individual patient. It is anticipated that the project will require approximately four months to complete. The status of the patients to be selected will be male with both civilian and military subjects being eligible. All subjects will sign an informed consent for this minimal risk study.

**Progress:** Approximately 30 subjects have been studied so far. Several publications have been generated. We are now in a stage of analyzing the data, but anticipate studying additional subjects in the near future.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/74

STATUS: Ongoing

TITLE: Echocardiographic Standards for Adolescents Based on Tanner Staging

START DATE: Aug 88

ESTIMATED COMPLETION DATE: Sep 89

PRINCIPAL INVESTIGATOR: COL William Pearl

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Dr. Maatinko and Dr. Stafford, Dept of Pediatrics

KEY WORDS: Echocardiography

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**Study Objective:** To establish echocardiographic standard for healthy adolescents based on Tanner staging, which measures biologic age rather than chronologic age. The new standards will allow a more narrow definition of normal.

**Technical Approach:** We propose to obtain an echocardiogram on consenting patients presenting to the Pediatric and Adolescent Clinic for school or sport physicals, between 10 and 17 years of age. Tanner staging will be assessed by examiners, which is part of the normal physical examination. Complete physical examinations will be performed and subjects with evidence of chronic illness or heart or lung disease will be excluded. Furthermore, a questionnaire is to be completed by each subject which elicits additional information on athletic activities and health. The patient will be sent to the Cardiology Clinic upon completion of the physical examination for an echocardiogram to be performed by a trained technician.

Echocardiographic data will be measured by computer analysis and reviewed by a pediatric cardiologist. Measurements will include the thickness of the right free ventricular wall, interventricular septum, left ventricular free wall, aortic root, left atrium, aortic valve opening, and each of the identifiable portions of the mitral valve motion. From the data collected, mean values and standard deviations will be determined for males and females in each of the five Tanner stages. Additional data to be collected on each subject will include height, weight, race, and body surface area.

**Progress:** 76 subjects have been entered into this protocol. There have been no adverse reactions. There is no other progress to report at this time.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/53

STATUS: Completed

TITLE: Relationship Between Hiatal Hernia and Esophageal Motility Disorders in Patients without Gastroesophageal Reflux Disease

START DATE: Jul 1987

ESTIMATED COMPLETION DATE: Oct 1988

PRINCIPAL INVESTIGATOR: CPT Luis A. Ramirez

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ German Oliver, MC

KEY WORDS: Gastroesophageal reflux disease

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**Study Objective:** This study has been designed to evaluate the relationship between hiatal hernia and esophageal motility disorders in patients without gastroesophageal disorders.

**Technical Approach:** The records of the patients referred to the Gastroenterology Service at Walter Reed Army Medical Center for esophageal manometry between 1981 and 1986 will be reviewed. The study group will include all patients seen with the following data: sex, barium esophagogram, age, endoscopy, symptoms with duration, pH monitoring, esophageal manometry.

With this information, the relationship between esophageal symptoms, hiatal hernia, gastroesophageal reflux and motility disorders will be evaluated.

Fischer's exact test will be used to compare categorical data for 4 groups. Linear data will be compared using ANOVA.

GROUP A-1: Patients with normal 24-hour pH monitoring, normal manometry with hiatal hernia.

GROUP A-2: Patients with normal 24-hour pH monitoring, normal manometry without hiatal hernia.

GROUP B-1: patients with normal 24-hour pH monitoring, abnormal manometry with hiatal hernia.

GROUP B-2: Patients with normal 24-hour pH monitoring, abnormal manometry without hiatal hernia.

**Progress:** Presented in abstract form at the 17th William Beaumont Symposium in San Francisco, California, October 1988.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/60

STATUS: Completed

TITLE: Comparison Between Laparoscopy, Ultrasonic Localization and Blind Needle Biopsy in the Evaluation of Diffuse and Localized Hepatic Processes

START DATE: Jul 1986

ESTIMATED COMPLETION DATE: Jul 1987

PRINCIPAL INVESTIGATOR: CPT Luis A. Ramirez

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Earl Washington, MC

KEY WORDS: Laparoscope, liver biopsy

Study Objective: Compare the diagnostic value of laparoscopy, ultrasonic guidance and blind needle puncture liver biopsies in the evaluation of both diffuse and localized hepatic processes.

Technical Approach: Records of the patients that underwent liver biopsies at William Beaumont Army Medical Center between 1985 and 1986 will be reviewed. The study group will include all patients with the following data:

Sex

Age

Indications for biopsy (diffuse process vs localized lesion)

Technique used

Adequacy of biopsy in establishing a diagnosis

With this information the relationship between direct vision-guided liver biopsy (laparoscopy), ultrasonic guidance and blind needle puncture liver biopsy will be evaluated for both diffuse and localized hepatic processes.

Linear data will be compared using ANOVA.

GROUP A-1: Patients with diffuse parenchymal process and the biopsy was done under direct vision using laparoscopy.

GROUP A-2: Patients with diffuse parenchymal process and the biopsy was done under direction using ultrasound.

GROUP A-3: Patients with diffuse parenchymal process and the biopsy was done using blind needle puncture.

GROUP B-1: Patients with localized process and the biopsy was done under direct vision using laparoscopy.

GROUP B-2: Patients with localized process and the biopsy was done under direction using ultrasound.

GROUP B-3: Patients with localized process and the biopsy was done using blind needle puncture.

Progress: This project was completed before the principal investigator left the Army. There is no progress available to report.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/07

STATUS: Completed

TITLE: Relationship Between Hiatus Hernia and Esophageal Motility Disorders in Patients with Significant Gastroesophageal Reflux

START DATE: Jul 1987

ESTIMATED COMPLETION DATE: Nov 1987

PRINCIPAL INVESTIGATOR: CPT Luis A. Ramirez

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ German Oliver, MC

KEY WORDS: Gastroesophageal reflux disease

**Study Objective:** This study has been designed to evaluate the relationship between hiatus hernia and esophageal motility disorders in patients with significant gastroesophageal reflux.

**Technical Approach:** The records of the patients referred to the Gastroenterology Service at Walter Reed Army Medical Center for esophageal manometry between 1981 and 1986 will be reviewed. The study group will include all patients seen with the following data:

Sex	Barium esophnagogramosis
Age	Endoscopy
Symptoms with duration	pH monitoring
Esophageal manometry	

With this information, the relationship between esophageal symptoms, hiatal hernia, gastroesophageal reflux and motility disorders will be evaluated.

Fischer's exact test will be used to compare categorical data for 4 groups. Linear data will be compared using ANOVA.

GROUP A-1: Patients with abnormal 24-hour pH monitoring, normal manometry with hiatal hernia.

GROUP A-2: Patients with abnormal 24-hour pH monitoring, normal manometry without hiatal hernia.

GROUP B-1: patients with abnormal 24-hour pH monitoring, abnormal manometry with hiatal hernia.

GROUP B-2: Patients with abnormal 24-hour pH monitoring, abnormal manometry without hiatal hernia.

**Progress:** Abstract printed in May 1988 issue of Gastroenterology.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 85/21

STATUS: Ongoing

TITLE: Treatment of Graves' Ophthalmopathy With Cyclosporin: A Multicenter Study (Sandoz IND 2476') (Monitor: Dr. Amegin)

START DATE: Nov 1985

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: MAJ Leonard Sanders,

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Cyclosporin, Grave's Ophthalmopathy

Study Objective: To assess the efficacy of cyclosporin treatment on the ophthalmopathy of Grave's Disease.

Technical Approach: Approval to undertake this project was first requested at WRAMC with collaborative studies in Endocrinology Services at other MEDCENs on a slightly more limited basis in order to enroll as many patients as possible with this relatively rare problem and attain an earlier completion date. The study will be composed of a random cross-over design comparing Cyclosporin treatment to the most commonly employed current therapy, high dose oral prednisone. Due to the nature of these drugs and their potential side-effects, a double-blind design is not feasible. Since responses tend to be seen rapidly (if they occur at all) with steroids, and the favorable responses to Cyclosporin in the recent reports by both Weetman et al., and Nussenblatt et al., were seen within seven to ten days, we plan to administer each drug for three weeks. Each patient's response to one drug will be compared to their own response to the other drug. A total of 20 patients will be initially evaluated with random alternating allocation to either: Group A (1) Prednisone 40 mg t.i.d. x three weeks, (2) full evaluation of response, and (3) cyclosporin 5-10 mg/kg/day x three weeks; Group B Reverse order of Group A.

Progress: One patient has been treated with Cyclosporin with no problems to report. No new patients have been entered into the study. Although Graves' ophthalmopathy is not uncommon, disease severe enough to enter the study is very uncommon.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/79

STATUS: Terminated

TITLE: Combination Therapy in the Treatment of Severe Reflux Esophagitis

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: CPT Stanley A. Toelle

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ German Oliver, MC

KEY WORDS: Esophagitis

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**Study Objective:** Compare the efficacy of Ranitidine to Ranitidine and Sucralfate in the treatment of esophagitis.

**Technical Approach:** Fifty patients will be randomly assigned by sealed envelopes to one of two equal sized groups. One group will be treated with Ranitidine (150mg PO bid) and Sucralfate suspension (1gm dissolved in 50cc of 5% glycerol in water), 1 gm PO qid PC and HS. The other group will be treated with the same dose of Ranitidine, but no sucralfate. In addition, both groups will use Mylanta II tablets, 1 PO every two hours as needed for pain which they attribute to esophagitis. In addition other Phase I measures will be encouraged, other than use of alginate.

Patients will maintain a log of symptoms, antacid consumption and missed doses of medication. On a daily basis they will record the number of episodes and severity of discomfort from that day they feel discomfort from esophagitis according to a scale. At the end of six weeks of therapy patients will undergo repeat fiberoendoscopy, at which time the severity of esophagitis will be regraded. The physician grading the esophagitis will be blinded to the patient's therapy. At the completion of the study, groups will be compared with regard to endoscopic improvement, symptomatic improvement and antacid consumption.

**Progress:** Project terminated due to principal investigator's relocation from this area.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/24

STATUS: Ongoing

TITLE: The Effect of Relaxation Therapy on Patients with Asthma

START DATE: Jun 87

ESTIMATED COMPLETION DATE: Sep 89

PRINCIPAL INVESTIGATOR: RN Helen Villegas

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: LTC Raghava Charya, MC

KEY WORDS: Asthma

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**Study Objective:** To measure the effects of relaxation therapy on asthma symptoms, frequency of prn medications, and emergency medical care.

**Technical Approach:** Fifty intrinsic asthma patients, 20-40 years of age, followed daily in the Allergy clinic, will be involved in participating in this pilot study for 6 weeks. History and biographical data will confirm the diagnosis of intrinsic asthma. Pulmonary function tests (PFT) will be measured on the first visit. PFT will also be recorded on the second and last visit. Patients will keep an asthma diary which will document daily peak expiratory flow rate, asthma symptoms, assessment of mood and use of prn medications and medical care. After 3 weeks, subjects will return to the Allergy Clinic with their completed diaries. Their PFT will be recorded. They will be instructed in the use of a relaxation tape to use each morning upon awakening and each night after retiring. This relaxation tape will include facial muscle exercises and positive thoughts and imaging. Medical news in the Journal of the Medical Association reported in 1983 that the imagination can be used to relieve asthma symptoms while Connors has concluded that tension changes in the facial musculature reliably influences the PEFR. The patient will be given a new asthma diary to record the next 3 weeks. The hypothesis is that the relaxation therapy component of the patient's multifactorial therapy will improved asthma symptoms and decrease medication intake and the need for emergency medical care.

**Progress:** Six asthma patients, 35-62 years of age, are entered in a 3-month, self-care and relaxation therapy study. Nineteen more patients will be recruited. Data from 25 asthma patients, 35-62 years of age, will be recruited from the self-care component only (asthma diary and Peak Expiratory Flow Rate (PEFR) BID, a standard intervention for asthma patients.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 83/37

STATUS: Ongoing

TITLE: Cardiopulmonary Effects of Stressful Exercise at 4,000 Feet on SCT Individuals

START DATE: Jul 84

ESTIMATED COMPLETION DATE: Oct 90

PRINCIPAL INVESTIGATOR: LTC Idelle M. Weisman

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Sick Cell Trait, Stress

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**Study Objective:** To establish baseline pulmonary function data (spirometry, helium dilution lung volumes, maximum voluntary ventilation L/min (MVV), arterial blood gas analyses (ABG), single breath diffusing capacity DLCO<sub>SB</sub> (ml/min/mmHg) and steady state diffusing capacity DLCO<sub>SS</sub> (ml/min/mmHg) (Fillee technique) as well as values for the partial pressure of oxygen at 50 saturation (mmHg) (P50) in HgbAS individuals and controls and to determine percent HgbS and percent HgbF in individuals heterozygous for sickle cell trait (HgbAS) at 4000 ft.

To carefully document cardiopulmonary response of individuals identified as having hemoglobin AS during both strenuous incremental and submaximal steady-state exercise at altitude with age, race, sex, smoking, matched non-HgbAS controls.

To correlate observed abnormalities (if any) in parameters of cardiopulmonary performance with levels of HgbS in individuals with sickle cell trait (i.e. are patients with 40 percent of HgbS more likely than controls to experience abnormalities during vigorous exercise. Also, to determine whether HgbF levels may be protective as they are in patients with sickle cell disease.

To determine whether conditioning (repeat studies after six weeks) is operative in modulating cardiopulmonary performance in both SCT individuals and controls.

Conclusive data is not anticipated from this protocol, but a preliminary statement or suggestion may be offered on the important question of occupational restriction of subjects with HgbAS. This is in keeping with the National Academy of Science - National Research Council Report of 1973.

**Technical Approach:** The details are lengthy and specified in the protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

**Progress:** Three major publications have resulted from this study. There have been no complications seen thus far.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/25

STATUS: Ongoing

TITLE: Axillary Venous Sickling in Individuals with Sickle Cell Trait During Upper Extremity Exercise in a Hypoxic Environment (Monitor: Dr. Levey)

START DATE: Mar 87

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC Idelle M. Weisman

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Dr. Jorge Zeballos

KEY WORDS: Sickling, Armcrank Exercise

Study Objective: To determine the relationship between cardiopulmonary performance, blood gas and the degree of sickling in individuals with sickle cell trait during progressive armcrank exercise. To characterize the cardiopulmonary performance of individuals with sickle cell trait during progressive upper extremity exercise. To determine the effects of armcrank exercise on blood gases in individuals with sickle cell trait. To study the effects of environmental hypoxia on upper extremity exercise performance and venous blood gases at 1270 meters and during exposure to inspiratory hypoxia equivalent to 4000 meters on upper extremity exercise performance, venous blood gases and percent sickling.

Technical Approach: We anticipate using fifteen SCT individuals and a similar number of controls. Subjects will be 18 to 28 years of age and have less than a three-pack year smoking history. Volunteers will be obtained from the basic training reception station, similar to previous studies. Recruits are screened for SCT with a sickledex test and positive results are confirmed by hemoglobin electrophoresis.

Upon our request, in-processing NCOs will assemble groups of black trainees with either SCI or normal hemoglobin. We prefer to speak to the groups separately because individuals with SCT tend to have more concerns regarding their status. The trainees will be informed that a group of researchers need volunteers for an exercise study involving SCT. Previously, the reception station NCOs have vouched for our credibility, but otherwise have not encouraged the trainees to volunteer. In fact, many of the reception station NCOs would prefer the trainees did not volunteer, because of the extra administrative work it entails; i.e., transportation and personnel accounting.

After the NCO leaves, a member of our group will explain the project's purpose, risks, and benefits. After all questions have been answered, we will ask for volunteers. In the past, 10-20 of controls and 30-50 of SCTs have volunteered to participate. We will attempt to match an SCT volunteer with a control of similar body habitus for each experiment. The two volunteers will then be transported to the SCT lab.

Upon arrival, the subjects will read the volunteer agreement and ask any remaining questions. We will explain that they may withdraw from the study at any time without penalty. If the volunteer withdraws, he will be transported back to his original unit. The NCO will not be informed of the circumstances surrounding the trainee's return. Usually, within hours, the former volunteer and the rest of his unit is transferred to a training battalion and a new NCO.

After obtaining informed consent, documented in writing, we will examine each volunteer and obtain a medical history. If the subject has no contraindication to exercise, he will be accepted into the study.

A 20-gauge catheter will be inserted into a median cubital vein and advanced proximally. The insertion length will be equivalent to the distance between the subject's median epicondyle and the

apex of his axilla. If an Allen's test reveals a palmar blush within five seconds, a second 20-gauge catheter will be inserted into a radial artery. Using this technique in over 100 catheter insertions, we have had no ischemic complications and all volunteers have successfully completed basic training. Approximately 50% of subjects have experienced minor wrist discomfort which typically resolved within 24 hours without sequelae. No other complications have occurred.

Exercise will be performed on a cycle ergometer, modified for armcranking and mounted on a steel frame. After the subject is familiar with the apparatus, he will perform two 35-watt incremental armcrank tests to exhaustion. Interval length will be two minutes and the anticipated duration of the test is 10 minutes. Both tests will be performed on the same day, one on room air (FI02 21%) and another on 14% FI02. The order of the tests will be varied and the subject will equilibrate, by mask, for 30 minutes on 14% FI02 prior to that test.

Exercise performance will be monitored with an ECG, mass spectrometer, and pneumotachograph interfaced with a computer system. Simultaneous blood samples will be drawn from each catheter pre- and post-exercise, and during the intervals corresponding to 0, 70, 140 watt and/or peak exercise. The following parameters will be analyzed: VD/VT and P(A-a)02, V02, VC02, VE, MR, VT, V02/kg, PO2, PC02, pH, %02 sat, % sickling, 02 content. Percent sickling will be determined on all SCT samples and on an occasional control sample.

An ACLS-qualified physician will monitor patient appearance and heart rhythm during the test. Testing will be interrupted if the patient experiences significant discomfort or if a dysrhythmia is noted. A crash cart and defibrillator will be available at all times. In over 100 prior cycle exercise tests we have had no significant complications.

We anticipate the catheters will be in place for six to eight hours. After the tests are completed, the catheters will be removed immediately and direct pressure will be placed on the wound. A vascular surgery consult will be obtained if the patient develops signs of ischemia.

Statistical analysis, using SPSS Student's t-test and ANOVA for repeated measures, will be used where appropriate.

Progress: 28 subjects have been studied so far. There have been no complications.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/05

STATUS: Ongoing

TITLE: IND Janssen Pharmaceutica # R51,211 Treatment of Systemic Mycoses with Itraconazole

START DATE: Nov 87

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC Idelle Weisman

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Itraconazole, Systemic mycoses

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Study Objective: To assess the efficacy of Itraconazole therapy in fungal dissemination disease.

Technical Approach: The details are lengthy and specified in the Pharmaceutical Companies' protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress: The patient on this study is doing very well clinically, with improvement since starting this drug. No unexpected drug effects noted to date.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/38

STATUS: Ongoing

TITLE: Comparison of Physiologic Responses to Prolonged Exercise Simulating Army Field Training in Sickle Cell Trait and Controls (Phase IVa)

START DATE: Indefinite

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC Idelle M. Weisman

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: R.J. Zeballos, M.D.; COL John Little, ADA; T.W. Martin, CPT, MC

KEY WORDS: Sickle Cell Trait

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### Study Objective:

1. To determine if submaximal (50-70%  $\text{VO}_2$  max) prolonged treadmill exercise (1 hour 30 minutes) with a final maximum exercise (5 minutes), similar to Army field training conditions, would elicit differences in exercise performance between Sickle Cell Trait (SCT) and control volunteers.

2. To evaluate changes in Percent Sickling (%S) and blood viscosity with prolonged exercise in SCT volunteers and to analyze their relationship to venous oxygen saturation, hydration status and temperature.

3. To assess biochemical and enzymatic changes in blood and urine that would suggest muscle damage (rhabdomyolysis) during prolonged exercise.

4. To compare the effect of prolonged exercise on renal function in SCT and controls.

5. To determine whether subtle pulmonary microcirculatory abnormalities not present at rest would be detected during exercise in SCT compared to controls.

Technical Approach: The details are lengthy and specified in the protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress: Awaiting FY89 funding allotments prior to initiating this project. Principal investigator is prepared to initiate project as soon as funding is received.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/62

STATUS: Ongoing

TITLE: Armcrank and Cycle Exercise in the Evaluation of Dyspnea

START DATE: Jul 88

ESTIMATED COMPLETION DATE: Dec 89

PRINCIPAL INVESTIGATOR: Dr. Jorge Zeballos

DEPARTMENT: Med

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Armcrank, cycle exercise

Study Objective: Compare the cardiopulmonary response to armcrank and cycle exercise in subjects with dyspnea on exertion.

Technical Approach: We will use 20 male or female patients, 18-65 years old, referred to the pulmonary department for evaluation of dyspnea on exertion. These patients routinely undergo cycle exercise testing with an arterial line in place. Subjects will be excluded if they have orthopaedic, neurologic, or vascular abnormalities which limit arm or leg exercise.

Subjects will perform both upper and lower extremity exercise on an electronically braked cycle ergometer. For the upper extremity test, the cycle will be placed on a table so that the crank shaft will be level with the seated patient's shoulders. The order of the tests will vary so that a similar number of subjects begin with either arm or leg exercise. Beginning with no added resistance or 0 watts, the work rate will increase 10-20 W/min until the subject is unable to maintain a 60 rpm crank rate. The test will also be discontinued if the subject has ventricular tachycardia, more than a 20 mm drop in systolic blood pressure, or > 3 mm ST depression.

While exercising, the subjects will breathe through a two-way valve. We will measure respiratory gases at the mouthpiece using a mass spectrometer (Perkin Elmer). Ventilation will be measured with a pneumotachometer (Hans Rudolph). An on-line computer (MGC 2001) will perform breath-by-breath calculation of  $O_2$  uptake ( $VO_2$ ),  $CO_2$  production ( $VCO_2$ ), minute ventilation (VE), and other measurements. We will monitor heart rhythm on an oscilloscope and measure heart rate from a rhythm strip obtained during the last five seconds of each minute.

One hour before the first exercise test, a 20 gauge catheter will be inserted in the patient's radial artery. A 25cm tube with a three-way stopcock will be attached to the catheter to permit anaerobic sampling while the subject exercises. Patency of the catheter and connecting tube will be maintained with a heparin solution (10 USP unit/ml).

We will draw blood samples with the subject at rest and every 2-4 minutes during exercise. We will measure  $PO_2$ ,  $PCO_2$ , and pH with an automated blood gas analyzer (IL System 1303). Hemoglobin saturation and concentration will be measured with a spectrophotometric oximeter (IL 282 CO-Oximeter). The dead space-tidal volume ration and the alveolar-arterial oxygen difference will be calculated using standard equations.

Progress: Twelve patients have been entered into the protocol thus far. There have been no complications noted.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/41

STATUS: Ongoing

TITLE: 25-Hour Prospective Concurrent Acuity Determination vs Unpredicted Patient Acuity Determination on Evening and Night Shifts, Critical Care Areas

START DATE: Nov 88

ESTIMATED COMPLETION DATE: Jul 89

PRINCIPAL INVESTIGATOR: LTC Ruth Cheney

DEPARTMENT: Nsg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Acuity, nursing workload

**Study Objective:** To ascertain whether or not significant nursing workload is lost in critical care areas by categorizing unpredicted patients arriving on the evening and/or the night shifts. The evening and night shifts would complete the patient acuity worksheet only if a new admission or transfer in occurs on their shift; or, in the case of the night shift, to further capture the direct nursing care requirements of a patient received on the evening shift. Data obtained will be analyzed to determine if workload lost is significant enough to negatively affect the manpower requirements of the specific unit.

**Technical Approach:** The patient acuity worksheet will continue to be filled out, and data entered into UCAPERs, on a prospective concurrent basis. There will be no change to this aspect of the existing system. Data required by OTSG and HSC will continue to be generated and be available in accordance with OTSG, HSC, and WMSN instructions.

The study design requires the patient acuity worksheet also be filled out by the ANC/RN on both the evening and night shift, with these two shifts reflecting only their unanticipated workload created by the admission of new patients or transfer in of patients another area of the hospital. The study will not address the hours between 1200 and 1500, after acuity has been entered into UCAPERs and prior to the beginning of the evening shift.

The ANCs/RNs responsible for completing the patient acuity worksheet on the evening and night shifts will be trained on the system by the principal investigator in accordance with WMSN guidelines. All nursing personnel are routinely taught to document to support acuity.

At the conclusion of training, a 10-20 day pilot study will be conducted to elicit problem areas, clarify instructions/procedures, and implement corrections/improvements in the study design. (The actual length of the pilot study will be determined by the number of unpredicted patients arriving on the evening and night shifts.) The tools used to elicit problems will be:

- a. communication with the participants in data collection
- b. conduct of inter-rater reliability

Inter-rater reliability will be performed by the principal investigator on a daily basis on each ANC/RN assigned to the evening and night shifts who will be filling out the patient acuity worksheet. All 8 factors will be evaluated on each patient in each unit. An inter-rater reliability score below 80% will determine the need for retraining of the specific individual(s).

Once the principal investigator is confident that data obtained on the evening and night shifts is valid and reliable, a 6-month period of data collection will commence. (Confidence is inherent on inter-rater reliability scores consistently 80% or greater.) During the 6-month study period, inter-rater reliability will be performed by the principal investigator on a monthly basis on ANCs/RNs on the evening and night shifts who are filling out the patient acuity worksheet.

**Progress:** Project will not begin until November 1988.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/94

STATUS: Completed

TITLE: Assessment of Knowledge, Attitudes, and Beliefs of Health Care Providers in Caring for HIV/AIDS Patients

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: LTC Rita Hadersbeck

DEPARTMENT: NSG

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Theresa M. Lindell, R.N.

KEY WORDS: HIV/AIDs, assessment of knowledge

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Study Objective:

- a. To obtain assessment data of knowledge, attitudes, and beliefs of the hospital health care workers in the care of HIV/AIDS patients.
- b. To analyze the assessment data and incorporate the results into a hospital education program on HIV/AIDS (Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome).
- c. To utilize the information obtained from the conclusions of the study into a multi-level HIV/AIDS program for health care workers.
- d. To compare changes in knowledge, beliefs, and feelings of caring for/working with HIV/AIDS program to consist of a didactic and group discussion session.

Technical Approach: General Cameron has been briefed and has endorsed a mandatory HIV/AIDS educational program for all health care workers at WBAMC. A voluntary, anonymous questionnaire adopted by Fred M. Gordin, M.D. and associates will be given to each health care worker with a letter of endorsement from General Cameron. The questionnaire will consist of 22 questions to assess the health care workers' knowledge, beliefs, feelings, and previous exposure to HIV/AIDS patients and potential risk factors; one question with an anxiety rating scale; and eight questions to obtain demographic data information. An explanation on confidentiality and the health care worker's right to participate in the study will be included with the questionnaire. A 90-minute briefing will be scheduled for all health care workers with a multi-level educational program and a multi-disciplinary approach. Scheduling for the education program will be determined by the individual department chiefs, coordinated by the HIV/AIDS Staff Education Logistics Committee. An initial questionnaire will be administered two weeks prior to the implementation of the HIV/AIDS staff education program. A second questionnaire will be given two weeks post training, to determine the effectiveness of the session, and assess changes in knowledge, attitudes, and beliefs of caring for HIV/AIDS patients.

A descriptive statistical analysis will be done on the questionnaire assessment data with a comparison of two questionnaires. A four point scale will be utilized to rank the questions with four being the most correct answer and one being the least correct. Dependent variables will be comprised of assessment data and demographic data. Administrative support will be needed in implementing the first questionnaire determined by the department chiefs prior to the HIV/AIDS educational program.

Progress: The questionnaires were distributed and collected. Data was entered into SPSS/PCT and was reviewed by Mrs. Lindell, associate investigator. Mrs. Lindell has departed the area, and LTC Hadersbeck does not have access to the data.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/18

STATUS: Ongoing

TITLE: Community Health Needs Assessment

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: LTC Rita Hadersbeck

DEPARTMENT: NSG

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Ms. Cheryl Aldridge, MN, RN; Ms. Carin McCoy, RN

### KEY WORDS:

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**Study Objective:** A Community Health Needs Assessment will be utilized to assess the knowledge, attitudes, and beliefs regarding several health related subjects of a sample of the military community that uses Ft. Bliss and WBAMC Services. Future health promotion programs will be developed based in results of the survey.

**Technical Approach:** Surveys will be sent to a random sample of each military beneficiary group represented in the community. Demographic information plus questions addressing attitudes, knowledge, and beliefs will be used in the survey. Participants will be asked to return the surveys in the self-addressed, stamped envelopes that will be provided. Surveys will be sent to approximately 10,000 individuals (10% of the military community) of all ages and will include Department of the Army Civilians (DAC), military (active duty and retired), and dependents. The University of Texas at El Paso (UTEP), College of Nursing and Allied Health, has designed the questionnaire and will analyze the results.

**Progress:** Surveys were distributed and collected by the Community Health Nurse and given to the University of Texas at El Paso for analysis and report. Results have not been received. 2170 subjects were entered into the study.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/54

STATUS: Completed

TITLE: Validation of the Concept of Learned Helplessness in Cancer Patients Receiving Chemotherapy

START DATE: May 1988

ESTIMATED COMPLETION DATE: Jun 1988

PRINCIPAL INVESTIGATOR: RN Rosalinda Kellner

DEPARTMENT: NSG

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Learned helplessness

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**Study Objective:** Validation of the concept by 80% or more patients testing positive for learned helplessness by interview and questionnaire.

**Technical Approach:**

- a. Method: Assess patients by interview and direct observation for signs and symptoms of negative reactions, i.e., nausea and vomiting, weight loss, loss of appetite, depression, etc.
- b. Variables: The Learned Helplessness Scale (Quinless and Nelson, 1988).
- c. Number of subjects: 10 to 15 cancer patients receiving chemotherapy.
- d. Additional support: N.A.
- e. Estimate of time required for experimental phase: 4 days.
- f. Statistical method: Percentage base.

**Progress:** The sample consisted of 12 participants ranging from 34 to 76 years of age. There were 7 males (58%) and 5 females (42%). Of the sample, there were 7 caucasians, 3 hispanics, and 2 blacks. Breast cancer was diagnosed in 80% of the females; and of the males, 57% had cancer originating in the colon.

The majority of the sample, 9 (75%), were initially diagnosed within the last year. chemotherapy began as early as the same month of diagnosis to as late as 4 years after the diagnosis, with 50% receiving chemotherapy within 3 months of diagnosis. Infusion rates of the chemotherapy were from 5 minutes to 5 hours, with most infusing 5 to 10 minutes (67%).

Gastrointestinal disturbances were experienced by 11 (92%) of the sample, with 6 (50%) complaining of varying degrees of nausea and/or vomiting. The females (2) complained of alopecia. Other symptoms assessed were: pain in 5 persons (42%), anxiety in 3 persons (25%), and depression in 3 persons (25%).

Scoring on the Learned Helplessness Scale (LHS) ranged from possible scores of 20 to 80. The higher the score, the higher the degree of learned helplessness. Those scoring 40 or above on the LHS. There appeared to be no correlation between symptoms (pain, anxiety, nausea and vomiting, or depression) and scores on the LHS. The one person who had the longest infusion rate of 5 hours scored the highest on the LHS.

In summary, cancer patients receiving chemotherapy may experience learned helplessness. Further studies involving larger sample size and with more specific data, i.e., cancer patients with metastatic involvement or cancer patients on long chemotherapy infusion rates may validate the concept of learned helplessness.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/48

STATUS: Completed

TITLE: Effects of Non-Gynecological Surgery on the Menstrual Cycle

START DATE: May 88

ESTIMATED COMPLETION DATE: Jul 88

PRINCIPAL INVESTIGATOR: MAJ Diane Kessler

DEPARTMENT: Nsg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Diane T. Dunn, BSN, UTEP

KEY WORDS: Menstrual Cycle, Surgery

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**Study Objective:** The purpose of this replication study will be to answer the following questions:

1. How is menstrual cycle length affected by surgery performed under general anesthesia in adult females?
2. What is the relationship between menstrual cycle phase at the time of surgery and the onset of the first postoperative menses?
3. What is the relationship between the extent to which hospitalization is stressful and postoperative menstrual cycle length alterations?
4. How do women perceive menstrual cycle length alterations following non-gynecological surgery?

**Technical Approach:** Subjects will be first interviewed in the hospital 48-72 hours postoperatively, since it has been noted by the principal investigator and colleagues that unexpected menses can begin on the third postoperative day. The second interview, in approximately 5-6 weeks will be conducted by telephone.

Subjects will complete the Hospital Stress Rating Scale (HSRS) developed by Volicer and Bohannon in 1975. The scale yields a quantitative measure of psychosocial stress related to the experience of hospitalization. The scale was assessed to have both content and concurrent validity. Test-retest reliability was reported as .90. It consists of 49 items that are to be checked by the subjects with mean rank scores given for each item.

The Menstrual cycle Information Questionnaire (MCIA) was developed by McKeever and Galloway (1984) for their original study. The MCIA is a structured interview guide in 3 sections.

1. Section I collects demographic and medical-surgical data from the hospital chart. Since anesthetic time and medications can be predictive of menses onset, this information will also be collected.

2. Section II is designed as a face-to-face interview to obtain menstrual history prior to hospitalization and during present hospitalization. This section will be completed at the first interview.

3. Section III consists of a brief telephone interview at least 5-6 weeks postoperatively to determine menstrual patterns subsequent to the initial interview.

**Progress:** Of the 12 subjects interviewed, 8 consented to be in the study. Four subjects had orthopedic surgery, 2 had plastic surgery, and 2 had abdominal surgery. The median age was 28.5 years.

**Research Question 1:** How is menstrual cycle length affected to surgery performed under general

**anesthesia in adult females?**

The onset of early menses was calculated by subtracting the subject's first postoperative cycle length (in days) from her shortest usual cycle length. Delayed menses were determined by subtracting the subject's longest usual cycle length (in days) from her postoperative cycle length. Normal postoperative menses were those that occurred on the expected date plus or minus the subject's usual cycle length variability. Postoperatively, 87.5% of subjects reported a menstrual cycle length alteration.

**Research Question 2:** What is the relationship between menstrual cycle phase at the time of surgery and the onset of the first operative menses? Data was collected to determine if the menstrual phase at the time of surgery was associated with a particular type of menstrual cycle alteration. The phase - preovulatory, ovulatory, and postovulatory - were determined by reported dates of the last menstrual onset, usual cycle length, and usual cycle variability. No subject was in the ovulatory phase at the time of surgery. A Mann-Whitney U test demonstrated that there was no significant association between the menstrual cycle phase on the operative day, and the type of alteration postoperatively. This finding is tentative, as the cycle phase was grossly assessed, and no hormonal levels were determined.

**Research Question 3:** What is the relationship between the extent to which hospitalization is stressful and postoperative menstrual cycle length alterations? Postoperative cycle lengths and stress scores were compared by first a Kruskal-Wallis one-way ANOVA. Although no significant association, there was a tendency for early or delayed menses associated with stress. Second, a Kendall's Tau C revealed no significant relationship between postoperative cycle patterns and stress scores. However, there was a trend for early, normal, and delayed postoperative menses associated with psychological stress levels.

To determine whether menstrual cycle alterations were associated with specific factors, a Kendall's Tau C was utilized to compare the number of days a cycle was altered, age, and anesthetic time. Negative correlations were found between age - time and age - days. This suggests that the older a subject, the less chance for an alteration in menstrual cycle length. No significant differentiation was found by the length of time spent under anesthetic, and menstrual cycle alterations.

**Research Question 4:** How do women perceive menstrual cycle length alterations following non-gynecological surgery? Early menses proved distressing to 12.5% of the subjects, where as 87.5%, perceived delayed menses as non-threatening. Perhaps this yields some insight as to how women feel about menstruation in the first place!

The findings suggest that the majority of women undergoing non-gynecological surgery may experience a menstrual cycle length alteration postoperatively. It is likely that psychological factors and age are implicated.

Due to the McKeever and Galloway (1984) study, the investigator expected more equal numbers of early and delayed menses. However, with this particular population, more women reported delayed menses. Also, their study revealed that anesthetic time was a factor in differentiating menstrual cycle alterations. However, this small population did not reveal such a finding.

If the study is replicated, a collection of more physiological data such as, hormonal assays could be done. This would allow for a more accurate account of the phases - preovulatory, ovulatory, postovulatory - that each subject was in during the operative day. Also, a comparison group of females have surgery under local anesthesia might clarify what role the physiological stress of general anesthesia plays in cycle length alterations. Although the HSRS seemed appropriate for measuring the stress of hospitalization, another stress-related tool, such as the Holmes and Rahe Social Adjustment Scale could also be administered. This could provide information on the degree of stress a subject is experiencing when admitted to the hospital.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/68

STATUS: Ongoing

TITLE: Perceived Learning Needs and Quality of Life of Patients with Ventricular Arrhythmias

START DATE: Jul 1988

ESTIMATED COMPLETION DATE: Jun 1989

PRINCIPAL INVESTIGATOR: MAJ Diane Kessler

DEPARTMENT: Nsg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Ann E. Sossong, MSN Candidate

KEY WORDS: Arrhythmias, quality of life, knowledge

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### Study Objective:

1. To describe the learning needs of patients with ventricular arrhythmias.
2. To describe what the quality of life is for patients with ventricular arrhythmias.
3. To describe what the relationships are between patient's learning needs and their perceptions of quality of life.

**Technical Approach:** Convenience sample of patients with ventricular dysrhythmias currently attending the cardiac rehabilitation program will be obtained. Criteria: documented ventricular dysrhythmias, with or without current antiarrhythmic therapy; age > 18 years; and consent to participate in the study. We anticipate 15 volunteers.

**Tools:** Learning Needs Assessment Questionnaire, designed by the investigator, which includes sections for demographic information, experience with ventricular dysrhythmias, and a learning needs section. Subjects will be presented with a list of learning needs derived from the literature and asked to indicate the importance of each learning need and then indicate the extent to which they feel that they are knowledgeable about the topic (diet, exercise, medications, smoking, sexual activity, return to work, stressors, denial, and follow-up). Subjects will be asked to place an "X" mark on a linear scale (100mm) to indicate how they feel about each question. 0 = not at all important, to 100mm point - the most important. The score for each question is the number of millimeters from the 'not important' anchor of the scale. Subjects score on an item are determined by measuring from "0" point to the "X" mark. The LNA score equals the total number of millimeters divided by 24, the total number of items.

**Quality of Life Tool** (Padilla, et al., 1983) measures subjects' perceptions of quality of life in 3 groups: general physical condition, normal human activities and personal attitudes related to general quality of life. It is a linear scale which was developed to measure oncology patients' quality of life. However, permission has been granted by the author to establish reliability for use in patients with ventricular dysrhythmias. Scoring will be on a linear scale. Subjects will be asked to place an "X" on the linear scale (100mm) to indicate how they feel about each question presented. The "0" point denotes the poorest quality of life while the end of the scale 100mm point denotes the best quality of life. Subjects score on an item are determined by measuring from "0" point to the "X" mark. The QLI score equals the total number of millimeters divided by 29, the total number of items.

**Reliability Studies:** Items for cancer patients sampled had significant test-retest reliability coefficients of  $r = .60$ ,  $p < .01$ . Since neither tool has reliability data for use with patients with ventricular dysrhythmias, reliability studies will be attempted. Subjects will be asked to complete the 2 tools at the time of interview and then complete the tools again 48 hours later. Correlational tests will be performed to determine test-retest reliability for both LNA and QLI.

Once cardiac rehabilitation patients who meet the criteria agree to participate in the study, interviews will be held for collection of data in the health fitness center or cardiac clinic. Interviews will be conducted, then subjects will be asked to complete the LNA and QLI tools. The investigator will be present to answer questions. At the completion of data collection, subjects will be given another copy of the LNA and QLI and asked to fill out again with 48 hours. A stamped,

self-addressed envelope will be provided for the return questionnaire. Chart reviews will be done after the interviews so as not to bias the investigation.

**Progress:** Nine patients who met the study criteria have been entered into the study. The semi-structured interview, learning needs assessment tool, and modified Padilla Quality of Life tool have been completed by each subject. Each subject also completed the learning Needs Assessment and modified Padilla Quality of Life tool 48 hours after the initial interview and returned the forms to the principal investigator in order to attempt to establish test-retest reliability. No data analysis has been performed on the data collected. We anticipate enrolling another six subjects over the next few months in order to complete the study.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/73

STATUS: Completed

TITLE: The Influence of Home Blood Glucose Monitoring Teaching on the Control of Type II Diabetes Mellitus

START DATE: Sep 87

ESTIMATED COMPLETION DATE: May 88

PRINCIPAL INVESTIGATOR: CPT B. Mulhern

DEPARTMENT: Nsg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Susan D. Plumley, AN

KEY WORDS: Glucose Monitoring

**Study Objective:** Determine if home blood glucose monitoring is a management tool that can be used to improve long-term control of diabetes, as measured by glycosylated hemoglobin levels, in adults with Type II Diabetes Mellitus, not requiring insulin. The research hypothesis is that there is a greater decrease in the glycosylated hemoglobin levels in adults with Type II Diabetes Mellitus who begin and use self-blood glucose monitoring as compared to those who do not.

**Technical Approach:** A quasi-experimental design with a randomized control group, pre-test/post-test method will be used to measure the effects of SBGM on the control of diabetes. Glycosylated hemoglobin levels will be the measure of control used. Each group will have a hemoglobin level drawn before intervention and then two and six months after intervention. The difference in the levels will be calculated and coded appropriately as interval level data. Sixty subjects will be selected and randomly assigned to one of two groups. The control group will receive two pamphlets entitled "Talking About Diabetes" and "Meal Planner". The experimental group will receive the same two pamphlets in addition to a one to two hour teaching session. Written information to reinforce the teaching will be given. Each subject will be asked to test their blood glucose level once each day, alternating between fasting samples and 2-hour postprandial samples. A Chemstrip bG log book will be used to record results. Chemstrip bG Blood Glucose Test Strips and the visual reading method will be used for the SBGM. At the end of the study, a diabetes knowledge survey will be administered to compare knowledge levels. It will be given at the end of the study to avoid any testing effects.

**Progress:** Thirty subjects entered into the project; two withdrew due to lack of interest. No adverse reactions were recorded.

A nonprobability sample of 28 individuals with Type II diabetes mellitus, not requiring insulin and not performing BGSM, was selected from the population of diabetic patients receiving outpatient care in the Adult Medicine Clinic. The outcome variable was glycosylated hemoglobin. The major difference between the experimental and control groups was the addition of the BGSM procedure. Statistical procedures used for data analysis included descriptive statistics, one way analysis of variance, and Pearson Correlation Coefficients. The hypothesis, there is a decrease in the levels of glycosylated hemoglobin in adults with type II diabetes mellitus who begin BGSM as compared to the levels of those who do not, was not supported. No significant difference was found in the glycosylated hemoglobin means between the experimental and control groups ( $p < .05$ ). Glycosylated hemoglobin levels measured at each two month interval differed significantly between males and females ( $p < .05$ ), with the levels found in males being lower than that found in females. In addition, a significant difference was found in the glycosylated hemoglobin mean change between the second and fourth visit when subjects who exercise regularly were compared to those who do not. The subjects who exercise demonstrated a significantly smaller increase in glycosylated hemoglobin level. The findings suggest that daily knowledge of blood glucose level obtained through BGSM does not lead to improvement in the long-term control of glucose levels in the adult with non-insulin dependent diabetes.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/26

STATUS: Terminated

TITLE: The Effects of Pressure on the Maintenance of a Surgical Barrier During Surgery

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: MAJ Jeffrey B. Peterson

DEPARTMENT: Nsg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Surgical barrier

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**Study Objective:** To study the effect that weight and/or pressure has on the surgical barrier qualities of non-woven surgical barrier materials with respect to the transfer of microorganisms through these materials.

**Technical Approach:** This study will be a controlled experimental design utilizing three major variables--time, pressure, and barrier quality materials. Seven surgical barrier quality products identified only by an alphabetical letter designation will be subjected to three varied pressures for four varied time frames. Each material will be tested twelve times.

The pressures are weights of 8 ounces, 5 pounds, and 10 pounds. These weights are representative of the forces placed upon the surgical drapes during a routine surgical procedure. They correspond to the weights of surgical instruments and the weight of personnel leaning on the patient.

The time variable provides a closer approximation of surgical exposure periods and should show a distinct correlation with the bacterial contamination when used with varying degrees of pressure.

Each test (84 plates) will be done in an operating room environment under conditions that replicate surgery.

A sterile plastic based table cover will be aseptically opened. A known dry bacteria will be placed on the table cover; this will then be covered by the test material, then the specific weight.

The barrier material, a 4 inch circle, will be obtained from a larger sterile product. The test weights will be steam sterilized prior to use and terminally, to eliminate cross-contamination. After the appropriate time the weight will be removed and cultured onto the appropriate media. All materials, except the bacterial seed, will be sterile and no material except the weights will be reused.

**Progress:** Data collection was not started prior to principal investigator departing this duty station.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/55

STATUS: Completed

TITLE: Effect of Anterior Versus Posterior Placement of Hypothermia Blanket

START DATE: Oct 88

ESTIMATED COMPLETION DATE: Oct 88

PRINCIPAL INVESTIGATOR: MAJ Carol J. Pieniadz

DEPARTMENT: Nsg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: CPT Mary P. Ruppert, AN

KEY WORDS: Hypothermia blanket, placement, temperature

**Study Objective:** To Determine how anterior versus posterior placement of a hypothermia blanket effects body temperature.

**Technical Approach:** The study will use an experimental design. The independent variable is the anterior or posterior placement of the blanket. The dependent variable is the oral body temperature.

Subjects will consist of 16 adult males and females between the ages of 18 and 40.

One thermal unit with 2 blankets and 1 model 600 Diatek Electronic Thermometer will be used. This equipment will be processed through Medical Maintenance to ensure they are functioning correctly.

Instructions to volunteers include directions on dress and other activities which could effect body temperature. A period of 30 minutes is planned to permit preliminary data collection and to allow the subject to rest quietly adjusting to the environment. It has been suggested that prior exposure to hypothermia may effect subsequent responses. To prevent such a response which would bias the study, one half of the subjects will have posterior placement of the blanket on the first day and anterior placement of the blanket on the second day. One half of the subjects will have reverse placement. Subjects will blindly select their sequence. A minimum of 24 hours is planned between first and second cooling sessions. Following collection of preliminary demographic data and a waiting period of 30 minutes, the procedure sequence is as follows:

Subject's temperature, blood pressure, pulse and respiratory rate are taken. Subject will be placed immediately upon the cooling blanket. The hypothermia blankets will be turned on at 40 degrees fahrenheit for 15 minutes prior to use. Subject will be instructed to lie flat in order to maintain maximum body surface contact with the thermal blanket. The same digital thermometer will be used to take oral temperatures every 10 minutes. Pulse, blood pressure, and respiratory rates will also be monitored every 10 minutes. Subjects will remain on the thermal units for a total of 40 minutes. Temperatures will not be allowed to go below 35 degrees centigrade orally. A television set or radio will be provided to relieve boredom. Temperature, blood pressure, pulse and respiratory rate will be taken 10 minutes after removal from hypothermia and every 10 minutes until stable if necessary. Subjects will be asked to return the following day for reverse placement of the hypothermia blanket. Methodology will remain the same for each session with the exception of placement of the cotton blanket. When the hypothermia blanket is placed posteriorly, a thin cotton bath blanket will be placed over the thermal blanket and the subject lies on the cotton blanket. When the hypothermia blanket is positioned anteriorly, the cotton bath blanket is placed over the subject followed by the thermal blanket.

**Progress:** No statistically significant difference in temperature change over 40 minutes of cooling based on blanket placement. Posterior blanket placement produced statistically significant increase in respirations over time.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/45

STATUS: Completed

TITLE: The Effects of Touch on Perceived Anxiety and the Physiological Parameters of Stress Among Hospitalized Older Adult Hypertensive Patients

START DATE: Apr 1988

ESTIMATED COMPLETION DATE: Spring 1989

PRINCIPAL INVESTIGATOR: LTC Darlene Reimers

DEPARTMENT: NSG

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS:

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**Study Objective:** To determine if a relationship exists between touch, operationally defined as a backrub, perceived anxiety and the physiologic stress level. Perceived anxiety will be measured by the A-State Anxiety Inventory and changes in the physiologic stress level will be measured by changes in blood pressure and pulse of hospitalized older adult hypertensive patients. The goal is to affirm that touch can be utilized as a therapeutic adjunct therapy in nursing and validate its effect on physiologic stress and/or perceived anxiety of hospitalized hypertensive patients.

**Technical Approach:** A quasi-experimental design will be utilized to establish 3 groups, a control, a placebo, and a experimental group. A pilot study will be conducted initially with a total of 3 to 9 subjects per group. The formal sample will be composed of a random selection of minimum of 15 to 30 subjects in each of the 3 groups (total of 45-90 patients). Subjects will be selected from those patients admitted to one of the 3 general medicine nursing units in this Army Medical Center.

**Sample Selection Criteria:** Age - between 50-70 years old. Gender - either male or female. Diagnosis - hypertension listed as primary or secondary diagnosis; usually on medication for hypertension. Must be able to hear, speak and write. Must be able to comprehend instructions in English. Neither neurological or sensory deprivation noted in the history or physical. Subjects agree to participate in the study.

The independent variable is touch which if present is administered as a backrub using a prescribed procedure, and if absent, is no touch. The dependent variables consist of one, physiologic parameters of blood pressure and pulse obtained by a digital sphygmomanometer, and secondly, the anxiety level as measured by the A-State and A-Trait Anxiety Inventory by Spielberger, Gorsuch, and Lushene (1979).

Upon selection, subjects will be randomly assigned to 1 of 3 groups. The subject's demographic data will be obtained using a short data form. On the initial visit the purpose of the study will be explained and written approval obtained from each subject. The research will be conducted during the evening hours between 7:00 PM to 10:00 PM, as these hours are normally reserved for PM care.

On the second visit, the experimental, control or placebo group procedures will be conducted. Each subject will be asked to complete the A-Trait and A-State Anxiety Inventory by Spielberger as a pre-test within 5 minutes of entering the room. The A-State Anxiety Inventory will be administered as a post-test within 5 minutes of completing the experimental, control or placebo procedures.

The physiologic parameters of blood pressure and pulse will be obtained within 5 minutes of entering the room and again within 5 minutes of completing the respective procedures. The blood pressure will be obtained using a portable digital sphygmomanometer which is calibrated with a dynamap manometer.

The experimental group will be given a backrub for approximately 10 minutes, using the established protocol. The pre and post test and the physiological parameters will be obtained as previously described.

The control group will be asked to complete the pre and post test and have their blood pressure and pulse obtained as outlined above. Routine PM care will be administered by the

researcher, except for the exclusion of the backrub.

The placebo group will follow the same procedure as the other two groups except that no physical care other than obtaining the physiological measurements will be administered by the researcher. The patient and researcher will talk on any subject for a period of approximately 10 minutes. Then the room will be straightened before leaving.

Progress: Pilot study indicated a tendency toward a correlation between touch (backrub) and a reduction in the A-State Anxiety Inventory and a drop in the systolic blood pressure. Results warrant further collection of data.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/43

STATUS: Terminated

TITLE: The Effects of the Admission Interview on Psychiatric Patients' Anxiety

START DATE: Apr 87

ESTIMATED COMPLETION DATE: Oct 87

PRINCIPAL INVESTIGATOR: CPT B.J. Thomas

DEPARTMENT: Nsg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Anxiety

**Study Objective:** This study will be a measurement of the anxiety level of the new psychiatric patient on admission and after the intake interview with the nurse. It is expected that the anxiety level of the patient will drop significantly at the .05 level at the second measurement. The anxiety of both the control group and the experimental group is expected to be significantly lower at the .05 level.

**Technical Approach:** The normal admitting procedure will be followed during this study (Ward 11E SOP, 1986). In addition, the patients will be administered the Spielburger STAI and the Rotter I-E scale (Rotter, 1966) in conjunction with the initial vital signs. The patient will then be strip searched and dressed in hospital pajamas per Ward 11E SOP (1986). The vital signs will be taken for a second time to eliminate what the nursing tech has done as a confounding variable. The patients will be randomly divided into a control group and an experimental group using a random numbers list. The experimental group will be divided into internal and external groups using the results of the Rotter I-E scale. Patients with an 8 or below will be internal and patients with a 9 or above will be external for the pilot study. The patient in the internal group will be given information during the initial interview with the nurse and the external group will be given directions. The control group will be treated as the nurse would normally. The Spielburger STAI will be readministered and the patient's vital signs retaken at the end of the intake interview with the patient. This will end the study for the patient. The patient will be integrated into the Ward 11E milieu per SOPs.

The Spielburger STAI will be used in conjunction with vital signs to determine anxiety level. The Rotter I-E scale will be used to place the experimental group into internal or external groups.

It is anticipated that 90 subjects will be needed for this study. Thirty for the control group, 30 for the external group, and 30 for the internal group. The control and experimental groups will be picked randomly. Patients under the influence of alcohol and/or drugs will be eliminated from the study. Patients deemed out of touch with reality and unable to complete the two tests without increasing anxiety unduly will not be tested. All other military patients who sign the consent will be included in the study.

**Progress:** The study was terminated after completion of the pilot study due to unavoidable difficulties with the study design.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/08

STATUS: Ongoing

TITLE: OB-GYN Bowel Training Utilizing the Pig Model

START DATE: Nov 85

ESTIMATED COMPLETION DATE: Open-ended

PRINCIPAL INVESTIGATOR: CPT P. Hill

DEPARTMENT: OB

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Carla Hawley-Bowland, MC

KEY WORDS: OB-GYN Training

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Study Objective: This training is designed to teach physicians the basic knowledge and operative skills required to perform basic small and large bowel surgery.

Technical Approach: Through a midline incision in the abdomen, the abdominal cavity will be opened and explored. Small bowel lacerations and anastomosis procedures will be performed as outlined in the surgical texts. Procedures will be performed every 3 weeks and at the time of the third procedure, a colostomy procedure will be performed as outlined in texts.

Progress: Training procedures are being performed weekly. No issues to report.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/64

STATUS: On-going

TITLE: Genitourinary Tract Surgery Training Utilizing a Pig Model and Comparing Stenting Technique

START DATE: Oct 86

ESTIMATED COMPLETION DATE: Open-ended

PRINCIPAL INVESTIGATOR: MAJ Pamela S. Hill

DEPARTMENT: OB-GYN

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Carla Hawley-Bowland, MC

KEY WORDS: Surgical Training

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Study Objective: The training is designed to teach resident physicians the basic knowledge and operative skills required to perform genitourinary surgery while simultaneously evaluating the need for ureteral stenting following the operative procedures.

Technical Approach: This laboratory exercise will concentrate on developing the surgeon's confidence in recognizing genitourinary injuries and repairing ureteric or urinary bladder injuries, as well as increasing surgical accumen in handling the GU tract during standard gynecologic procedures.

Progress: Training procedures are performed weekly. Only 2 major procedures are being performed on each animal. No issues to report.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/13

STATUS: Ongoing

TITLE: Accuracy of Transvaginal Ultrasound in the Diagnosis of Ectopic Pregnancy

START DATE: Jan 88

ESTIMATED COMPLETION DATE: Jul 89

PRINCIPAL INVESTIGATOR: CPT Vincent Lyons

DEPARTMENT: OB-GYN

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

MAJ Andrew W. Robertson; MAJ George G.

SanMiguel; CPT Philip

CPT Vincent Lyons; LTC Marcia Kossman; LTC James Brown

KEY WORDS: Ectopic pregnancy, transvaginal ultrasonography

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**Study Objective:** To compare the predictive accuracy of transvaginal sonography to transabdominal sonography in the diagnostic evaluation of patients with suspected ectopic pregnancies.

**Technical Approach:** One hundred unselected stable patients undergoing diagnostic work-up for a suspected ectopic pregnancy will be recruited to voluntarily participate in the study. Once enlisted in the study, they will receive a transvaginal sonogram utilizing a technique described by Brown, et al. in the antepartum diagnostic center. All transvaginal sonography will be performed by the attending or resident staff using an ultramark four ultrasound machine. A 3.5 MHZ end fire sector transducer covered with an aquasonic gel filled glove will be used. The information obtained will be retained in the ADC and blinded to the physicians who will then perform the standard diagnostic work-up. Once the patient's care is completed, her hospital chart will be reviewed for the information listed on the attached data collection record.

A Fisher exact test with a P of .05 will be used to compare the accuracy of the T/V to the T/A technique for predicting the presence or absence of an ectopic pregnancy.

**Progress:** To date 30 patients have entered this project. 75-100 more patients will be need to complete this study.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/33

STATUS: Ongoing

TITLE: OB-Gyn Microsurgical Tubal Re-Anastomosis Training Utilizing A Rabbit Model

START DATE: Mar 86

ESTIMATED COMPLETION DATE: Open-ended

PRINCIPAL INVESTIGATOR: MAJ Allan R. Mayer

DEPARTMENT: OB-Gyn

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: LTC Cesar Rosa, MC

KEY WORDS: Tubal Re-anastomosis

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Study Objective: To teach resident physicians the basic knowledge and operative skills required to perform microscopic tubal surgery.

Technical Approach: This laboratory exercise will concentrate on developing the surgeon's confidence in utilizing the operating microscope and microsurgical instruments as well as planning and accomplishing the operative procedures.

Progress: Training procedures are being performed on a rotating basis. No issues to note.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/65

STATUS: Ongoing

TITLE: The Antepartum Diagnostic Center (ADA): Its Development and Implementation

START DATE: Jan 1987

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: MAJ Andrew Robertson

DEPARTMENT: OB

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: CPT J. Vincent Lyons; COL L.L. Morgenstern; Franz Theard, M.D.

KEY WORDS: Antepartum diagnostic center

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**Study Objective:** The specific objectives are to see if all fetal well-being assessment can be performed in one area by a centralized staff and to evaluate various testing schemata specifically to see if one is superior. This concept will be utilized to compare various accepted plans of management to see which is best for the high-risk obstetrical population at this institution.

**Technical Approach:** Upon entry into the obstetrical population, patients will be screened for risk factors in a routine fashion. Accordingly, they will be programmed to receive routine prenatal care, if considered low risk or complicated obstetrical care if listed as high risk. At any time during pregnancy, any patient who develops high risk factors will be transferred to complicated obstetrics and begin testing.

For the purpose of this study, all high risk patients followed in the Complicated Obstetrics Clinic will be placed in the study. They will be counselled by attending or resident staff in the Department of Obstetrics and Gynecology. Counselling will include indication for placement into Complicated Obstetrics Clinic and that testing is to be performed in the Antepartum Diagnostic Clinic as a one-day admission. After counselling, patients will be referred to the ADC where appropriate testing will be scheduled by the ADC staff. Results will be given directly to patients by ADC staff and any additional testing will be scheduled by ADC staff. All results will be in the patient's chart and a convenience file in the ADC. When indicated, management recommendations will be given by the ADC staff. The ADC staff will consist of a perinatologist, PGY3 or PGY4 OB-GYN resident, a LVN and a 91A. All activities of the ADC will be under the direct supervision of the perinatologist. The potential benefit which may accrue is a more rapid and comprehensive evaluation which may decrease the delay in timely management decisions; therefore, decreasing neonatal morbidity and possibly mortality.

**Progress:** To date, in excess of 2,000 patients have been followed. There are presently five ongoing or completed studies utilizing the database created. These studies are being prepared for presentation and publication.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/42

STATUS: Ongoing

TITLE: An Evaluation of Daily and Intermittent Uterine Contraction Monitoring in Identifying Obstetric Patients with Preterm Labor

START DATE: May 88

ESTIMATED COMPLETION DATE: Feb 89

PRINCIPAL INVESTIGATOR: MAJ Andrew W. Robertson

DEPARTMENT: OB-GYN

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: CPT Janet Lyons, MC

KEY WORDS: Preterm labor, Contraction monitoring

**Study Objective:** To evaluate the ability of daily or intermittent uterine contraction monitoring in assisting in the early diagnosis and treatment of patients with preterm labor.

**Technical Approach:** Over a 6 month period, those obstetric patients between 24 and 36 weeks gestation who have risk factors for preterm birth or who have been diagnosed as having preterm labor will be evaluated for entry into the study. Lists of inclusion and exclusion criteria will be as follows:

**Inclusion:** Prior preterm birth; multiple gestations; hydramnios; known uterine anomaly; symptomatic placenta previa; preterm labor (i.e., cervical dilatation/effacement in association with regular uterine contractions between 24 and 36 weeks of gestation); preterm cervical dilatation/effacement; preterm contractions requiring IV tocolytics.

**Exclusion:** PROM (premature rupture of the membranes); known fetal anomaly; chorioamnionitis; maternal or fetal contraindications to tocolytic therapy; cerclage placement; patients transferred to or from WBAMC who cannot be monitored.

Patients will be evaluated initially in the ADC (Antepartum Diagnostic Center) for inclusion in the study. Informed written consent will be obtained before entry into the study.

The study will consist of 2 groups. Thirty patients will then be selected based on their indications for inclusion and followed with daily home monitoring by Healthdyne Perinatal Services. The remainder of the study patients (estimated 120 patients) will be followed in the ADC on a once or twice weekly basis depending on their indication for entry into the study.

All other laboratory and routine obstetric visits will be conducted in the ADC by the resident staff assigned to that area. Any therapeutic decisions will be carried out by one of the principal investigators or the physician on call based on the available data.

Data to be collected on each patient entered into the study include the following: Age, gravidity, parity, race; prior obstetric history; dating criteria - first examination, fetal heart tones heard with doppler and fetoscope, detailed ultrasound examination; indication for entry into the study; physical examination (with special attention to cervical exam); length of time in the study; time from diagnosis of preterm labor to delivery; indication for tocolytic therapy and/or delivery; neonatal statistics to include length of stay, birth weight, and need for specialized care.

Retrospective data will be obtained for a similar period (i.e., 6 months) from FY87 at WBAMC. NOTE: Contraction monitoring was not routinely used during this period of time.

A cohort to the 30 Healthdyne patients will be obtained for the ADC group. Analysis of these 2 groups will be done to compare the effectiveness of the monitoring techniques. As a whole, these 2 groups will be compared to the unmonitored period in FY87 with particular attention placed on perinatal morbidity/mortality and cost-effectiveness of monitoring.

**Progress:** Five patients have been entered into this project to date. Thirty additional patients will be enrolled to complete this project.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988  
Dec 1984

PROTOCOL #: 84/76

STATUS: Ongoing

TITLE: Improved Pregnancy Rates After Using Oil-Soluble Contrast Media (OSCM) for Hysterosalpingography (HSG)

START DATE: Indefinite

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: MAJ Cesar Rosa

DEPARTMENT: OB

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: HSG, Pregnancy Rates, Contrast Media

Study Objective: To determine whether OSCM used for HSG improves pregnancy rates in patients with patent fallopian tubes and no other major cause for infertility.

Technical Approach: Patients from the Gynecology Infertility Clinic will be invited to participate. After a complete initial evaluation which includes history, physical exam, semen analysis, documentation of adequate ovulatory function by BBT and serum progesterone, and postcoital test; patients will be scheduled for HSG to evaluate tubal patency as is routine in the evaluation of these infertility cases. All HSGs will be done using water soluble contrast media (WSCM) in order to establish tubal patency and to evaluate presence or absence of rugal marks. Those individuals with a normal study as evidenced by unilateral or bilateral spillage, without evidence of distal obstruction in either tube, will then be randomized to receive 5 ml of OSCM injected through the HSG cannula or no OSCM at all. For this purpose a table of random numbers will be used assigning each group to odd or even numbers. No effort will be made to blind the study as far as the follow-up will be similar in both groups and the measured parameter will be an objective, all or none end result - pregnancy. Patients with normal studies will be followed expectantly for a minimum of four menstrual cycles during which they will be encouraged to maintain BBT charts and to time intercourse with ovulation. After this period of time, those patients with persistent infertility will be progressed through their infertility evaluation as otherwise indicated. Participation in this study will not change in any way the couple's infertility evaluation. The proposed waiting period after a HSG is presently the norm after any normal study; so no unnecessary or extra delay is being introduced into these patient's evaluation. The HSG will be performed by residents from the Dept Obstetrics and Gynecology, under the direct supervision of one of the principal investigators, as is the norm for all HSGs performed presently. Generally, whether OSCM or WSCM are used for HSG is a matter of personal choice by the operator. Both contrast media to be used WSCM (Renografin-Squid Pharmaceuticals, Princeton NJ) and OSCM (Ethiodol-Savage Co, Missouri City, TX) have been in common use for a number of years and are accepted as safe. Patients allergic to iodine, seafood, or x-ray contrast material will be excluded from the study. Statistical Methods: Contingency tables, using chi-square analysis, comparing OSCM vs no OSCM; pregnancy rates in one group vs the other. The subjects to be considered will be healthy females in their reproductive years, attending the Gynecology Infertility Clinic due to involuntary infertility of more than one year duration. This group is heterogeneous in terms of military status and age range 18-36. Facilities to be used will be the same fluoroscopy room in the x-ray department which presently is allotted to the Gynecology Department for HSGs one afternoon a week. The maximum number of studies per day will be six, as is the norm presently. We do not anticipate the use of any additional facilities or resources other than the one routinely used for HSGs.

Progress: Protocol has been inactive since the last report. Study is to be reactivated in the next few weeks.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/30

STATUS: Ongoing

TITLE: Effectiveness of Historical Markers in Determining HBsAg (Hepatitis B Surface Antigen) Positivity in an Obstetrical Population

START DATE: Jun 1987

ESTIMATED COMPLETION DATE: Jan 1989

PRINCIPAL INVESTIGATOR: MAJ Cesar Rosa

DEPARTMENT: OB

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: CPT C. Butterfield, MC; CPT M. Shockley, MC; MAJ G. San Miguel, MC

KEY WORDS. Hepatitis, pregnancy

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**Study Objective:** To determine if the traditional historical markers associated with HBsAg carrier state are good predictors of HBsAg positivity in an obstetrical population.

**Technical Approach:**

a. Since the inception of the routine HBsAg screening on all patients and anticipating a retrospective evaluation on our population and its HBsAg positivity rate, the following system was implemented.

At the time of initial evaluation, the physician filled out a data sheet (see appendix A). To facilitate the correlation between historical risk factors and HBsAg results.

b. The variables to be evaluated will be:

- HBsAg: positive or negative
- Historical markers: present or absent

c. This study will be a review and evaluation of an established, routine procedure on all obstetrical patients. No controls or populations outside of the obstetric group will be reviewed. At this point, we are ready to start analysis on the patient group for the first year of this screening test, a population of approximately 2,000 patients.

d. Editorial and statistical support will be required from the Department of Clinical Investigation.

e. This review of the initial 2,000 patients will take approximately 3-4 months.

f. For statistical analysis, logistic regression analysis using a multivariable logistic model is planned.

**Progress:** This is a retrospective study of accumulated historical information and laboratory data on pregnant patients. No consent forms were deemed to be necessary.

Preliminary information on the first 1664 patients is being presented at the Annual Meeting of the Annual Meeting of the Armed Forces District of the American College of Obstetricians and Gynecologists in San Antonio, Texas in November 1988.

Data collection process is planned through December 1988.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/47

STATUS: Ongoing

TITLE: Continuous Estrogen/Progesterone Replacement Therapy (Monitor: Dr. Knodel)

START DATE: Nov 1988

ESTIMATED COMPLETION DATE: Jan 1990

PRINCIPAL INVESTIGATOR: LTC Cesar Rosa

DEPARTMENT: OB

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: CPT W.T. McGrail, Jr., MC; CPT Mitchell Silver, MC; CPT Rebecca Cavazos, MC; CPT M.D. Wood, MC; COL Ana Rodriguez, MC;

KEY WORDS: Estrogen, Progesteron, Hormone replacement

**Study Objective:** Assess the effect of the continuous administration of estrogen/progesterone as replacement therapy on the endometrium, bone, and lipid profile of postmenopausal women.

**Technical Approach:** In this study, we intent to offer continuous estrogen-progesterone replacement to suitable candidates. In so far as this is a relatively new method of estrogen administration, data will be obtained to evaluate the effect of this replacement regimen on bleeding patterns, endometrial stimulation, effect on bone mineral content, and effect on serum lipids.

In this study, no control group will be used. We understand that when given the possibility of not having a monthly bleeding episode, it would be extremely difficult to have the patients agree to submit themselves to randomization (cyclic vs continuous). In addition blinding such a study would be extremely difficult due to the almost certain withdrawal bleeds associated with cyclic therapy. Our goal is to acculate data on the effects of this type of replacement.

Females presenting to the Gynecology Clinic with symptoms or evidence of estrogen deficiency (hot flashes, genital atrophy, premenopausal syndrome) will be offered inclusion in the study. Criteria for exclusion will be: undiagnosed abnormal uterine bleeding, estrogen dependent malignancies (endometrium or breast), and known pregnancy. Relative contraindications: uterine fibroids, previous thromboembolic disorders. The previous use of estrogens will not be considered a contraindication. Postmenopausal state will be documented with an elevated FSH (over 40 MIU/ML).

a. Conjugated estrogens (Premarin) 0.625mg and medroxyprogesterone acetate 2.5mg daily will be offered as standard replacement.

b. For those patients requiring a higher estrogen dose, conjugated estrogens 1.25mg, and medroxyprogesterone acetate 5mg will be offered. This will be evaluated according to patient's symptoms.

\* 0.625mg of CE has been shown to be the minimal effective dose for protection against osteoporosis.

**Progress:** Data collection has not begun on this project. The preliminary coordination to start this study has just been completed. Subjects should start being enrolled in the next few weeks.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/71

STATUS: Terminated

TITLE: Transvaginal Sonographic Assessment of the Cervix in the Standing and Dorsal Lithotomy Position

START DATE: Oct 1988

ESTIMATED COMPLETION DATE: Dec 1988

PRINCIPAL INVESTIGATOR: MAJ George G. San Miguel

DEPARTMENT: OB-GYN

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

CPT Vincent Lyons, MC; MAJ Andrew Robertson, MC

KEY WORDS: Transvaginal, cervical length

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Study Objective: To determine whether positional changes affects the length and dilatation of the cervix. Also to ascertain the relationship of the cervix to the lower segment and whether this may predict patients at high risk for preterm delivery.

Technical Approach: After appropriate counseling and signing of a permit, consecutive high and low risk patients will have a transvaginal scan by an ADR Ultramark 4 transvaginal ultrasound probe. A polaroid picture of the cervix and lower uterine segment will be done in the vertical and horizontal plane. The probe will then be removed and the patient will then stand. After 5 minutes the ultrasound probe will then be reinserted with the patient in the standing position. the patients will have two sets of scans. One scan at 16-20 weeks and the other at 26-30 weeks. Using caliper measurements and direct measurements from the picture, the length of cervix from internal os to the extocervix and dilatation of the internal os can be obtained. Attention will also be given to the angle formed by the axis o; the cervix to the axis of the lower uterine segment. Data will be analyzed by the paired T-test.

Progress: Project has been terminated due to slow accumulation of patients.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/83

STATUS: Ongoing

TITLE: Analysis of Hospital Bacterial Pathogens - Chromosomal and/or DNA Fingerprinting

START DATE: Oct 1987

ESTIMATED COMPLETION DATE: Jul 1989

PRINCIPAL INVESTIGATOR: CPT R.R. Gomez

DEPARTMENT: Path

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Michael Lieberman,MS; CPT David Smith, MS

KEY WORDS: Bacterial pathogen fingerprinting

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Study Objective: Identification of bacterial strains by subjecting plasmid DNA or chromosomal DNA to restriction endonuclease digestion and then agar gel electrophoresis.

Technical Approach: Plasmid DNA fingerprinting. Methods for plasmid DNA fingerprinting have been described in the literature. A typical method involves isolation of plasmid DNA by lysis and centrifugation. The plasmid DNA is digested with restriction endonuclease. The resultant DNA fragments are analyzed by agarose gel electrophoresis and the pattern obtained from different isolates and compared. Electrophoresis patterns obtained will be compared by visual inspection; thus, statistical analysis is not required.

Progress: Several strains of *Pseudomonas* has been studies, and DNA patterns have been preliminarily identified. However, the plasmid DNA concentrations, although present, are not presently sufficiently high enough to enable us to obtain good, reproducible results. We have obtained a gene probe (*E. coli* plasmid) and will incorporate this into the study to facilitate identification of several different strains.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/72

STATUS: Ongoing

TITLE: Susceptibility of Burned and Irradiated Mice to Lethal Infection with Pseudomonas aeruginosa and Protective Effect of Specific Immunotherapy

START DATE: Jul 87

ESTIMATED COMPLETION DATE: Dec 89

PRINCIPAL INVESTIGATOR: MAJ Michael Lieberman

DEPARTMENT: Path

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Dennis A. Stewart, MS; MAJ K.O. O'Hair, VC

KEY WORDS: Pseudomonas aeruginosa, immunotherapy

**Study Objective:** Investigate the effects of infection with Pseudomonas aeruginosa in burned and irradiated mice and to determine if specific immunotherapy (active and/or passive immunization) can protect these traumatized mice (i.e., enhance their survival) subsequent to lethal infection.

**Technical Approach:** Four groups of 50 mice each are designated as follows: burned only, irradiated only, burned and irradiated, and nontraumatized controls. Pseudomonas aeruginosa strain 1244 is grown and prepared for mouse challenge. Appropriate dilutions of the challenge culture are prepared and administered by the intraperitoneal route or subcutaneously under the burn site subsequent to burning and/or irradiation as described in Protocol 86/48 (MAJ Stewart). Five dilutions of culture will be administered to groups of ten mice each within each group of 50 mice listed above. Mouse survival data will be tallied from each group and the culture dilution yielding 50% lethality calculated. The effect of individual or combined trauma on susceptibility to lethal infection can be determined by comparison of these 50% lethal doses (LD-50) dilutions obtained in each of the four experimental groups. Comparison of the lethality obtained without infection in such traumatized mice to that obtained above in traumatized and infected mice can be done using three additional groups of mice consisting of the individually or combined burned and irradiated, but not infected mice. Effect of active immunization on susceptibility to lethal infection with Pseudomonas aeruginosa in burned and irradiated mice. Ribosomal vaccine from Pseudomonas aeruginosa strain 1244 has previously been prepared and available. Mice are vaccinated and comparison between vaccinated, traumatized, and infected mice and nonvaccinated, traumatized and infected mice for susceptibility to lethal infection.

**Progress:** The effects of infection with P. aeruginosa in mice that were burned only, irradiated only, or burned and irradiated were determined. The results demonstrated that the combination of burning and irradiation dramatically increased the susceptibility of mice to lethal infection with this organism compared to either burning or irradiation alone. Relative to non-traumatized (control) mice, the 50% lethal dose of the challenge organism is decreased about 10-fold in mice that were subjected to either trauma alone. However, the combination of the two traumatic injuries resulted in a 250-fold decrease in the 50% lethal dose of the challenge organism compared to non-traumatized controls. Experiments in which the protective effect of specific immunotherapy in this combined injury and infection animal model are assessed have not yet been performed.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/90

STATUS: Ongoing

TITLE: Survey of Patients' Serum for Anti-Pseudomonas aeruginosa Ribosomal Antibodies

START DATE: Nov 87

ESTIMATED COMPLETION DATE: Dec 89

PRINCIPAL INVESTIGATOR: MAJ Michael Lieberman

DEPARTMENT: Path

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Pseudomonas aeruginosa ribosomal antibodies

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**Study Objective:** Determine if patients with confirmed Pseudomonas aeruginosa infections have antibodies to ribosomes from these bacteria.

**Technical Approach:** Patients identified in the clinical microbiology laboratory with Pseudomonas aeruginosa infection will have bacteria isolated and serotyped using a commercially obtained kit. A blood specimen will be drawn from these patients at the time of identification and, if possible, at a later time. Antibodies to ribosomes in the patients' serum will be determined by an enzyme-linked immunosorbent assay that has previously been developed. Test serum ribosomal antibody titers are determined as the reciprocal of the highest serum dilution yielding a specified photometric absorbance. The procedure involves ultrasonic disruption of the bacterial cells and isolation and purification of the ribosomes by ammonium sulphate fractionation, differential ultracentrifugation, and molecular sieve chromatography. ELISA analyses on individual serum dilutions will be performed in triplicate and the mean values and standard deviations calculated. Differences greater than two standard deviations between test serum and control serum values at equivalent dilutions are considered significant.

**Progress:** Serum specimens from appropriate patients have been collected and the bacterial isolates from the patient saved. However, to date no patient has been found with an isolate of P. aeruginosa of the same serotype as one of the two from which ribosomal vaccine preparations are presently on hand. Thus, the determination of the anti-ribosomal antibody titer in these patients' sera has not been performed yet. New preparations of ribosomes from the patients' own bacterial strains will have to be made before this determination can be done.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/63

STATUS: Ongoing

TITLE: Analysis of Cellular Immunity Against Pseudomonas Aeruginosa Engendered by Immunization of Mice with Ribosomal Vaccine From P. Aeruginosa

START DATE: Jul 88

ESTIMATED COMPLETION DATE: Sep 1989

PRINCIPAL INVESTIGATOR: MAJ Michael M. Lieberman

DEPARTMENT: Path

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Dennis A. Stewart, MS; Bruce Veit, Ph.D;

KEY WORDS: Pseudomonas aeruginosa, ribosomal vaccine, cellular immunity

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**Study Objective:** To determine if the cellular immunity (i.e., the adoptive transfer of protection with splenocytes from immune to non-immune mice) engendered by immunization of mice with ribosomal vaccines from P. aeruginosa is mediated by T lymphocytes or B lymphocytes.

**Technical Approach:** Vaccination of mice and preparation of immune spleen cells. P. aeruginosa ribosomal vaccine (previously prepared as described [1-3] and available for use) is used to immunize a group of about 100 mice. After an appropriate interval post-vaccination and booster vaccination, the vaccinees are killed and their spleens excised aseptically. Spleen cell suspensions are prepared by mincing the spleens in a liquid medium and passing the resulting material through a sterile nylon gauze filter. (Suspensions of spleen cells from normal mice are also prepared as controls.)

Separation of splenocytes into T and B cell fractions. Plastic petri plates are coated with rabbit anti-mouse immunoglobulin antibodies (obtained commercially). The spleen cell suspensions are allowed to incubate on the anti-mouse Ig coated plates and then removed. The B cells (which have Ig molecules on the exterior of their cell membrane) should adsorb to the surface of the anti-mouse Ig coated plates. The T cells should be removed with the supernatant medium. The adsorbed cells can then be recovered by gentle agitation of the plates in fresh medium. Both the T and B cell fractions can be further purified by a second cycle of adsorption to anti-mouse Ig coated petri plates.

Analysis of T and B lymphocytes. To confirm the separation of the spleen cell suspensions into T and B cell fractions, these fractions will be analyzed by specific mitogen stimulation and by flow cytometry.

(1) T and B lymphocytes are specifically stimulated by particular mitogens. Concanavalin A and phytohemagglutinin A stimulate certain populations of T cells but do not affect B cells, whereas bacterial lipopolysaccharide (LPS) stimulates B cells but not T cells. Thus, these mitogens will be used in lymphocyte stimulation assays (involving uptake of radio-labeled thymidine by stimulated cells in culture) with the T and B cell fractions of the splenocyte suspensions. (Similar assays are currently being performed in the Clinical Investigation Laboratory under other protocols.)

(2) Using the capabilities of the cytofluorograf in the Department of Clinical Investigation, the T and B cell suspensions will be analyzed for the presence of specific surface antigens. Fluorescein (or other fluorescent molecule) conjugated monoclonal antibodies to surface antigens of murine T or B lymphocytes are available for use. These reagents will be mixed with the cell suspensions and the resulting fluorescent-labeled cells will be analyzed by flow cytometry. This type of analysis should be able to determine the relative purity of the T and B cell fractions. D. Adoptive transfer of immunity. Isolated T and B lymphocytes (as well as whole spleen cells from both immune and non-immune mice) will be injected (intraperitoneal) into normal (non-immune) mice ( $10^8$  cells per mouse). One day later all of these mice (as well as mice that did not receive any cells) will be

directly challenged by inoculation with a live culture of P. aeruginosa. Mice will be scored for survival on a daily basis after challenge.

Progress: Initial experiments have been performed in which splenocytes from mice vaccinated with ribosomes have been separated into T and B cell fractions by absorption on petri plates coated with anti-mouse immunoglobulins as described above. Cytofluorograf and mitogenesis analysis indicated that the separation technique had resulted in two fractions of splenocytes, one highly enriched for T cells and the other highly enriched for B cells. Adoptive transfer of immunity with these fractionated spleen cells yielded somewhat equivocal results, however, in that partial protection was observed with both fractions. (Adoptive transfer of whole, unfractionated spleen cells provided complete protection.) These experiments will be repeated with larger groups of animals and extended to include macrophages as well as the T and B lymphocytes for determination of protective capacity.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/64

STATUS: Terminated

TITLE: Short-term Visual Processing in Attention Deficit Disorders with Hyperactive Methods of Assessment and Comparison with Auditory Processing

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: Maj T.E. Atkinson

DEPARTMENT: Peds

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: R. LaGrone, PhD; M. Voss, MA, DAC; LTC A.W. Atkinson, MC

KEY WORDS: Attention Deficit Disorders

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Study Objective: To determine whether children with ADD have visual processing problems and to compare their incidence to the incidence of auditory processing problems.

Technical Approach: Children who are referred to the Developmental Pediatrics Service with a primary concern of attention problems will be screened. Inclusion criteria include age 5-8; 40 percentile for attention on ACIR scale; no history of MR/depression; not on stimulants for ADD/H. Children then receive evaluation for speech, audiology, optometry, and child psychology.

Progress: This project was terminated.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/29

STATUS: Ongoing

TITLE: Ceftriaxone for Outpatient Management of Suspected Occult Bacteremia

START DATE: Apr 1988

ESTIMATED COMPLETION DATE: Apr 1990

PRINCIPAL INVESTIGATOR: CPT Valerie A. Bell

DEPARTMENT: Ped

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Suzanne Cuda, M.D., Robert Goldbah, M.C.

KEY WORDS: Ceftriaxone, occult bacteremia, pediatrics

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Study Objective: To compare the effectiveness of ceftriaxone versus augmentin in the treatment of children with a possible blood infection.

Technical Approach: The details are lengthy and specified in the protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress: 32 patients have been enrolled in the study. Of these 32, 4 have had positive blood cultures for strep pneumonia. All 4 have done well on this protocol.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/61

STATUS: Ongoing

TITLE: Neonate Emergency Procedure Training in the Rabbit Model

START DATE: Jul 1988

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC Edwin Bollerup

DEPARTMENT: Ped

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Emergency training, neonate

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Study Objective: To train physicians who have not been previously trained in emergency management of neonates, but who will be called upon to perform this function in the Neonatal Intensive Care Unit. The rabbit model will simulate human neonates.

Technical Approach: This training is designed for junior house staff who are inexperienced in the management and emergency care of sick infants. Demonstration by a staff neonatologist of the various procedures to be learned will be performed before any hands-on attempts by the interns and residents. The housestaff will then rotate through practical skill stations to perform the assigned tasks. The skill stations and animal lab allow the student to observe and practice to proficiency those life-saving skills necessary in the management and stabilization of the neonatal patient. The animal lab will be held on two separate days with a staff neonatologist and staff veterinarian present on both days.

Progress: At the beginning of each training cycle this protocol is used in the training of new interns. The sessions were successful and no adverse reactions to the animals utilized were associated with this project.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/65

STATUS: Ongoing

TITLE: Pediatric Intubation Training Utilizing the Feline Model

START DATE: July 1988

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC Edwin Bollerup

DEPARTMENT: Ped

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Lynn Whittington, MC

KEY WORDS: Intubation, pediatric training

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**Study Objective:** This training is designed to teach physicians and other health care professionals basic knowledge and endotracheal intubation skills required to resuscitate a neonate (newborn) or infant.

**Technical Approach:** The laboratory exercise described below will concentrate on developing the health professional's confidence in establishing an airway. Each new house officer will be required to intubate 2 cats employing a laryngoscope and endotracheal tube.

Animals will be anesthetized with ketamine HCL (22 mg/kg, given intramuscularly), with atropine (0.04 mg/kg, subcutaneously). Up to 2 additional half-doses (11 mg/kg) of ketamine may be given if needed. Pre-anesthesia with tranquilizer (Acepromazine, 0.2 mg/kg, subcutaneously) may be given to allow easier intubation for first-time trainees. Administration and monitoring of anesthesia will be directly supervised or performed by the attending veterinarian. The veterinarian will be present at all times to assist, modify, or terminate the procedure. Butorphanol tartrate (0.2 mg/kg SC every 8 hours) will be administered after the procedure to alleviate any possible pain.

At the discretion of the instructor, the stages and planes of anesthesia may be defined and assessed by the students. The animal will be placed in dorsal recumbency. Each trainee will visualize the larynx, noting the similarity of the feline larynx to that of the human infant; palpate the larynx externally; and perform visual intubation using the laryngoscope and endotracheal tube.

Two animals will be intubated by each first-time trainee in each laboratory session. Previously trained individuals will use one animal.

**Progress:** At the beginning of each training cycle (July) this protocol is used during the endotracheal intubation training of new pediatric, medicine-pediatric, OB-Gyn interns. Invitations are also extended to current staff and housestaff of the Pediatric and OB-Gyn Departments for refresher training of this procedure. This protocol is required to justify the animal utilization for this training since no suitable nonanimal model exists to obtain the required training objectives. The last session was held in July 1988 and was highly successful and was not associated with adverse reactions to the animals utilized.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/21

STATUS: Completed

TITLE: IgG Subclass Deficiency in Chronic Otitis Media

START DATE: Jul 1988

ESTIMATED COMPLETION DATE: Sep 1988

PRINCIPAL INVESTIGATOR: CPT Young S. Choi

DEPARTMENT: Ped

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: CPT Scot Lewey, MC

KEY WORDS: IgG subclass, otitis media

**Study Objective:** To perform a preliminary study to see if some children may have an immunologic deficiency which predisposes them to chronic otitis media. We are interested in determining IgG subclass levels, particularly 2 and 4 on 50 patients with chronic otitis media and noting any trends that may develop.

**Technical Approach:** Identify 50 children who have had or have chronic otitis media as identified by the need for bilateral myringotomy tubes (past, present, or future). Maximum age will be 5 years. Children will be non-medicated and non-febrile when their blood is drawn. Total immunoglobulin levels (IgG, IgA, and IgM) will require 0.5ml serum and can be performed by the WBAMC laboratory. IgG 1-4 subclass determinations will be performed by Dr. Bruce Viet, Department of Clinical Investigation, WBAMC. Results will be compared to pre-established normal values. Separate controls will not be included in this preliminary study. Three to 6 months will be required to complete this preliminary study.

**Progress:** With the increase in awareness of immunoglobulin G (IgG) subclass deficiency, it is not uncommon for pediatricians to order IgG subclass determinations or to prescribe gammaglobulin therapy for recurrent infections including otitis media. This may be inappropriate since the natural history of this entity is unknown and most children, particularly those with otitis media, will outgrow their infections. We hypothesized that 1) IgG subclass determinations are not indicated for isolated recurrent otitis media and 2) IgG subclass deficiency will spontaneously resolve over time. To test this hypothesis, we determined IgG subclasses in 36 children (0-3 yr: 13, 3-6 yr: 10, 8-10 yr: 8, 10+: 5) with histories of recurrent otitis media as evidenced by the need for myringotomy and pressure equalizing tubes. The average time from tube placement to sampling was 0-6 yr: 10 mos, 6-10 yr: 15 mos, 10+ years: 47 mos. Subclass determinations were made by radial immunodiffusion using the IgG AccraAssay (ICN Biomedicals, Inc., Lisle, IL). Results were compared to values in 281 normal children obtained by Dr. Peter H. Schur (Brigham and Women's Hospital, Boston). The mean IgG subclass 2-4 levels were not significantly lower than established normal values. 6 of 36 patients had IgG2 levels at least 2 SD less than normal values. IgG2 deficiency was likely to be found if at least 2 episodes of pneumonia had occurred ( $p$  less than 0.005) and if the age at that time of sampling was less than 6 years ( $p$  less than 0.05). IgG2 deficiency was not significantly associated with socioeconomic status, race, family history of recurrent ear or respiratory infections, or patient history of asthma, allergy, or frequent upper respiratory tract infections. Thus, history of pneumonia identified the subset of patients most likely to have IgG subclass deficiency; only 4 of 36 patients without such a history had abnormal subclass determinations. Additionally, abnormal IgG subclass levels were not found in patients over 6 years old. We concluded that routine screening for IgG subclass deficiency is not justified in isolated recurrent otitis media and that the natural history of IgG subclass deficiency is spontaneous resolution.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/63

STATUS: Terminated

TITLE: Androgen Responsiveness to LHRH Infusion in Adolescent Females with Polycystic Ovarian Syndrome

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: Maj A.G. Getts

DEPARTMENT: Peds

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Polycystic Ovarian Syndrome

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Study Objective: Determine the androgenic response to LHRH over 24 hours with maximal doses of LHRH (100 micrograms), under conditions where ovarian production alone occurs (dexamethasone suppression), and by including free testosterone (Free-T) levels, to exclude any interference by changing sex steroid binding globulin.

Technical Approach: The proposed study will include all adolescent and young adult women referred for evaluation of hirsutism, oligomenorrhea, or obesity undergoing LHRH stimulation who give consent for participation. A maximum of 100 patients will be included. Laboratory tests and pelvic ultrasound if menstrual irregularity or clinical conditions warrant. All subjects will begin a seven-day outpatient low dose dexamethasone suppression test and blood will be examined for androgen levels. Patients will be off any other medication three months prior to the study. Those individuals having regular menstrual cycles will be evaluated during the early follicular phase.

Progress: This protocol was terminated due to the principal investigator's reassignment.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/57

STATUS: Terminated

TITLE: The Evaluation of Hirsutism in Adolescent Females

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: MAJ A.G. Geïts

DEPARTMENT: Peds

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Adolescent, Hirsutism

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Study Objective: To determine normal or average body hair in adolescent females by race and Tanner maturation.

Technical Approach: Consenting patients are examined using a previously published scale for hirsutism. Results are correlated by Tanner stage, race, height, and weight.

Progress: This protocol was terminated due to the principal investigator's reassignment.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/33

STATUS: Terminated

TITLE: Study of Parents of Hospitalized Children

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: MAJ Catharine Herrick

DEPARTMENT: Pediatrics

FACILITY: Holloman AFB, New Mexico

ASSOCIATED INVESTIGATORS:

KEY WORDS: Parents, hospitalized children

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Study Objective: To determine the degree of anxiety of parents of hospitalized pediatric patients regarding their child's hospitalization; their perceptions of the child's degree of anxiety, and their perception of what could have been done to decrease their anxiety.

Technical Approach: Interviews will be conducted with selected parents of hospitalized pediatric patients within 72 hours of their child's admission. Patients and parents will not be identified by name. Patient's diagnosis may be referenced (although probably not). Parent's sex, i.e., father/mother, will be referenced.

Progress: Project was terminated due to principal investigator could not use an inpatient setting for that particular class.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/31

STATUS: Completed

TITLE: One year Followup of Class Specific Immunogenicity of the Haemophilus Influenza Type B (HIB) Capsular Polysaccharide Vaccine (HBPV) Administered Children 2-6 Years of Age

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: COL L.A. Popejoy

DEPARTMENT: Ped

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Haemophilus influenzae Type B

Study Objective: Broaden the scope of a previous study which yielded valuable information concerning side effects and nonspecific immunogenicity of the Hbpv vaccine in our population. The intent is to specify the class of immunoglobulins comprising the previous response to vaccination and repeating this serologic evaluation at 6 and 12 months post-vaccination. This will provide important information concerning the length of immunity from vaccination with the Hbpv at various ages in children.

Technical Approach: As many as possible of the 121 participants in the previous study will be asked to participate in this new study. Sera will be collected late March 1986 (six months post-vaccination) and late September 1986 (12 months post-vaccination). These samples, as well as sera remaining from pre- and 3-week post-vaccinations will be evaluated for IgG and IgM specific anti-Hib antibody level. The data will be analyzed by ANOVA.

Progress: This study was terminated with the six month post vaccination sample and the data was included in a paper which was a finalist for the Howard Johnson Award at the Tri-Service Pediatric Meeting, Spring 1988, and will be published in the American Journal of Diseases in Children, January 1989.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/60

STATUS: Ongoing

TITLE: The Effect of Stress and Exercise on Serum DHEAS and Cortisol Levels

START DATE: 1 July 1988

ESTIMATED COMPLETION DATE: 30 June 1989

PRINCIPAL INVESTIGATOR: MAJ Rita Svec

DEPARTMENT: Ped

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: CPT Suzanne E. Cuda, MC

KEY WORDS: Stress, DHEAS, Cortisol

**Study Objective:** To follow DHEAS and cortisol levels in a stressed population with and without exercise and to correlate this data with percentage body fat, work hours, level of stress and amount of exercise.

**Technical Approach:** Stress is an interesting phenomenon; there are different types of stress: physical stress due to exercise, physical and emotional stress due to working long hours with no periods of relaxation, physical stress due to severe illness, emotional stress.

One group of individuals with a high stress job are medical interns. Interns are sleep deprived, eat poorly, and have a high degree of emotional stress due to the novelty of the job and the amount of knowledge yet to be acquired. Most interns lead a sedentary existence, with little exercise and a lot of sitting or standing in one place.

We propose to study the interns as a high stressed group, comparing those interns who exercise regularly, and those who get little physical activity. We intend to compare the following parameters:

DHEAS  
AM Cortisol  
Activity survey  
Stress survey  
% Body fat

Measurements at beginning and end of study:

- (a) % body fat using Armed Forces tape test
- (b) Have participant fill out Jenkins Activity Survey

Measurements every 2 months, beginning the last week in June/first week in July:

- (a) DHEAS (Dehydroepiandrosterone Sulfate) using Radioimmunoassay.
- (b) 8 AM Cortisol by Radioimmunoassay.
- (c) Have participants fill out a chart of hours worked/week, exercise pattern, perception of stress.
- (d) Have participant fill out a Self-Evaluation Questionnaire.

**Progress:** Data collection has begun, however, at this point the data is too preliminary to make any projections.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/01

STATUS: Completed

TITLE: In Vitro Comparison of the Sensitivity of Group A Streptococcal Rapid Antigen Detection Kits

START DATE: 1988

ESTIMATED COMPLETION DATE: 1988

PRINCIPAL INVESTIGATOR: MAJ C.B. White

DEPARTMENT: Ped

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Michael Liberman, MS

KEY WORDS:

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**Study Objective:** To compare the in vitro sensitivity of 8 commercially available rapid streptococcal antigen detection kits.

**Technical Approach:** Four strains of GABHS will be used for the study. Each strain will be incubated overnight in an appropriate liquid medium. The next day, serial 10-fold dilutions will be made to  $10^{-4}$  of the original concentration of organism (i.e., eight dilutions). Each dilution will undergo two procedures in triplicate. First, a dacron swab will be dipped into each dilution of organisms and plated as completely as possible onto 5% sheep blood agar plates. Second, a dacron swab will be dipped into each dilution and will undergo testing for GABHS antigen using each of the eight streptococcal antigen detection kits. Those performing the antigen detection tests will be blinded to the dilution of GABHS organisms on each swab.

To determine the actual number of CFU's of GABHS in each dilution tested, known volumes of various dilutions will be plated on 5% sheep blood agar until quantifiable numbers of organisms can be identified (50-300 on an entire plate). Once the number of CFU's in each dilution is known, then the minimum number of CFU's which can be detected by each GABHS antigen detection kit can be quantitated and compared.

**Progress:** The principal investigator has PCS'ed to another area. There is no progress to report.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/52

STATUS: Completed

TITLE: Rapid Detection of Infectious Mononucleosis in Adolescents by Enzyme Immunoassay

START DATE: 1988

ESTIMATED COMPLETION DATE: 1988

PRINCIPAL INVESTIGATOR: MAJ C.B. White

DEPARTMENT: Ped

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS:

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Study Objective: To evaluate the performance characteristics (reliability, accuracy, ease of use) of the Ventrescreen Mono-Test for use in detecting infectious mononucleosis heterophile antibodies in fingertip blood and venipuncture samples.

Technical Approach: Patients presenting to the Adolescent Clinic clinically suspected of having infectious mononucleosis will be eligible to participate in the study. A fingertip blood sample and a venipuncture sample will be tested in the Adolescent Clinic for the presence of heterophile antibodies by the Ventrescreen EIA Test. Blood samples will also be sent to the laboratory for heterophile antibody test, CBC with differential, and EB virus serology.

Progress: The principal investigator has PCS'ed to another area. There is no progress to report.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/52

STATUS: Completed

TITLE: Rapid Detection of Infectious Mononucleosis in Adolescents by Enzyme Immunoassay

START DATE: 1988

ESTIMATED COMPLETION DATE: 1988

PRINCIPAL INVESTIGATOR: MAJ C.B. White

DEPARTMENT: Ped

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS:

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Study Objective: To evaluate the performance characteristics (reliability, accuracy, ease of use) of the Ventrescreen Mono-Test for use in detecting infectious mononucleosis heterophile antibodies in fingertip blood and venipuncture samples.

Technical Approach: Patients presenting to the Adolescent Clinic clinically suspected of having infectious mononucleosis will be eligible to participate in the study. A fingertip blood sample and a venipuncture sample will be tested in the Adolescent Clinic for the presence of heterophile antibodies by the Ventrescreen EIA Test. Blood samples will also be sent to the laboratory for heterophile antibody test, CBC with differential, and EB virus serology.

Progress: The principal investigator has PCS'ed to another area. There is no progress to report.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/01

STATUS: Completed

TITLE: In Vitro Comparison of the Sensitivity of Group A Streptococcal Rapid Antigen Detection Kits

START DATE: 1988

ESTIMATED COMPLETION DATE: 1988

PRINCIPAL INVESTIGATOR: MAJ C.B. White

DEPARTMENT: Ped

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Michael Liberman, MS

KEY WORDS:

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Study Objective: To compare the in vitro sensitivity of 8 commercially available rapid streptococcal antigen detection kits.

Technical Approach: Four strains of GABHS will be used for the study. Each strain will be incubated overnight in an appropriate liquid medium. The next day, serial 10-fold dilutions will be made to  $10^{-4}$  of the original concentration of organism (i.e., eight dilutions). Each dilution will undergo two procedures in triplicate. First, a dacron swab will be dipped into each dilution of organisms and plated as completely as possible onto 5% sheep blood agar plates. Second, a dacron swab will be dipped into each dilution and will undergo testing for GABHS antigen using each of the eight streptococcal antigen detection kits. Those performing the antigen detection tests will be blinded to the dilution of GABHS organisms on each swab.

To determine the actual number of CFU's of GABHS in each dilution tested, known volumes of various dilutions will be plated on 5% sheep blood agar until quantifiable numbers of organisms can be identified (50-300 on an entire plate). Once the number of CFU's in each dilution is known, then the minimum number of CFU's which can be detected by each GABHS antigen detection kit can be quantitated and compared.

Progress: The principal investigator has PCS'ed to another area. There is no progress to report.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/16

STATUS: Terminated

TITLE: Enhanced Smoking Cessation Treatment Outcome: A Comparison Between a Short Term Smoking Cessation Program With and Without Components from Protection Motivation Theory

START DATE: May 88

ESTIMATED COMPLETION DATE: Jan 89

PRINCIPAL INVESTIGATOR: MAJ K. Rollins

DEPARTMENT: Psych

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: W. Allberg, M.Ed.; MAJ R. Rankin, MS; CPT G. Southwell, MS

KEY WORDS: Smoking Cessation

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**Study Objective:** To determine if treatment outcome for the William Beaumont Army Medical Center smoking cessation program can be enhanced through incorporation of protection motivation theory.

**Technical Approach:** Two different smoking cessation programs will be run. One of the smoking cessation programs will not incorporate protection motivation into its design while the other smoking cessation program will. In addition to the two experimental groups which will be conducted, a wait listed, no treatment control group will also be used. All treatment groups will run concurrently, meeting twice a week for four weeks with each session lasting 1 hour. Four therapists will be counterbalanced across treatment groups to control for the effects of experimenter bias and experimenter expertise.

The current WBAMC smoking cessation program, which does not incorporate protection motivation theory into its design, has already been shown to provide success equal to rates reported in the literature. Because of this, it will be kept intact during this study. This current program combines cognitive/behavior therapy, education and hypnosis together in a brief group therapy format. specific to the program is the fact that it does not utilize the fear component as a method of motivating patients to stop smoking. viewing the fear component as a variable that often raises the patient's anxiety level to a point which blocks successful treatment, the WBAMC program focuses instead on emphasizing the efficacy of the coping response and the ability of the patient to successfully engage in that response.

The other smoking cessation program to be conducted, which will incorporate protection motivation into its design, will also utilize cognitive/behavior therapy, education and hypnosis in a brief group therapy format. The significant difference between the 2 groups, however, is that it will utilize the fear component. Located in the threat appraisal process of the protection motivation model, the fear component is one of the main variables stressed by protection motivation theory. It is comprised of 2 elements: (1) abstinence rates; (2) the vulnerability of the individual to the threat. the other major component in the model is the coping appraisal process. Here response efficacy and self efficacy are stressed. In accordance with the recommendations of the theory, these 4 variables (severity of the threat, vulnerability to the threat, response efficacy and self-efficacy) will be balanced in this program, i.e., equally stressed.

There will be 3 dependent variables: (1) abstinence rates; (2) a cigarette gain score derived by subtracting the amount of cigarettes being smoked daily at post-treatment from the amount of cigarettes being smoked daily before treatment; and (3) drop-out rates. Data will be obtained by questionnaires filled out by the subjects before treatment begins, immediately after the program is completed and at 3 months follow-up.

**Progress:** Eighteen subjects were entered in the program. Four subjects withdrew (did not formally withdraw, but have "disappeared" when attempts were made to contact them to collect follow-up data. One of the subjects had a PCS move, the others cannot be contacted.

When the most recent groups reach their 3 month followup in January 1989, this study will be terminated. No more research groups will be conducted due to the difficulties encountered in enrolling and following patients for 3 months. The total number of subjects treated was too small to allow for meaningful statistical comparisons.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/32

STATUS: Terminated

TITLE: Military Performance Aspects of Driving While Intoxicated Evaluation Program

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: LTC David J. Kruzich

DEPARTMENT: RTF

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: DWI

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**Study Objective:** This study exploits the unique geographical isolation of El Paso, the captive nature of the DWI population at Fort Bliss under current policy, and the presence of a major residential treatment facility (RTF).

**Technical Approach:** The separate elements of this study will examine the DWI soldier for the presence and frequency of associated pathology, the potential for salvage of a useful soldier, the ease of identification of salvageable versus nonsalvageable soldiers. The relative utility of screening or evaluative tools available to local CCCs or medical facilities, the degree of intervention necessary for salvaging those soldiers who are salvageable, and the potential impact on the unit of the untreated versus treated DWI soldiers.

1. A thorough descriptive study of the entire DWI population apprehended over a two-year period from a major Army post. Approximately 150 variables collected on each subject will be correlated to include: demographics, social history, family and personal drinking history, prior alcohol related problems, commander's performance appraisal, psychological profile (MMPI, Shipley-Hartford), scores on six alcohol abuse inventories, and a blood chemistry profile (SMAC 20 and CBC) place and time of arrest, BAC at arrest, stimulus for the arrest, diagnosis and treatment recommendations (LTG Elton has expressed his support for tracking these individuals through MILPERCEN records to determine their performance during the two years following their arrest).

2. A categorization of offenders utilizing psychological test results and current psychiatric diagnostic nomenclature will be accomplished. This categorization will characterize severity and potential for rehabilitation. The following groups are anticipated: severe personality disorders with little rehabilitative potential, moderate disorders requiring extensive effort, mild disorders requiring minimal effort, and those types with single offenses that may be expected to perform well without rehabilitation.

3. An expanded extension of previous RTF work by Hawkins et al., 1984) toward the development of alcoholism clinical screening procedures based on commonly measured blood chemistry/hematology variables. Preliminary examination of DWI patients utilizing this discriminant analytic technique has shown some promise in the development of an ability to rule out alcohol abuse and alcoholism.

4. Administration of six standardized alcohol abuse screening instruments on a pre/post basis will include: (a) subjects will be administered the instruments on the Monday of their entrance into the program, a time when they are typically quite defensive and denying of any problems; (b) all diagnoses and treatment recommendations are made on Thursday and shared with the patients; (c) subjects will be retested on Friday after a briefing to explain that retests are for research purposes only and their answers will have no bearing on their status, this being a time when patients are typically least defensive; (d) the pre/post test results will be of great value to the substance abuse field as they will help to illuminate those instruments most useful with persons attempting to "fake

good" while in a defensive psychological posture. This particular study has never been previously attempted

5. The use of DWI patient's Social Security Numbers (SSNs will be used to screen MP blotters for arrests other than DWI. Also screened by SSN will be Psychiatry, Social Work, Psychology, Mental Health Clinics, and Army Community Service (family violence) to determine the amount of overlap between DWI and other behavioral difficulties.

6. A study of close friends in the social network of 100 DWI offenders will determine if being apprehended and going through the DWI program has an effect on the drinking and/or drinking and driving habits of one's social network.

7. A study of two brigade-size troop units, using battalion-size components as experimental and control groups, will be used to determine if anti-DWI education has an effect on DWI rates. Baseline data is available for the units one-two years prior to the planned educational intervention.

8. A study to determine the extent to which (a) demographics, (b) BAC at time of arrest, (c) psychological test profiles, (d) blood chemistry variables, and (e) scores on alcohol abuse measurement instruments predict shared or independent variance in diagnoses (no diagnosis, alcohol abuse, and alcohol dependence) and ultimate military performance during a follow-up study.

9. A prospective study of basic trainees will involve various hematology/chemistry testing and psychological instruments without intervention, but with MILPERCEN tracking, will be used to determine the predictive ability of various instruments as well as documenting natural history without intervention.

Progress: There was no progress reported in 1987, and the project was terminated.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 78/03

STATUS: Ongoing

TITLE: National Intraocular Lens Implantation Study

START DATE: Oct 1977

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC George Amegin

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Surgery/Ophthalmology

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Study Objective: To participate in the study of clinical results of implantations of intraocular lens organized by the intraocular Lens Manufacturer's Association in response to directives of the Ophthalmic Classification Panel, FDA.

Technical Approach: An intraocular lens is a prosthetic replacement for the eye's crystalline lens. It is placed in the eye at the time of cataract surgery, where it is fixated by a variety of means, with the intention that it remain permanently and correct the large refractive error remaining after conventional cataract surgery.

Progress: The product is excellent, with no complications encountered; no post-operative inflammatory problems. The lens centers nicely with little need for manipulation. 181 volunteers have been entered into this project.

## **DETAIL SUMMARY SHEET**

**DATE:** 1 October 1988

**PROTOCOL #:** 88/02

**STATUS:** Ongoing

**TITLE:** Surgical Stapling Procedures Laboratory (In Dogs)

**START DATE:** Jun 1988

**ESTIMATED COMPLETION DATE:** Indefinite

**PRINCIPAL INVESTIGATOR:** LTC Warren F. Bowland

**DEPARTMENT:** Surg

**FACILITY:** William Beaumont Army Medical Center

**ASSOCIATED INVESTIGATORS:** Fourth Year Surgical Residents

**KEY WORDS:** Stapling

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**Study Objective:** To train accredited attending physicians and residents in the use of automatic suturing devices including their applications and limitations in a laboratory environment before they are called upon to use these instruments in human surgery.

**Technical Approach:**

- I. Gastrointestinal Applications Procedures**
  - a. Splenectomy
  - b. Hemigastrectomy w/Billroth II Reconstruction or Hemigastrectomy w/Billroth I Reconstruction
  - c. Small Bowel Resection w/Functional End-to-End Anastomosis
- II. Other Abdominal Applications**
  - a. Nephrectomy
  - b. Large/Small bowel Resection w/End- to-End Anastomosis by Triangulation
- III. Closure**
  - a. Fascial Closure Techniques
  - b. Skin Closure Techniques

**Progress:** The fourth year general surgery residents are trained in the use of the surgical stapling instruments in preparation for assuming future complex surgical procedures.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/26

STATUS: Ongoing

TITLE: Advanced Trauma Life Support (ATLS) Procedure (Training) (In Carpine Model)

START DATE: Jun 1988

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC W. Bowland

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Steve Carey, MC

KEY WORDS: Surgery, Trauma

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Study Objective: To train accredited physicians who are not dealing with major trauma on a day-to-day basis, but may be called upon to perform this function. The goat model will simulate human trauma.

Technical Approach:

ANIMAL PROCEDURES:

- (1) Cricothyroidotomy
- (2) Venous Cutdown
- (3) Chest Trauma Management
- (a) Needle decompression
- (b) Tube thoracostomy
- (c) Pericardiocentesis
- (4) Peritoneal Lavage

Training manuals will be used for each training procedure.

Progress: The animal lab is a requisite part of the ATLS course and is going well. All students have enjoyed the experience.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/59

STATUS: Ongoing

TITLE: Animal Model (Ovine) Laboratory, Advanced Trauma Life Support Course (ATLS)

START DATE: Jun 1988

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC Warren F. Bowland

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Steve Carey, MC

KEY WORDS: Trauma

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**Study Objective:** To train accredited physicians who are not dealing with major trauma on a day-to-day basis, but may be called upon to perform this function. The goat model will simulate human trauma.

**Technical Approach:** Animal Procedures -

1. Cricothyroidotomy
2. Venous Cutdown
3. Chest Trauma Management
  - a. Needle decompression
  - b. Tube thoracostomy
  - c. Pericardiocentesis
4. Peritoneal Lavage

Training manuals will be used for each training procedure.

**Progress:** The animal lab is a requisite part of ATLS. All students have enjoyed the experience.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/84

STATUS: Completed

TITLE: Omental Transposition to the Lower Extremity in Rabbits

START DATE: Jan 88

ESTIMATED COMPLETION DATE: Mar 88

PRINCIPAL INVESTIGATOR: CPT Paul Cordts

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: LTC J.S. Ramirez, MC

KEY WORDS: Omental transposition

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**Study Objective:** Determine if vascular connections will develop between the pedicled omentum and the venous system of the leg.

**Technical Approach:** Eleven rabbits will be divided as follows: a) One rabbit will undergo omental transposition to the femoral vein system with no occlusion of the vein; and b) ten rabbits will undergo omental transposition to the femoral vein system with complete occlusion of the common femoral vein. Occlusion of the vein will be performed at the time of omental transposition.

Venogram of the experimental extremity will be performed at two-four weeks postoperatively in an attempt to demonstrate venous collaterals between the femoral system and omentum. The surgical site will be excised and examined by light microscopy for evidence of vascular connections.

**Progress:** Upon completion of this project, it was determined that vascular connections do develop between an omentalpedicle to the thigh and the vessels of the thigh; the significance of these connections is unknown. Whether or not these connections would significantly improve venous outflow from the leg remains to be determined. This technique could potentially benefit patients with chronic venous insufficiency or phlebitic syndrome.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/39

STATUS: Terminated

TITLE: Cystic Disease of the Biliary Tree; The Role of Pancreatic Secretions (in the Dog Model)

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: CPT N. Hetzler

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Cystic Disease

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**Study Objective:** To examine the changes in the biliary tract after chronic exposure to pancreatic secretions in an animal model.

Chronic exposure of the biliary tract to pancreatic secretions have been implied, but not proven, as the etiology of choledochal cyst and Caroli's disease. The definition of physiologic and histologic changes in the biliary tract, after chronic exposure to pancreatic secretions, will help in the assessment of the etiology of choledochal cyst and Caroli's disease.

**Technical Approach:** The study will follow the format indicated below.

(1) Control animals. Two animals will undergo laparotomy for interruption of the duodenum and reconstitution of bowel continuity by means of a cholecystoenterostomy, a gastroenterostomy, and an enteroenterostomy. The common duct will be ligated. A percutaneous catheter will be placed in the gallbladder to allow sampling of fluid for pancreatic enzyme levels. In these animals the pancreatic secretions will be diverted from the biliary systems. The animals will undergo repeat laparotomy for evaluation of changes and biopsies of the biliary system at three and six months.

(2) Study animals. Six animals will undergo laparotomy for interruption of the duodenum and reconstitution of bowel continuity by means of a cholecystoenterostomy and a gastroenterostomy. A percutaneous catheter will be placed in the gallbladder to allow sampling of fluid for pancreatic enzyme levels. In these animals, the pancreatic fluid will be flowing through the biliary system. All animals will undergo repeat laparotomy for evaluation of changes and biopsies of the biliary system. Two animals will be explored at one month, two at three months, and two at six months.

In this study, all animals will be anesthetized and surgeries monitored by CPT O'Hair, VC. Pain will be controlled by the use of Rompun (xylazine) 5 mg/kg. In the event of uncontrollable pain, the animal will be euthanized with T-61. During the postoperative period, animals that appear to have uncontrollable pain will be euthanized. All procedures will be performed in the Biological Research facilities. Following the final laparotomy study, animals will not awaken from anesthesia, but be euthanized with T-61.

Determination of number of animals required. This study will require a total of eight dogs.

Data analysis plan. This is a descriptive study. The animals will be evaluated for anatomical changes at the time of exploration and histological changes on biopsies.

**Progress:** This project was terminated due to the relocation of the principal investigator to another area.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/64

STATUS: Ongoing

TITLE: Microvascular Anastomosis of the Rat Femoral Vessels

START DATE: May 88

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: LTC Rosendo Icochea

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Microvascular Anastomosis

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Study Objective: To gain proficiency in microvascular technique so that the technical proficiency gained can be applied to clinical conditions.

Technical Approach: Two survival femoral vessel anastomosis procedures and a third non-survival abdominal vessel surgical procedure will be conducted on each of 40 rats during the training year. At least one staff surgeon will supervise the resident training until they have become proficient. The first procedure (right femoral vessel anastomosis) will be conducted on day 0; the second (left femoral vessel anastomosis) on day 14; and the third (aortic artery anastomosis) will be conducted on day 28 for each respective rat. By the third training day, one of each of these procedures will be done every training period using 3 different rats. The rats will always be euthanatized immediately following completion of the abdominal procedure.

Progress: Seventeen rats were used. Resident training now applies to clinical practice with patients in need of microsurgical techniques. Continuation of present protocol is needed to continue training residents.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/28

STATUS: Ongoing

TITLE: Anastomosis of Flap Veins to Bone: An Alternative for Microvascular Free Flaps in Tibial Wound Coverage (Pig Model)

START DATE: Mar 1989

ESTIMATED COMPLETION DATE: Apr 1989

PRINCIPAL INVESTIGATOR: CPT S.D. Jones

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Dr. Icochea, MC

KEY WORDS: Surgery Anastomosis, Tibial Wound Coverage

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**Study Objective:** To determine the efficacy of anastomoses of free flap veins to bone via pre-drilled channels into the Haversian canals.

**Technical Approach:** The pig will be prepped and placed in dorsal recumbent position. An incision will be made over the medial aspects of the lower extremity bilaterally. The tibias will be exposed and holes drilled into the bone in two sites per tibia. The resting pressure of the Haversian canals will be measured. The holes will be approximately 2mm in diameter to correspond with the veins found in the flaps. Free myocutaneous flaps will then be taken from the calf of each lower extremity. These flaps will be designed with one artery and two veins per flap. The anastomoses of the veins will be to periosteum immediately adjacent to the predrilled holes.

**Progress:** Project has been on hold due to the departure of an associate staff member. The assistance of Dr. Icochea has been secured, and the project will resume January or February 1989.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/67

STATUS: Terminated

TITLE: The Role of Intravenous Antibiotics in the Delay of Gangrene and Perforation in Closed-Loop Intestinal Obstruction (In Rabbits)

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: CPT Joseph Llewelyn

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ R. Bernhard Rochon, MC, LTC Jose Ramirez, MC

KEY WORDS: Gangrene, perforation, obstruction

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Study Objective: Determine whether intravenous antibiotics delay the onset of gangrene or perforation in closed-loop intestinal obstruction.

Technical Approach: In each of the experimental rabbits closed loop distal ileal obstruction will be created by isolating a 10cm segment of ileum just proximal to the ileo-cecal junction with suture. Control animals will be given no antibiotics and will then be re-explored at two-hour intervals until grossly identifiable gangrene is evident. The study group animals will each receive intravenous mefoxin in doses based on weight of the animals and half-life of the drug starting after the obstruction has been created. The study animals will then be re-explored in the same fashion as the controls until the end-point (gangrene or perforation occurs) or 24 hours is reached. Antibiotic levels will be measured in the serum as well as in the compromised intestinal and normal intestinal tissue of study animals. Bacteriological studies will be performed on luminal specimens and peritoneal fluid of both the control and study animals. Operations will be performed on ten control and ten study animals.

Progress: No progress was made on this project.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/03

STATUS: Terminated

TITLE: NSABP Clinical Trial Evaluating the Postoperative Portal Vein Infusion of 5-Fluorouracil and Sodium Heparin in Patients with Resectable Adenocarcinoma of the Colon (Monitor: Dr. Levey)

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: COL John McPhail

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Cancer, 5-Fluorouracil, Sodium Heparin

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Study Objective: As part of a NSABP C02 protocol multi-institutional to determine whether adjuvant therapy with portal hepatic perfusion of 5-FU and sodium heparin is effective in prolonging the disease-free interval and increasing survivorship in patients undergoing curative resection of colonic adenocarcinomas.

Technical Approach: This study will evaluate the efficacy of postoperative 5-FU portal hepatic perfusion in patients with Dukes A, B and C adenocarcinoma of the colon. Patients will be assigned by random selection to one of the following groups.

(1) Continuous portal vein infusion with 5-FU 600 mg/M2 + 5,000 units sodium heparin per day given for a total of seven consecutive days.

(2) No further treatment.

(3) Portal vein catheters will be inserted intraoperatively. It is recommended that portal vein infusion be commenced intraoperatively after the colonic anastomosis has been completed. All portal vein infusions will be started within six hours of the operative procedure.

Progress: No progress was made on this project during this reporting period.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/69

STATUS: Completed

TITLE: Prevention of the Detrimental Effect of Cigarette Smoking on Flap Survival by the use of Pentoxifylline (Trental) (in Rats)

START DATE:

ESTIMATED COMPLETION DATE: Jan 88

PRINCIPAL INVESTIGATOR: MAJ Michael V. Novia

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: COL George Smith, MC

KEY WORDS: Flap Survival, Pentoxifylline

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Study Objective: Evaluate the effect of Pentoxifylline on the survival of skin flaps. Evaluate the effect of Pentoxifylline on the prevention of the detrimental effect of cigarette smoking on flap survival.

Technical Approach: Thirty rats will be divided into six groups of five each. Group I will have a standard McFarlane flap raised. Group II will be exposed to smoke inhalation for four weeks prior to surgery and for two weeks postoperatively. Group III will be treated with Pentoxifylline for four weeks preoperatively and two weeks postoperatively. Group IV will be subjected to smoking and Pentoxifylline for four weeks preoperative and two weeks postoperatively. Group V will receive Pentoxifylline on the day of surgery and for two weeks postoperatively. Group VI will smoke for four weeks preoperatively and two weeks postoperatively and receive Pentoxifylline on the day of surgery and postoperatively for two weeks. All groups will be compared at two weeks postoperatively.

Progress: No flaps died, even in the control groups. No conclusions could be drawn. Investigators are not reviewing the literature for a more sensitive test.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 85/56

STATUS: Ongoing

TITLE: Porocoat Synatomic Knee Device (Depuy IND #G830152) (Monitor: COL Scully)

START DATE: Dec 1985

ESTIMATED COMPLETION DATE: Dec 1991

PRINCIPAL INVESTIGATOR: CPT Kenneth Pitz

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Synatomic Knee Device

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Study Objective: To demonstrate the safety and efficacy of the Porocoat Synatomic Knee System.

Technical Approach: Investigators will follow the manufacturer's protocol, which has been approved by the FDA. This protocol is extensive and is available in the Department of Clinical Investigation.

Progress: Post follow-up has been difficult. A follow-up clinic has been planned for November and December 1988, to up-date all participants' files. No complications or untoward effects have been reported so far in our group, although the manufacturing company did report some problems with the metal backed patella component.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 84/55

STATUS: Ongoing

TITLE: Radiolabeled Triazines for Evaluation of Soft Tissue Damage in Rabbits

START DATE: 1984

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Thomas J. Scully

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Soft tissue damage

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Study Objective: To synthesize and test a series of radiolabeled triazine compounds as nuclear imaging agents for soft tissue damage in rabbits.

Technical Approach: Phase I: Synthesize a stable complex of Indium with a chlorotriazine dye.

Phase II: Inject rabbits with radio-indium-labeled chlorotriazine dye after producing controlled soft tissue and bone lesions. Scan for radiotracer distribution within four hours.

Progress: Because of absence of a radiochemist or nuclear pharmacist, no progress was made on this protocol during the past year. However, a nuclear pharmacist has been assigned to WBAMC and is interested in this project.

Previous attempts to synthesize a stable complex with Indium were unsuccessful because of the formation of insoluble Indium trichloride precipitates. We are now investigating the possibility of complexing triazine dyes with Technetium.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 85/15

STATUS: Terminated

TITLE: A Multi-Center Study on Rehabilitation of the Hand Following Flexor Tendon Repair

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: COL Thomas Scully

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Monsivais, Jose J. M.D.

KEY WORDS: Flexor Tendon Repair

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Study Objective: Development and implementation of a new postoperative management regimen for Zone II flexor tendon injuries.

Technical Approach: Primary repair is performed as soon as possible using a Tajima stitch with 3.0 or 4.0 Ethibond 6-0 nylon and meticulous repair or reconstruction of fibro-osseous tunnel.

Progress: Project has been terminated.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 85/55

STATUS: Terminated

TITLE: Evaluation of Low Dose Heparin in the Postoperative Management of Digital Reimplantation (In the Rabbit Model)

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: COL Thomas Scully

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Surgery

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Study Objective: To investigate heparin therapy for improvement of the present survival rate on amputation reimplantation. Preoperative medications (ketamine and rompun) will be used according to the advice of the veterinarian.

Technical Approach: Study animals will be randomly assigned to "heparin-first" or "heparin-second" groups by Biological Research personnel, without knowledge of the surgeon. The left ear will be amputated in a standard semi-traumatic manner. The two surfaces will be surgically debrided and reattached by the investigators. At a later date, the right ear will be similarly treated. The "heparin-first" animals will be given 50 units/kg of heparin every six hours by the intravenous route for 72 hours during the initial reimplantation and equal volume of normal saline during the second. The "heparin-second" animals will receive normal saline during the initial reimplantation and heparin during the second.

Success and failures for both groups will result in a 2x2 table for chi-square analysis.

Progress: This project was terminated due to the principal investigator's retirement from the Army.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/42

STATUS: Ongoing

TITLE: Torsion as a Factor in Patency of Microvascular Anastomosis in a Rat Model

START DATE: Oct 1988

ESTIMATED COMPLETION DATE: Oct 1989

PRINCIPAL INVESTIGATOR: COL Thomas J. Scully

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: Dr. Jose Monsivais

KEY WORDS: Microvascular anastomosis

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**Study Objective:** To determine the effect of torsion on the patency rates of microsurgical venous grafts.

**Technical Approach:** The rat will be prepped with surgical scrub, sterile drapes applied and placed in a dorsal recumbent position. An incision will be made over the medial aspects of the lower extremities bilaterally. The femoral artery will be exposed from the femoral canal to the bifurcation of the profundus, as well as exposing numerous branches.

The femoral artery of the rat will be transected and a vein graft of equal diameter will be sutured into place. A series of five grafts using 20o, 40o, 60o, and 90o of torsion will be performed. The contralateral leg will be used as a control, grafting a vein with 0o torsion into the transected femoral artery.

The animals are to be kept alive and allowed to heal for approximately two weeks, at which time they will be explored, and the patency of the vascular grafts determined by direct visualization.

**Progress:** Amendment was requested for this study October 1988. The amount of torsion to be done was changed to the following: 0° (control); 90°, 180°, 270°, and 360°.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 86/51

STATUS: Ongoing

TITLE: Changes in Bone Micromorphology and Fatigue Fracture Resistance Resulting from Repeated Physical Stress, Phase II. (Monitor: LTC Bowland)

START DATE: Jul 86

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Thomas J. Scully

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: COL R. Turnbull, MC; MAJ A. Moreno, MC

KEY WORDS: Stress fracture

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**Study Objective:** To determine the changes in fatigue fracture resistance of human living bone resulting from repeated physical stresses and to correlate these changes with changes in bone micromorphology.

**Technical Approach:** Small (approximately 1 cm square) biopsies of cortical bone will be taken from the proximal medial tibial metaphysis of basic trainees undergoing surgical procedures on their lower limbs for other acute conditions such as arthrotomy of the knee for treatment of a torn meniscus. The specimen will be cut and ground with a Buehler isomet and a lap machine to produce rectangular beams 2mm x 2mm by 18 mm. The fatigue life of the prepared specimens will be determined using a Beaumont cyclic stress apparatus. The specimens will be cyclically stressed by four point bending loads producing a deformation of 500 microns at 10 cycles per second. The fatigue life of the specimens (number of cycles to failure) will be recorded. The fracture specimens will then be examined by scanning electron microscopy and routine light microscopy. Findings of these studies will be correlated with the number of days of completed training.

Basic trainees at Fort Bliss will be asked to participate in the study. Each trainee will complete a training activities questionnaire which will provide data on the number of days of training completed, pre-entry physical fitness activities, and routine medical historical information. Each trainee will then undergo technetium bone scan. Bone biopsies will then be obtained from the proximal, posteromedial tibial crest (a common site for stress fractures) of each trainee. The biopsies will be examined by scanning electron microscopy and by conventional histology. The fatigue life of each biopsy specimen will be determined.

**Progress:** In the past year no basic trainees meeting the criteria for entry into the protocol have been treated by the Orthopaedic Service. Therefore, no additional specimens have been obtained. However, procedures for specimen processing have been repeatedly performed (and improved) in specimens from laboratory animals.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/05

STATUS: Terminated

TITLE: Effects of Immobilization vs Controlled Active Motion vs continuous Passive Motion Following Primary Flexor Tendon Repair Using the Chicken Model

START DATE: ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: COL Thomas Scully

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Surgery, Flexor Tendon Repair

Study Objective: Study and compare results of three types of post-flexor tendon repair rehabilitation techniques: immobilization, controlled active motion, and continuous passive motion.

Technical Approach: The chicken will be anesthetized followed by a surgical scrub prep and draped sterilely with one of the claws draped free. A plantar incision will be made over the middle toe and the tendon sheath exposed between the second and fourth pulley. The flexor digitorum profundus tendon and its overlying sheath will be sharply divided in a transverse fashion. The tendon will then be repaired using a Tajima stitch with a 7-0 nonabsorbable suture and completing the repair with a 10-0 nonabsorbable suture. The tendon sheath will be repaired using a 9-0 nonabsorbable suture. The above repairs will be carried out with the aid of the operating microscope. The wounds will then be sterilely closed and dressed and one of three rehabilitation protocols will be started.

One group will be immobilized postoperatively with a plaster cast in flexion for four weeks. A second group will be placed in a protective splint to allow active motion without excessive extension of the digit. A stimulator will be employed to produce active firing of the muscle and thus ensure active motion of the tendon for four weeks. A third group will be placed in a continuous passive motion device that will place the digit through a range of motion continuously and passively without excessive extension for four weeks.

At the end of four weeks the surgical sites will be re-explored and gliding ability, continuity of repair, and simulated active range of motion by constant traction of the tendons of both sides will be measured. The animals will be sacrificed and specimens of the surgical sites taken for histologic study.

Progress: This project was terminated due to the principal investigator's retirement from the Army

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/80

STATUS: Ongoing

TITLE: The Role of the Flexor Carpi Radialis and its Retinaculum in the Stability of the Wrist

START DATE: June 1989

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: COL Thomas J. Scully

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ Joan Sullivan, MC

KEY WORDS: Wrist, stability

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**Study Objective:** We hypothesize that the flexor carpi radialis and its retinaculum is the strongest stabilizer of the wrist on the radial side and as such should be included in the surgical repair of wrist injuries.

**Technical Approach:** Thirty fresh frozen adult cadaver wrists will be rapid loaded to failure utilizing Instron biomechanical testing equipment. Each wrist will be prepared by stripping the soft tissue from the radius and ulna to within 4cm of the wrist. The intraosseous membrane and the flexor carpi radialis will be preserved. The radius and ulna will then be cemented into a steel pipe to preclude forearm rotation. The forearm-assembly will be mounted vertically in the Instron with a force plate across the palmar aspect of the metacarpal head at an angle of loading to create wrist extension with ulnar deviation (equivalent to forces observed in actual clinical injuries). Proximal portion of the FCR will be fixed in one group by attaching it to the acrylic base and the tension should be 1.2 kilogram. Radiographs will be obtained of the wrists prior to and following loading. Photographs and dissection of the wrists will document the type and extent of injury. Three groups of 10 wrists each will be loaded to test the author's hypothesis:

Group I - Whole undissected cadaver wrists.

Group II - Wrists with the FCR and its retinaculum divided.

Group III - Wrists with radial side wrist ligaments divided (radial collateral ligament, radio-capitate ligament, radio-triquetral ligament), but with the FCP intact.

The force required to disrupt each wrist will be measured by the Instron. Then each disrupted wrist will be radiographed, photographed and a limited dissection performed to document extent and type of injury.

The second portion of the cadaver wrist study will retest surgically repaired wrists. Wrists from Groups I, II, and III will be equally divided (five from each group) and balanced for extent of injury, then repaired surgically. Repair Group A will be corrected in the "Standard" manner, i.e., without requiring the FCR and its retinaculum. Repair Group B will be surgically corrected to include the FCR and its retinaculum. Force loading will then be repeated in each repair group in the same manner as above.

**Progress:** An Instron materials testing system has been funded and is scheduled for delivery within 6 months. This project cannot be initiated until this equipment is installed.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/17

STATUS: Ongoing

TITLE: Free Vascularized Parathyroid Gland Transfer in Dogs

START DATE: 1987

ESTIMATED COMPLETION DATE: June 1989

PRINCIPAL INVESTIGATOR: COL Thomas J. Scully

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: CPT Paul R. Cordts, MC; MAJ Albert J. Moreno, MC

KEY WORDS: Parathyroid, transplant

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**Study Objective:** To determine if a total parathyroidectomy with vascularized autotransfer can be performed with consistently greater success than avascular autotransfer techniques.

**Technical Approach:** A total of 12 dogs are required. Each will be identified by ear tattoo and randomly selected for one of two equal sized groups (6 experimental, 6 controls). The experimental dogs will undergo a total thyroparathyroid excision with a unilateral microvascular thyroparathyroid autograft and the control animals will undergo a total thyroparathyroid excision with an avascular unilateral parathyroid autograft.

All dogs will have baseline serum, parathyroid hormone, calcium, phosphate levels drawn prior to surgery.

All experimental and control dogs will undergo the following evaluations postsurgically in order to assess parathyroid gland viability:

1. Proof of the function of the gland will be accomplished by technetium-Thallium parathyroid scan at 3 weeks.
2. Proof of the production of parathyroid hormone will be accomplished by measuring parathyroid hormone levels in the femoral vein proximal to the parathyroid graft.
3. Proof of the preservation of normal histology of the parathyroid gland will be accomplished by pathologic microscopic examination. The parathyroid tissue will be surgically removed following euthanasia.
4. Frequent postsurgical clinical examinations will be conducted in order to identify animals with symptoms of acute parathyroid insufficiency.

Experimental dogs only will undergo the following: Proof of the patency of the anastomosis will be accomplished by arteriogram at 3 weeks.

**Progress:** Six experimental group dogs and four control dogs have been studied. The project is proceeding satisfactorily.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/44

STATUS: Ongoing

TITLE: Determination of Bone Manganese Levels in Patients with Chondromalacia Patella.  
(Monitor: COL Maldonado)

START DATE: Jan 89

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL Thomas Scully

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: MAJ John Cook, MC; MAJ John Uhorchak

KEY WORDS: Chondromalacia, Manganese

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### Study Objective:

1. Identify and characterize by symptoms and physical findings the patient group with patellofemoral pain syndrome.
2. When performing diagnostic arthroscopy of patients with knee impairments, observe and record the character of the patellofemoral articular cartilage including objective measurement of cartilage softness.
3. Obtain 1 gram bone biopsy specimens from the distal femoral metaphysis at the time of arthroscopy and determine manganese content of bone mineral.
4. Perform multivariate analysis of data to observe possible correlations of bone manganese levels with severity of signs and symptoms of chondromalacia, cartilage appearance and measure cartilage softness.

**Technical Approach:** The study will be conducted at WBAMC and UTEP. Clinical evaluation will take place at WBAMC. The patients presenting to the Orthopaedic Clinic with knee disorders requiring arthroscopy or arthrotomy will be counseled and asked to volunteer for this study. If their informed consent is obtained they will be asked to provide information to complete the clinical questionnaire. The results of a comprehensive physical examination of the knees will also be recorded. At arthroscopy or arthrotomy the character of the articular cartilage will be noted and graded for severity of chondromalacia by the criteria of Hugston, et al. The indentation hardness of the cartilage will then be measured by a modification of the Brinell hardness measurement technique. This will be done with a locally fabricated instrument which can be autoclave sterilized. A biopsy specimen consisting of 1 gram of bone will be obtained from the distal femoral metaphysis using standard bone biopsy techniques. A portion of the specimen will be submitted for routine histology and the remainder will be analyzed for manganese content. The portion for manganese assay will be asked at 900 degrees centigrade, the ash weighed, dissolved in EDTA decalcifying solution, and analyzed with a Beckman plasma spectrophotometer at UTEP. All biopsy specimens sent to UTEP will be identified by code number only.

**Progress:** Fabrication, in vitro testing and modification of the orthoscopic cartilage testing system is not yet complete. Testing in patients will not begin until a reliable, durable instrument is perfected.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/63

STATUS: Terminated

**TITLE:** Comparison of Calcium Channel Blockers with Allopurinol in the Suppression of Tissue Damage From Oxygen Radicals (in Rabbits)

**START DATE:**

**ESTIMATED COMPLETION DATE:**

**PRINCIPAL INVESTIGATOR:** CPT John Urochak

**DEPARTMENT:** Surg

**FACILITY:** William Beaumont Army Medical Center

**ASSOCIATED INVESTIGATORS:**

**KEY WORDS:** Calcium Channel Blockers

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**Study Objective:** To determine if the calcium channel blockers confer the same degree of protection from oxygen free radicals produced from reperfusion injuries as Allopurinol.

**Technical Approach:** Island skin flaps will be created in the left or right groin in Rabbits A-D. Cauterization of the deep anastomosis with pharmacologic agents. Rabbit B will receive Allopurinol 30 minutes prior to surgery. Rabbit C will receive Verapamil 30 minutes prior to surgery. The femoral vein, branch to the flap, which is now the sole venous drainage from the flap, will be occluded for six hours with restoration of blood flow. Graft survival is an "all or none" phenomenon and will be observed for 7-10 days post-surgery. Biopsies of the grafts will be taken in both viable and nonviable grafts to assess the degree of damage. Rabbit E will be a spare animal. To assess the dosage of Nifedipine/verapamil, it will be necessary to exteriorize a segment of omentum and observe venodilation while giving Nifedipine and verapamil to ensure therapeutic levels of the medication. This will be performed on Rabbits B and C.

**Progress:** This project was never initiated due to the principal investigator's departure from the service.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/86

STATUS: Completed

TITLE: Does Host Splenectomy Reduce Rejection Rate and Immunosuppressive Drug Dosage in Dogs Receiving Kidney Transplants?

START DATE: 1987

ESTIMATED COMPLETION DATE: 1987

PRINCIPAL INVESTIGATOR: BG Yassin M. Yassin

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: COL J.F. McPhail; LTC J. Ramirez; MAJ Paul Cordts; MAJ M. Halpert, MC

KEY WORDS: Kidney Transplant Rejection

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**Study Objective:** Investigate whether host splenectomy at the time of recipient operation would influence the rejection of transplanted organs and what effect this would have on the requirement for immunosuppressive drugs. This project will also serve as a training program for the surgical staff and housestaff.

**Technical Approach:** Experimental design. Twelve dogs will be included in this study and all will be donors and recipients at the same time. Two dogs will be used in each experiment donating to and receiving from each other. Two experiments will be performed weekly. In each experiment, the left kidney of either dog is transplanted to the right iliac region of the other, and the right kidneys of both dogs will be removed and their histology will serve as a baseline. The spleen will be removed in eight of the dogs only, and not in the remaining four, early during the operation. The dogs will be allocated to three groups.

Group I will include four splenectomized dogs who will receive reduced dose of immunosuppressive drugs (one-third) postoperatively. Group II includes four splenectomized dogs who will receive reduced dose of immunosuppressive drugs (one-third) postoperatively. Group III will include four splenectomized dogs not receiving any immunosuppression at all postoperatively. The animals will be followed up for one month for signs of rejection as well as other data. Survivors may be sacrificed at one month to collect histopathologic data (percutaneous biopsy may be attempted).

**Progress:** Four dogs were utilized in this training, with two surgeries done per animal. Three physicians were trained on each animal.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/87

STATUS: Completed

TITLE: Liver Transplantation Training Utilizing a Pig Model

START DATE: 1987

ESTIMATED COMPLETION DATE: 1987

PRINCIPAL INVESTIGATOR: BG Yassin M. Yassin

DEPARTMENT: Surg

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: John F. McPhail; LTC J. Ramirez; MAJ P. Cordts; MAJ R. Rochon

KEY WORDS: Liver transplantation

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**Study Objective:** This training is designed to allow involved surgeons to acquire experience in the technique of liver transplantation in the pig which is very similar to that in man. It will be used also to highlight the problems incurred and find ways to overcome them, and to standardize a method for its use in man.

**Technical Approach:** This laboratory exercise will concentrate on developing the surgeon's confidence in handling the liver during various transplantation procedures of procurement, preservation, and grafting. It will also enhance his surgical technique, particularly with regard to organ procurement and perfusion, and vascular and biliary anastomosis.

The pig will be anesthetized using gas and oxygen, after premedication. Administration and monitoring of anesthesia will be performed by the attending veterinarian. Postoperatively Demerol will be given.

The animals will be placed in the supine position. Two animals will be operated upon at the same time on two neighboring operating tables. One animal will serve as a donor and the other as recipient.

**Progress:** Two pigs were utilized for this training, with two surgeries being done per animal. Three physicians were trained on each pig.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/52

STATUS: Ongoing

TITLE: Combat Trauma Life Support Procedure in the Sheep Model

START DATE: Jul 88

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: CW2 G.A. Bendeck

DEPARTMENT: 3rd CAV, FBT

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS: CPT Leo Conger, MC; CW2 Mark Adelman, PA-C

KEY WORDS: Life support, combat trauma

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Study Objective: To train Physicians Assistants and Line Medics who are not dealing with major trauma on a day-to-day basis, but may be called upon to perform this function in a combat environment. The sheep model will simulate human trauma.

Technical Approach:

ANIMAL PROCEDURES:

1. Cricothyroidotomy
2. Venous Cutdown
3. Entubation
4. Chest Trauma Management
  - a. Needle decompression
  - b. Tube thoracostomy

ATLS training manuals will be used for each training procedure.

Progress: One training day has been held, utilizing 4 animals. Sixteen medics were trained in July. The next training will be 10 January 1989, and another training day is tentatively scheduled for February 1989.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/86

STATUS: Completed

TITLE: Hospital Liquid Diet Evaluation (previously BAMC #C-27-87)

START DATE: 1 March 1988

ESTIMATED COMPLETION DATE: 31 March 1988

PRINCIPAL INVESTIGATOR: LTC Katie Boyd

DEPARTMENT: Nutrition Care

FACILITY: Darnall Army Community Hospital

ASSOCIATED INVESTIGATORS:

KEY WORDS: Liquid diet, jaw injury

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Study Objective: To determine the acceptability of commercially produced menu items for patients with jaw injuries and/or dental problems.

Technical Approach: The study will be conducted in 12 military hospitals. Hospitals participating in the evaluation will be asked to provide support from dietitians and/or diet technicians who will be responsible for the following: 1. briefing patients; 2. obtaining patients' signatures on volunteer agreement forms; 3. preparing the liquid products according to instructions provided by NATICK; 4. measuring liquid product and beverage intake according to the protocol; 5. providing a description of the currently used liquid diet products; 6. providing information regarding each patient's hospitalization; 7. obtaining the attending physicians' written permission for eligible patients to participate; 8. distributing and collecting the questionnaires; and 10. forwarding completed questionnaires to NATICK.

Progress: All information on this project was forwarded to U.S. Army Natick Research, Development and Engineering Center. The findings/results will be published by Natick.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/70

STATUS: Terminated

TITLE: Perceived Learning Needs of Individuals Diagnosed with Positive HTLV-III

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: MAJ Al Brooks

DEPARTMENT: Medicine

FACILITY: Darnall Army Community Hospital,  
Ft Hood, Texas

ASSOCIATED INVESTIGATORS:

KEY WORDS: Learning Needs

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Study Objective: Identify the importance of individuals' specific perceived learning needs. Identify at what stage of HIV viral infection the individual most needs or wants certain information. Identify when teaching would be most readily accepted.

Technical Approach: An interview questionnaire has been developed from the literature. The questionnaire is in two parts: part I elicits demographic and personal information; part II elicits importance of learning needs. Clients will be asked to determine which factors they see as important and to what degree of importance by a four-point Likert scale.

Progress: Principal investigator changed duty stations, and does not care to pursue the protocol.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: #88/77

STATUS: Ongoing

TITLE: Use of Venous pH in the Initial Evaluation of Pediatric Patients with Diabetic Ketoacidosis

START DATE: Nov 1988

ESTIMATED COMPLETION DATE: May 1990

PRINCIPAL INVESTIGATOR: CPT Charles W. Callahan

DEPARTMENT: ER

FACILITY: Darnall Army Community Hospital

ASSOCIATED INVESTIGATORS: CPT Daniel J. Dirz, MC

KEY WORDS: Venous pH, diabetic ketoacidosis

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Study Objective: To determine the utility of venous pH to define the degree of acidosis in the initial evaluation of the pediatric patient with diabetic ketoacidosis.

Technical Approach: We will compare an arterial and venous pH sample in all patients who present in diabetic ketoacidosis to the emergency room at Darnall Army Community Hospital over an 18 month period, or until a sufficient population size is reached (N=100). Patients will be eligible for this study if they are between the ages of 1 and 18 years old, and have clinical and laboratory evidence consistent with ketoacidosis or who are known diabetics who have presented with similar symptoms of ketoacidosis in the past. A single (1.5cc) sample of arterial blood will be obtained from the radial artery of the patient by an emergency room staff member or by the investigators, as is the standard for defining acidosis in this setting. A single (1.5cc) sample of venous blood will also be obtained simultaneously with the other venous samples taken from the IV once intravenous access has been established. These two values will be compared and the results analyzed statistically. consent for the additional laboratory study will be obtained, although no additional sampling procedures will be necessary.

Demographic and laboratory data will be recorded on a database form initiated in the emergency room and subsequently entered into a computer for statistical analysis in collaboration with the department of Clinical Investigation at William Beaumont Army Medical Center.

Progress: This study was started on 1 Nov 1988. Three patients have been enrolled to date. No data has been analyzed so far. There have been no adverse patient outcomes.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/56

STATUS: Completed

TITLE: Adjunctive Use of Ipratropium Bromide in the Emergency Management of Acute Asthma

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: CPT P.K. Cellucci

DEPARTMENT: Darnall

FACILITY: William Beaumont Army Medical Center

ASSOCIATED INVESTIGATORS:

KEY WORDS: Ipratropium bromide

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Study Objective: To determine whether ipratropium bromide adds significantly to the bronchodilation obtained with B-agonists alone, when used in the setting of an acute asthmatic exacerbation.

Technical Approach: Patients aged 18 to 65 who present to the Emergency Department with a history of asthma and clinical evidence of an acute exacerbation, or those presenting with new-onset asthma will be considered for enrollment in the study. After a brief history is obtained and supportive measures instituted, initial spirometry will be performed. The best FEV1 of three attempts will be recorded as the pre-treatment baseline. Those with an initial FEV1 in the 25 to 75% range of predicted values will be randomized into one of two treatment groups. The first group will receive an initial treatment consisting of two puffs of ipratropium bromide and two puffs of albuterol. The second group will receive two puffs of albuterol only. Both treatment groups will receive additional doses of two puffs of albuterol at 20 and 40 minutes after the initial doses. Post-treatment spirometry will be performed 60 and 90 minutes after the initial dose.

Progress: The clinical data has been secured, and the principal investigator is in the process of writing his paper.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/85

STATUS: Completed

TITLE: Treatment of Mammalian Bites

START DATE: Jun 85

ESTIMATED COMPLETION DATE: Jun 87

PRINCIPAL INVESTIGATOR: CPT Daniel J. Dire

DEPARTMENT: ER

FACILITY: Darnall Army Community Hospital

ASSOCIATED INVESTIGATORS: MAJ Steve Walker, MC

KEY WORDS: Bite, mammalian

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**Study Objective:** (1) To show whether there is a statistically significant difference in the infection rate of mammalian animal bite wounds that require suturing among those wounds which are closed immediately in the Emergency Room and those utilizing delayed primary closure. (2) To show whether there is a statistically significant difference in the infection rate of mammalian bite wounds that are treated with good wound cleaning and debridement compared to those also treated with a prophylactic course of oral antibiotics (excluding puncture type wounds and wounds of the hands and feet).

**Technical Approach:** All patients 1-year-old and up with mammalian bites who present to the Emergency Room are eligible. Those with wounds not requiring stitches will be randomly assigned to either receive or not receive a 7-day course of antibiotics. Those with wounds requiring stitches will be randomly assigned to either have the wound immediately sutured or will be required to return in 3-days for suturing. Patients in this latter group will either receive or not receive a 7-day course of antibiotics.

**Progress:** Data was collected on 1079 patients. 194 patients were treated for dog bites and prospectively randomized into the prophylactic antibiotic part of the study. This data was presented at the 2nd International Conference on Emergency Medicine in Brisbane, Australia on 24 Oct 88. A manuscript has been submitted to the Annals of Emergency Medicine for consideration for publication.

Data on approximately 200 feline bites, sutured wounds, hand wounds, and "high risk" bite wounds are pending statistical analysis. The authors plan to submit abstracts to the annual UA/EM scientific meeting and the 6th World Congress on Emergency Medicine in 1989.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/28

STATUS: Ongoing

TITLE: Marital Dynamic Survey

START DATE: Jun 1988

ESTIMATED COMPLETION DATE: Jul 1989

PRINCIPAL INVESTIGATOR: CPT David Hurlbert

DEPARTMENT: Social Work Svc

FACILITY: Darnall Army Community Hospital  
Ft Hood, TX

ASSOCIATED INVESTIGATORS:

KEY WORDS: Spouse abuse, family violence, marital adjustment

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**Study Objective:** To study many facets of the interrelationship of married couples in order to better understand the complexities of wife abuse and some of the dynamics associated with it.

**Technical Approach:** The research design includes a questionnaire to be administered to both spouses involved in one of two types of marital therapy groups: the DCCP (Domestic Conflict Containment Program) and the Social Work Couples Group. The Social Work Couples Group includes people who seek therapy for the purpose of marital enrichment, to improve communication, to help them to attain greater levels of intimacy. These couples were screened to eliminate those with problems of family violence or drug or alcohol abuse. It may be assumed that these are relatively happily married people who are seeking to enrich an already stable relationship. The second group consists of people who were referred because of reports of family violence, which usually means wife abuse. They are required to participate in the group. Among the variables to be studied are: length of marriage, how long couples knew each other before marriage, attitudes toward traditional gender roles, household division of labor, power distribution within the family, autonomy of spouses, liking and loving, marital satisfaction, and levels of marital conflict. Participating couples in each group will be matched by racial or ethnic background, age, and military rank in order to provide as much control as possible over possibly relevant variables. The questionnaire is self-administered, with utmost precaution taken to protect confidentiality, even between spouses. It should take between 30 to 45 minutes to administer. Couples in each group will be asked to complete a questionnaire at the beginning and end of the eight-week session, in order for within-group and between-group comparisons to be made. The use of the two groups provides a perfect opportunity for comparison because if there are significant differences on any of the measures between the groups, then these measures might be inferred to be predictors of potential wife abuse. If scores on any of these measures change after therapy, particularly for the couples in the DCCP group, then some conclusions might be drawn about the effects of therapy, particularly if spouses become more egalitarian with regard to power or less rigid with regard to gender roles. A precursory review of the relevant literature suggests some preliminary hypotheses:

- (1) Wife abuse is associated with subscription to traditional gender roles.
- (2) Wife abuse is associated with a rigid household division of labor.
- (3) Wife abuse is associated with an unequal power distribution within the family.
- (4) Wife abuse is associated with significantly less autonomy for the wife than for the husband.
- (5) Wife abuse is associated with lack of outside employment for the wife.
- (6) Wife abuse is associated with higher liking and loving scores for the wife than for the husband.

**Progress:** Continuing to administer questionnaires and gather data.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/57

STATUS: Ongoing

TITLE: Animal Model (Caprine) Laboratory, Advanced Trauma Life Support Course (ATLS)

START DATE: Jul 1988

ESTIMATED COMPLETION DATE: Indefinite

PRINCIPAL INVESTIGATOR: COL John W. Kolmer

DEPARTMENT: ER

FACILITY: Darnall Army Community Hospital

ASSOCIATED INVESTIGATORS: MAJ Michael W. Yehle

KEY WORDS: Trauma

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**Study Objective:** This protocol will mandate the following - proper procurement of animals, humane care of animals prior to and during surgical procedures, appropriate anesthetics and monitoring of anesthesia level during the procedures, detailed description of surgical procedures involved, and humane euthanasia with proper disposal of euthanized animals.

**Technical Approach:** The Advanced Trauma Life Support (ATLS) training program is designed for physicians who are primarily responsible for managing the critically injured patient; The American College of Surgeons (ACS) Committee on Trauma defines the standards that the ATLS course must adhere to. Initial assessment and management of specific types of injuries are presented to the students through lecture and slide presentations. Students then rotate through practical skill stations associated with the lecture content previously presented. The skill stations and animal lab allow the student to observe and practice to proficiency those life-saving skills necessary in the initial management and stabilization of the trauma patient. The animal lab is a one hour affair with one instructor and four students assigned to each animal.

**Procedures:**

- a. Preparation of animals
- b. Intravenous administration of fluids
- c. Tracheal intubation
- d. Venous cutdown
- e. Peritoneal lavage
- f. Needle Thoracocentesis
- g. Chest tube insertion
- h. Pericardiocentesis
- i. Cricothyroidotomy

**Progress:** Twenty-four students and six instructors participated in the Animal Model (Caprine) Laboratory, Advanced Trauma Life Support course (ATLS). All procedures were successfully completed and all students completed the laboratory. There were six animals (goats) used during the laboratory.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/19

STATUS: Completed

TITLE: Comparison of Intramuscular Benadryl and Cimetidine in the Treatment of Acute Urticaria

START DATE: Jul 1988

ESTIMATED COMPLETION DATE: Oct 1988

PRINCIPAL INVESTIGATOR: Dr. R. Moscati

DEPARTMENT: ER

FACILITY: Darnall Army Community Hospital

ASSOCIATED INVESTIGATORS: CPT G. Moore, MC

KEY WORDS: Cimetidine urticaria

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**Study Objective:** To compare the use of cimetidine and Benadryl in the treatment of acute urticaria. Demonstrate IM cimetidine as an effective treatment of acute urticaria would provide an inexpensive, nonsedating alternative to Benadryl for use in the acute setting.

**Technical Approach:** Double blind randomized study with 50 patients each in the cimetidine and Benadryl groups. Subjects of this study will include 100 male and female patients between the ages of 18 and 55 presenting to the ER at Darnall with signs and symptoms consistent with acute urticaria of less than 24 hours duration. Presenting symptoms should include itching, swelling and rash. Presenting signs should include wheal formation in a nonlocalized pattern. Patients to be excluded include those with any respiratory involvement, hypotension, allergy to Benadryl or cimetidine, current use of an H1 or H2 blocker, current use of steroids, history of chronic respiratory, cardiovascular, renal or hepatic disease. Subjects initially will be evaluated by a physician. If eligible for inclusion in the study, the physician will inform a nurse. Eligible patients will be alternately assigned to the Benadryl or cimetidine treatment groups by the nurse with the treating physician and patient remaining blinded. the nurse will then administer the appropriate medication.

The medication used in this study will be diphenhydramine 50mg, cimetidine 300mg and normal saline 2cc. The medications will be administered intramuscularly to the subjects following their initial evaluation. Thirty minutes later the subjects will be reevaluated to determine improvement, no change or worsening of signs and symptoms.

Evaluation of patients will center on the patient's perception of pruritis and sedation, as well as the physician's assessment of wheal coverage and intensity. These items will be recorded prior to medication administration and after thirty minutes. Vital signs will also be recorded at these times.

**Progress:** Ninety-three patients were entered into this study. The study has been completed with no adverse reactions occurring.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/23

STATUS: Completed

TITLE: Comparison of Intraosseous Versus Intravenous Phenytoin (in the Pig Model)

START DATE: Feb 1988

ESTIMATED COMPLETION DATE: Feb 1988

PRINCIPAL INVESTIGATOR: CPT Paul J. Vinsel

DEPARTMENT: ER

FACILITY: Darnall Army Community Hospital

ASSOCIATED INVESTIGATORS: CPT Gregory P. Moore, MC

KEY WORDS: Phenytoin, intraosseous infusion

Study Objective: (1) To determine if therapeutic serum levels of Phenytoin may be obtained using the intraosseous route and how quickly in comparison to intravenous administration. (2) To determine the effect of intraosseous administration of Phenytoin on the bone marrow.

Technical Approach: The pig will be weighed and placed in four point restraints in the animal lab. Vital signs will be taken. Intravenous line will be established using 0.9% saline solution. Anesthesia will be achieved using Ketamine 22mg/kg intravenous with additional doses as needed. The animal will have intraosseous site of tibia and overlying skin anesthetized with 0.5% marcaine (10cc) which should last 4-6 hours. This is comparable to human anesthesia with bone marrow biopsy. An intraosseous line will be obtained using a 15 gauge bone marrow needle in the proximal anterior tibia under sterile conditions. 100cc's of normal saline will be infused into the intraosseous line to ensure it is functioning. Phenytoin will be infused through the intraosseous line at a dose of 15mg/kg. This will be given at a rate of 25mg/min to avoid the side effect of hypotension. The animal will have repeat vital signs every 5-10 minutes to watch for hypotension. After the phenytoin infusion, blood levels of phenytoin will be drawn at 0, 1, 5, 10 and 15 minutes. Pain will be treated as per attending veterinarian and the animal will be euthanized if pain is uncontrollable. The intraosseous line will be removed. The site will be marked with a colored suture for future identification. Topical bacitracin applied, and the sight bandaged. The animal will be housed post-operatively at the animal holding facility at the Department of Clinical Investigation, and will be observed for three days for signs of local infection. The incidence of osteomyelitis is less than 1%. Each animal will have the procedure repeated using phenytoin infusion by intravenous, rather than intraosseous route. Group A (3 animals) will have phenytoin intraosseous infusion on day 1 and intravenous infusion on day 3. Group B (3 animals) will have phenytoin intravenous infusion on day 1 and intraosseous infusion on day 3. This will serve to use each animal as its own control.

Two months after the infusion, the animal will be sacrificed using T-61 intravenous at a dose of 1.1 mg/kg. bone marrow usually recovers from invasion within 2 months. Bone marrow biopsies will be performed for hypocellularity or signs of osteomyelitis (these are the complications possibly associated with infusion of alkaline or hypertonic solutions).

Progress: Project was completed. Research paper is presently being reviewed by American Journal of Emergency Medicine for publication.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/82

STATUS: Completed

TITLE: Irrigation of Suturable Wounds

START DATE: Sep 1987

ESTIMATED COMPLETION DATE: Jan 1988

PRINCIPAL INVESTIGATOR: CPT Anthony P. Welsh

DEPARTMENT: ER

FACILITY: Darnall Army Community Hospital

ASSOCIATED INVESTIGATORS:

KEY WORDS: Suturable Wounds

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**Study Objective:** To show whether there is a statistically significant difference in the infection rate of wounds that require suturing among those wounds which are irrigated with 1% Povidine-iodine versus those irrigated with normal saline versus those irrigated with Pluronic-F68.

**Technical Approach:** All patients who present to the Emergency Room for treatment of wounds will be evaluated for participation. Only those patients who have their wounds sutured on their initial presentation will be entered into the study. All patients will receive tetanus prophylaxis if indicated. Wounds will be irrigated in a standardized fashion. Wound irrigation will be performed in one of three ways, depending on the time period: (1) with a 1% Povidine-iodine solution; (2) with normal saline; or (3) with Pluronic-F68 (Shur-clens). Patients will be evaluated for evidence of infection at the time of suture removal.

**Progress:** This study was completed in January 1988. 533 patients were enrolled. There was no statistical difference in the infection rates between the 3 treatment groups. This study was presented at the University Association for Emergency Medicine annual meeting in Cincinnati, Ohio in May 1988. This study was submitted to the ANNALS OF EMERGENCY MEDICINE for consideration for publication.



## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 88/66

STATUS: Ongoing

TITLE: Treatment of Hypercholesterolemia with Psyllium Hydrophilic Mucilloid (Metamucil)

START DATE: Sep 1988

ESTIMATED COMPLETION DATE: Jul 1990

PRINCIPAL INVESTIGATOR: CPT Richard E. Whitlow

DEPARTMENT: Med

FACILITY: Darnall Army Community Hospital

ASSOCIATED INVESTIGATORS: Julia A. Morgan, D.O.; Richard D. Harwood, R.N.P.; Rebecca J. Oskey, R.N.P.; Elizabeth Kist, R.D.; Ann Andersen, R.D.

KEY WORDS: Hypercholesterolemia, Psyllium Hydrophilic Mucilloid (Metamucil)

---

**Study Objective:** To define the optimal safe dosing of psyllium hydrophilic mucilloid to lower total and LDL cholesterol and define the long-term efficacy and safety of psyllium hydrophilic mucilloid. This study will be conducted in a randomized prospective, controlled manner.

**Technical Approach:** Patients will be enrolled from a variety of sources: random cholesterol screening tests, over-40 physical examinations, commanders' physical examination, commanders' total fitness course, and patients referred to Nutrition Clinic for dietary therapy. The patients will initially undergo a battery of screening tests as well as a history and physical exam to determine secondary causes of hypercholesterolemia (untreated hypothyroidism, obstructive liver disease, nephrotic syndrome). The study medication is psyllium hydrophilic mucilloid (brand Plantago psyllium, Metamucil) in varying doses and intervals. Only patients with serum cholesterol between 200 and 260 mg/dl with two coronary heart disease risk factors will be studied since therapy is recommended for this group by the NCEP and the magnitude of expected response is reasonable to assume a lowering of serum cholesterol by Metamucil to a normal range. Throughout the study laboratory evaluations will be obtained to assess known aberrations induced by increased dietary fiber.

**Progress:** The ongoing nutrition care division cholesterol classes are continuing to be conducted and potential patients are being recruited. The restrictive cholesterol values of 200-240 with two coronary artery disease risk factors or 240-260 without risk factors are severely limiting the availability of qualified patients for the study. Time has also become a major factor in that with no administrative support, there is not enough time to conduct the teaching, screening, and enrollment of subjects.

To date, five patients have been enrolled. These five have been recruited from a population of about 80 patients. We have an additional 26-28 patients awaiting enrollment when time becomes available. We are averaging about 4-8 patients per class/25-40 who are eligible for the study.

## DETAIL SUMMARY SHEET

DATE: 1 October 1988

PROTOCOL #: 87/81

STATUS: Terminated

TITLE: The Relationship Among Role Attitude, Role Strain, Social Support and Health in Active Duty Military Mothers

START DATE:

ESTIMATED COMPLETION DATE:

PRINCIPAL INVESTIGATOR: LTC C.A. Rupkalvis

DEPARTMENT: ER

FACILITY: USAMEDDAC Ft. Huachuca, AZ

ASSOCIATED INVESTIGATORS:

KEY WORDS: Military Mothers

---

Study Objective: Describe the relationship of health in four groups of military mothers (partnered and single; those with traditional jobs and those with nontraditional jobs) with their role attitudes, the role strain produced by combining roles and the social support received. To describe the differences between the groups as well as between officers and enlisted.

Technical Approach: Active duty women who are mothers residing with their children will be sampled. This will be done in two ways. Company Commanders will be contacted and meetings set up at the workplace. At the meeting time the study will be explained by the researcher, who will also be available for answering questions during the administration of the instruments. No identifying information will be requested. The participants will be offered results of the study. Military mothers will be asked to complete questionnaires while they wait for appointments in OB-GYN clinics, or they may be mailed in envelopes provided.

Progress: This project was terminated due to the principal investigator's relocation.



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