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DEPARTMENT OF CLINICAL INVESTIGATION ANNUAL RESEARCH
PROGRESS REPORT FISCAL YEAR 1985 VOLUME 1(U) BROOKE
ARMY MEDICAL CENTER FORT SAM HOUSTON TX F H GOLDNER

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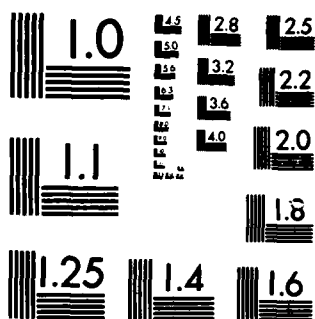
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DEPARTMENT OF CLINICAL INVESTIGATION

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ANNUAL RESEARCH PROGRESS REPORT

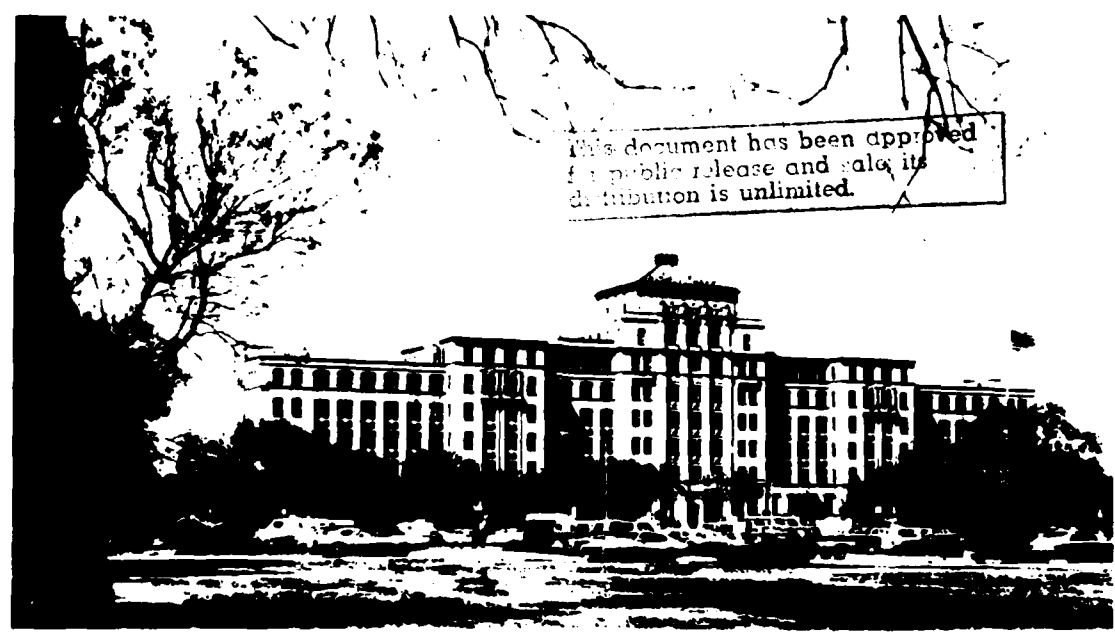
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FISCAL YEAR 1985
VOLUME I

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BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234



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REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER RCS MED-300 (R1)	2. GOVT ACCESSION NO. DD-4163	3. RECIPIENT'S CATALOG NUMBER 262
4. TITLE (and Subtitle) ANNUAL RESEARCH PROGRESS REPORT	5. TYPE OF REPORT & PERIOD COVERED ANNUAL - FY 85	
	6. PERFORMING ORG. REPORT NUMBER	
7. AUTHOR(s) FRED H. GOLDNER Colonel, MC	8. CONTRACT OR GRANT NUMBER(s)	
9. PERFORMING ORGANIZATION NAME AND ADDRESS Department of Clinical Investigation Brooke Army Medical Center Fort Sam Houston, TX 78234-6200	10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS	
11. CONTROLLING OFFICE NAME AND ADDRESS Commander Brooke Army Medical Center Fort Sam Houston, Texas 78234-6200	12. REPORT DATE 1 October 1985	
	13. NUMBER OF PAGES 487	
14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office) Office of The Surgeon General Department of the Army Washington, D.C. 20314	15. SECURITY CLASS. (of this report) Unclassified	
	15a. DECLASSIFICATION/DOWNGRADING SCHEDULE	
16. DISTRIBUTION STATEMENT (of this Report) APPROVED FOR PUBLIC RELEASE; DISTRIBUTION UNLIMITED		
17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report) n/a		
18. SUPPLEMENTARY NOTES The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents		
19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Clinical Investigations, all medical specialties Publications, presentations Detail Summary Sheets (Study Objective; Technical Approach; Progress; Status)		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee, the Institutional Review Board, and the Animal Care Committee and registered with the Department of Clinical Investigation during FY 1985. Report also includes known presentations and publications by the Brooke Army Medical Center staff. The research protocols described were (continued on reverse side)		

Block 20. Abstract

conducted under the provisions of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; USAMRDC 70-25, Use of Volunteers as Subjects of Research; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports; and BAMC Memo 40-98, Department of Clinical Investigation, to insure the medical well-being, preservation of rights and dignity of human subjects who participated in these investigational studies. Research studies involving the use of laboratory animals were conducted under the provisions of AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs.

See Studies Vol. 1

FOREWORD

The Department of Clinical Investigation at Brooke Army Medical Center has completed another outstanding year. The number of protocols, as well as the general quality of work, has continued to improve year by year. This work could not be accomplished without the continued superior expertise and support of the assigned personnel, both technical and administrative.

While this progress has been gratifying, it has been my general impression that the overall awareness of the mission and capabilities of the DCI could stand improvement throughout the medical center. Many people simply do not know what is available or are confused by perceived priorities within the department. To this end, an educational program in the form of a conference has been offered to all departments and services within the hospital. During this session a general presentation is made on all the mechanisms, facilities and resources and questions are answered, supplemented by reading materials. The response to this program has been very gratifying. In addition, a bimonthly newsletter to supplement the above program is in its inception. A very successful open house was held with many subsequent positive comments. Of course, time will tell whether this enthusiasm will be translated into actual increase in productive investigative interest, but my hopes are high.

Another highlight of the year has been the long awaited start of the autologous bone marrow transplant program which the DCI is pleased to support. This has been accomplished primarily through the diligent efforts of the Hematology-Oncology Service and should prove to a true "feather" in the cap of BAMC.

Of course, problem areas will always remain. Foremost among these is the lack of AAALAC accreditation of our animal facility. Supplemental and alternative means for dealing with this problem are being explored. While short term solutions may be found, the only real solution will be the completion of BAMC's new animal and clinical research facility which hopefully will long antedate the construction of the new hospital.

Congratulations again to all personnel who have worked so hard to make this program successful.

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Fred Goldner

FRED GOLDNER

COL, MC

Chief, Department of Clinical Investigation

UNIT SUMMARY - FISCAL YEAR 1985

A. Objectives

The objectives of the Department of Clinical Investigation are as follows:

1. To achieve continuous improvement in the quality of patient care.
2. To assist in the professional growth and development of the house staff by providing guidance and support in clinical research.
3. To provide a milieu conducive to retention of competent staff personnel and recruitment of new personnel.
4. To provide a review body for research proposals by investigators currently assigned to MEDDAC Units in an effort to promote an interest in Army medicine and retention in the Army Medical Corps.
5. To maintain an atmosphere of inquiry consistent with the dynamic nature of the health sciences.
6. To maintain a high professional standard and accreditation of advanced health programs.
7. To assure the highest level of professional standards in the conduct of human research and animal research.

B. Technical Approach

All research, investigational and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-38, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

C. Staffing

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Goldner, Fred H.*	COL	60G00	Chief, Gastroenterologist
Anderson, James H., Jr.***	LTC	61C00	Chief, Endocrinologist
Gunn, Bruce A.	MAJ	68A00	Microbiologist
Krikorian, Debra J.	CPT	68C00	Biochemist
Hadick, Clayton L.	CPT	64A00	Veterinary Lab Animal Officer
Loyd, Charles M.	SFC	92B3R	NCOIC
Diaz, Noel	SSG	92B2R	Med Lab Specialist
Bretthauer, Ricky W.	SSG	92B2R	Med Lab Specialist
Tchernowitz, Clark	SGT	92B2	Med Lab Specialist
Blomgren, Wendy E.	SGT	91T20	Animal Care Specialist
Jones, Sheila	SGT	92B2	Med Lab Specialist

* Assigned 1 Apr 85

***REFRAD 30 Jun 85

C. Staffing (continued)

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Murphy, Thomas**	SP4	92B1	Med Lab Specialist
Davis, Geri M.***	SP4	92B1	Med Lab Specialist
Parker, Timothy A.	SP4	91T20	Animal Care Specialist
Hicks, Jeninne M.	SGT	92B1	Med Lab Specialist
Gaines, Marlene*	SP4	91T20	Animal Care Specialist
Merrill, Gerald A.	GS11	00401	Research Immunologist
Vaughn, George K.	GS11	00345	Medical Technologist (Micro)
Ayala, Eleanor	GS9	00644	Medical Technologist
Posch, John	GS9	00644	Medical Technologist
Reeb, Barbara	GS9	00644	Medical Technologist
Peek, Michael W.	GS9	01320	Chemist
Marshall, Regina	GS9	00610	Clinical Nurse
Chapa, Isidoro	GS7	00645	Medical Technician
Wolcott, Karen M.	GS7	00404	Biological Technician
Rios, Roberto	GS9	01020	Medical Scientific Illustrator
Bratten, Dodie	GS9	00301	Clin Research Protocol Coord
Smith, Helen J.	GS6	01087	Editorial Assistant

* Assigned 5 Nov 84

** Reassigned 15 Jun 85

***REFRAD 18 Jul 85

D. Funding

<u>Type</u>	<u>Fiscal Year 84</u>	<u>Fiscal Year 85</u>
Civilian personnel to include benefits	276,590.00	395,863.00
Consumable supplies	135,247.00	132,309.00
Civilian contracts to include consultants	16,002.00	36,318.00
TDY	1,400.00	4,550.00
Publications	7,939.00	7,769.00
Noninvestment equipment (Minor MEDCASE)	-----	-----
Other OMA		
OMA Total	437,198.00	576,809.00
MEDCASE	114,500.00	153,768.00
Other		
Military	482,072.00	369,283.00
TOTAL	1,033,770.00	1,099,860.00

E. Progress

Protocol Disposition FY 85

	<u>Terminated</u>	<u>Transferred</u>	<u>Completed</u>	<u>Ongoing to FY 86</u>
FY 77	-		0	1
FY 78	0		0	1
FY 79	0		1	0
FY 81	2		2	4
FY 82	2		2	8
FY 83	4		7	15
FY 84	15	1	15	39
FY 85	<u>5</u>	<u>—</u>	<u>7</u>	<u>74</u>
	28	1	44	142

*C-14-81 was reopened for additional studies.

Group Protocol Disposition FY 85

	<u>Terminated</u>	<u>Completed</u>	<u>Ongoing to FY 86</u>
SWOG	1	23	74
GOG	0	1	27
PVSG	0	0	1
POG	<u>0</u>	<u>1</u>	<u>32</u>
	1	25	134

F. Problems

It became evident in FY 85 that a problem existed between the mission that our department was originally meant to follow and the mission that it had, in time, opted to follow. In summary, the "service" part of our mission needed to be rejuvenated and we needed to "bring the department to the physician." To accomplish this, we instituted the following:

a. Open House. On 17 October 1985, we had our first annual Open House. Through this we were able to introduce the hospital staff to our facility and our professional and administrative staff.

b. Slide Show. This year every department and service in the hospital allowed us to present to their physicians an hour of slides and discussion concerning the Department of Clinical Investigation and what we can do for them.

c. Newsletter. The first quarterly newsletter for our department is to be published and distributed throughout the hospital during November of this year. This newsletter will include topics concerning bone marrow transplantation, ethical issues, biostatistics, microbiology, immunology, monoclonal antibody technology, DNA probe technology and many others. All are written by the staff of DCI.

Another problem area that we have faced this year is the continuing need for our department to provide the hospital staff biostatistical advice and support. Since a requirement for a statistician was recognized during the manpower survey of FY 84 but we were not authorized to fill the requirement, we have had to task our analytical chemist with this duty. Presently, we are obtaining one to two new requests for statistical support each week, and we anticipate these requests to increase in number as we are recognized as a resource for these analyses. Authorization of a full-time statistician would insure continued support by our department in the area of biostatistics and would enhance our theme of "service to the physician."

Renovation of the Laboratory Animal Facility has been cancelled by the Fort Sam Houston Directorate of Engineering and Housing. We remain unaccredited by the American Association for Accreditation of Laboratory Animal Care. The animal care issue remains critical and needs to be resolved. The Department is also in need of adequate space for studies with infectious agents (containment laboratories) and space for human volunteer studies.

Funds for equipment procurement and consumable supplies were satisfactory for FY 85. However, funds available for the Capital Expense Equipment Program were insufficient.

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DEPARTMENT OF THE ARMY
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DEPARTMENT OF CLINICAL INVESTIGATION

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Anesthesia and Operative Service

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Cardiothoracic Surgery Service

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General Surgery Service

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Neurosurgery Service

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Ophthalmology Service

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Urology Service

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Pharmacy Service

Dasher, T. Pharmaceutical services in a United States Army field hospital. Am. J. Hosp. Pharm. 4:576-580, 1985.

DEPARTMENT OF THE ARMY
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DEPARTMENT OF CLINICAL INVESTIGATION

PRESENTATIONS

Department of Clinical Investigation

Allen, R.C. Micromethod for differential quantification of leukocyte oxygenation activities in unseparated whole blood: A chemiluminogenic probe method. American Society of Clinical Pathologists, New Orleans, LA, 27 Oct - 2 Nov 84. (C)

Anderson, J.H., Jr. Faculty Member "Public Responsibility in Medicine and Research (PRIM&R)" Conference, Boston, Mass., 1-2 Nov 84.

Anderson, J.H., Jr. Guest Lecturer, Mount Sinai Hospital, New York City, NY, 4 Nov 84.

Anderson, J.H., Jr. Guest Lecturer, Cornell University, New York City, NY, 5 Nov 84.

Anderson, J.H., Jr. Faculty Member "Conference on the pursuit of knowledge: Rules, roles, relationships - A discussion of ethical issues in scientific inquiry." Houston, TX, 28 Jan 85.

Burleson, D.G. Changes in lymphocyte subpopulations after burn injury and burn injury with infection. FASEB, Oct 84.

Krikorian, Debra J. Use of HeNe Lasers: An evaluation of "enhanced healing effect" using ^{67}Ga -citrate and $^{99\text{m}}\text{Tc}$ pyrophosphate. Tripler Army Medical Center, 20 Sep 85. (C)

Vaughn, G.M. Clinical application in flow cytometry. Armed Forces Military Laboratory Scientists Meeting, Reno, NV, 24-29 Mar 85. (C)

Department of Emergency Medicine

Grigsby, W.S. Case presentation. Southern Medical Association's 78th Annual Scientific Assembly, New Orleans, LA, 4-7 Nov 84.

Department of Medicine

Office of the Chief

Johnson, J.E. Content of ambulatory internal medicine practice in an army medical center and an army community hospital. Society for Research and Education in Primary Care Internal Medicine, Washington, DC, 2-3 May 85.

Johnson, J.E. Physical examination errors by housestaff. Society for Research and Education in Primary Care Internal Medicine, Washington, DC, 2-3 May 85.

Allergy-Immunology Service

Carpenter, B.G., Ortiz, A.A. Hypersensitivity reaction to acetylcysteine. Carl W. Tempel Pulmonary-Allergy-Immunology Symposium, Denver, CO, 23-25 Jan 85.

Cardiology Service

Craig, W.E., Bailey, S.R., Layton, S., et al. High resolution digital subtraction angiography: application to left ventricular and coronary cineangiography. 31st Annual Meeting American College of Angiography, San Antonio, TX, 4-8 Nov 84.

Murgo, J.P. Diastolic and systolic function in hypertrophic cardiomyopathy. International Symposium on Cardiomyopathies, Lisbon, Portugal, 1-3 Oct 84. (C)

Craig, W.E., Digital subtraction angiography. Henry Ford Hospital, Detroit, MI, 19-20 Oct 84.

Miller, J.W. Integration of divergent views of obstructive and early systolic ejection in hypertrophic cardiomyopathy: hemodynamic (H), echocardiographic (E) and angiographic (A) correlates. 57th Annual Scientific Sessions of the American Heart Association, Miami, FL, 14 Nov 84.

Hoadley, S.D. Second heart sound splitting in aortic stenosis; right heart ejection dynamics. 57th Annual Scientific Sessions of the American Heart Association, Miami, FL, 14 Nov 84.

Bird, J.J. High resolution digital subtraction angiography: application of left ventricular and coronary cineangiography. 31st Annual Meeting of the American College of Angiology and the International College of Angiology, San Antonio, TX, 3 Nov 84. (C)

Latham, R.D. Regional pulse wave transmission along the human aorta: first micromanometric study in man. 34th Annual Scientific Session, American College of Cardiology, Anaheim, CA, 10-14 Mar 85. (C)

Latham, R.D., Cawthon, M.A., Rubal, B.J., Murgo, J.P. Radionuclide ventriculography with intravenous dipyridamole: Value for coronary artery disease. 14th Annual Session, Association of Army Cardiology, William Beaumont Army Medical Center, El Paso, TX, 21-23 May 85. (C)

Wrenn, R.C., Latham, R.D. Acute hemodynamic effects of intravenous dipyridamole: Comparison of normal population to subjects with coronary artery disease. 14th Annual Session Association of Army Cardiology, 21-23 May 85. (C)

Gantt, D.S. Correlation between left ventricular end diastolic pressure during exercise and post-ventriculography. 14th Annual Session Association of Army Cardiology, 21-23 May 85.

Bulgrin, J.R., Layton, S.A., Alamo, M.G., Rubal, B.J. Design for a digitally integrated catheterization laboratory automated acquisition system. 14th Annual Session Association of Army Cardiology, 21-23 May 85.

Latham, R.D., Westerhof, N., Rubal, B.J., Murgo, J.P. Aortic input impedance during the Muller maneuver: Influence of arterial wave reflections. 14th Annual Session Association of Army Cardiology, 21-23 May 85.

Latham, R.D., Baker, J., Rubal, B.J., Murgo, J.P. Circulating anti-heart antibody in idiopathic dilated cardiomyopathy. 14th Annual Session Association of Army Cardiology, 21-23 May 84.

Rubal, B.J., Latham, R.D., Richey, H., Starnes, E. Angioscopic visualization of the cardiovascular system. 14th Annual Session Association of Army Cardiology 21-23 May 85. (C)

Schatz, R.A. PTCA at BAMC. 14th Annual Session Association of Army Cardiology, 21-23 May 84. (C)

Hoadley, S.D., Bailey, S.R., Murgo, J.P. Transmitral flow in patients with mitral valve B-Bump. 14th Annual Session Association of Army Cardiology, 21-23 May 85.

Morera J., Pasipoularides A., Hoadley, S.D., et al. Doppler echocardiographic estimation of pulmonary artery systolic pressure. 14th Annual Session Association of Army Cardiology, 21-23 May 85.

Pasipoularides, A., Murgo, J.P. Ejection dynamic in man with and without outflow obstruction. 20th Annual Meeting of the Association for the Advancement of Medical Instrumentation, Boston, MA, 4-8 May 85. (C)

Cox, W.R., Pasipoularides A., Rubal, B.J., et al. Amplification of the arterial pulse between aortic root and brachial artery. 20th Annual Meeting of the Association for the Advancement of Medical Instrumentation, Boston, MA, 4-8 May 85.

Dermatology Service

Clemons, D.E. Malignant fibrohistiocytoma. American College of Chemosurgery Scientific Session and the American Society of Dermatopathology, Washington, D.C., December 1984.

Haddock, N.F. Psoriasis and inflammatory bowel disease: A case report and literature review. American Academy of Dermatology, Washington, D.C., December 1984.

Kraus, E.W., Dermatologic Aspects of AHUIAS TARA II: Honduras and life in a combat support hospital; AHUAS TARA II: Honduras. American Academy of Dermatology, Washington, D.C., December 1984.

Winton, G.B. Surgical tips. American College of Chemosurgery, Washington, D.C., December 1984.

Salasche, S.J., Cutaneous manifestations of chronic solar exposure. American College of Chemosurgery and the American Academy of Dermatology, Washington, D.C., December 1984.

Adnot, J. Immersion foot syndromes. American Academy of Dermatology, Washington, D.C., December 1984.

Salasche, S.J., Wound dressing for difficult anatomic sites. American Society for Dermatologic Surgery, Epcot, FL, 17-21 Apr 85.

Salasche, S.J. Dog ear repair and surgical connection of nail disorders. Texas Dermatologic Society, San Antonio, TX, 10-11 May 85.

Salasche, S.J. Planning the excision, dog ear repair, anesthesia, introduction to flaps, and the rhomboid flap, soft tissue workshop, Providence RI, 1-2 Jun 85.

Kraus, E.W. Interesting cases from BAMC and Honduras. Harvard Medical School/Massachusetts General Hospital, Boston, MA, 18 Jun 85.

Winton, G.B. Introduction to surgical flaps. Dermatologic Surgery Workshop, San Antonio, TX, 10 May 85

Winton, G.B., Wound dressing for dermatologic surgery. Annual Meeting of Association of Military Dermatologists, San Antonio, TX, 15 May 85.

Coquilla, B.H. Pseudofolliculitis barbae. Educational Video, BAMC, Jun 85.

Clemons, D.E. Histopathologist for CPC. Texas Dermatologic Society, San Antonio, TX, 11-12 May 85.

Clemons, D.E. Moderator for CPC. Dermatology Tri-Services Meeting, San Antonio, TX, 15-17 May 85.

Keeling, J.H. Randomized, controlled and comparative clinical trials of sunscreen. 46th Annual Society for Investigative Dermatology, 1-5 May 85. (C)

Lewis, C.W. Clues for the externist. Wilford Hall USAF Medical Center, 1 and 29 Aug 85.

Kraus, E.W. Interesting dermatology cases from BAMC. University of Texas Health Science Center at San Antonio, 19 Jul 85.

Salasche, S.J. Nail surgery. Texas Dermatologic Society, El Paso, TX, 5 Sep 85.

Clemons, D.E. Partners in crime. Sonoran Derm/Texas Derm Meeting, El Paso, TX, 6 Sep 85.

General Medicine Service

Kroenke, K.K. Paramedical consultations: utilization and physician compliance. Society for Research and Education in Primary Care Internal Medicine, New Orleans, LA, 1 Feb 85.

Kroenke, K.K. Educational efforts to improve the utilization of three common laboratory tests. Society for Research and Education in Primary Care Internal Medicine, Washington, D.C., 2-3 May 85.

Kroenke, K.K.. Paramedical consultation: utilization and physician compliance. Society for Research and Education in Primary Care Internal Medicine, Washington, D.C., 2-3 May 85.

Kroenke, K.K., Carpenter, J.L. Procedure cards: A computerized system for documenting housestaff procedures. Society for Research and Education in Primary Care Internal Medicine, Washington, D.C., 2-3 May 85.

Pinholt, E. Comparison of geriatric assessment instruments with the clinical judgment of housestaff and nurses. American Geriatrics Society, New York City, 11-12 Jul 85.

Hematology/Oncology Service

Harvey, W.H., Reed, K., Pick, T., et al. Totally implantable venous access, Port-a-Cath (PC) in leukemia patients. Leukemia Society of America Medical Conference, First National Symposium, Reno, NV, 14-16 Mar 85.

Harvey, W.H. Evaluation of fludarabine phosphate in colorectal carcinoma. A Southwest Oncology Group Phase II Study. American Society of Clinical Oncology Annual Meeting, Houston, TX, 19-21 May 85.

Schuller, D.E., McCracken, J.D., et al. Preoperative reductive chemotherapy for stage III or IV operable epidermoid carcinoma of the oral cavity, oropharynx, hypopharynx, or larynx, Phase III. A Southwest Oncology Group Study. International Conference on Head and Neck Cancer, Baltimore, MD, Jul 85.

Balducci, L., Boyd, J.F., Stutz, F.H., et al. Evaluation of fludarabine phosphate (NSC 312887) in renal cell carcinoma. ASCO, Mar 85.

Brown, T., Boyd, J., et al. Concomitant medications during phase I trials. ASCO, Mar 85.

Brown, T., et al. A phase I study of menogaril (MEN) in patients with advanced cancer. ASCO, Mar 85.

McCrackey, J.D., et al. Concurrent chemoradiotherapy for limited small cell carcinoma of the lung (SCCL). A Southwest Oncology Group Limited Institutional Pilot Study. ASCO, Mar 85.

Infectious Disease Service

Hawkes, C.A. Host defense mechanisms in amebiasis. U.S. Army Internists at the "Present Concepts in Internal Medicine Course," Oct 84.

Hawkes, C.A. Catheter and infusion-related sepsis: The nature of the problem and its prevention. Advanced Cardiac Life Support Course, Jan 85.

Davis, C.E. Immunocytochemical diagnosis of candida peritonitis. 85th Annual Meeting of the American Society for Microbiology, Mar 85.

Hawkes, C.A. Effect of sodium fluoride on caries-associated lactobacilli. American Association for the Advancement of Science, Mar 85.

Hawkes, C.A. Tuberculosis: Pathogenesis and transmission. State Chest Hospital, San Antonio, TX, 20 Jun 85.

Hawkes, C.A. Tuberculosis and pregnancy. State Chest Hospital, San Antonio, TX, 21 Jun 85.

Nephrology Service

Copley, J.B. "Primary" hematuria - A prospective evaluation. Concepts in Internal Medicine, San Francisco, CA, Oct 84. (C)

Foulks, C.J. Calcium Carbonate: An effective phosphorus binder in patients with chronic renal failures. Concepts in Internal Medicine, San Francisco, CA, Oct 84. (C)

Tapp, D.C. Clinical pathological correlations of IgA nephropathy. Concepts in Internal Medicine, San Francisco, CA, Oct 84. (C)

Foulks, C.J., Mills, G.M., Wright, L.F. Erythrocyte osmotic fragility studies in hyperparathyroidism. North American Symposium on Dialysis and Transplantation, Maui, Hawaii, 5-8 Aug 85. (C)

Foulks, C.J. Calcium carbonate: An effective phosphorus binder in patients with chronic renal failure. North American Symposium on Dialysis and Transplantation, Maui, Hawaii, 5-8 Aug 85.

Pulmonary Disease Service

Blanton, H.M. Chronic eosinophilic pneumonia: Case presentation and literature review. Carl W. Tempel Symposium on Pulmonary Disease, Letterman Army Medical Center, San Francisco, CA, 1-3 Oct 84.

Matarese, S.L. Endobronchial tuberculosis. Carl W. Tempel Symposium on Pulmonary Disease, Letterman Army Medical Center, San Francisco, CA, 1-3 Oct 84.

Matthews, J.I. The utility of CT scans in evaluation of lung cancer. XV World Congress on Diseases of the Chest, Sydney, Australia, 25-30 Aug 85

Matthews, J.I. Exercise responses during incremental, and high intensity and low intensity steady state exercise in patients with obstructive lung disease and normal controls. XV World Congress on Diseases of the Chest, Sydney, Australia, 25-30 Aug 85.

Richey, H.M. Efficacy of computed tomography in the evaluation of the liver in patients with non-small cell bronchogenic carcinoma. XV World Congress on Disease of the Chest, Aug 85.

Department of Obstetrics and Gynecology

Barnhill, D.R. Radial hysterectomy and pelvic lymphadenectomy for stage IB carcinoma of the cervix: 20 years experience. Armed Forces District Meeting (AFD), American College of Obstetricians and Gynecologists, Atlanta, GA, 7-12 Oct 84.

Barnhill, D.R. Microinvasive carcinoma of the cervix. AFD, American College of Obstetricians and Gynecologists, Atlanta, GA, 7-12 Oct 84.

Barnhill, D.R. Hormone replacement after radiation therapy for cervical carcinoma. AFD, Atlanta, GA, 7-12 Oct 84.

Barnhill, DR. Intraoperative evaluation of depth of invasion in Stage I endometrial adenocarcinoma. AFD, Atlanta, GA, 7-12 Oct 84.

Barnhill, D.R. Cervical carcinoma found incidentally in a uterus removed for benign indications. AFD, Atlanta, GA, 7-12 Oct 84.

Barnhill, D.R. Papillary adenocarcinoma of the endometrium. AFD, Atlanta, GA, 7-12 Oct 84.

Barnhill, D.R. Pulmonary embolization of a vascular clip as a complication of para-aortic lymph node sampling. AFD, Atlanta, GA, 7-12 Oct 84.

Barnhill, D.R. Non-squamous cancer of the vagina. AFD, Atlanta, GA, 7-12 Oct 84.

Barnhill, D.R. Hidradenitis suppurativa: a case presentation and review of the literature. AFD, Atlanta, GA, 7-12 Oct 84.

Barnhill, D.R. Histiocytosis-X in gynecology: a case presentation and review of the literature. AFD, Atlanta, GA, 7-12 Oct 84.

Barnhill, D.R. The association of primary uterine corpus malignancy with primary adenocarcinoma of the fallopian tube. AFD, Atlanta, GA, 7-12 Oct 84.

Barnhill, D.R. The effect of intestinal resection versus bypass on survival in patients with primary epithelial ovarian carcinoma. AFD, Atlanta, GA, 7-12 Oct 84.

Barnhill, D.R. Uterine sarcoma. AFD, Atlanta, GA, 7-12 Oct 84.

Barnhill, D.R. Repair of vaginal prolapse and perineal hernia after pelvic exenteration. Society of Gynecologic Surgeons, New Orleans LA, 25-27 Feb 85.

Barnhill, D.R. Papillary adenocarcinoma of the endometrium. Society of Gynecologic Oncologists, Miami, FL, 3-6 Feb 85.

Barnhill, D.R. Intraoperative evaluation of depth of invasion in Stage I endometrial adenocarcinoma. Society of Gynecologic Oncologists, Miami, FL, 3-6 Feb 85.

Barnhill, D.R. Radical hysterectomy and pelvic lymphadenectomy for Stage IB carcinoma of the cervix: 21 years experience. Society of Gynecologic Oncologists, Miami, FL, 3-6 Feb 85.

Barnhill, D.R. Cervical carcinoma found incidentally in a uterus removed for benign indications. 33rd Annual Clinical Meeting of the American College of Obstetricians and Gynecologists, Washington, D.C., 11-16 May 85.

Barnhill, D.R. Microinvasive carcinoma of the cervix. American College of Obstetricians and Gynecologists, Washington, D.C. 11-16 May 85.

Barnhill, D.R. Persistence of endometrial activity after radiation therapy for cervical carcinoma. American College of Obstetricians and Gynecologists, Washington, D.C. 11-16 May 85.

Barnhill, D.R. The effect of intestinal resection versus bypass on survival in patients with epithelial ovarian carcinoma. American College of Obstetricians and Gynecologists, Washington, D.C., 11-16 May 85.

Department of Pathology and Area Laboratory Services

Allen, R.C. Micromethod for differential quantification of leukocyte oxygenation activities in unseparated whole blood: A chemiluminescent probe approach. American Society of Clinical Pathologists/College of American Pathologists, New Orleans, LA, 27 Oct-2 Nov 84.

Perez, Tom Combined use of cell cultures with Ortho's HSV antigen ELISA test system for detection of herpes simplex virus infection. International Symposium on Medical Virology, Los Angeles, CA, 8-10 Nov 84.

Farr, W.D. Aviation night vision imaging systems and the aging aviator. Joint Commission on Aviation Pathology, 18 Oct 84.

Alm, P.F. The role of the veterinary laboratory in support of the overseas theater of command. USAREUR Veterinary Medical Training Conference, Berchtesgaden, Germany, 10 Oct 84.

Farr, W.D. Aeromedical aspects of drugs and alcohol. 5th US Army Aviation Resource Management Conference, San Antonio, TX, 27 Mar 85.

Farr, W.D. Aerospace pathology. Nebraska Army National Guard Aviation Safety Conference, Lincoln, NE, 16 Feb 85.

Farr, W.D. Aerospace pathology and toxicology. 5th U.S. Army I/SIP Conference, San Antonio, TX, 3 May 85.

Department of Pediatrics

Wiswell, T.E. Resuscitation of the Newborn. Departments of Family Practice/Pediatrics, Fort Polk, LA, 20 Nov 84.

Pick, T.E. Update on improved survival of children with cancer. Texas Tumor Registrars Association 12th Annual Meeting, San Antonio, TX, 7 Nov 84.

Shoupe, B. Epilepsy. Military Co-Op for Handicapped Children, 21 Jan 85.

Wiswell, T.E. Circumcision decreases the incidence of urinary tract infection in male infants. Department of Neonatology, USUHS, 15 Jan 85.

Parry, W.H. Airway endoscopy in children. Pediatrics for the Practitioner 22nd Annual Teaching Conference, 21 Apr 85.

Wiswell, T.E. Infantile myofibromatosis. San Antonio Neonatology Club, 3 Apr 85.

Takao, R. Health care of adolescents within the military sector. Pediatric Grand Rounds, UTHSC at San Antonio, 3 May 85.

Wiswell, T.E. Corroborative evidence for the increased incidence of urinary tract infections in uncircumcised male infants. 5th Annual Conference on Perinatal Research, Aspen, CO, 16 Jul 85.

Department of Psychiatry

Gillooly, D.H. Use and control of psychological test materials: The development, implications, and effects of a new health service regulation. 1985 AMEDD Clinical Psychology Short Course, Letterman Army Medical Center, 4-8 Mar 85.

Gillooly, D.H. Quality assurance programs and the practice of psychology in clinical settings: A focus on initiatives and directions in the army medical department health service delivery. 1985 AMEDD Clinical Psychology Short Course, Letterman Army Medical Center, 4-8 Mar 85.

Gillooly, D.H. A collection of references pertaining to confidentiality issues in professional practice of army medical department psychologists. 1985 AMEDD Clinical Psychology Short Course, Letterman Army Medical Center 4-8 Mar 85.

Gillooly, D.H. How to deal with the angry patient. HSC Clinical Support Division/Patient Appointment System Conference, Broadway Plaza Hotel, San Antonio, TX, 4-5 Sep 85.

Department of Radiology

Baikadi, M. Role of radiotherapy in inoperable lung cancer. Surgical Oncology Symposium Group, San Antonio, TX, 30 Nov-2 Dec 84.

Hartshorne, M. Army Nuclear Medicine update. Augsberg Medical Reunion, 14 Oct 84.

Hartshorne, M. SPECT LVEDV. Western Regional Society of Nuclear Medicine, 14 Oct 84.

Hartshorne, M. Bone scans for beginners. American Physical Therapy Association, 16 Oct 84.

Hartshorne, M. SPECT surprises. Texas Association of Physicians in Nuclear Medicine, 20 Oct 84.

Landry, S. Nuclear pharmacy practice. Incarnate Word College Nuclear Medicine Students, San Antonio, TX, 23 Oct 84.

Bauman, J. Non-invasive estimation of renal function. San Antonio Nuclear Medical Society, 25 Oct 84.

Landry, A. Dosimetry, protection and regulations. Incarnate Word College Nuclear Medicine Students, San Antonio, TX, 30 Oct 84.

Bauman, J. Lung ventilation and perfusion studies. UTHSC at San Antonio Nuclear Medicine Conference, 2 Nov 84.

Landry, A. NRC guidelines. Incarnate Word College Nuclear Medicine Students, 6 Nov 84.

Landry, A. Introduction to Nuclear Medicine. MacArthur High School Science Club, San Antonio, TX, 8 Nov 84.

Cawthon, M. GI bleeding and Meckel's studies. UTHSC at San Antonio Radiology Department, 9 Nov 84.

Landry, A. Pharmacology of Nuclear Medicine. Incarnate Word College Nuclear Medicine Students, 20 Nov 84.

Landry, A. Pharmacology of Nuclear Medicine. Incarnate Word College Nuclear Medicine Students, 27 Nov 84.

Landry, A. Pharmacology of Nuclear Medicine. Incarnate Word College Nuclear Medicine Students, 4 Dec 84.

Landry, A. RBC labeling - optimum labeling. Webster University, 10 Dec 84. (C)

Hartshorne, M. Nuclear tomography. UTHSC at San Antonio Nuclear Medicine Fellows, 14 Dec 84.

Huggins, T. Mammography research. Exhibit at the Annual Meeting of Radiological Society of North America, Washington, D.C., 25-30 Nov 84. Received Honorable Mention.

Hartshorne, M. Podiatric Nuclear Medicine. San Antonio Podiatry Association, 27 Feb 85.

Landry, A. Radiopharmaceutical quality control. UTHSC at San Antonio Teleconference, 28 Feb 85.

Bauman, J. In-111 labeled leukocytes, clinical applications. San Antonio Nuclear Medicine Society, 13 Mar 85. (C)

Bauman, J. In-111 labeled leukocytes, clinical applications. Nuclear Medicine Physicians, Dallas, TX, 21 Mar 85.

Hartshorne, M. Bone scintigraphy I. Wilford Hall Radiology Department, Lackland AFB, TX, 25 Mar 85.

Hartshorne, M. Bone scintigraphy II. Wilford Hall Radiology Department, Lackland AFB, TX, 25 Mar 85.

Bauman, J. In-111 leukocytes and CNS lesions. Society of Nuclear Medicine SW Regional Meeting, New Orleans, LA, 29 Mar 85.

Hartshorne, M. SPECT update lecture. Society of Nuclear Medicine SW Regional Meeting, New Orleans, LA, 30 Mar 85.

Cawthon, M. Labeled WBCs - Splenic bed findings. Society of Nuclear Medicine SW Regional Meeting, New Orleans, LA, 30 Mar 85.

Cawthon, M. Case presentations - tomographic studies. Society of Nuclear Medicine SW Regional Meeting, New Orleans, LA, 30 Mar 85.

Hartshorne, M. SPECT update. Wilford Hall Radiology Department, Lackland AFB, TX, 27 Apr 85.

Hartshorne, M. Bone scintigraphy extravaganza. UTHSC at San Antonio Radiology Residents, 6 May 85.

Hartshorne, M. Clinical applications of SPECT. Texas Medical Association Meeting, San Antonio, TX, 10 May 85.

Bauman, J. Indium-labeled leukocytes: Clinical application. Texas A&M Veterinary School, College Station, TX, 15 May 85.

Bauman, J. Nuclear Medicine: Overview. Texas A&M Veterinary School, College Station, TX, 22 May 85.

Landry, A. Cellular blood component labeling. Wilford Hall Radiology Residents, Lackland AFB, TX, 22 May 85.

Hartshorne, M. SPECT overview. Moncrief Radiation Center, Fort Worth, TX, 20 Jun 85.

Landry, A. Introduction to nuclear pharmacy. UTHSC Pharmacy Students, San Antonio, TX, 17 Jul 85.

Hartshorne, M. Blood pool imaging. Nuclear Cardiology Update Course, Teton Village, WY, 23 Jul 85.

Landry, A. Introduction to nuclear pharmacy. UTHSC Pharmacy Students, San Antonio, TX, 11 Sep 85.

Bennett, W.F. CT of adrenal glands. Ohio State University, Columbus, OH, 22 Jul 85.

Department of Surgery

Office of the Chief

Antopol, M.R. Bronchogenic carcinoma of the lung. Surgical Oncology Update, San Antonio, TX, 29 Nov 84.

Anesthesia and Operative Service

Middaugh, R.E. Laser and the operating room environment. El Paso, TX, 27 Sep - 5 Oct 84.

Middaugh, R.E. Pediatric resuscitation and infant resuscitation. Brighton School, 29 Oct 84.

Middaugh, R.E. Grand Rounds and Teaching Rounds. St. Luke's Hospital, Houston, TX, 5-7 Dec 84.

Reynolds, W.J. Pharmacology of local anesthetics. NW Anesthesia Associates Annual Meeting, Las Vegas, NV, 20-21 Mar 85.

Reynolds, W.J. Toxicity of local anesthesia. NW Anesthesia Associates Annual Meeting, Las Vegas, NV, 20-21 Mar 85.

Reynolds, W.J. Selection of drugs/dosages. NW Anesthesia Associates Annual Meeting, Las Vegas, NV, 20-21 Mar 85.

Reynolds, W.J. Course in "Local Anesthesia and Regional Anesthesia." NW Anesthesia Associates Annual Meeting, Las Vegas, NV, 20-21 Mar 85.

Middaugh, R.E. Verbal induction techniques for the pediatric patient. Texas State CRNA, 24-25 May 85.

Middaugh, R.E. Something old, something new, something borrowed, something blue. Texas State CRNA, 24-25 May 85.

Baumgarten, R.K. Closed circuit anesthesia. University of Rochester Medical School, Jun 85.

Baumgarten, R.K. Can nondepolarizing relaxants replace succinylcholine for rapid sequence induction. Canadian Anesthesia Society, Jun 85.

Middaugh, R.E. Update in monitoring. Texas State Society of Respiratory Therapists, 18 Jul 85.

Zablocki, A.D. Anesthesia for congenital cardiac surgery. Department of Anesthesiology, University of Tennessee, 8-10 Sep 85.

Reynolds, W.J. Burn anesthesiology. Department of Anesthesiology, University of Kentucky, 23 Sep 85.

Middaugh, R.E. Misunderstood concepts in anesthesia. Department of Anesthesiology, University of Arkansas, 26 Sep 85.

Middaugh, R.E. New technology for monitoring patients in critical care. Arkansas Society of Anesthesiologists, 27 Sep 85.

Cardiothoracic Surgery Service

Head, H.D. Clinic staging methods in lung cancer. BAMC Surgical Oncology Update, 29 Nov 84.

Grishkin, B.A. Treatment of cancer of the esophagus. BAMC Surgical Oncology Update, 29 Nov 84.

Head, H.D. Open heart surgery - where it came from, where it is going. 17th Annual Conference of the Association of Surgical Technicians, San Antonio, TX, 15 Jun 85.

Joseph, D. Cardiopulmonary perfusion. 17th Annual Conference of the Association of Surgical Technicians, San Antonio, TX, 14 Jun 85.

Grishkin, B.A. Surgical treatment of mediastial masses. William Beaumont Army Medical Center, El Paso, TX, 2 Jul 85.

General Surgery Service

Rosenthal, D. Retroperitoneal mesh interposition for recurrent groin hernias. Texas Surgical Society, Lubbock, TX, 1 Oct 84.

Solenberger, R. Experience with "Port-a-Cath" in children. Pediatric Oncology Group, St. Louis, MO, 1 Oct 84.

Rosenthal, D. Squamous cell carcinoma of the anus. BAMC Surgical Oncology Update, 29 Nov 84.

Walters, M.J. Management of locally advanced breast cancer. BAMC Surgical Oncology Update, 29 Nov 84.

Solenberger, R. Staging laparotomy in pediatric Hodgkin's disease. BAMC Surgical Oncology Update, 29 Nov 84.

Reed, K. Lymphoma of the GI tract. BAMC Surgical Oncology Update, 29 Nov 84.

Reed, K. Venous access in adult cancer patients. BAMC Surgical Oncology Update, 29 Nov 84.

Reed, K. Hepatic resections for cancer. Mid America Osteopathic Society, Des Moines IA, 17 Nov 84.

Reed, K. Needle localized breast biopsy - The BAMC experience. American College of Osteopathic Surgeons In-Depth Review Course, Houston, TX, Jan 85.

Reed, K. Surgical endocrine ablation for metastatic breast cancer. American College of Osteopathic Surgeons, Houston, TX, Jan 85.

Solenberger, R. Gastroesophageal reflux in pediatric patients. Grand Rounds University of Texas Health Science Center, JAN 85.

Solenberger, R. Gastroesophageal reflux in pediatric patients. Department of Pediatrics, Corpus Christi Naval Air Station, Jan 85.

Solenberger, R. Biliary atresia. Department of Pediatrics Grand Rounds, Fort Sill, OK, Jan 85.

Solenberger, R. Biliary atresia. Department of Pediatrics Grand Rounds, Fort Polk, LA, Jan 85.

Solla, J. Breast cyst aspiration - the BAMC experience. South Texas Chapter of the American College of Surgeons, Corpus Christi, TX, Jan 85. (Second Prize)

Simmang, C. Leiomyoma of the GI tract. South Texas Chapter of the American College of Surgeons, Corpus Christi, TX, Jan 85.

Lafon, P. Complications of chemotherapy infusion through the hepatic artery. South Texas Chapter of the American College of Surgeons, Corpus Christi, TX, Jan 85.

Rosenthal, D. What's new in ileostomy techniques. Southwest Chapter of United Ostomy Association, San Antonio, TX, Mar 85.

Solenberger, R. BAMC experience with twenty-three Port-a-Caths in children. Pediatric Oncology Group Meeting, Clear Water, FL, Mar 85.

Rosenthal, D. Preperitoneal teflon hernia repairs. General Surgical Meeting of USAREUR Surgeons, Heidelberg, Germany, Mar 85.

Rosenthal, D. Abdominal trauma - the lessons learned at BAMC. General Surgical Meeting of USAREUR Surgeons, Heidelberg, Germany, Mar 85.

Rosenthal, D. Management of common anorectal problems. General Surgical Meeting of USAREUR Surgeons, Heidelberg, Germany, Mar 85.

Solenberger, R. Reflux esophagitis in children. Family Practice Grand Rounds, Fort Sill, OK, Apr 85.

Walker, L. Dehiscence: Smoking as a major contributing factor. Gary P. Wratten Surgical Symposium, San Antonio, TX, Apr 85.

Solla, J. Wound infection in elective colon surgery. Gary P. Wratten Surgical Symposium, San Antonio, TX, Apr 85.

Otchy, D. Complications of msatectomy. Gary P. Wratten Surgical Symposium, San Antonio, TX, Apr 85.

Hamelink, J. Parastomal hernia repair. Gary P. Wratten Surgical Symposium, San Antonio, TX, Apr 85.

Dowden, D. Penetrating colorectal trauma. Gary P. Wratten Surgical Symposium, San Antonio, TX, Apr 85.

Lafon, P. Acute and chronic acalculous cholecystitis associated with continuous hepatic artery infusion with implantable pumps. Southwestern Surgical Congress, Las Vegas, NV, Apr 85.

Rosenthal, D. Preperitoneal repair of recurrent inguinal hernias. Poster presentation, Southwestern Surgical Congress, Las Vegas, NV, Apr 85.

Rosenthal, D. Neutropenic enterocolitis. Poster presentation, American Society of Colorectal Surgeons, San Diego, CA, May 85.

Solenberger, R. Why children are not little adults. CME and Business Meeting, Surgical Technologists, San Antonio, TX, Jun 85.

Reed, K. Hepatic resection for metastases. American College of Osteopathic Surgeons, Hilton Head, SC, Jun 85.

Reed, K. verwhelming post-splenectomy infections. American College of Osteopathic Surgeons, Hilton Head, SC, Jung 85.

Solenberger, R. Surgical causes of abdominal pain in children. Department of Pediatrics, Darnall Army Hospital, Fort Hood, TX, Aug 85.

Neurological Surgery Service

Youngblood, L. Case presentations and discussion. San Antonio Neurosurgical Society (Fred Kingman Neurosciences Society), 24 Oct 84.

Youngblood, L. Case presentations and discussion. San Antonio Neurosurgical Society, 27 Nov 84.

Youngblood, L. Case presentations and discussion. San Antonio Neurosurgical Society, 22 Jan 85.

Youngblood, L. Case presentations and discussion. San Antonio Neurosurgical Society, 26 Feb 85.

Youngblood, L. Case presentations and discussion. San Antonio Neurosurgical Society, 26 Mar 85.

Youngblood, L. Case presentations and discussion. San Antonio Neurosurgical Society, 23 Jul 85.

Youngblood, L. Case presentations and discussion. San Antonio Neurosurgical Society, 27 Aug 85.

Foley, K.T. The role of radiation therapy in the treatment of low-grade astrocytomas - The UCLA experience. Western Neurosurgical Society, 22-25 Sep 85.

Ophthalmology Service

Cheung, D.S. Down's syndrome in ophthalmology practice. National Down's Syndrome Society, 22 Oct 84.

Burns, C. Accomodative esotropia. UTHSC at San Antonio, 11 Oct 84.

Burns, C. Botulinum treatment of strabismus. El Paso Ophthalmology Society, 12 Oct 84.

Burns, C. A&V patterns. UTHSC at San Antonio, 21 Oct 84.

Lloyd, W.C., III. Special tissue stains in ocular histopathology. American Academy of Ophthalmology, Atlanta, GA, 11 Nov 84.

Lloyd, W.C., III. Treatment protocol for orbital inflammatory disease. American Academy of Ophthalmology, Atlanta, GA, 13 Nov 84.

Lloyd, W.C., III. Repair of medial orbital wall fractures. Oculoplastic Reconstructive Surgeons, Atlanta, GA, 16 Nov 84.

O'Hara, M. Malignant hyperthermia and the ophthalmic surgery patient. American Academy of Ophthalmology, Atlanta, GA, 11 Nov 84.

Walker, J.D. Diagnosis of glaucoma. UTHSC at San Antonio, 15 Feb 85.

Walker, J.D. Treatment of glaucoma. UTHSC at San Antonio, 8 Mar 85.

Burns, C. Nystagmus blockage syndrome. UTHSC at San Antonio, 24 Jan 85.

Burns, C. Ophthalmia neonatorum. UTHSC at San Antonio, 14 Feb 85.

Walker, J.D. Ocular dystrophy. UTHSC at San Antonio, 22 Mar 85.

Rogers, C. Ocular toxicity of plaquenil. Alamo City Ophthalmology Residents Conference, 12-13 Apr 85.

Gagliano, D. Early alignment of congenital esotropia. Alamo City Ophthalmology Residents Conference, 12-13 Apr 85.

Walker, J.D. Static perimetry and pupil size. Alamo City Ophthalmology Residents Conference, 12-13 Apr 85.

Burns, C. Long term results of early surgery for infantile esotropia. Alamo City Ophthalmology Residents Conference, 12-13 Apr 85.

O'Hara, M. Retinal toxicity of intravitreal cefaperazone. Alamo City Ophthalmology Residents Conference, 12-13 Apr 85.

Cheung, D.S. Down's syndrome in an ophthalmology practice. Alamo City Ophthalmology Residents Conference, 12-13 Apr 85.

Cook, M. Atracurium and intraocular pressure. Alamo City Ophthalmology Residents Conference, 12-13 Apr 85.

Liu, S.J. One hundred YAG capsulotomies. Alamo City Ophthalmology Residents Conference, 12-13 Apr 85.

Prestowitz, W.F. A modified tarsorrhaphy technique for selected patients. Alamo City Ophthalmology Residents Conference, 12-13 Apr 85.

Hammer, B.D. Ocular findings in disorders of copper metabolism. Alamo City Ophthalmology Residents Conference, 12-13 Apr 85.

Mazzoli, R.A. Child abuse - every ophthalmologist's problem. Alamo City Ophthalmology Residents Conference, 12-13 Apr 85.

Speicher, P.J. Creature feature. Alamo City Ophthalmology Residents Conference, 12-13 Apr 85.

Burns, C. Botulinum toxin and adjustable sutures. Air Force Clinical Surgeons Meeting, Hilton Hotel, San Antonio, 29 Apr 85.

Brown, C. Congenital esotropia. UTHSC at San Antonio, 31 May 85.

Burns, C. Adjustable sutures. UTHSC at San Antonio, 4 Jun 85.

Burns, C. Basic motility of eyes. UTHSC at San Antonio, 3 Jul 85.

Burns, C. Anatomy of eye muscles. UTHSC at San Antonio, 26 Jul 85.

Burns, C. Congenital esotropia. UTHSC at San Antonio, 12 Sep 85.

Burns, C. Amblyopia and strabismus. UTHSC at San Antonio, 6 Sep 85.

Walker, J.D. Introduction to glaucoma. UTHSC at San Antonio, 2 Jul 85.

Walker, J.D. Gonioscopy. UTHSC at San Antonio, 2 Jul 85.

Orthopaedic Service

Markey, K.L. Anterior cruciate replacement with carbon fiber - a preliminary report. Texas Chapter of the American College of Sports Medicine, 5-6 Oct 84.
(C)

Williams, S.M. Open versus arthroscopic meniscectomy: An analysis of intermediate term results at Brooke Army Medical Center. Southern Orthopaedic Association, 4-5 Nov 84.

Santos, M.A. Treatment of pathologic humeral fractures. Society of Military Orthopaedic Surgeons, 26-30 Nov 84.

Williams, S.M. Open versus arthroscopic meniscectomy. Society of Military Orthopaedic Surgeons, 26-30 Nov 84.

Norwood, S.M. Sacroiliac joint infection: diagnosis with computer tomography - A case report and review of the literature. Society of Military Orthopaedic Surgeons, 26-30 Nov 84.

McMillin, J.N. Percutaneous pin fixation of distal radius fracture. Society of Military Orthopaedic Surgeons, 26-30 Nov 84.

Carlos, F.J. The treatment of adult hip fractures - Endoprosthesis versus internal fixation: A radiologic evaluation with clinical correlation. Society of Military Orthopaedic Surgeons, 26-30 Nov 84.

Kouba, S.H. Ultrasound assessment of hip abnormalities in the infant. Society of Military Orthopaedic Surgeons, 26-30 Nov 84.

Dreher, G.f. Surgical stabilization of the spine for metastatic disease. Society of Military Orthopaedic Surgeons, 26-30 Nov 84.

Bucknell, A.L. A clinical review of the TATA prosthesis. American Academy of Orthopaedic Surgeons, Jan 85.

Bucknell, A.L. "Adolescent spondylolisthesis" 225 cases. American College of Spinal Surgeons, Inc., Jan 85.

Otolaryngology Service

Hoang, K.G. Sialadenoma papilliferum in the adenoids of a two year old boy - A histologic and ultrastructural study. Western Section Meeting of the Tiological Society, Santa Barbara, CA, 4-6 Jan 85.

Jarchow, R.C. Principles of face lift. San Antonio Society of Otolaryngology, 15 Jan 85.

Lepore, M.L. Embryology and anatomy of the skin and blood supply. Soft Tissue Workshop, Tripler Army Medical Center, 8-13 Feb 85.

Jarchow, R.C. Local flaps of the head and neck. Armed Forces Institute of Pathology Basic Science Course for Otolaryngology-Head and Neck Surgery Residents, Washington, D.C., 24 Apr 85.

Jarchow, R.C. Lip reconstruction. AFIP Basic Science Course for Otolaryngology-Head and Neck Surgery Residents, Washington, D.C., 24 Apr 85.

Jarchow, R.C. Dermabrasion. AFIP Basic Science Course, Washington, D.C., 24 Apr 85.

Jarchow, R.C. Selected soft tissue techniques in head and Neck Reconstruction. Society of Air Force Clinical Surgeons Symposium, San Antonio, TX, 30 Apr 85.

Lepore, M.L. Embryology of the skin/vascular supply. AFIP Basic Science Course, Washington, D.C., 24 Apr 85.

Lepore, M.L. Factors necessary in obtaining a fine scar. AFIP Basic Science Course, Washington, D.C., 24 Apr 85.

Lepore, M.L. Factors influencing regional and local flaps. AFIP Basic Science Course, Washington, D.C., 24 Apr 85.

Lepore, M.L. Preop medications: Their use and adverse reactions. AFIP Basic Science Course, Washington, D.C., 24 Apr 85.

Lepore, M.L. Auricular prosthetics. Society of Air Force Clinic Surgeons Symposium, San Antonio, TX, 30 Apr 85.

Brown, L.W. Effects of in-utero ultrasonography on fetal hearing. XIII World Congress of Otorhinolaryngology, Miami Beach, FL, 25-30 May 85. (C) Commander's Award - Honorable Mention.

Webb, D.L. Malignant fibrous histiocytoma of the head and neck. XIII World Congress of Otorhinolaryngology, Miami Beach, FL, 25-30 May 85.

Peripheral Vascular Surgery Service

Elliott, B.M. Non-invasive evaluation of vasculogenic impotence. Chesapeake Vascular Society, Anapolis, MD, 1984.

Elliott, B.M. Intraoperative local anesthetic injection of the carotid sinus nerve: A prospective randomized trial. 12th Annual Vascular Surgery Sminar, Society for Military Vascular Surgeons, Bethesda, MD, 29 Nov 84.

Elliott, B.M. The non-invasive diagnosis of vasculogenic impotence. 1985 Symposium on Noninvasive Diagnostic Techniques in Vascular Disease, San Diego, CA, 18-22 Feb 85.

Wesen, C.A. Fibromuscular dysplasia of the carotic arteries. Second Annual Vascular Surgery Symposium, San Antonio, TX, 4 Apr 85.

Hamelink, J. Localized intraarterial streptokinase therapy. Second Annual Vascular Surgery Symposium, San Antonio, TX, 4 Apr 85.

Urology Service

Thompson, I.M. Adenocarcinoma of the prostate: results of routine screening. 63rd Annual South Central Section of the AUA, Houston, TX, 2 Oct 84. (C)

Thompson, I.M. Chemotherapy of transitional cell carcinoma with glucan and cyclophosphamide. 63rd Annual South Central Section of the AUA, Houston, TX, 2 Oct 84. (C) First Prize in Resident's Essay Contest.

Spence, C.R. Cancer of the prostate - surgical treatment. Urology Workshop, International Urological Sciences, Inc., San Antonio, TX, 5 Oct 84.

Spence, C.R. Bilateral Wilms tumor. Kimbrough Urological Seminar, Scottsdale, AZ, 11-16 Nov 84.

Norbeck, J.C. Application of computers in military urology. Kimbrough Urological Seminar, Scottsdale, AZ, 11-16 Nov 84.

Corrie, D. Establishment of human urothelial tissue culture. Kimbrough Urological Seminar, Scottsdale, AZ, 11-16 Nov 84. (C)

Rounder, J.B. Intra-arterial infusion of cisplatin in combination with direct hemoperfusion - An experimental approach to advanced bladder cancer. Kimbrough Urological Seminar, Scottsdale, AZ, 11-16 Nov 84. (C) First Prize Winner, Commander's Award.

Thompson, I.M. Development of a porcine model of the Koch continent ileal reservoir. Kimbrough Urological Seminar, Scottsdale, AZ, 11-16 Nov 84.

Thompson, I.M. Chemoimmunotherapy of transitional cell carcinoma. Kimbrough Urological Seminar, Scottsdale, AZ, 11-16 Nov 84. (C) Second Prize Best Paper - Resident Competition.

Teague, J.L. Chemoprophylaxis of implantation of murine transitional cell carcinoma. Kimbrough Urological Seminar, Scottsdale, AZ, 11-16 Nov 84. (C)

Thompson, I.M. Impact of routine urologic screening upon stage distribution of cancer of the prostate. Kimbrough Urological Seminar, Scottsdale, AZ, 11-16 Nov 84.

Teague, J.L. Impact of unilateral ureteral obstruction upon total renal clearance of calcium and phosphate. Kimbrough Urological Seminar, Scottsdale, AZ, 11-16 Nov 84. (C) First Prize Best Paper Basic Science Resident Competition. Second Prize, Commander's Award

Thompson, I.M. Renacidin dissolution of renal calculi in polycystic disease. Kimbrough Urological Seminar, Scottsdale, AZ, 11-16 Nov 84.

Thompson, I.M. Adenocarcinoma of the prostate: Results of routine urologic screening. Display, 70th Annual Clinical Congress of the American College of Surgeons, San Francisco, CA, 21-26 Oct 84. (C)

Rounder, J.B. Intra-arterial infusion of cisplatin in combination with direct hemoperfusion - an experimental approach to advanced bladder cancer. Society of University Urology Residents 23rd Annual Meeting, Pine Mountain, GA, 8-11 May 85. (C)

Thompson, I.M. Chemoimmunotherapy of transitional cell carcinoma with glucan and cyclophosphamide. Society of University Urology Residents, Pine Mountain, GA, 8-11 May 85. (C)

Norbeck, J. Prostate cancer. 17 Annual Conference of the Association of Surgical Technologists, Hilton Palacio Del Rio, San Antonio, TX, 14 Jun 85.

Directorate of Nutrition Care

CPT Gallo. Nutrition and the infant toddler. Babysitters' Class, Fort Sam Houston, Community Service, 10 Oct 84.

2LT Finegan. Making peanut butter. 5 year olds at Child Care Center, Fort Sam Houston, 5 Nov 84.

2LT Finegan. Making peanut butter. 3 year olds at Child Care Center, Fort Sam Houston, 5 Nov 84.

2LT Murray. Vegetables. Pre-schoolers at Fort Sam Houston, Child Care Center, 15 Nov 84.

2LT Farling. Nutrition and dental health. 4-5 year olds at Fort Sam Houston Child Care Center, 27 Nov 84.

2LT Farling. Nutrition and dental health. 3 year olds at Fort Sam Houston Child Care Center, 27 Nov 84.

1LT Milner. Nutrition and athletics. John Pernel Runner's Clinic, Brackenridge Park, San Antonio, TX, 30 Dec 84.

CPT Gallo. Nutrition. Army Community Service, 16 Jan 85.

CPT Arnold. Nutrition for the elderly. Sara Roberts French Home, 22 Jan 85.

CPT Gallo. Nutrition and the special child. Parents of Handicapped Children, Easter Seal Society, 22-23 Jan 85.

2LT Hemingway. General nutrition principles. Northside Baptist School, 23 Jan 85.

2LT Hemingway. Milk. 3 and 4 year olds at Fort Sam Houston Child Care Center, 29 Jan 85.

CPT Hottovy. Good nutrition for pre-teens. Texas Military Institute, 28 Jan 85.

Ms. Gooden. Oral nutrition. Fort Sam Houston Elementary School, 5 Feb 85.

MAJ Phelan. Test your knowledge of fitness. Display at San Antonio Livestock and Rodeo Show, Joe Freeman Coliseum, 10 Feb 85.

LT Oertling. Fruits. 3 and 4 year olds at Fort Sam Houston Child Care Center, 12 Feb 85.

LT Goyette. Four food characters and cartoon chractres. 3, 4 and 5 year olds at Fort Sam Houston Child Care Cetner, 26 Feb 85.

2LT Hemingway. Nutrition and exercise for the elderly. Palacio del Sol Senior Citizen Center, 7 Mar 85.

2LT Farling. Normal and sports nutrition. Roosevelt High School, 11 and 14 Mar 85.

2LT Farling. Normal and sports nutrition. Randolph High School, 28 Mar 85.

2LT Hemingway. Good nutrition with an emphasis on weight control. Bethany Church Women's Group, 19 Mar 85.

2LT Ellison-Murphy. Snaks. 3 and 4 year olds at Fort Sam Houston Day Care Center, 19 Mar 85.

CPT Arnold. Nutrition and Fitness Guidelines. Robert E. Lee High School, 1 Apr 85.

CPT Arnold. Nutrition for the health of it. Alamo Iron Works, 25 Apr 85.

CPT Arnold. Nutritional considerations of burn therapy. RN, LVN, and Social Worker Meeting, Gunter Hotel, San Antonio, TX, 8 May 85.

CPT Arnold. Participant in panel discussion on "Herbalife". KSAT TV, San Antonio, TX, 9 May 85.

Ms. Gooden. Good nutrition. Fort Sam Houston Child Care Center, 14 May 85.

LT Milner. Nutrition and exercise. American Heart Association 8 Jun 85.

CPT Arnold. Nutrition and weight control guidelines. TOPS group at Sheppard Hills Church.

LT Milner. Nutrition and your child. Circle of Hope, 16 Jul 85.

LT Milner. Nutrition and sports competition. Tri-sports Ladies Fitness Seminar, 20 Jul 85.

CPT Boone. Nutrition for the health of it. WINGS, Randolph AFB Officers Club, 5 Sep 85.

CPT Arnold. Nutritional support during athletic performance in the hospital. Physical Therapy Conference, Wilford Hall USAF Hospital, 9 Sep 85.

Physical Medicine and Rehabilitation Service

Singer, J. Electromyographic Evaluation and Follow-up in paresis subsequent to herpes zoster. Poster presentation, PM&R Academy Meeting, Boston, MA, 24-26 Oct 84.

Veterinary Laboratory Service
Department of Pathology and ALS

Kelch, W.J. Animal welfare and control programs on military installations in the United States. American Veterinary Medical Association, Las Vegas, NV, 23-26 Jul 85.

Detail Summary Sheet

Date: 3 Oct 85 Proj No: C-5-79 Status: Completed
 Title: Assessment of Opsonic Capacity and Phagocyte Functionality in Microliter Quantities of Whole Blood.

Start Date 4 Jan 79	Est Comp Date:
Principal Investigator Robert C. Allen, M.D., Ph.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Thomas J. Murphy, SP4 Sheila Jones, SP5 Michael Peek, DAC
Key Words: Chemiluminogenic probes Complement	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$14,698.62
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): To research and develop a rapid, objective, and quantitative approach to the assessment of phagocyte activity in microliter quantities of whole blood by introduction of high quantum yield oxidizable substrate and use of photomultiplication techniques to quantitate chemiluminescence.

Technical Approach: Phagocytosis by granulocytes and monocytes results in activation of redox metabolism and generation of oxygenating agents as required for effective microbicidal action. Available techniques for quantifying phagocyte function are technically complex and time consuming. The technical advantages obtained using the chemiluminescent probe (CLP) approach for measurement of phagocyte oxygenation activity has been developed. CLP's are substrates whose oxygenation results in a high yield of excited products that relax by photon emission, i.e. chemiluminescence (CL). CLP's with different physical and chemical properties allow differential quantification of phagocyte oxidase and peroxidase activities.

The CLP approach to measurement of phagocyte function can also be extended to the analysis of microbe-specific or antigen-specific opsonification kinetics. When the quantity of phagocytes, antigen, and CLP are not rate limiting, the CL velocity can be related to the opsonin content of the specimen tested.

Progress: A laboratory technique for functional analysis of complement has been developed. The methodology is based on complement-dependent opsonification of microbes resulting in stimulation of granulocyte oxygenation activity as measured by chemiluminogenic probing. As expected, the kinetic order of complement activation is complex compared to the relative first order nature of IgG-dependent opsonification.

Detail Summary Sheet

Date: 3 Oct 85 Proj No: C-4-81 Status: Ongoing
 Title: Chemiluminescence (CL) in Populations of Immunocompetent Cells.

Start Date 4 Feb 81	Est Comp Date:
Principal Investigator David G. Burleson, Ph.D., MAJ, MSC	Facility Institute of Surgical Research
Dept/Svc Biochemistry Section	Associate Investigators: Robert C. Allen, M.D., Ph.D., MAJ, MC Karen M. Wolcott, DAC George K. Vaughn
Key Words: Chemiluminescence Immunocompetent cells	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review n/a	Results

Objective(s): 1) To quantitate the oxidative metabolic response of stimulated populations of immunocompetent cells isolated from mouse or guinea pig spleen, thymus, liver, and lymph nodes using chemiluminogenic probes.

2) To quantitate and characterize the chemiluminescent response from various populations of immunocompetent cells in the presence of cyanide, superoxide dismutase, and catalase.

Technical Approach: Several methods are employed to analyze immunocompetent cells from animal models of inflammation, infection, and trauma. Sterile inflammation is induced by IP injection of sodium caseinate. Trauma is induced by application of a 30% scald burn with or without infection induced by seeding with *P. aeruginosa*. Phagocyte respiratory burst activity is analyzed by chemiluminescence and flow cytometry using oxidation sensitive molecular probes. Lymphoid cells from various tissues are analyzed for ability to be stimulated by mitogen stimulation and flow cytometry analysis. Cell populations are characterized by morphological analysis by light microscopy after Wright's stain and surface marker analysis by flow cytometry after staining with chromophore labeled monoclonal antibodies.

Progress: Lymphoid cell subpopulations from animals with induced inflammation and infection have been characterized. Results from flow cytometry analysis of blood, spleen and lymph node cells from traumatized (inflammation induced) animals showed no significant change in light scatter characteristics compared to controls. Blood and spleen cells from the "lymphocyte" fraction of Ficoll-hypaque gradients of cell preparations from infected animals, however, showed a significant number of cells with scatter characteristics similar to granulocytes and monocytes. The change in light scatter corresponded to the presence of cells with morphological characteristics of immature myelocytes (blood) and atypical mononuclear cells (spleen) in samples obtained from infected animals.

C-4-81 (continued)

There was no significant change in light scatter characteristics or cellular morphology of lymph node cells from infected animals compared to traumatized or control animals. This finding is of far reaching significance because Ficoll-hypaque gradients have been considered a standard lymphocyte purification technique for immunological studies in human trauma patients for many years. Reports in the literature rarely contain verification of the purity of these "lymphocyte" preparations. The atypical cells adsorbed monoclonal stains nonspecifically, making interpretation of monoclonal staining results difficult. Flow cytometry studies which do not consider this problem should be viewed with caution.

Surface antigen analysis was performed on those blood mononuclear cells which scatter light typical of normal lymphocytes. Results obtained using traumatized rats indicated that the ratio of helper T lymphocytes to suppressor T lymphocytes in these animals was not significantly different from the control animals. In infected animals, however, the ratio was significantly decreased. The increased proportion of suppressor cells in the blood was due to a relatively greater depletion of helper cells than suppressor cells. Lymph node cells from infected animals compared to normal controls or traumatized animals contained decreased proportions of T cells, helper T cells, and an increased proportion of Ia positive cells (which includes B cells and monocytes). Both cells compared to controls which caused the helper:suppressor ratio in these animals to increase over that of control animals. There was no difference in any of the spleen lymphoid cell subpopulations obtained from traumatized or control animals. Spleen cells from infected animals contained a subpopulation of cells that bound control monoclonal reagents nonspecifically so that the true amount of surface antigen could not be determined.

A technique for measuring oxidative activity of phagocytes has also been developed. This technique will now be applied to the quantification of phagocyte function in the animal model of trauma and infection.

Detail Summary Sheet

Date: 28 Mar 85 Proj No: C-13-81 Status: Terminated
 Title: Therapeutic Manipulation of Metabolic Endocrine Controls During Infection.

Start Date 11 Mar 81	Est Comp Date:
Principal Investigator James H. Anderson, Jr., M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Gerald A. Merrill
Key Words: Metabolic endocrine controls	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: n/a	
Total Number of Subjects Enrolled to Date: n/a	
Date of Periodic Review n/a	Results

Objective(s): To clearly define the mechanisms of hormonal action and metabolic alterations in infectious disease and thus establish the best therapeutic and supportive care for personnel exposed to infectious agents.

Technical Approach: Animals with a variety of induced infections will be studied for glucose tolerance and insulin secretion, binding and effects as well as specific biochemical and physiological function of the islets of Langerhans and cellular insulin receptors on monocytes, hepatocytes, and adipocytes. In addition, lipid and protein breakdown and metabolism will also be evaluated.

Progress: This study was terminated due to lack of an adequate laboratory animal facility.

Detail Summary Sheet

Date: 20 Aug 85 Proj No: C-16-82 Status: Completed
 Title: Biosynthetic Human Insulin in Treatment of Diabetes.

Start Date 20 Jan 82	Est Comp Date:
Principal Investigator James H. Anderson, Jr., M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators:
Key Words: Diabetes Human insulin	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 11 May 85	Results Continue

Objective(s): To evaluate the efficacy and safety of biosynthetic human insulin (BHI) in the treatment of insulin-dependent diabetes, and to detect, if present, immunologic evidence of E. coli proteins in patients who have received BHI.

Technical Approach: Newly diagnosed insulin-dependent diabetics were begun on biosynthetic human insulin using only regular insulin delivered by means of a continuous subcutaneous insulin infusion pump. This was a cooperative study with the Eli Lilly Company.

Progress: Two patients were entered on the study. Both did well with no complications from the insulin or the pump. No adverse effects have been detected. The study has been closed to new entries.

Detail Summary Sheet

Date: 20 Aug 85 Proj No: C-40-83 Status: Terminated
 Title: Viral Infection and Diabetic Disease in Laboratory Animals.

Start Date 6 May 83	Est Comp Date:
Principal Investigator (vice Pedersen) James H. Anderson, Jr., M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators:
Key Words: Diabetic disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To determine whether VEE virus subtypes localize and replicate in pancreatic tissue, as well as the degree of virus induced pancreopathy, the proposed experiments will determine whether attenuated VEE viruses do indeed replicate the pancreas and to what degree; and whether focal pancreatic lesions are indeed virus-induced or the consequences of other events.

Technical Approach: None.

Progress: Terminated due to lack of an adequate animal facility in which to conduct the study.

Detail Summary Sheet

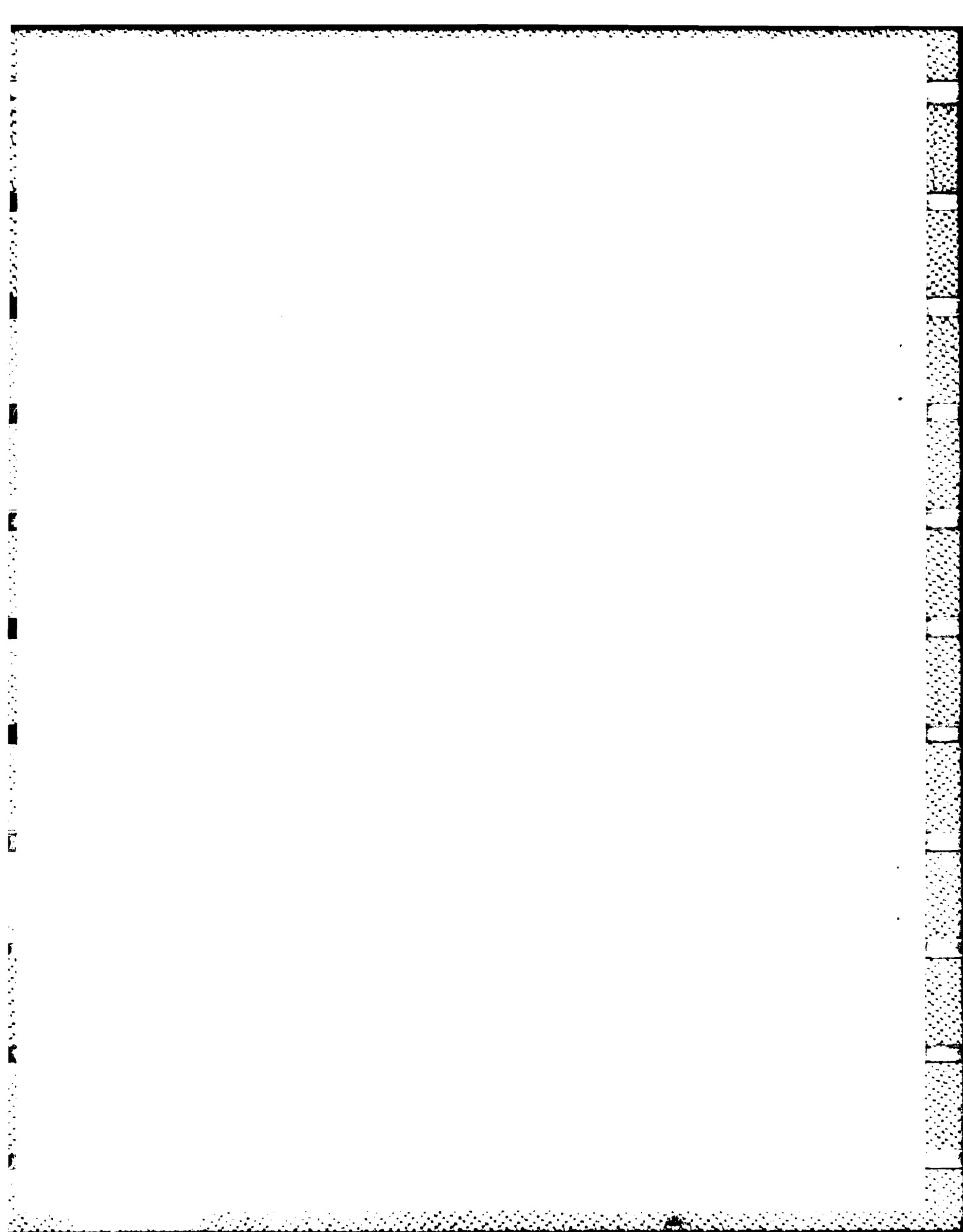
Date: 25 Sep 85 Proj No: C-41-83 Status: Completed
 Title: Rheumatoid Synovial Dendritic Cell - Its Possible Origin and Regulation of Collagenase Production.

Start Date 7 Jun 83	Est Comp Date:
Principal Investigator Debra J. Krikorian, CPT, MSC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators:
Key Words: Rheumatoid Arthritis Collagenase	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$184.40
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To determine the production of collagenase by the rheumatoid dendritic cell utilizing collagenase assay.

Technical Approach: Rheumatoid dendritic cell cultures were maintained with and without fetal calf serum in a supplemented media. Cultures were fed every three days and the media removed and frozen at 20°C. Samples were collected and pooled by patient number with and without fetal calf serum. These samples were semipurified and assayed for the presence of collagenase.

Progress: Collagense assays were completed in triplicate, data were tallied and will be mailed to original principal invsetigator for evaluation. Indications are that some RA patients have dendritic cells which will produce collagenase in vitro.



Detail Summary Sheet

Date: 27 Sep 85	Proj No: C-45-83	Status: Ongoing
Title: Development of a Chemiluminescent Enzyme Linked Immunoassay (CELIA) System for Detection of Antigens of Medical Importance in Serum and Tissue Fluids.		
Start Date 17 May 83	Est Comp Date:	
Principal Investigator Gerald A. Merrill, DAC	Facility Brooke Army Medical Center	
Dept/Svc Department of Clinical Investigation	Associate Investigators: Robert C. Allen, M.D., Ph.D., MAJ, MC	
Key Words: Antibody system		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 7,730.61	
Number of Subjects Enrolled During Reporting Period: _____		
Total Number of Subjects Enrolled to Date: _____		
Date of Periodic Review n/a Results _____		

Objective(s): To develop an enzyme-linked antibody system for antigen-specific detection of fungi, bacteria, viral agents, hormones, and immune complexes.

Technical Approach: This study was designed to be conducted in three phases: 1) isolation of haloperoxidases, 2) kinetic analysis of enzymes, and 3) assay development. Haloperoxidase isolation from granulocytes by several techniques was to be examined. The study of the microbicidal function of animal granulocytes in relation to the haloperoxidase activity of these cells is a secondary objective of this study. Isolated enzymes will be used for analysis of substrate dependence to determine optimal enzyme conditions for both halogenation activity and chemiluminescent activity. Investigation of inhibitors of the haloperoxidases will permit selection of suitable methods of collection of biological samples which may ultimately be assayed by this immunoassay system. Once optimal conditions have been determined, the enzymes can be covalently bound to antibodies of choice, and correlations between chemiluminescence and antigen concentration can be determined.

Progress: Kinetic analysis of chloroperoxidase (CPO), one of the haloperoxidases being studied as a possible candidate for CELIA development has established pH dependent halide/HOOH ratios for optimum chemiluminescent responses. Although the enzyme has a halogenation optimum at pH 2.75, luminol dependent chemiluminescence was not observed at pHs below 4.0. At any halide/HOOH ratio examined, maximum chemiluminescent velocity was observed at pH 6.8. Using more basic conditions, increased nonspecific chemiluminescence was noted. Chloride inhibition of chemiluminescence was observed to occur at lower chloride concentrations for each HOOH concentration as more acidic conditions were achieved.

C-45-83 (continued)

At each HOOH concentration, chemiluminescence became non rate limiting with respect to halide of much lower bromide than chloride concentrations. Optimal chemiluminescent reaction conditions were achieved at pH 6.8 with 500-1000 μ M HOOH and chloride concentrations of 1600-2400 meq/L. Alternatively, optimal chemiluminescent reaction conditions when bromide is utilized as halide occur at pH 6.8, 500 μ M HOOH, and 12.4 meq/L bromide. CPO has been covalently bound to protein A using heterbifunctional cross linking agents (SPDP). CPO activity was lost unless halide was present during the binding of SPDP to CPO to presumably prevent steric hinderence of the catalytic site of CPO by SPDP.

Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-72-83 Status: Ongoing
 Title: An Investigation into Biotyping of Staphylococcus epidermidis Sensu Stricto and Correlation of Biotype with Virulence and Human Disease.

Start Date 30 Sep 83	Est Comp Date:
Principal Investigator Bruce A. Gunn, Ph.D., MAJ, MSC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: William Nauscheutz, M.S., CPT, MSC Geri Davis, SP4
Key Words: <u>Staphylococcus epidermidis</u>	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 6,175.64
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review n/a	Results

Objective(s): 1) Clinical strains of S. epidermidis will be tested for presence of selected morphologic and physiologic characters.

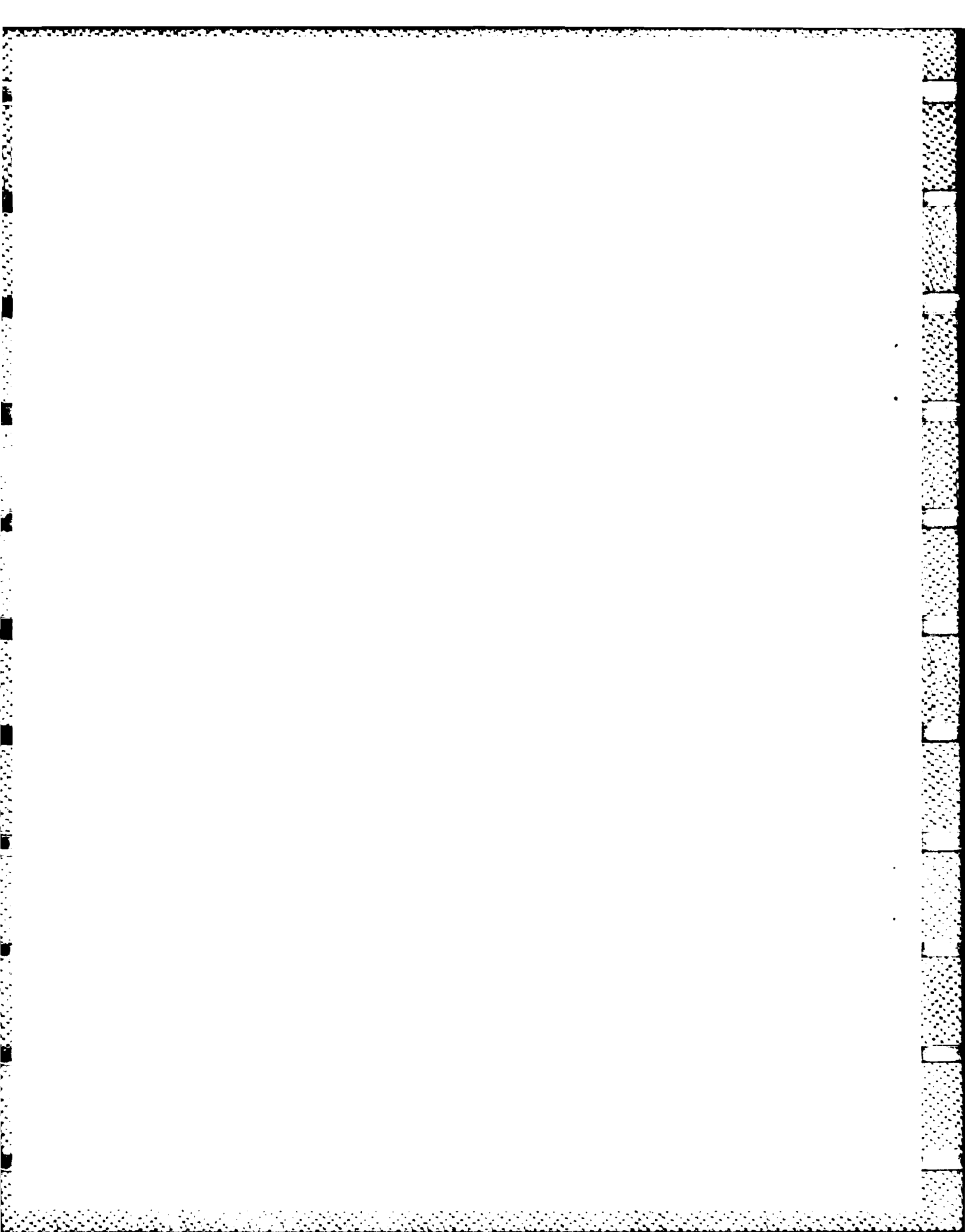
2) Phenotype profiles will be used to sort strains of S. epidermidis into biotypes.

3) Biotypes will be correlated with: 1) significance in human disease; 2) resistance to antibiotics; 3) predilection for a certain body site; 4) possession of virulence factors; and 5) virulence, as measured by growth rate, delta toxin, tissue culture, and mouse virulence assays.

Technical Approach: Strains of S. epidermidis sensu stricto cultured from blood, urine, wounds, and fluids will be assessed as to their significance in human disease.

Ten or more organisms from each of nine category types will be selected and identified using a commercially available identification kit. The first ten strains from each category identified as S. epidermis sensu stricto will be studied. Strains identified as one of the other eight recognized coagulase-negative species will be stored on agar slant media for later use. Thus 90 strains of S. epidermis will be selected for study.

Progress: The first two phases have been completed. A total of 152 coagulase negative staphylococci (CNS) were cultured from wound, blood or urine specimens. The results are being analyzed. Phase 3 was activated in 1985. Thirty six strains representative of 10 species of CNS have been selected for virulence testing using two-day old Swiss mice. Presently, five strains have been tested in mice for ability to retard growth.



Detail Summary Sheet

Date: 30 Sep 85 Proj No: C-73-83 Status: Ongoing
 Title: The Effect of Lysine on Herpes Simplex Virus (HSV) Infection.

Start Date 30 Sep 83	Est Comp Date:
Principal Investigator Eleanor Ayala, MT, DAC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators:
Key Words: Herpes simplex virus L-lysine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 7,586.26
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review n/a	Results

Objective(s): To evaluate the in vitro effect of L-lysine on HSV infected cells and the in vivo effect of topical applications of L-lysine in treatment of HSV skin infections in laboratory animals.

Technical Approach: In vivo studies were performed on male, white Dunker-Hartley guinea pigs (g.p.) inoculated with 20 l of HSV-1 (KOS) (titer 5×10^6 + CI D₅₀/ml) at each of 8 sites/animal. Topical applications of pulverized crystalline lysine or leucine (amino acid control) (50 mg/site) were made 30-60 minutes post inoculation when sites were dry. Treated or untreated animals were sacrificed 1-6 days post inoculation, appearance of skin was noted, skin biopsies of inoculated areas were collected and extracts cultured on primary rabbit kidney cells (PRK). In some experiments skin biopsies and dorsal root ganglia (DRG) (C1-S3) were collected in pairs from treated and control animals 2, 3, or 6 days post inoculation and co-cultivated on PRK cells. All cultures were passaged twice. All isolates from DRG's or epidermis were identified by neutralization of rabbit anti HSV-1 hyperimmune serum.

Progress: Epidermal inoculation of guinea pigs with KOS strain of HSV-1 developed local inflammatory reaction in untreated animals. This was not seen in animals treated with topical applications of lysine although HSV-1 could be recovered from inoculation site in all animals. Co-cultivation of DRGs on PRK cells yielded recovery of HSV-1 from ganglia of T-11 and L-1 if L-lysine was applied and from T-10 when L-leucine was applied. No HSV-1 was recovered from co-cultivated untreated DRG. No viral particles were detected in any skin biopsies or DRGs when examined by electron microscopy.

Detail Summary Sheet

Date: 26 Aug 85 Proj No: C-62-84 Status: Terminated
 Title: Diabetes Management and Personal Interests.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator	Facility
James H. Anderson, Jr., M.D., LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Clinical Investigation	Wm. H. Havin, Graduate Student, Texas
Key Words:	Tech University
Diabetes management	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine how the kinds of things people like to do affect the way they manage their diabetes.

Technical Approach: Patients seen in the Diabetic Clinic were sked to complete a questionnaire to determine how the things people like to do affect the way they manage their diabetes. In addition, the results of three most recent glycosylated hemoglobin were furnished the investigator at Texas Tech University.

Progress: This study was terminated due to release from active duty of the principal investigator at BAMC.

Detail Summary Sheet

Date: 30 Sep 85 Proj No: C-81-84 Status: Ongoing
 Title: Production of Monoclonal Antibodies to Synovial Fluid Cells Obtained from Patients with Rheumatoid Arthritis.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Eleanor Ayala, DAC	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Robert Brewer, M.D., MAJ, MC Clark Tchernowitz, SP5 Debra J. Krikorian, CPT, MSC
Key Words: Monoclonal antibodies	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$775.56
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To use monoclonal antibodies for the differentiation and analysis of cell types in synovial fluid from rheumatoid arthritis patients.

Technical Approach: Synovial fluid specimens obtained from selected patients will be centrifuged in order to separate the cells according to size and buoyant density. Cells will be analyzed for hyaluronidase production reaction to MCF and collagenase production. Those cell populations given positive tests will be selected and their membrane preparations utilized for in vivo and in vitro immunization of spleen cells. Monoclonal antibody production will be as outlined in the protocol.

Progress: Cells obtained from selected patients have been obtained, cultured, photographed, sized according to buoyant density using marker beads and on Ficoll-hypaque. The intermediate layer yielded the largest fibroblast-like cells. Cells were cultured, photographed and used for in vitro immunization of mouse spleen cells. Fusion of human myeloma cells and in vitro immunized spleen cells have been performed. Stable hybridomas are being sought.

Detail Summary Sheet

Date: 21 Aug 85 Proj No: C-3-85 Status: Terminated
 Title: Educational Programs for Diabetes Patients.

Start Date 14 Nov 84	Est Comp Date:
Principal Investigator Regina Marshall, R.N.	Facility Department of Clinical Investigation
Dept/Svc Department of Clinical Investigation	Associate Investigators: James H. Anderson, Jr., M.D., LTC, MC Thomas J. Taylor, M.D., LTC, MC
Key Words: Diabetes	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine if by incorporating video disc instruction with classes taught by a diabetes nurse specialist, the patients' understanding will increase and result in better control of their diabetes.

Technical Approach: None.

Progress: After approval of the protocol and attempts to initiate the program, it was determined that it was inadvisable to attempt the study as proposed. Therefore, the protocol was terminated.

Detail Summary Sheet

Date: 3 Oct 85 Proj No: C-11-85 Status: Ongoing
 Title: Assessment of Immunocompetence in Patients with Lymphomas and Solid Tumors Prior to and During Therapy.

Start Date 15 Jan 85	Est Comp Date:
Principal Investigator Darold Lance, 2LT, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: David G. Burleson, MAJ, MS James F. Boyd, M.D., LTC, MC George Vaughn
Key Words: Immunocompetence	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To evaluate immunocompetence in tumor patients receiving chemotherapy or radiation therapy before and after therapy is begun by (1) assess several accepted in vitro measures of immunocompetence and (b) identify and quantify the various mononuclear cell subpopulations present in peripheral blood.

Technical Approach: Peripheral blood cells from patients will be analyzed by several immunological function tests and surface analysis by flow cytometry after staining with monoclonal antibodies. Functional tests include mitogen stimulation, mixed lymphocyte culture, antibody production by pokeweed mitogen stimulated cells and induction of surface stimulation antigens by lectins. Surface marker analysis will include all currently accepted clinically significant markers.

Progress: There has been no progress on this project due to a lack of technical personnel available to conduct the procedures in the study.

Detail Summary Sheet

Date: 27 Sep 85 Proj No: C-46-85 Status: Ongoing
 Title: Isolation and Characterization of the Chlorinating Moiety of Aspergillus
sp. and Penicillium sp.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator Gerald A. Merrill	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: James H. Anderosn, Jr., M.D., LTC, MC Paul M. Horowitz, Ph.D.
Key Words: <u>Aspergillus</u> <u>sp.</u> <u>Penicillium</u> <u>sp.</u>	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): 1) To isolate a haloperoxidase from a readily available source which has characteristics that would enable it to be utilized in a chemiluminescent immunoassay system currently being developed under protocol C-45-83.

2) To gain understanding of the mechanism of action of haloperoxidase, so insight into the physiological roles of this class of enzymes (i.e., the microbicidal action) in various cell types (granulocytes, plants, fungi, etc.) can be gained.

Technical Approach: Selected fungi (Aspergillus sp. and Penicillium sp.) would be cultured in Czapek Dox media and homogenized. Following centrifugation, both supernatant and pellet would be assayed for haloperoxidase activity at various chloride/HOOH ratios at a series of pH's using a standard assay for halogenating activity employing monochlorodimedon. If a significant halogenating activity is detected further purification of the responsible enzyme would be initiated. The methods employed for purification would depend on gross characteristics of the enzyme such as pI, carbohydrate content, molecular weight, etc. The purified enzyme would then be tested for optimum conditions for HOOH dependent halogenation and for its ability to catalyze the chemiluminogenic dioxygenation of cyclic hydrazides (luminol derivatives) at various pH's and halide/HOOH ratios in an attempt to achieve a practical enzyme for use in development of a chemiluminogenic enzyme linked immunoassay system. Proposal of an enzyme mechanism of action would involve use of methods designed to show conformational changes in substrates and enzyme during catalysis, to include fluorescent techniques.

Progress: Due to concern by other investigators regarding contamination of lab areas with fungi, the study has not yet been initiated. Semi confinement apparatus which can be easily decontaminated has been ordered to ensure a minimal risk laboratory contamination during growth and homogenization of the fungi.

Detail Summary Sheet

Date: 25 Jan 85 Proj No: C-65-82 Status: Completed
 Title: Electrocardiographic Changes During Outpatient Oral Surgery.

Start Date 24 Sep 82	Est Comp Date:
Principal Investigator Richard A. Kraut, D.D.S., COL, DC	Facility Brooke Army Medical Center
Dept/Svc Department of Dentistry/Oral Surgery	Associate Investigators:
Key Words: Oral Surgery	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 6	
Total Number of Subjects Enrolled to Date: 100	
Date of Periodic Review n/a	Results

Objective(s): To determine the type and frequency of dysrhythmias that occur during outpatient oral surgery.

Technical Approach: An Electronics for Medicine CM 140 Physiologic Monitor®, containing an arrhythmia function block, was attached to patients via standard electrodes and set to monitor lead V₂. The arrhythmia monitor was activated and individualized to the patient's QRS configuration. The monitor remained in place throughout the surgical procedure.

Progress: None of the patients in this study experienced dysrhythmias that required therapeutic intervention. Seven of ten bradycardias were present prior to initiation of treatment and were attributable to the patient's excellent cardiovascular status secondary to physical conditioning. The three remaining patients with bradycardias were hemodynamically stable and converted to normal sinus rhythm without therapeutic intervention. Sinus tachycardia was present in seven baseline recordings and occurred early in the treatment of 35 patients. This was consistent with apprehension, the use of methohexital as part of the

C-65-82 (Continued)

sedation technique and the use of local anesthetic containing epinephrine. All of sinus tachycardias resolved to normal sinus rhythm without therapeutic intervention.

The ability to accurately record all alterations in cardiac rhythm during ambulatory oral surgery provided the capability of determining the incidence of dysrhythmias during ambulatory oral surgery.

Detail Summary Sheet

Date: 6 Aug 85 Proj No: C-76-83 Status: Terminated
 Title: Evaluation of Changes in PtcO₂ and PtcCO₂ in Patients with Chronic Obstructive Pulmonary Disease (COPD) While Undergoing Outpatient Oral Surgery with Intravenous Sedation and Local Anesthesia.

Start Date 30 Sep 83	Est Comp Date:
Principal Investigator George D. Suchko, D.D., MAJ, DC	Facility Brooke Army Medical Center
Dept/Svc Department of Dentistry/Oral Surgery	Associate Investigators: Richard A. Kraut, D.D.S., COL, DC
Key Words: Chronic obstructive pulmonary disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 10	
Total Number of Subjects Enrolled to Date: 10	
Date of Periodic Review 13 Jul 84	Results Continue

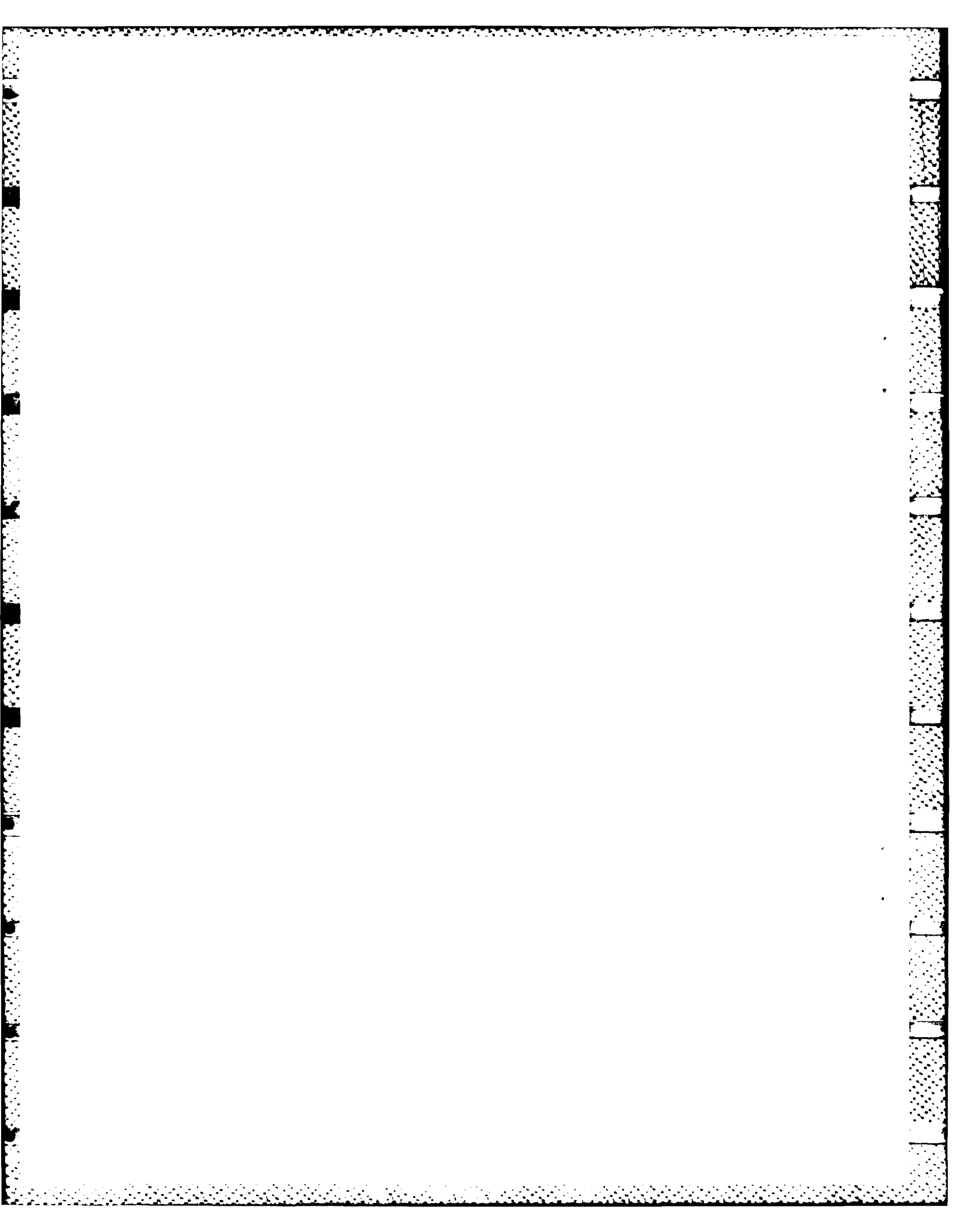
Objective(s): 1) To determine the change of baseline PtcO₂ and PtcCO₂ in patients with chronic obstructive pulmonary disease while undergoing outpatient oral surgical procedures under intravenous sedation and local anesthesia.

2) To evaluate the effects of flow O₂ (1-2 liters) administered by nasal mask on baseline PtcO₂/PtcCO₂.

3) To evaluate the effects of sedation with titrated intravenous diazepam on respiratory depression in patients with COPD.

Technical Approach: Transcutaneous oxygen and carbon dioxide are being monitored on patients undergoing ambulatory oral surgery utilizing IV sedation and low flow supplemental oxygen.

Progress: This study was terminated due to an inability to enroll a sufficient number of patients to obtain statistically significant data.



Detail Summary Sheet

Date: 8 Mar 85 Proj No: C-25-83 Status: Terminated
 Title: Determination of PtcO₂ During the Perioperative Period of Patients Undergoing Orthognathic Surgery.

Start Date 3 Mar 83	Est Comp Date:
Principal Investigator Richard A. Kraut, D.D.S., COL, DC	Facility Brooke Army Medical Center
Dept/Svc Department of Dentistry/Oral Surgery	Associate Investigators:
Key Words: Orthognathic surgery	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 7	
Total Number of Subjects Enrolled to Date: 22	
Date of Periodic Review	Results

Objective(s): To determine the baseline PtcO₂ of each patients studied; to determine the PtcO₂ of patients who have just undergone orthognathic surgery and who are still intubated; to determine the PtcO₂ when patients are extubated following orthognathic surgery; to determine the PtcO₂ in patients 48 hours after orthognathic surgery.

Technical Approach: Transcutaneous oxygen monitor was utilized to monitor patients preoperatively, immediately postoperatively, and in their postoperative convalescent period to determine if there was any alteration in transcutaneous PO₂ secondary to being in intermaxillary fixation.

Progress: Termination of this project is based on preliminary analysis of 22 completed patients. The individual variation from patient to patient, plus the variation that occurred in anesthetic technique resulted in a lack of cohesiveness of the data. It is evident from the data generated that there is a decrease in PtcO₂ of about 50 mm of Hg when patients are converted from endotracheal intubation on a "T" piece with 10 l flow of 40% O₂ to a nasal hood with the same gas flow rate and percentage.

Detail Summary Sheet

Date: 22 Jul 85 Proj No: C-59-83 Status: Completed
 Title: A Comparison of the Effects of Ethrane and Forane on PO₂, PCO₂, Blood Pressure and Pulse When Used for Outpatient Oral Surgery.

Start Date 10 Aug 83	Est Comp Date:
Principal Investigator Glenn Reside, D.D., MAJ, DC	Facility Brooke Army Medical Center
Dept/Svc Department of Dentistry/Oral Surgery	Associate Investigators: Richard A. Kraut, D.D.S., COL, DC
Key Words: Oral surgery	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 27	
Total Number of Subjects Enrolled to Date: 50	
Date of Periodic Review 13 Jul 84	Results

Objective(s): To compare the changes from baseline PO₂, PCO₂, blood pressure and pulse in patients undergoing outpatient general anesthesia with either Ethrane or Forane.

Technical Approach: The effects of enflurane and isoflurane were compared on fifty consecutive adults who had their third molars removed under outpatient general anesthesia. The parameters measured were transcutaneous oxygen, transcutaneous carbon dioxide, mean arterial pressure and pulse rate.

Progress: The results indicate that for the healthy patient undergoing a short oral surgery procedure, isoflurane is preferable to enflurane as a general anesthetic inhalational agent for the parameters tested.

etail Summary Sheet

Date: 22 Jul 85 Proj No: C-65-84 Status: Transferred
 Title: Comparison of Sublimaze and Sufentanil Citrate in Intravenous
 Conscious Sedation for Outpatients Oral Surgery.

Start Date 13 Sep 84	Est Comp Date:
Principal Investigator	Facility
Raymond A. Kurowski, D.D., MAJ, DC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Dentistry/Oral Surgery	Richard A. Kraut, D.D.S., COL, DC
Key Words:	
Oral surgery	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To compare the blood pressure, pulse, respiratory rate, PtcO₂ and PtcCO₂ in patients sedated with sublimaze versus sufentanil citrate for surgical removal of impacted wisdom teeth.

Technical Approach: Patients scheduled to have impacted wisdom teeth removed under local anesthesia are eligible. They will be assigned to one of two groups. Group A will receive local anesthesia plus Valium and Fentanyl. Group B will receive local anesthesia plus Valium and Sufentanil. Blood pressure, heart rate, breathing rate, and blood oxygen and carbon dioxide will be monitored.

Progress: This study will be completed by COL Kraut at Tripler Army Medical Center.

Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-11-83 Status: Completed
 Title: The Effect of MAST Trousers in the Prehospital Management of Penetrating Abdominal Injuries.

Start Date 6 Jan 83	Est Comp Date:
Principal Investigator William H. Bickell, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Kenneth Mattox, M.D., Baylor College of Medicine, Houston, TX
Key Words: MAST trousers	Michael E. DeBakey, M.D.
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To define the statistical significance of MAST trouser use in the prehospital management of penetrating abdominal injuries. Parameters to be examined include: 1) survival, 2) estimated blood loss, and 3) postoperative complications.

Technical Approach: Patients entered into the study were victims of blunt or penetrating injuries found to have a systolic blood pressure (BP) of 90 mm Hg or less at the time of the initial prehospital assessment by paramedics from the City of Houston Emergency Medical Services (EMS). Gravid females and patients less than 15 years of age were excluded from the study as were patients with evisceration or impaled objects in a body region that would be encompassed by the MAST.

Progress: The results demonstrate no significant difference between the control and MAST-treated groups (9.8 ± 6.6 vs 10.6 ± 5.9).

Detail Summary Sheet

Date: 27 Sep 85 Proj No: C-15-85 Status: Completed
 Title: H₂ Histamine Receptor Blockade in Human Subjects with Acute Clinical Urticaria and/or Angioedema.

Start Date 21 Jan 85	Est Comp Date:
Principal Investigator Daniel J. Boyle, II, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: James A. Morgan, D.O., CPT, MC
Key Words: Blockade, H ₂ histamine Urticaria Angioedema	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 24	
Total Number of Subjects Enrolled to Date: 24	
Date of Periodic Review n/a	Results

Objective(s): To determine the efficacy of H₂ blockade in the treatment of urticaria and/or angioedema in human subjects.

Technical Approach: Twenty-four patients presenting to the BAMC Emergency Medicine Department seeking treatment of acute urticaria were included in the study. Patients were randomized, using a table of random numbers, into two groups. One group initially received saline as the placebo while the second group received cimetidine over a 15 minute period. At the end of one hour, patients were re-evaluated and treated using standard therapy (epinephrine and/or diphenhydramine). They were again re-evaluated at the end of 30 minutes and were allowed to go home with instructions to return in 4 days. At the time of discharge from the clinic, Group I patients received diphenhydramine + placebo q.i.d. x 4 days and Group II patients received diphenhydramine + cimetidine q.i.d. x 4 days.

Progress: Wheal size and %BSA involved decreased significantly ($p < 0.01$) in the cimetidine group as compared to the control group. There was significant improvement in response in the group treated with cimetidine compared to placebo as determined by two way analysis of variance.

Conclusion: This double-blinded, small population study suggests that the urticarial lesion size and patient's subjective evaluation can be favorably changed by the use of a selective antagonist of histamine at H₂ receptors in the treatment of acute urticaria.

Detail Summary Sheet

Date: 27 Sep 85 Proj No: C-2-81 Status: Ongoing
 Title: Evaluation of the Coagulation, Fibrinolytic, and Humoral Immune Abnormalities Induced by Crotalus Atrox (Western Diamondback Rattlesnake) Snakebite.

Start Date 10 Oct 82	Est Comp Date:
Principal Investigator John J. Posch, DAC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hematology	Associate Investigators: Glenn J. Mills, M.D., MAJ, MC Barbara Reeb, DAC
Key Words: Snakebite	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1,983.31
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 54	
Date of Periodic Review 8 Nov 84	Results Continue in vitro study

Objective(s): To evaluate and characterize the coagulation, fibrinolytic and humoral immune abnormalities induced in patients envenomated by Crotalus atrox (western diamondback rattlesnake).

Technical Approach: Patients envenomated by rattlesnakes were evaluated for possible bleeding abnormalities. Coagulation profiles and fibrinolytic enzyme workups were performed on plasma specimens and pertinent hematological data compiled from admission workups. In vitro studies using crude venoms from three rattlesnake species (C. atrox, C. adamanteus, and C. hor. horridus) were performed to measure thrombin-like, fibrinolytic, and chromogenic enzyme activities of these venoms. Individual venoms were obtained from different size snakes of C. atrox in order to observe the effects of age on venom activity. Additional chromogenic substrate tests have been added to determine kalikrein-like activity. Crude pooled venoms are presently being fractionated and enzyme components will be characterized with respect to procoagulant, fibrinolytic, and chromogenic properties.

Progress: Coagulation profiles, fibrinolytic workups and hematological data have been compiled from 54 different envenomation cases. Coagulation abnormalities have been detected in some of these patients. The in vivo portion of this study has been completed.

Additional in vitro testing of crude venoms and isolations of enzyme fractions have been initiated to further characterize the thrombin-like and/or fibrinolytic enzymes present in rattlesnake venoms.

Detail Summary Sheet

Date: 20 Jun 85 Proj No: C-33-81 Status: Completed
 Title: Renal Function in Primary Hyperparathyroidism.

Start Date 12 May 81	Est Comp Date:
Principal Investigator Charles J. Foulks, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators:
Key Words: Hyperparathyroidism	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 775.80
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 14	
Date of Periodic Review 13 Jun 85	Results Completed

Objective(s): To gather detailed information about renal function in patients with primary hyperparathyroidism at the time of diagnosis and to follow these functions serially in patients not undergoing surgery. These data should permit a more precise estimate of the risk of "medical" therapy versus "surgical" therapy in patients with mild, asymptomatic, primary hyperparathyroidism.

Technical Approach: Serial 24 hours urine collections were submitted for GFR measurement with serial Ca^{++} , PTH determinations.

Progress: No decrease in renal function was noted. The study was closed due of paucity of eligible patients.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-34-81 Status: Terminated
 Title: The Effect of Propranolol on Cardiac Ejection Fractions as Determined
 By Gated Scans in Thyrotoxic Patients.

Start Date 15 Jun 81	Est Comp Date:
Principal Investigator Thomas J. Taylor, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Endocrinology	Associate Investigators: William J. Georgitis, M.D., MAJ, MC Michael F. Hartshorne, M.D., MAJ, MC
Key Words: Thyrotoxic patients	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 13 Jun 85	Results Continue

Objective(s): To study the effects of Inderal on cardiac ejection fractions in thyrotoxic patients and thereby critically assess the relative merits of this mode of therapy.

Technical Approach: MUGA studies are used to evaluate cardiac parameters in thyrotoxic patients before and after administration of Propranolol.

Progress: Study terminated due to poor patient accrual.

Detail Summary Sheet

Date: 25 Sep 85 Proj No.: C-52-81 Status: Ongoing
 Title: Effect of Aspirin (ASA) on Airway Responses.

Start Date 7 Jul 81	Est Comp Date:
Principal Investigator Ana A. Ortiz, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Allergy-Immuno.	Associate Investigators: Dane C. McBride, M.D., MAJ, MC
Key Words: Airway responses	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 11 Sep 85 Results Continue	

Objective(s): To investigate the effects of aspirin on airway responses in man. Specifically, the following questions will be answered: a. What effect does ASA have on upper and lower airway resistance in patients with non-allergic rhinitis with eosinophilia (NARES)? and b. Are patients with NARES - or any identifiable subset thereof - at particular risk of developing lower airway obstruction from aspirin?

Technical Approach: Subjects are to be challenged with 10 grains of aspirin and their nasal airway resistance and pulmonary functions will be measured and followed.

Progress: No patients have been enrolled since the capacity to measure nasal airway responses is not available. Equipment to measure nasal airway responses is being purchased by ENT this next year, and hopefully we will be able to use their equipment to proceed with this protocol.

etail Summary Sheet

Date: 25 Sep 85 Proj No: C-58-81 Status: Ongoing
 Title: The Specificity of Priming on the Nasal Mucous Membranes by Allergens and the Effect of Pharmacological Intervention.

Start Date 20 Aug 81	Est Comp Date:
Principal Investigator Ana A. Ortiz, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Allergy-Immunol.	Associate Investigators: Dane C. McBride, M.D., MAJ, MC
Key Words: Allergens	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 11 Sep 85 Results Continue	

Objective(s): To investigate further phenomena of mucous membrane priming by antigens. a. Does it occur in different aeroallergen systems; b. Is the priming effect on the nasal mucosa specific for the allergen that induces it? c. What is the effect, if any, of antihistamines, intranasal corticosteroids and cromolyn sodium on nasal priming? d. Is the priming effect due to an increase in specific IgE?

Technical Approach: Study subjects will be challenged intranasally to the appropriate allergens over successive days to prime their mucus. By challenging with a different allergen to which the patient is also resistive, we will determine if the phenomenon is specific or not. Also, antihistamines, corticosteroids and cromolyn sodium will be used prior to the study to determine whether priming can be pharmacologically inhibited. Specific IgE will then be obtained.

Progress: No patients have been enrolled since the capacity to measure nasal airway resistance is not available. It is my understanding that ENT will be obtaining equipment to measure airway resistance this next year, and hopefully we will be able to use their equipment and proceed with this protocol.

Detail Summary Sheet

Date: 27 Sep 85 Proj No: C-3-82 Status: Ongoing
 Title: Assessment of Sunscreen Substantivity.

Start Date 21 Oct 81	Est Comp Date:
Principal Investigator Eric W. Kraus, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: James H. Keeling, M.D., MAJ, MC
Key Words: Sunscreen	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 43	
Date of Periodic Review 8 Nov 84	Results Continue

Objective(s): To compare the protection offered by sunscreens after swimming with that achieved when not exposed to water.

Technical Approach: Bilateral paired comparison of one side of test site (back) exposed to water, the other side not exposed, was done. All sites exposed to natural sunlight was measured by four UVB detectors. Degree of erythema was determined after 24 hours.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 20 Aug 85 Proj No: C-10-82 Status: Ongoing
 Title: Effects of Asynchronous and Nonhomogeneous Regional Function on Global Parameters.

Start Date 18 Nov 81	Est Comp Date:
Principal Investigator William E. Craig, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgo, M.D., COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: n/a	
Total Number of Subjects Enrolled to Date: n/a	
Date of Periodic Review n/a	Results

Objective(s): 1) To establish a model for nonhomogeneous, segmental contraction and relaxation patterns in the chronically instrumented conscious dog.

2) To use the model to further understand and evaluate the abnormalities of diastolic function similar to those seen in clinical disease states.

Technical Approach: The purpose of this project is to use hemodynamic data obtained from instrumented dogs through collaboration with Dr. Pagani in Milan, Italy. This data is then analyzed by computer techniques using mathematical models of the effects which asynchronous ventricular contraction has on overall ventricular function.

Progress: Collection of data has been completed and data analyzed. Manuscript in preparation for submission.

etail Summary Sheet

Date: 25 Sep 85 Proj No: C-13-82 Status: Ongoing
 Title: Intracardiac Pressure and Flow Changes Following Amyl Nitrite Inhalation.

Start Date 8 Jan 82	Est Comp Date:
Principal Investigator Steven Bailey, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: William E. Craig, M.D., LTC, MC Joseph P. Murgu, M.D., COL, MC Bernard J. Rubal, Ph.D., DAC
Key Words: Intracardiac pressure	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 9 Apr 85	Results Continue

Objective(s): To better understand the hemodynamic events responsible for the auscultatory changes following amyl nitrite inhalation in normal man.

Technical Approach: Patients on no medical therapy who are felt to be probably normal are offered a chance to participate after a routine heart catheterization using a 3 sensor catheter in the right heart and a 2 sensor catheter in the left heart. They inhale amyl nitrite and the intracardiac pressure and flow response is recorded.

Progress: One patient was enrolled and completed the protocol during Jan 85-Aug 85. This is due to the infrequency of catheterization of probably normal patients on no medication.

Detail Summary Sheet

Date: 20 Jun 85 Proj No: C-29-82 Status: Terminated
 Title: A Comparison of the Accuracy of the Sphygomomanometric and Oscillometric Blood Pressure Measuring Techniques.

Start Date 5 May 82	Est Comp Date:
Principal Investigator William R. Cox, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgu, M.D., COL, MC Bernard J. Rubal, Ph.D., DAC
Key Words: Blood pressure Pulse wave velocity Oscillometry	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0 u	
Total Number of Subjects Enrolled to Date: 32	
Date of Periodic Review 13 Jun 85	Results Terminate

Objective(s): 1) To compare the systolic, diastolic and mean blood pressure obtained by sphygomomanometry and oscillometry with an intravascular measurement of blood pressure obtained by high fidelity micromanometry during cardiac catheterization.

2) To evaluate the effect of occlusion cuff length on the accuracy of the noninvasive measurement of blood pressure.

Technical Approach: The accuracy of sphygomomanometry and oscillometry was compared using high-fidelity brachial artery blood pressure measurements obtained during cardiac catheterization.

Progress: The study was terminated due to transfer of principal investigator.

Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-37-82 Status: Ongoing
 Title: Evaluation of Sodium Iodate as an Adjunctive Therapy to Radioactive Iodine for Graves' Hyperthyroidism.

Start Date 7 Jul 82	Est Comp Date:
Principal Investigator Thomas J. Taylor, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Endocrinology	Associate Investigators: Michael J. Hartshorne, M.D., MAJ, MC Alfred Landry, Ph.D., MAJ, MS
Key Words: Graves' hyperthyroidism	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 11 Sep 85 Results Continue	

Objective(s): To evaluate the potential advantages of the use of sodium iodate following radioactive iodine administration in the treatment of Graves' hyperthyroidism.

Technical Approach: The protocol was amended to study two groups. One group would receive the placebo and the other group the drug. Since the investigators have been unable to obtain the placebo, this phase of the study was deleted.

Progress: There is good evidence of the efficacy of this treatment in the literature. The study is now being done in collaboration with the Nuclear Medicine Service.

Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-38-82 Status: Ongoing
 Title: Autologous Bone Marrow Transplantation in Resistant Neoplasms: A Phase I Study.

Start Date 7 Jul 82	Est Comp Date:
Principal Investigator Walter H. Harvey. D.O., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: James F. Boyd, M.D., LTC, MC Glenn M. Mills, M.D., MAJ, MC Barbara Reeb, DAC John J. Posch, Jr., DAC
Key Words: Bone marrow transplant	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: n/a	
Total Number of Subjects Enrolled to Date: n/a	
Date of Periodic Review n/a	Results

- Objective(s): 1) To develop a bone marrow transplantation program at Brooke Army Medical Center.
- 2) To participate in research and clinical studies individually as part of the Southwest Oncology Group.
- 3) To establish a competent transplantation service for all eligible DOD patients for present clinical indications and future indications.

Technical Approach: Bone marrow stem cells will be obtained by multiple bone marrow aspirations under general or local anesthesia. The marrow will be prepared by accepted methods and either frozen for storage or returned to the patient after intensive chemotherapy.

Progress: This project is finally getting underway. Equipment procurement continues and space has been allocated. Two technicians have been trained in the autologous transplant procedure.

Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-63-82 Status: Ongoing
 Title: Evaluation of Catheter-Mounted Micromanometers vs External Fluid
 Transducers for Continuous Pressure Monitoring in the Coronary Care Unit.

Start Date 27 Sep 82	Est Comp Date:
Principal Investigator William S. Craig, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgo, M.D., COL, MC Bernard J. Rubal, Ph.D., DAC
Key Words: Transducers Micromanometers	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 11 September 1985 Results Continue	

Objective(s): To evaluate the use of high-fidelity catheter-mounted micromanometer transducers on flow-directed balloon-tipped right heart catheters in the coronary care unit; to determine whether the more accurate pressures obtained from the micromanometers are significantly different than those obtained from conventional fluid-filled transducer systems and whether or not these differences would change or improve the clinical management of patients requiring hemodynamic monitoring.

Technical Approach: Standard 7F Swan-Ganz catheters have been modified with high-fidelity micromanometer pressure transducer for monitoring pulmonary pressure. Data then obtained from continuous CCU monitoring by both standard fluid transducer and the high-fidelity transducer.

Progress: Excellent data obtained thus far which demonstrates superiority and clinical benefit to use of high-fidelity techniques. Progress limited by availability of catheters.

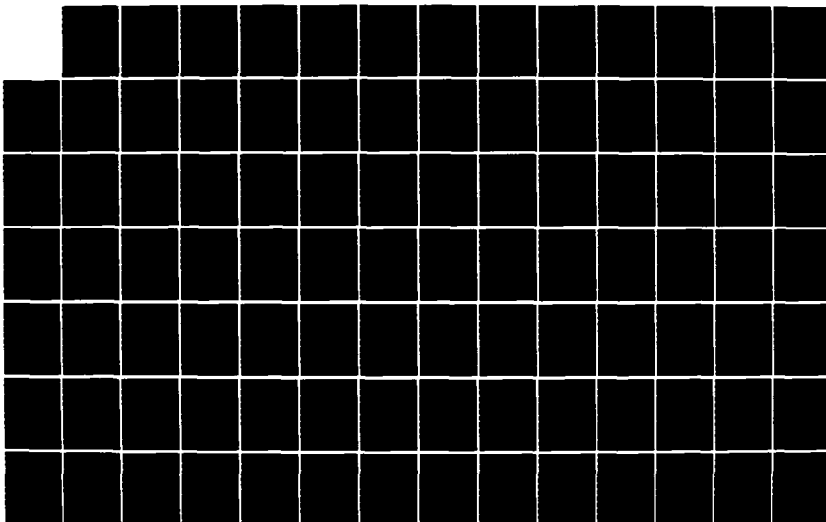
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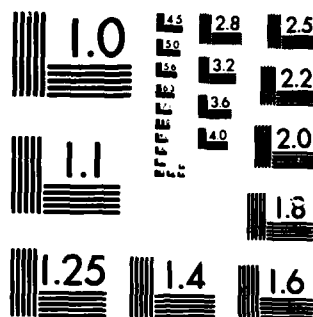
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Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-67-82 Status: Ongoing
 Title: Pathogenesis of Tissue Injury in Porphyria.

Start Date 27 Sep 82	Est Comp Date:
Principal Investigator Charles W. Lewis, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: James H. Keeling, M.D., MAJ, MC Deborah Spiva, M.D.
Key Words: Porphyria	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review 11 September 1985 Results Continue	

Objective(s): 1) To investigate the pathophysiology by which circulating porphyrins produce hyperviscosity states and to determine the extent of tissue injury produced.

2) To determine the effects of ultraviolet rays (UVA, UVB, Soret Band) on the deposition of porphyrins in the skin.

3) To evaluate the role of erythropoietin as the primary stimulus of the bone marrow's overproduction of porphyrin precursors/heme and to determine the effect of suppressing this stimulus.

Technical Approach: Red cell exchanges and limited plasmapheresis are performed with the Haemonetics PEX in the MICU with continuous cardiac monitoring, using washed autologous units and random blood units to maintain hematocrits about 35%. Donor units were matched for all major blood group antigens and underwent same washing procedures.

Induction phase consisted of 1000 ml RBC exchanges every 3 to 7 days until complete remission of clinical symptoms and normal porphyrin levels were obtained (3 to 10 exchanges). Multiple parameters were monitored pre- and post exchange.

Progress: Three patients with erythropoietic protoporphyria were treated with combined plasmapheresis and neocyte exchange transfusions that induced and maintained clinical and biochemical remissions. Red cell and plasma porphyrin levels normalized and patients developed a more normal tolerance to ultraviolet exposure. This treatment modality was an effective method of reversing other newly described abnormalities such as excessive erythropoiesis, abnormal RBC osmotic fragilities, elevated plasma viscosities, and hepatic and renal impairments.

Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-15-83 Status: Completed
 Title: The Treatment of Cellulitis.

Start Date 3 Mar 83	Est Comp Date:
Principal Investigator C. Kenneth McAllister, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 19	
Total Number of Subjects Enrolled to Date: 25	
Date of Periodic Review 9 Apr 85	Results Completed

Objective(s): To compare the response of outpatients with cellulitis who are randomized to receive either erythromycin or dicloxacillin; to compare the response of in-patients with cellulitis who are randomized to receive either erythromycin or nafcillin.

Technical Approach: Patients with the clinical diagnosis of cellulitis who were candidates for outpatient therapy were randomized to receive either erythromycin or clindamycin treatment. The response to therapy from patients receiving the respective antibiotics was measured by clinical response and quantitative measurements of the cellulitis.

Progress: No statistically significant difference was observed with either regimen. For cellulitis, as defined by this study, either erythromycin or diclosicillin produced comparable results.

Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-16-83 Status: Ongoing
 Title: Prospective Evaluation of Clinical, X-ray, Histologic, Scintigraphic, and Microbiologic Characteristics of Diabetic Feet. (Collaborative Study with Walter Reed Army Medical Center)

Start Date 3 Mar 83	Est Comp Date:
Principal Investigator	Facility
C. Kenneth McAllister, M.D., LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Infectious Dis.	
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review n/a	Results

Objective(s): To correlate specific x-ray, scintigraphic, clinical and microbiologic characteristics with each other and with the histology of the diseased diabetic foot so clinicians may better manage their patients.

Technical Approach: To look at the histologic appearance of osteomyelitis in the amputated diabetic foot. To compare the histologic appearance with clinical and radiographic findings to determine the specificity of diagnosing osteomyelitis.

Progress: Study originated from Walter Reed. No patients have been added from Brookw Army Medical Center. Problem of obtaining, shipping specimens is ongoing.

Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-26-83 Status: Ongoing
 Title: A Study of the Transmission of the Arterial Pulse Pressure Wave Form in the Descending Aorta of Man.

Start Date 16 Mar 83	Est Comp Date:
Principal Investigator Ricky D. Latham, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgo, M.D., COL, MC Nico Westerhof, Ph.D.
Key Words: Arterial pulse pressure wave form	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 14	
Total Number of Subjects Enrolled to Date: 18	
Date of Periodic Review 9 Apr 85	Results Continue

Objective(s): To examine the changes in the arterial pulse pressure wave form throughout the descending aorta of man; to determine the pulse wave velocity at various sites in the descending aorta; to determine the significance of wave reflection sites in the descending aorta.

Technical Approach: Routine Sones procedure. 6-sensor catheter positioned by fluoro in descending aorta. Control, Valsalva, Muller and femoral artery occlusions performed

Progress: Control studies have been completed. One patient has been enrolled in the hypertensive group. No reportable data are available at this time.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-39-83 Status: Ongoing
 Title: Mechanism of Exercise Limitation in Patients with Obstructive Lung Disease.

Start Date 6 May 83	Est Comp Date:
Principal Investigator Joseph I. Matthews, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary Dis.	Associate Investigators: Bruce A. Bush, M.D., MAJ, MC Frank W. Ewald, Jr., M.D., MAJ, MC
Key Words: Obstructive lung disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 16	
Total Number of Subjects Enrolled to Date: 26	
Date of Periodic Review 13 Jun 85	Results Continue

Objective(s): 1) To determine the mechanism by which patients with obstructive lung disease are limited in their ability to perform exercise.

2) To examine ventilatory patterns in patients with obstructive lung disease during different types of exercise.

3) To determine if age matched control patients with reasonably normal lung function develop abnormal ventilatory patterns during similar modes of exercise.

Technical Approach: Patients who have been previously selected who have evidence of obstructive lung disease will be studied with various parameters of lung function following various types of exercise. Results will be compared with age-matched controls with normal pulmonary function to determine the mechanisms of exercise limitations.

Progress: Due to limited resources and time, progress has been very slow.

Detail Summary Sheet

Date: 30 Sep 85 Proj No: C-51-83 Status: Ongoing
 Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma.

Start Date 16 Jun 83	Est Comp Date:
Principal Investigator Stuart J. Salasche, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators:
Key Words: Basal cell carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 57	
Total Number of Subjects Enrolled to Date: 85	
Date of Periodic Review 13 Jun 85	Results Continue

Objective(s): To evaluate the effectiveness of low dosage levels of isotretinoin in reducing the incidence of basal cell carcinomas in a high risk population; to examine possible side effects associated with long term administration of low doses of isotretinoin.

Technical Approach: Patients having at least two basal cell carcinomas in the last five years are contacted. If interested in participation, they are screened according to protocol. If all inclusion factors are met, they are randomized and begun on medication or placebo. After beginning medication, follow-up will occur at two weeks, three months, six months and every six months thereafter for the duration of the study. Patients are on medication for three years and have follow-up for two years afterward. Physical exams are done yearly. History, laboratory data, total skin exam, and necessary biopsies are done at each visit. Lateral cervical and thoracic spine films are done at 0 and 36 months on each patient and at 6, 12, or 18 months depending on entry date.

Progress: Patient identification and screening are ongoing. Recruitment continues on schedule. Participants' interest and compliance remain high.

Due to length and double-blind nature of the study, no results can be ascertained at this time.

Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-77-83 Status: Ongoing
 Title: High Dose Busulfan with Autologous Bone Marrow Rescue for Solid Malignancies.

Start Date 30 Sep 83	Est Comp Date:
Principal Investigator (vice Boyd) Walter H. Harvey, DOD., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Terry E. Pick, M.D., LTC, MC Glenn M. Mills, M.D., MAJ, MC John J. Posch, Jr., MT, DAC Barbara Reeb, MT, DAC
Key Words: Bone marrow rescue Busulfan	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 11 September 1985 Results Continue	

Objective(s): To study the response rate and toxicity of oral, high dose busulfan in malignancies refractory to standard therapy.

Technical Approach: Patients agreeing to participate will be admitted to the hospital and a Hickman catheter inserted into a large vein in the region of the shoulder. Following insertion of the catheter, approximately 600-900 cc. of marrow will be drawn from the hip bones and stored for transfusion the next day. Approximately two hours following the marrow collection, they will be given busulfan orally. The next morning they will receive transfusion of their bone marrow through the Hickman catheter.

Progress: Three patients have been entered on this study. The first patient died on day 23 due to progressive metastatic disease. The second and third patients have shown no toxicity due to busulfan. It is too early to report any response data.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-2-84 Status: Ongoing
 Title: Left Ventricular Systolic Dynamics in Normal Man.

Start Date 6 Dec 83	Est Comp Date:
Principal Investigator Ares Pasipoularides, M.D., Ph.D.	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgo, M.D., COL, MC Bernard H. Rubal, Ph.D., Ph.D. Jerry W. Miller, M.D., MAJ, MC Stuart Damore, M.D., MAJ, MC
Key Words: Ventricular systolic dynamics	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 10	
Total Number of Subjects Enrolled to Date: 18	
Date of Periodic Review 8 Nov 84	Results Continue

Objective(s): To assess whether flow velocity-associate intraventricular pressure gradients represent a considerable intrinsic component of the total left ventricular systolic load when ejection is rapid, as in exercise.

Technical Approach: Simultaneous intraventricular (LV) pressure gradients and flow velocity patterns are measured at rest and submaximal exercise during heart catheterization and combined with angiocardiographic measurements of left ventricular geometry. Data applied to fluid dynamic models of ejection have been developed by the principal investigator to assess the contributions of convective and local acceleration effects to the intrinsic component of the left ventricular load.

Progress: This work has shown that the intrinsic, inertial component of the total systolic LV load can be considerable in early ejection even in absence of any pathology.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-3-84 Status: Ongoing
 Title: Determination of Left Ventricular Volume by Two-Plane Angiography:
 Correlation to Autopsy Left Ventricular Casts.

Start Date 6 Dec 83	Est Comp Date:
Principal Investigator(vice Anderson) Bernard J. Rubal, Ph.D.	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgu, M.D., COL, MC Ares D. Pasipoularides, M.D., Ph.D. William E. Craig, M.D., LTC, MC
Words: Ventricular volume Angiography, two-plane	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 154.40
Number of Subjects Enrolled During Reporting Period: n/a	
Total Number of Subjects Enrolled to Date: n/a	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the best methodology for calculating left ventricular volume measurements for each of Brooke Army Medical Center's Cardiac Catheterization Laboratories.

- 2) To correlate calculated left ventricular volume measurements with left ventricular volumes from hearts obtained by autopsy.
- 3) To compare mathematical models for left ventricular volumes with single plane and biplane angiography and also by area length method and Simpson's rule method.

Technical Approach: The hearts from autopsy will be obtained by the usual methods at Brooke Army Medical Center. Atria, atrioventricular valves and papillary muscles will be removed and the coronary arteries perfused with a fixative solution. A latex solution will then be infused into the left ventricle under slight pressure and allowed to gel 24 to 48 hours. One incision will be made in each ventricular wall and the cast removed. Cineangiograms will be obtained for all casts in each of the Cardiac Catheterization Laboratories at BAMC.

Progress: No new casts have been added to the study, because of logistic problems. We hope to correct these problems and continue the study.

Detail Summary Sheet

Date: 26 Sep 85	Proj No: C-6-84	Status: Ongoing
Title: Treatment for Locally Advanced Non-Small Cell Lung Cancer: Radiation Therapy plus Cis-Platinum and VP-16, a Pilot Study.		

Start Date 19 Dec 83	Est Comp Date:
Principal Investigator Gregory G. Friess, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC James F. Boyd, M.D., LTC, MC Mudhad Baikadi, M.D., MAJ, MC
Key Words: Lung cancer, non-small cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 8 Nov 84	Results Continue

Objective(s): To assess the toxicity and response rate for combined chemotherapy plus radiation therapy in the initial treatment of locally advanced on-small cell lung cancer.

Technical Approach: Concurrent radiation therapy and chemotherapy are being given in Stage III, locally advanced, non-small cell lung cancer.

Progress: No undue toxicity has been determined with concurrently administered chemotherapy and radiotherapy. Efficacy of this is awaiting further follow-up. Study continues to enroll patients.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-7-84 Status: Terminated
 Title: Evaluation of Continuous Infusion Vinblastine Sulfate and Concomitant Verapamil in Advanced Malignancy.

Start Date 19 Dec 83	Est Comp Date:
Principal Investigator W. E. Jordan, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: James F. Boyd, M.D., LTC, MC
Key Words: Verapamil	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 8 Nov 84	Results Continue

Objective(s): 1) To determine the resistance modifying effects of verapamil on tumors demonstrated to be resistant to vinblastine infusion.

2) To determine if there is enhanced toxicity from the addition of verapamil.

Technical Approach: Resistant malignancy is treated with Velban infusion for five days. If patients fails Velban, then Verapamil is added to the 5 day Velban infusion.

Progress: Study terminated; both investigators moved.

etail Summary Sheet

Date: 26 Sep 85 Proj No: C-8-84 Status: Ongoing
 Title: IGA Nephropathy: A Prospective Evaluation.

Start Date 6 Feb 84	Est Comp Date:
Principal Investigator John B. Copley, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: David C. Tapp, M.D., CPT, MC
Key Words: IGA nephropathy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review 9 Apr 85 Results Continue	

Objective(s): To determine pathologic and clinical-pathologic criteria for the diagnosis of IGA nephropathy, the prognosis of patients with such a diagnosis and their suitability for continued military service, the extent of evaluation and degree of follow-up required for such patients, and the sensitivity and specificity of various noninvasive diagnostic techniques which potentially could obviate the necessity for renal biopsy.

Technical Approach: Patients must have biopsy proven IgA nephropathy. They are prospectively followed for evidence of renal deterioration and development of hypertension.

Protocol is a multicenter study being conducted at BAMC, FAMC, and WRAMC. During the reporting period two individuals have been enrolled and a total of eight individuals have been enrolled in the protocol since its inception at BAMC. Accumulative number of patients enrolled in this protocol approximates 60 at all three medical centers.

Progress: During the reporting period two component studies have come to fruition. The first pertains to the utility of skin biopsy in the diagnosis of IgA nephropathy. It is concluded that the value of skin biopsy for diagnosing IgA nephropathy is minimal because of lack of sensitivity and specificity. As a result, skin biopsy is no longer being accomplished in these patients. Similarly, HLA data and serum IgA levels are of minimal value in diagnosing patients with IgA nephropathy and contribute little to prognosis. Thus, these, too, are no longer being accomplished. Finally, the scoring system for grading IgA nephropathy biopsies has been developed and clinical-pathological correlations are being developed as a result of this.

etail Summary Sheet

Date: 26 Sep 85 Proj No: C-9-84 Status: Ongoing
 Title: Primary Renal Hematuria: A Prospective Evaluation.

Start Date 6 Feb 84	Est Comp Date:
Principal Investigator John B. Copley, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: David C. Tapp, M.D., CPT, MC
Key Words: Hematuria, renal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review 9 Apr 85 Results Continue	

Objective(s): To determine the etiology and significance of hematuria, microscopic or macroscopic, as well as prognosis in patients who have neither personal nor family history of renal disease, nor evidence of systemic disease or extrarenal causes of hematuria.

Technical Approach: Patients are identified who have isolated hematuria, but no evidence of systemic disease and having normal renal function. Anatomical lesions are ruled out by IVP, cystoscopy and + angiogram. Serological evaluation is done. Patient then has a renal biopsy. Patients are followed every six months to check on blood pressure and renal function to determine possible onset of renal disease. This is a prospective study and thus far no one has developed evidence of renal function deterioration.

Protocol represents a collaborative study between BAMC, FAMC and WRAMC. Two subjects were enrolled during the reporting period and approximately eight individuals have been enrolled at BAMC to date. The total number of patients enrolled at the three medical centers approximates 60 patients.

Progress: Study represents a prospective evaluation of patients with primary renal hematuria and/or a normal renal biopsy who do not have IgA nephropathy. Because of the similarity of patients presenting with primary renal hematuria and IgA nephropathy, the primary renal hematuria protocol is necessarily closely related to the IgA nephropathy protocol. Results obtained during this study include the fact that it is impossible to differentiate clinically, primary renal hematuria from IgA nephropathy. Such differentiation must be done via a renal biopsy. Additionally, much valuable information has been gleaned concerning presentation of primary renal hematuria in patients with a normal renal biopsy concerning such clinical findings as flank pain. Finally, valuable

C-9-84 (continued)

HLA typing has been accomplished in these patients showing a trend towards two HLA subtypes. Research is ongoing in this area and includes an in vitro study of proteinuria which is actually pseudoproteinuria resulting from red blood cell lysis and hematuria states. Additionally, the effects of urokinase reference development of hematuria is being analyzed. Additionally, the significance of hematuria in patients being treated with anticoagulants is also being evaluated.

Detail Summary Sheet

Date: 10 Apr 85 Proj No: C-10-84 Status: Terminated
 Title: Cytosan (CTX) and ACTH Treatment in Chronic Progressive Multiple Sclerosis.

Start Date 6 Feb 84	Est Comp Date:
Principal Investigator David A. McFarling, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Neurology	Associate Investigators:
Key Words: Multiple sclerosis.	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 9 Apr 85	Results Terminate

Objective(s): Stabilization or reversal of symptoms and signs of neurological dysfunction in patients with documented multiple sclerosis by the use of immuno-suppressive medications.

Technical Approach: Patients with well-documented, progressive multiple sclerosis were admitted and, following baseline testing, administered a combination of cytosan and ACTH.

Progress: The study was terminated due to lack of progress.

Detail Summary Sheet

Date: 26 Aug 85 Proj No: C-16-84 Status: Ongoing
 Title: The Use of Monoclonal Antibodies to Classify Parapsoriasis.

Start Date 16 Mar 84	Est Comp Date:
Principal Investigator James H. Keeling, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: Eric W. Kraus, M.D., LTC, MC Charles W. Lewis, M.D., COL, MC Donald E. Clemons, M.D., COL, MC Michael V. Mulvaney, M.D., CPT, MC Neil F. Haddock, M. D., CPT, MC
Key Words: Monoclonal antibodies Parapsoriasis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$670.00
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 12 Apr 85	Results Continue

Objective(s): To compare the cellular infiltrates of small plaque parapsoriasis with that of large plaque parapsoriasis to ascertain whether differences are present and useful in separating the two diseases and their subsequent clinical course.

Technical Approach: Patients will be divided into two populations: those with large plaque parapsoriasis and those with small plaque/benign parapsoriasis. The study will require that an additional biopsy be taken at the time of routine follow-up. The additional biopsy will be assayed for the presence of cell types with a variety of specific monoclonal antibodies.

Progress: The monoclonal antibodies have been obtained. Three patients have agreed to let us do skin biopsies for the study. Using these specimens, we are working to obtain technical proficiency with the antibodies. Once we have achieved this goal, we plan to do follow-up biopsies and add new patients to the study.

Detail Summary Sheet

Date: 26 Sep 85	Proj No: C-18-84	Status: Ongoing
Title: Congestive Cardiomyopathy: Evaluation of Transvenous Myocardial Biopsy and Treatment with an Anti-Inflammatory Regimen.		

Start Date 16 Mar 84	Est Comp Date:
Principal Investigator Ricky D. Latham, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words: Cardiomyopathy, congestive	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$2500.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 9 Apr 85	Results Continue

Objective(s): To assess the efficacy of using an endomyocardial biopsy technique in the diagnosis and management of congestive cardiomyopathy by identifying specific etiologies and/or those patients with an inflammatory cellular reaction.

Technical Approach: Patients undergo complete noninvasive assessment with laboratory echocardiogram, MUGA, and Gallium. Then, if eligible, endomyocardial biopsy is performed. NIH interprets the histology and Hahnemann University does immunological assessment. Patients must have cath proven normal coronary arteries. Patients should be randomized to Prednisone and noninvasive studies repeated in 6 months, 12 months, and 18 months.

Progress: Now with eighteen month follow-up in some patients, we have obtained approval to initiate SGO sponsored patient registry for this disease. This will be Tri-Service wide. Collaborating centers at LAMC and WRAMC have been established.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-19-84 Status: Ongoing
 Title: Dipyridamole MUGA Studies Compared with Quantitative Tomographic Stress and Dipyridamole Infusion TL201 Scintigrams for Assessing Coronary Artery Disease.

Start Date 16 Mar 84	Est Comp Date:
Principal Investigator Ricky D. Latham, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Michael Cawthon, M.D., CPT, MC Michael F. Hartshorne, M.D., MAJ, MC Joseph P. Murgo, M.D., COL, MC
Key Words: Coronary artery disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 33	
Date of Periodic Review 9 Apr 85	Results Continue

Objective(s): To assess the sensitivity of dipyridamole MUGA study as compared to dipyridamole infusion TL 201 studies to detect significant coronary artery disease.

Technical Approach: IV Persantine, 60 mg/kg, is given over 4 minutes. TL201 is given 2 minutes after infusion. For MUGA, TCM⁹⁹ is given a 1 rest study performed before infusion. Studies are then done at 3 minute intervals x 4. All patients are submitted to cardiac catheterization and results of anatomy are determined.

Phase II approach changed and approved by IRB to use ventriculography instead of DSA.

Progress: Sufficient data have been collected. Conclusion: IVD-MUGA is not as sensitive as TL²⁰¹ but more specific in detecting significant CAD. Phase II is ongoing.

etail Summary Sheet

Date: 26 Sep 85 Proj No: C-20-84 Status: Ongoing
 Title: Evaluation of Amiodarone for the Therapy of Cardiac Arrhythmias.

Start Date 16 Mar 84	Est Comp Date
Principal Investigator Richard A. Schatz, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgu, M.D., COL, MC
Key Words: Arrhythmias, cardiac	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review 9 Apr 85	Results Continue

Objective(s): To control symptomatic cardiac arrhythmias which have been unresponsive to conventional and accepted forms of treatment, or whose control is dependent upon the use of a drug which has been shown to be harmful to, or in other ways not tolerated by, the individual.

Technical Approach: Patients who have failed conventional drug therapy for cardiac arrhythmias are eligible for the study. Patients are followed regularly with Holter monitors to judge success of therapy.

Progress: All patients responded to treatment. There have been no adverse reactions.

Detail Summary Sheet

Date: 9 Apr 85 Proj No: C-21-84 Status: Terminated
 Title: Effects of Long-Acting Propranolol and Nifedipine on Renal Blood Flow and Glomerular Filtration Rate in Patients with Hypertension.

Start Date 12 Apr 84	Est Comp Date:
Principal Investigator Charles J. Foulks, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: Jeffery F. Addison, M.D., CPT, MC
Key Words: Hypertension	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To show whether Inderal LA is associated with short-term or long-term decreases in renal blood flow and/or glomerular filtration rate.

2) To show whether Nifedipine, a calcium-channel blocker with vasodilator properties, effects a change in renal blood flow and/or glomerular filtration rate when added to Inderal LA therapy in the treatment of hypertension.

Technical Approach: Patients seen in the BAMC Hypertension Clinic and in the Renal Clinic with a diagnosis of essential hypertension determined by three separate blood pressure measurements on three separate occasions are eligible for the study. Each patient will undergo a radionuclide hippuran study to determine effective renal plasma flow and a Glofil study to determine glomerular filtration rate. Patient will then be placed on Inderal. When blood pressure has stabilized at ≥ 110 and the pulse is < 70 /minute, Nifedipine will be added.

Progress: This study was terminated because of reassignment of associate investigator.

Detail Summary Sheet

Date: 20 Aug 85 Proj No: C-22-84 Status: Completed
 Title: Effect of Oral Calcium Carbonate on Serum Phosphate in Chronic Renal Insufficiency and ESRD.

Start Date 12 Apr 84	Est Comp Date:
Principal Investigator Charles J. Foulks, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: Jeffery F. Addison, M.D., CPT, MC
Key Words: Chronic renal insufficiency ESRD	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 40	
Total Number of Subjects Enrolled to Date: 40	
Date of Periodic Review 13 Jun 85 Results Completed	

Objective(s): 1) To demonstrate whether or not oral calcium carbonate therapy with food ingestion results in control of serum phosphate in patients with chronic renal insufficiency ($\text{Ccr} \leq 30$ cc/minute) and ESRD without concomitant use of traditional phosphate binders.

2) To show whether serum aluminum levels decrease after implementation of the first objective.

Technical Approach: Thirty-eight dialysis patients and two patients with chronic renal insufficiency received calcium carbonate (2.3 g/d of elemental calcium) instead of their usual aluminum-containing phosphorus binders. Levels of calcium, phosphorus, alkaline phosphatase, carboxy-terminal PTH and plasma aluminum were followed by serial measurements for 21 ± 7 weeks.

Progress: Significant decreases in serum phosphorus, alkaline phosphatase, carboxy-terminal PTH and plasma albumin were seen ($P < 0.001$). Serum calcium significantly increased ($P < 0.001$) and calcium-phosphorus ion product changed significantly only in those patients with products greater than 70 falling from 80.9 ± 3.6 to 52.7 ± 3.7 ($P < 0.01$). Hypercalcemia occurred in two patients and resolved in one after cessation of calcitriol therapy. Two patients developed gastrointestinal distress necessitating their withdrawal from the study. No increases in vascular or soft tissue calcification were seen. Oral calcium carbonate is a safe, effective phosphorus binder, the use of which avoids potential problems of long-term aluminum exposure.

Detail Summary Sheet

Date: 23 Jun 85 Proj No: C-23-84 Status: Terminated
 Title: Relationship of Orthostatic Vital Signs and Extracellular Volume in
 Euvoletic and Hypovolemic Adult Patients.

Start Date 12 Apr 84	Est Comp Date:
Principal Investigator Howard Cushner, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: Charles J. Foulks, M.D., MAJ, MC Michael F. Hartshorne, M.D., MAJ, MC John B. Copley, M.D., LTC, MC
Key Words: Orthostatic vital signs Extracellular volume	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 17	
Date of Periodic Review 13 Jun 85 Results Terminate	

Objective(s): To define the relationship between various degrees of volume depletion and changes in mean arterial pressure and pulse from the supine to standing position.

Technical Approach: None.

Progress: The study was terminated at the request of the principal investigator.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-27-84 Status: Ongoing
 Title: Treatment of Graves' Ophthalmopathy with Cyclosporin. (Collaborative Study with WRAMC)

Start Date 12 Apr 84	Est Comp Date:
Principal Investigator Thomas J. Taylor, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Endocrinology	Associate Investigators: Leonard Wartofsky, M.D., COL, MC, WRAMC
Key Words: Graves' Ophthalmopathy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review 13 Jun 85 Results Continue	

Objective(s): To assess the efficacy of Cyclosporin treatment on the ophthalmopathy of Graves' Disease.

Technical Approach: 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.

Progress: Because of the relative infrequency of this condition, this is a multi-site trial, and we are awaiting cases to enter.

Detail Summary Sheet

Date: 20 Jun 85 Proj No: C-28-84 Status: Terminated
 Title: Intravenous Pulmonary Angiography Utilizing Digital Subtraction Angiography - A Comparison to Standard Pulmonary Angiography.

Start Date 12 Apr 84	Est Comp Date:
Principal Investigator David S. Gantt, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven R. Bailey, M.D., MAJ, MC William E. Craig, M.D., LTC, MC Michael J. Huggins, M.D., MAJ, MC Bernard J. Rubal, Ph.D. Joseph P. Murgu, M.D., COL, MC
Key Words: Subtraction angiography Pulmonary angiography	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 13 Jun 85 Results Terminate	

Objective(s): To demonstrate optimal technique of single plane and biplane intravenous digital angiography for visualization of pulmonary arteries and pulmonary arterial emboli.

Technical Approach: Each patient received three different injections in either the pulmonary artery, right atrium, or brachial vein of different contrast dosages to compare images obtained. In addition, when indicated, a standard pulmonary angiogram was compared to the digital images obtained.

Progress: This study was terminated due to release from active duty of the principal investigator.

Detail Summary Sheet

Date: 20 Jun 85 Proj No: C-31-84 Status: Terminated
 Title: Comprehensive Evaluation of Sexual Function in Male Patients with End-Stage Renal Disease (ESRD).

Start Date 10 May 84	Est Comp Date:
Principal Investigator Charles J. Foulks, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: Alan Hopewell, Ph.D.
Key Words: End-stage renal disease (ESRD)	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To define the pathophysiology of impotence in male patients undergoing therapy for ESRD with primary emphasis upon the contribution of hyperprolactinemia to the impotence.

Technical Approach: All patients selected for study will undergo a history and physical examination as well as neurological examination; chemistry profile; CBC with differential; PA and lateral chest x-ray; nerve conduction velocity; prolactin, FSH, LH, testosterone; MMPI; sexual history questionnaire of patient and spouse; and other studies as outlined in the protocol.

Progress: Terminated due to release from active duty of principal investigator.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-32-84 Status: Ongoing
 Title: Effect of Discontinuance of Smoking on Gastroesophageal Reflux.

Start Date 10 May 84	Est Comp Date:
Principal Investigator Fred Goldner, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators:
Key Words: Gastroesophageal reflux	
Accumulative MEDCASE Cost: \$9,920.00	Est Accumulative OMA Cost: \$225.00
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 13 Jun 85 Results Continue	

Objective(s): To determine if discontinuance of cigarette smoking will decrease gastroesophageal reflux in a population of smokers with pyrosis.

Technical Approach: Ambulatory 24 hour pH monitoring technology will be applied to a group of smoking patients with pyrosis before and after discontinuance of smoking. A standard set of criteria will e applied to determine if the discontinuance of smoking has a significant effect on gastroesophageal reflux.

Progress: The required MEDCASE equipment has just been received and in-service held. Patient acquisition will begin shortly.

Detail Summary Sheet

Date: 20 Jun 85 Proj No: C-36-84 Status: Terminated
 Title: Evaluation of the Photoprotective Abilities of the Army Caps Currently Recommended for Army Personnel Head Cover.

Start Date 21 Jun 84	Est Comp Date:
Principal Investigator Eric W. Kraus, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: James H. Keeling, M.D., MAJ, MC Madhu A. Pathak, M.D. Arthur J. Sober, M.D.
Key Words: Army caps	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 19	
Total Number of Subjects Enrolled to Date: 19	
Date of Periodic Review 13 Jun 85 Results Terminate	

Objective(s): 1) To test the photoprotective abilities of two US Army head caps currently used by Army personnel.

2) To determine to what extent the two US Army head caps minimize the impinging effects of solar UV radiation on the face and neck.

Technical Approach: Outdoor testing using natural sunlight, each volunteer had a vertical and horizontal UVB intensity reading done at 20 sites on the head and neck under three different conditions - no hat, wide brim hat, and BDU cap. An IL 700 radiometer and a Robertson-Berger meter were used to measure intensity.

Progress: Though the test was designed as a "use study," field conditions (Combat Casualty Care Course) were too uncontrolled. As a result data could not be collected or tabulated in any meaningful fashion. Therefore, the study was terminated.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-37-84 Status: Ongoing
 Title: Clinical Trial of Ipratropium Bromide (Atrovent [R]) in Patients with Refractory Asthma and/or Chronic Obstructive Pulmonary Disease.

Start Date 21 Jun 84	Est Comp Date:
Principal Investigator Herman M. Blanton, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary Dis.	Associate Investigators:
Key Words: Asthma, refractory Chronic obstructive pulmonary disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 7	
Date of Periodic Review 13 Jun 85	Results Continue

Objective(s): To provide emergency medication for patients who do not respond to currently marketed medications.

Technical Approach: Eligible patients must have a diagnosis of bronchial asthma, chronic bronchitis, or emphysema. Inhalations should not exceed 12 per day.

Progress: Atrovent is a quaternary-ammonium atropine analog, which has the unique property of not being systemically absorbed after inhalation. Systemic anticholinergic effects are avoided therefore and local bronchodilatory effects attained. We have acquired this drug under a compassionate-use program with Boehringer-Ingelheim for use in steroid-dependent, "refractory" asthmatics. Of the seven patients enrolled, three dropped out due to lack of subjective benefit (although objective spirometric improvement was documented). The four remaining patients have had subjective and objective improvement resulting in reductions of steroid dosage and ER visits/hospitalizations.

Detail Summary Sheet

Date: 26 Sep 85	Proj No: C-43-84	Status: Ongoing
Title: Assessment of Radiocontrast Induced Acute Renal Failure Following Coronary Angiography: An Evaluation of Intravenous Mannitol Infusion as a Preventive Measure.		
Start Date 17 Jul 84	Est Comp Date:	
Principal Investigator John R. Krouse, M.D., MAJ, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven Bailey, M.D., MAJ, MC Don Hammonds, M.D., CPT, MC Brian Copley, M.D., LTC, MC Terence Ross, M.D., CPT, MC	
Key Words: Angiography, Coronary Renal failure		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: _____		
Total Number of Subjects Enrolled to Date: 30		
Date of Periodic Review 11 Sep 85 Results Continue		

Objective(s): To determine the incidence of radiocontrast-induced acute renal failure in a high risk subgroup following selective cardiac angiography, to determine the effects of hemodynamic status on this incidence, and to compare the effect of intravenous mannitol infusion following angiography as compared to placebo on the incidence of development of acute renal failure.

Technical Approach: Patients with renal failure (creatinine > 2.0) or diabetes mellitus requiring treatment were randomized to receive either mannitol or saline at catheterization. Renal function was followed closely before and after catheterization to assess differences in development of renal failure.

Progress: No significant difficulties in occurrence of renal failure have been encountered. Number of patients enrolled too small to draw any conclusions.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-44-84 Status: Ongoing
 Title: Hematuria as a Complication of Anticoagulation.

Start Date 17 Jul 84	Est Comp Date:
Principal Investigator David C. Tapp, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: John C. Copley, M.D., LTC, MC Steven R. Bailey, M.D., MAJ, MC C. Ritchie Spence, M.D., COL, MC William S. Grabowski, M.D., COL, MC Joseph P. Murgu, M.D., COL, MC
Key Words: Hematuria Anticoagulation	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 11 Sep 85	Results Continue

Objective(s): To determine the incidence of hematuria in patients on various anticoagulants; specifically coumadin, heparin, and streptokinase; and then to identify the specific etiology of the hematuria by employing selected diagnostic tests (IVP, cystoscopy, etc.).

Technical Approach: Patients with hematuria on coumadin, heparin, streptokinase are identified and then receive a work-up to determine etiology (IVP, cystogram, culture, PPD, serologies).

Progress: This protocol entails a prospective review of patients placed on anticoagulation and followed by the coumadin clinic at BAMC. Thus far approximately 200 consecutive patients have been screened with urinalyses for the presence of hematuria and 4-5 patients have been found with hematuria. Only one patient, however, has consented to be enrolled in the study which involves an evaluation for the source of the hematuria when placed on anticoagulants. The study is ongoing and represents a chance not only to obtain an accurate incidence of hematuria occurring in the anticoagulated patient, but also represents a chance to determine the degree of significance of that hematuria and the need for evaluation of the urinary tract.

Detail Summary Sheet

Date: 22 May 85 Proj No: C-48-84 Status: Completed
 Title: The Subjective Assessment of the Effectiveness of Esophageal Dilation.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Andrew Bailey, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Frank P. Wilson, D.O., LTC, MC Fred Goldner, M.D., COL, MC
Key Words: Esophageal dilation	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 20	
Total Number of Subjects Enrolled to Date: 20	
Date of Periodic Review	Results

Objective(s): To assess subjectively the effectiveness of esophageal dilation.

Technical Approach: Esophageal dilatation utilizing Maloney dilators was observed under fluoroscopy. The physician performing dilation and the patient being dilated were unaware of the fluoroscopic findings. The physicians then predicted whether or not their dilations were successful. Various features were examined to determine their usefulness in predicting successful dilation.

Progress: If physicians predicted successful passage, they were correct 97% of the time; however, if they predicted unsuccessful passage, they were correct only 60% of the time. Features helpful in predicting successful passage included easy passage of the dilator (98%) and the patient feeling the dilator in the stomach (95%). Excessive resistance suggesting unsuccessful passage was an unreliable feature and was often due to the dilator curling in the stomach. We conclude that when Maloney dilators are used to dilate simple distal strictures, if the physician predicts successful passage, he is reliably accurate without the use of fluoroscopy; however if unsuccessful passage is suspected, fluoroscopy must be used to confirm his impression.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-49-84 Status: Ongoing
 Title: A Test of the Colonic Hyperalgesia Hypothesis in Patients with Irritable Bowel Syndrome (IBS).

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Fred Goldner, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: John B. Powell, Ph.D., CPT, MSC
Key Words: Irritable bowel syndrome (IBS)	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 8	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review 11 Sep 85	Results Continue

Objective(s): To determine if abdominal pain in patients with IBS is due to a hypersensitivity of the colon to distention versus a hypersensitivity of the patient to pain in general.

Technical Approach: Noxious stimuli will be applied in a controlled manner to a group of irritable bowel patients with abdominal pain. Gut distention pain will be evaluated by balloon distention of the rectum and somatic discomfort tested by cold water hand immersion. Control and IBS populations will be compared as to pain sensitivity in each parameter.

Progress: Too few patients have been enrolled in this study to report any meaningful results.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-50-84 Status: Ongoing
 Title: The Effect of Weight Loss on Gastroesophageal Reflux.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Fred Goldner, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators:
Key Words: Gastroesophageal reflux	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 11 Sep 85	Results Continue

Objective(s): To determine if weight loss achieved through caloric restriction will improve gastroesophageal reflux of acid.

Technical Approach: 24-hour ambulatory pH testing will be performed on a group of obese subjects with pyrosis, before and after weight loss. A standard set of reflux criteria will be applied to determine if weight loss affects the degree of gastroesophageal reflux.

Progress: The required MEDCASE equipment has just been received and in-service held two weeks ago.

Patient acquisition just now beginning.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-51-84 Status: Terminated
 Title: Incidence of Cardiac Arrhythmias During Labor and Delivery.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator David S. Gantt, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Charles Jeffries, M.D., CPT, MC
Key Words: Arrhythmias, cardiac	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To document the incidence of cardiac conduction abnormalities and arrhythmias during normal labor and delivery in healthy women.

Technical Approach: A 24 hour Holter monitor is placed and recordings obtained during labor, delivery, and approximately 12 hours post-delivery.

Progress: Study terminated because the principal investigator is no longer in the Army.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-52-84 Status: Terminated
 Title: Hemodynamics of Supine versus Upright Bicycle Ergometry: A Comparison.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator David S. Gantt, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Julio J. Bird, M.D., MAJ, MC Bernard J. Rubal, Ph.D., Ph.D. Joseph P. Murgo, M.D., COL, MC
Key Words: Ergometry	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To compare hemodynamic parameters at rest and during bicycle ergometry in both upright and supine positions.

Technical Approach: With high fidelity micromanometer tipped catheters in the left and right heart, hemodynamic measurements are obtained both in the supine and upright position, at rest and during exercise.

Progress: Study terminated because the principal investigator is no longer in the Army.

Detail Summary Sheet

Date: 22 Jul 85	Proj No: C-64-84	Status: Ongoing
Title: Utilization of Mixed Venous Oxygen Saturation (Sv ₂ Sat) in the Management of the Critically Ill.		

Start Date 13 Sep 84	Est Comp Date:
Principal Investigator(vice Glendening) Harvey M. Richey, III, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: Joseph I. Matthews, M.D., COL, MC Bruce A. Bush, M.D., MAJ, MC Herman M. Blanton M.D., CPT, MC
Key Words: Opticath	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$8,750.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine if continuous SvO₂ monitoring reduces numbers of other evaluative tests/procedures in the management of the critically ill.

2) To determine if continuous SvO₂ monitoring affects the duration of vasoactive drug therapy or mechanical ventilatory assistance.

3) To determine if insertion failures or procedure complications vary between catheters or indications.

Technical Approach: Information will be gathered regarding the effectiveness of a new catheter, called an Opticath, in the care of the seriously ill patient.

Progress: No reportable data are available at this time.

etail Summary Sheet

Date: 26 Sep 85	Proj No: C-73-84	Status: Ongoing
Title: Comparison of Micromanometer Tip Left Atrial Catheter Monitoring with Fluid Pulmonary Artery Pressure Monitoring in Postoperative Open Heart Surgery Patients, a Trend Analysis in the SICU.		
Start Date 25 Sep 84	Est Comp Date:	
Principal Investigator William E. Craig, M.D., LTC, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Julio J. Bird, M.D., MAJ, MC Joseph P. Murgo, M.D., COL, MC Ricky D. Latham, M.D., CPT, MC Harold D. Head, M.D., COL, MC Bernard J. Rubal, Ph.D.	
Key Words: Catheter, left atrial		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 2		
Total Number of Subjects Enrolled to Date: 2		
Date of Periodic Review 11 Sep 85 Results Continue		

Objective(s): To compare the pressures obtained from a high fidelity, micro-manometer transducer mounted on a left atrial catheter to those obtained from a flow-directed, balloon-tipped catheter in the pulmonary artery in patients recovering from open heart surgery.

Technical Approach: At the time of surgery, a micromanometer tip left atrial catheter will be inserted through the pulmonary vein into the atrium. A flow-directed, balloon-tipped catheter will be inserted into the pulmonary artery in the routine manner. Pressure and blood gas measurements will be recorded at two hour intervals or more often if indicated. Analysis will continue until the catheters are removed.

Progress: Limited cardiology personnel available to closely monitor data collections as needed has limited progress of study. Progress thus far has simply demonstrated feasibility of techniques.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-74-84 Status: Ongoing
 Title: Hemodynamic Effects of IV Dipyridamole in Normal Man Compared with Patients with Significant Arteriosclerotic Heart Disease.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Romel C. Wrenn, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Ricky D. Latham, M.D., CPT, MC Joseph P. Murgo, M.D., COL, MC
Key Words: Dipyridamole, IV	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 15	
Total Number of Subjects Enrolled to Date: 15	
Date of Periodic Review 11 Sep 85	Results Continue

Objective(s): To establish the acute effect of IV dipyridamole in normal subjects on cardiovascular hemodynamics routinely measured in the cardiac catheterization laboratory.

Technical Approach: Patients scheduled for elective cardiac catheterization will be asked to participate. Cardiac catheterization will be performed in the standard fashion. All hemodynamics will be measured at control, during exercise pre dipyridamole, and at five-minute intervals post-infusion of IVD. Baseline Fick and thermal dilution cardiac outputs will be obtained. Fick and Thermal dilution cardiac outputs will be used in post-infusion studies.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 3 Oct 85 Proj No: C-4-85 Status: Ongoing
 Title: Evaluation of Continuously Determined Mixed Venous Oxygenation (MVO₂)
 via Fiberoptic Catheter in the Critically-Ill Patient.

Start Date 14 Nov 84	Est Comp Date:
Principal Investigator Gregg T. Anders, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven R. Bailey, M.D., MAJ, MC Joseph P. Murgo, M.D., COL, MC
Key Words: Catheter, fiberoptic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review n/a	Results

Objective(s): To correlate a continuous spectrophotometric mixed venous oxygenation saturation to changes in cardiac output, peripheral/systemic vascular resistance, and other physiologic parameters in critically-ill cardiac patients.

Technical Approach: Various patients with cardiac dysfunction (AMI, acute decompensation of CHF) are monitored in BAMC CCU with fiberoptic Swan-Ganz catheter, and mixed venous oxygenation state is compared with more standardized critical-care monitoring parameters, including cardiac output and systemic vascular resistance.

Progress: Results obtained to date indicated that numerous changes in mixed-venous oxygenation occur without corresponding changes in cardiac output. In regard to adverse reaction in thos patients studied, none have developed adverse reaciton to the catheter itself.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-9-85 Status: Ongoing
 Title: Prevalence of Mitral Valve Prolapse in Syncope.

Start Date 15 Jan 85	Est Comp Date:
Principal Investigator David R. Wood, D.O., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department Medicine/Internal Medicine	Associate Investigators: Steven Atchley, D.O., CPT, MC Steven Hoadley, M.D., MAJ, MC Samuel T. Coleridge, D.O., LTC, MC
Key Words: Prolapse, mitral valve	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date: 239	
Date of Periodic Review n/a	Results

Objective(s): To determine the prevalence of mitral valve prolapse in patients presenting to a Military Emergency Room with a chief complaint of syncope and to see if this varies from a similar group of age-sex matched controls.

Technical Approach: The study population will consist of all patients being seen in the Emergency Room or the Troop Clinic complaining of "passing out" (syncope). The control group will consist of age-sex matched population complaining of upper respiratory infections. Studies on all patients include completion of a questionnaire, brief physical exam, m-mode echocardiogram and 2-D echocardiogram.

Progress: Results are being tabulated.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: C-10-85 Status: Ongoing
 Title: Altering Polypharmacy in the Elderly.

Start Date 15 Jan 85	Est Comp Date:
Principal Investigator Ellen M. Pinholt, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department Medicine/Internal Medicine	Associate Investigators: James Hanley, M.D., MAJ, MC Kurt Kroenke, M.D., MAJ, MC Tony Dasher, RPh, CPT MS
Key Words: Polypharmacy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine how best to assess a patient's drug misuse and potential for drug interactions.

2) To determine how best to decrease drug duplication, drug interactions, and complexity of drug regimens.

Technical Approach: Patients assigned to housestaff aged 65 and older were directed in filling out a questionnaire which looked at number of clinics visited, number of prescription drugs used, and the dosage intervals. Those patients on five or more prescription medications were then interviewed by a pharmacist and further information was gathered on over-the-counter medication use, side effects from medications, etc. The pharmacist then made recommendations regarding simplifying regimens, deletion of drugs, etc. The investigators then divided the patients interviewed (90) into a control and study group. The study group's physicians were shown the recommendations and were asked their reason(s) for any changes made in their prescribing practice.

Progress: The data gathering period is completed, and it is now being analyzed to see if prescription drug use in those patients with polypharmacy was altered by having all prescription drugs listed and recommendations to decrease complexity, etc. The questionnaire method vs. interview plus "brown bag" is also being looked at.

Detail Summary Sheet

Date: 26 Aug 85 Proj No: C-14-85 Status: Ongoing
 Title: Early Catheterization and PTCA vs Conservative Management for Initial Myocardial Infarction: A Comparison.

Start Date 21 Jan 85	Est Comp Date:
Principal Investigator (vice Gantt) John R. Krouse, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words: Infarction, myocardial	Richard A. Schatz, M.D., MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To compare the reinfarction rate of patients with an initial myocardial infarction associated with a peak CPK of <1000 ug% who are randomized to one of two groups: (1) cardiac catheterization within 48 hours of diagnosis followed by PTCA if feasible; (2) medical management, i.e., nitrates, beta blockers, and calcium channel blockers, for 10 days, and a rate-limited stress test prior to discharge.

Technical Approach: Patients diagnosed as having an initial myocardial infarction whose CPK level peaks at <1000 ug% will be randomized to one of two groups. Group I will undergo catheterization within 48 hours of diagnosis. Group II patients will be composed of patients randomized initially to medical management who will undergo a rate-limited stress test prior to discharge. Each group will be analyzed regarding reinfarction rate and mortality rate at the following time intervals: two weeks, six weeks, three months, and six months.

Progress: A new principal investigator has been appointed. No reportable data are available at this time.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-16-85 Status: Ongoing
 Title: Significance of Post Radiotherapy Constrictive Pericarditis in Patients.

Start Date 21 Jan 85	Est Comp Date:
Principal Investigator Terence C. Ross, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Ricky D. Latham, M.D., CPT, MC Gregory G. Friess, M.D., MAJ, MC Joseph P. Murgo, M.D., COL, MC
Key Words: Pericarditis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review n/a	Results

Objective(s): To study Hodgkins patients post thoracic radiation therapy in order to determine: 1) the incidence of overt constrictive pericarditis; 2) the incidence of occult constrictive pericarditis; 3) a correlation of Doppler flow profile across the tricuspid or mitral valve and right heart pressure events in overt constrictive and occult constrictive pericarditis; 4) a correlation between myocardial interstitial fibrosis with abnormal hemodynamics and abnormal pericardium in overt constrictive and occult constrictive pericarditis.

Technical Approach: Outpatient Echo/Doppler evaluation right heart catheterization with endomyocardial biopsy.

Progress: Number of patients too small for conclusive results.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-18-85 Status: Completed
 Title: Prospective Study of Intron and Doxorubicin in the Treatment of Patients with Solid Tumors.

Start Date 26 Feb 85	Est Comp Date:
Principal Investigator Thomas D. Brown, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC Kenneth Beougher, MAJ, MS G. A. Sarosy, M.D., UTHSCSA D. L. Kisner, M.D., UTHSCSA D. D. Von Hoff, M.D., UTHSCSA
Key Words: Solid tumors	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 6	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review n/a	Results

Objective(s): To assess the tolerance and efficacy of Intron and Doxorubicin given concomitantly in the treatment of solid tumors.

Technical Approach: Patients received α -2 recombinant interferon (Intron) at 10×10^6 IU/m² subcutaneously three times per week (M-W-F) during the first two weeks of every three week cycle. Doxorubicin was given at 20, 30 or 40 mg/m² IV on day 5 of the 21 day cycle.

Progress: This study accrued patients at both BAMC and UTHSCSA. At BAMC six patients were treated with a total of 17 cycles of Doxorubicin/Intron. Two cycles were given with Doxorubicin at 20 mg/m², 12 cycles were given at 30 mg/m², and 3 cycles were given at 40 mg/m².

Dose limiting toxicity was granulocytopenia that was reversible in all patients. One patient was deescalated from 50 to 20 mg/m² of Doxorubicin due to myelo-suppression. Another patient came off study (on 50 mg/m² of Doxorubicin) due to

C-18-85 (continued)

treatment associated malaise. Nonhematologic toxicity included flu-like symptoms, alopecia, nausea and vomiting, diarrhea and transient elevations in liver function studies. The maximum tolerated dose of Doxorubicin for this schedule is 50 mg/m². For Phase II studies a Doxorubicin dose of 50 mg/m² is recommended for minimally pretreated and good performance status patients while a dose of 50 mg/m² is recommended for heavily pretreated and poor performance status patients. One partial response was seen at BAMC in a patient with squamous cell carcinoma of unknown primary involving the sternum.

The BAMC data together with the UTHSCSA data are being prepared for publication.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-19-85 Status: Ongoing
 Title: Cardiorespiratory Effects of Injection Sclerotherapy.

Start Date 5 Feb 85	Est Comp Date:
Principal Investigator Richard C. Leib, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Floyd V. Burton, M.D., MAJ, MC Scott Deppe, M.D., MAJ, MC
Key Words: Sclerotherapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review n/a	Results

Objective(s): To monitor patients in the intensive care setting that are undergoing esophageal variceal sclerosis (EVS) and evaluate the possible effects of EVS.

Technical Approach: Candidates for EVS who are free of any significant active cardiorespiratory disease will be entered into the study. A control group will include six patients undergoing endoscopy for indications other than EVS. The patients will have pre-endoscopy measurements done which include systemic arterial systolic, diastolic, and mean pressures; cardiac output; pulmonary capillary wedge pressure; systolic pulmonary artery pressure; diastolic pulmonary artery pressure; mean pulmonary artery pressure; calculated systemic vascular resistance; pulmonary vascular resistance; arterial blood gases; A-a gradient and FiO₂. The control group will have measurements done pre-endoscopy and out to 12 hours.

Progress: Due to restrictive nature of protocol, enrollment is very slow.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-20-85 Status: Ongoing
 Title: Pressure Waveforms and Reflections in the Human Aorta: Comparison of a Cadaver Model with In Vivo Results.

Start Date 5 Feb 85	Est Comp Date:
Principal Investigator Ricky D. Latham, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Bernard J. Rubal, Ph.D. Joseph P. Murgo, M.D., COL, MC Nico Westerhof, Ph.D. Renu Virmani, M.D. M. Rabinowitz
Key Words: Pressure waveforms	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$5,648.25
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) Identify site(s) of wave reflection affecting wave shapes in the aorta of man.

2) Correlate changes in wave reflection and pulse transmission characteristics with changes in compliance in the cadaver aorta.

3) Investigate simultaneous regional impedances with changes in arterial reflection induced by controlled variance of terminal resistances or compliance.

4) Correlate changes in compliance with impedance changes and compare the cadaver results to in vivo results.

5) Compare descending aorta impedance changes in normals, hypertensive, and atherosclerotic peripheral vascular disease patients.

Technical Approach: The aorta will be measured in a fresh human cadaver for longitudinal dimensions to be maintained in the model set up. The aorta and its branches will be dissected free. In order to characterize the effects of handling procedures on elasticity, a pilot trial in swine aorta will be performed.

Progress: The experimental set-up was completed, and four cadaver aortas run. Design change were finalized. Dr. Rabinowitz from AFIP is doing the initial morphometric analyses.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-21-85 Status: Ongoing
 Title: Doppler Ultrasound Applied to Studies of Pulmonary Blood Flow in Pulmonary Hypertension.

Start Date 5 Feb 85	Est Comp Date:
Principal Investigator Stephen D. Hoadley, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Jacelyn F. Miller, R.D.M.S. Joseph P. Murgo, M.D., COL, MC
Key Words: Hypertension, pulmonary Doppler ultrasound	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 20	
Total Number of Subjects Enrolled to Date: 20	
Date of Periodic Review n/a	Results

Objective(s): To validate Doppler ultrasound as a non-invasive tool for evaluating pulmonary blood flow velocity in patients with pulmonary hypertension.

Technical Approach: In order to evaluate the accuracy of Doppler ultrasound in assessing pulmonary hypertension, it was performed in the cath lab with simultaneous right heart catheterization using Millar high fidelity multisensor catheters. Twenty patients were studied with mean pulmonary artery pressures in the range of 10 to 85 mmHg. A correlation was made between the pulmonary artery pressure and the pulsed Doppler signal obtained from the left parasternal window, with the sample volume in the right ventricular outflow tract. The following intervals were measured from the Doppler signal: (1) pre-ejection period, (2) acceleration time, (3) the right ventricular ejection time, (4) the ratio PEP/RVET, and (5) the ratio AT/RVET.

Progress: The best correlation was obtained between the mean pulmonary pressure and the acceleration time, with a correlation coefficient of -0.43 and a standard deviation in the mean pulmonary artery pressure of 17 mmHg. There was no improvement in predicting mean pulmonary artery pressure by using the ratio AT/RVET, with a correlation coefficient of -0.37. The acceleration time of over 90 ms suggested mean pulmonary artery pressure ≤ 22 mmHg.

Qualitative descriptions of the Doppler signal were also evaluated: (1) presence or absence of a pre-systolic flow (an "a-wave"); (2) an early-peaking

C-21-85 (continued)

triangular-shaped flow signal; (3) systolic notching of the flow signal; and (4) pulmonary insufficiency. The absence of an "a-wave" was specific, but not sensitive, for the presence of pulmonary hypertension. When no more than one of the above qualitative criteria was present, the lack of pulmonary hypertension was predicted in eight out of nine patients.

These data suggest that Doppler ultrasound can be used to help exclude the presence of pulmonary hypertension. It does not, however, appear to be highly accurate in determining the level of pulmonary pressure in adults undergoing cardiac catheterization.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-26-85 Status: Ongoing
 Title: Correlation of Breath Hydrogen Concentration and Bloating in Patients with Irritable Bowel Syndrome.

Start Date 26 Feb 85	Est Comp Date:
Principal Investigator	Facility
Christopher VanAsche, M.D., MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Gastroenterology	Fred Goldner, M.D., COL, MC
Key Words:	
Irritable Bowel Syndrome	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): To determine if the symptom of bloating in patients with irritable bowel syndrome (IBS) is related to carbohydrate malabsorption as measured by increased breath hydrogen excretion.

Technical Approach: A total of 50 patients will be studied. Fasting hydrogen values (while non-bloated) of subjects entered in this study will be the baseline comparison of values obtained subsequently. Samples will will be collected by the patients in Mylar-coated foil bags and stored until analyzed. They will be analyzed for hydrogen concentration within 72 hours of collection using the Quintron Model 12 breath hydrogen analyzer.

Progress: No patients have been entered into the study.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-27-85 Status: Ongoing
 Title: Hemodynamic Effects of the Muller Maneuver.

Start Date 26 Feb 85	Est Comp Date:
Principal Investigator William R. Condos, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Ricky D. Latham, M.D., CPT, MC Stephen D. Hoadley, M.D., MAJ, MC Joseph P. Murgo, M.D., COL, MC
Key Words: Muller maneuver	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 6	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review	Results

Objective(s): To study hemodynamic effects and changes in aortic compliance during the Muller maneuver.

Technical Approach: Routine Sones approach. Double-tip/flow on left and Triple-tip/flow on right. Rest hemodynamics with simultaneous Echo, then Muller maneuver. A-gram with simultaneous pressure.

Program: Five patients with usable data. One V-gram done. No complications. Analysis pending enrollment of five more patients for initial review.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-28-85 Status: Terminated
 Title: Prophylaxis of Upper Gastrointestinal Injury During Hepatic Artery
 5-Fluorodeoxyuridine (FUdR) Infusion.

Start Date 26 Feb 85	Est Comp Date:
Principal Investigator Christopher VanAsche, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroentoloergy	Associate Investigators: John R. Jones, M.D., MAJ, MC Walter Harvey, M.D., MAJ, MC Kenneth Reed, M.D., LTC, MC Fred Goldner, M.D., COL, MC
Key Words: Infusion, hepatic artery	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine whether sucralfate is effective in the prevention of
 FUdR-induced upper gastrointestinal mucosal damage.

Technical Approach: None.

Progress: The study was terminated as no patients could be found to enter into
 the study.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-29-85 Status: Ongoing
 Title: Apical Methods of Cardiac Output Determination with Doppler Ultrasound.

Start Date 26 Feb 85	Est Comp Date:
Principal Investigator Stephe D. Hoadley, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgo, M.D., COL, MC
Key Words: Doppler ultrasound	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 5	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review n/a	Results

Objective(s): To determine which of the apical views is more accurate in estimating cardiac output via doppler ultrasound.

Technical Approach: Five patients studied; four were technically adequate. Due to time constraints, have often had to delete pulmonary artery (RVOT) part of protocol.

Progress: Insufficient number of patients to report any results.

Detail Summary Sheet

Date: 27 Sep 85 Proj No: C-37-85 Status: Ongoing
 Title: Cardiovascular Monitoring in Patients Receiving Beta Interferon.

Start Date 29 Apr 85	Est Comp Date:
Principal Investigator Gregory G. Friess, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Thomas D. Brown, M.D., CPT, MC Juan C. Garcia, M.D., CPT, MC Glenn M. Mills, M.D., MAJ, MC Michael Hartshorn, M.D., MAJ, MC Michael Cawthon, D.O., MAJ, MC John Bauman, M.D., CPT, MC
Key Words: Interferon, Beta	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): 1) To assess cardiovascular state in oncology patients pre- and post-treatment with beta interferon.

2) To assess initial cardiac rhythm and possible disturbances over extended treatment with beta interferon.

Technical Approach: Not performed at the present time due to lack of Holter monitoring time.

Progress: Study will begin accruing patients upon completion of the Gamma interferon project.

Detail Summary Sheet

Date: 27 Sep 85 Proj No: C-38-85 Status: Ongoing
 Title: Carbohydrate Binding by Activated Charcoal In Vivo and In Vitro and Its Effect on the Production of Breath Hydrogen.

Start Date 29 Apr 85	Est Comp Date:
Principal Investigator Bernard Feldman, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine	Associate Investigators: Fred Goldner, M.D., COL, MC Regina Marshall, R.N
Key Words: Carbohydrate binding Breath hydrogen	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review N/a	Results

Objective(s): To assess the efficacy of activated charcoal in binding carbohydrates in the GI tract.

Technical Approach: A fasting breath hydrogen sample will be obtained. After ingesting the carbohydrate, subjects will blow a sample of their breath into special Mylar-coated foil bags and stored until analyzed. They will be asked to obtain samples hourly for eight hours and will be given a diary to record symptoms. Samples will be analyzed and a rise of greater than 20 parts per million of hydrogen gas over fasting concentration will be interpreted as carbohydrate malabsorption. Comparison will be made between the treated and placebo groups to determine if activated charcoal can bind carbohydrate and prevent fermentation and production of breath hydrogen.

Progress: An unanticipated delay in obtaining all necessary supplies was encountered. The materials have been received, and it is anticipated that the study will start o/a 1 October.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-40-85 Status: Ongoing
 Title: A Phase I Study of Recombinant Gamma Interferon in Patients with Solid Tumors.

Start Date 7 Jun 85	Est Comp Date:
Principal Investigator Thomas D. Brown, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC Kenneth Beougher, MAJ, MC James Koeller, M.D., UTHSC Daniel D. VonHoff, M.D., UTHSC
Key Words: Interferon, Gamma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 15	
Total Number of Subjects Enrolled to Date: 15	
Date of Periodic Review n/a	Results

Objective(s): To determine the tolerance and toxicity of the investigational drug Gamma Interferon in patients with refractory malignancy and to seek preliminary evidence for antitumor activity in patients.

Technical Approach: Two schedules of drug have been studied: (1) IV continuous infusion over 24 hours x 5 days, repeated every 28 days; and (2) IV bolus over 2 hours on days 1 through 5 and days 15 through 19, repeated every 28 days. Dose escalation performed as toxicity allowed per protocol.

Progress: This study has accrued patients at both BAMC and UTHSCA. At BAMC 15 patients have been treated to date. Nine patients have received 11 cycles of treatment on the continuous infusion schedule with 3 dosage levels studied. Dose limiting toxicity has consisted of fever, flu-like symptoms and associated hypotension. Two patients died while on study of disease related causes. Two patients came off study due to drug toxicity. No responses were observed on this schedule. The maximal tolerated dose on this schedule is 0.5×10^6 IU/m² IV continuous infusion over 24 hrs x 5 days. The recommended phase II dose is 0.25×10^6 IU/m² as IV continuous infusion over 24 hrs x 5 days.

C-40-85 (continued)

Six patients have received a total of 15 cycles of therapy on the bolus schedule with 3 dosage levels studied. Dose limiting toxicity has not been reached. Toxicity has generally consisted of mild to moderate fever and flu-like symptoms. One patient was taken off study due to drug associated neurotoxicity consisting of nonconvulsive status epilepticus that resolved with treatment. Hypotension was noted in one patient. To date toxicity on this schedule has been idiosyncratic, i.e., not clearly dose related. At present dose is being escalated from 2×10^6 IU/m² to 4×10^6 IU/m². No responses have been seen on this schedule.

Detail Summary Sheet

Date: 27 Sep 85 Proj No: C-42-85 Status: Ongoing
 Title: Comparison of the Two Topical Antifungal Agents, Ciclopirox Olamine and Econazole, in the Treatment of Onychomycosis of the Toenails.

Start Date 3 May 85	Est Comp Date:
Principal Investigator Eric W. Kraus, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: James A. Earhart, M.D., MAJ, MC
Key Words: Onychomycosis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$725.40
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): To compare, in a double-blind clinical study, the efficacy of two commercially available topical antifungal creams in the treatment of fungal infections of the toenails.

Technical Approach: KOM prep of fungal nail and subungual debris will be done. If KOM is positive then fungal culture will be done. If culture is positive then enrollment with either econazole or ciclopirox cream b.i.d. Baseline photographs and notching of toenail at the proximal end of involvement. Follow-up progress initially at one month and then every two months.

Progress: Initial fungal cultures and KOM preparations have been done on three patients. If cultures are positive, these patients will be officially enrolled.

Detail Summary Sheet

Date: 27 Sep 85 Proj No: C-43-85 Status: Ongoing
 Title: Usefulness of Calcium Citrate as an Alkalinizing Agent and Phosphorus-Binding Agent in Chronic Renal Failure (CRF).

Start Date 3 May 85	Est Comp Date:
Principal Investigator Charles J. Foulks, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: John B. Copley, M.D., LTC, MC Howard M. Cushner, M.D., MAJ, MC Jeffery F. Addison, M.D., CPT, MC
Key Words: Chronic renal failure (CRF)	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 28	
Total Number of Subjects Enrolled to Date: 28	
Date of Periodic Review n/a	Results

Objective(s): To demonstrate if calcium citrate when taken with meals will prevent hyperphosphatemia and control metabolic acidosis in patients with chronic renal failure.

Technical Approach: Calcium citrate, 8-16 meq, is given with meals in place of CaCO_3 or $\text{Al}(\text{OH})_3$.

Progress: Thus far, phosphate levels have been controlled and no change in CO_2 .

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-44-85 Status: Ongoing
 Title: Phase II Study of Recombinant Beta Interferon, Human (IFN- β_{ser}) in Colon Cancer.

Start Date 7 Jun 85	Est Comp Date:
Principal Investigator Thomas D. Brown, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/ Oncology	Associate Investigators: Kenneth Beougher, MAJ, MS Patricia K. Lillis, M.D., CPT, MC James Koeller, M.D., UTHSCSA Daniel D. Von Hoff, M.D., UTHSCSA
Key Words: Interferon, Beta	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 6	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review n/a	Results

Objective(s): 1) To define the safety and adverse effects resulting from this schedule and duration of administration of IFN- β_{ser} .

2) To determine the effect of IFN- β_{ser} when administered in a dose of 30×10^6 I.U. intravenously, daily Monday thru Friday with no dosing on Saturday and Sunday for two weeks, followed by 14 days without dosing, this four week cycle repeated for 12 weeks or longer, in patients with measurable colorectal cancer.

Technical Approach: Patients with metastatic colorectal cancer were given Beta-ser interferon as an IV bolus at 30×10^6 OV pm daus 1 through 5 and 8 through 12. Patients were treated for two cycles (each cycle 28 days) before response evaluation.

Progress: Six patients with metastatic colorectal cancer have been treated with three patient removed from study (after receiving two cycles of IFN- β_{ser}) due to progression of disease. The remaining three patients are not evaluable for response since they have not yet received two cycles of therapy. Toxicity has been as expected with mild to moderate fever and flu-like symptoms within 30 min. to 6 hrs of drug administraiton. No patient has been removed from study due to toxicity.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-45-85 Status: Ongoing
 Title: Biliary Sclerosis in Patients with Hepatic Metastases Receiving Hepatic Arterial Infusion Chemotherapy.

Start Date 3 May 85	Est Comp Date:
Principal Investigator (vice Haley) Douglas S. Price, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Christopher VanAsche, M.D., MAJ, MC Fred Goldner, M.D., COL, MC Peter C. Lafon, M.D., CPT, MC Kendall Reed, M.D., LTC, MC Walter H. Harvery, M.D., MAJ, MC
Key Words: Infusion, hepatic arterial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review n/a	Results

Objective(s): To determine the incidence of biliary sclerosis caused by chemotherapy in patients with implantable pumps and determine if this is a dose related event and specific for certain drugs.

Technical Approach: ERCP studies will be obtained on patients with metastatic liver disease before and after placement f hepatic artery infusion pump to determine frequency and dose relationship of biliary sclerosis from infusate chemotherapy.

Progress: We have had difficulty obtaining patients for study since this complication is becoming better recognized and the procedure is not being performed at this time.

Detail Summary Sheet

Date: 30 Sep 85 Proj No: C-49-85 Status: Ongoing
 Title: Skin Test Responses to Wholebody Fireant Extracts: Allergic vs. Irritant Reactivity.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator Ana A. Ortiz, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Allergy	Associate Investigators: Dane C. McBride, M.D., MAJ, MC
Key Words: Fireant extrcts	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review n/a	Results

Objective(s): To define a range of dilutions of imported fireant (IFA) whole-body extracts which will differentiate patients with immediate (Type I) hypersensitivity to imported fireants from those with negative or irritant responses to skin testing.

Technical Approach: Once participants have been classified into one of the three study groups, they will complete a questionnaire. They will then be skin tested by the prick method with commercially produced IFA wholebody extracts. Participants will also be skin tested by the intradermal method to IFA wholebody extracts.

Progress: Two patients have been entered into the study.

Detail Summary Sheet

Date: 30 Sep 85 Proj No: C-50-85 Status: Ongoing
 Title: Randomized Evaluation of Cis-platinum and 5-Fluorouracil with and without Etoposide (VP-16-213) in Extensive Non-Small Cell Lung Cancer. A Pilot Study.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator Irwin L. Levey, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC Gregory G. Friess, D.O., MAJ, MC Kenneth L. Beougher, MAJ, MS
Key Words: Non-small cell lung cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review n/a	Results

Objective(s): 1) To assess the response rate and toxicity of cis-platinum and 5-fluorouracil (5-FU) in the initial treatment of extensive non-small cell lung cancer.

2) To evaluate the contribution of a vinca alkaloid to the combination of cis-platinum and 5-FU in the treatment of extensive non-small cell lung cancer.

3) To offer structured investigational therapy to patients at BAMC with lung cancer not covered by current Southwest Oncology Group (SWOG) protocols.

Technical Approach: Technical approach as described in the initial proposal has been functional. The only problem encountered to date has been acquisition of eligible patients.

Progress: A single eligible patient has been registered and one course of therapy given. Treatment was tolerated well with minimal nausea and controlled hematopoietic toxicity. A measurable peripheral lymph node resolved within 2 weeks of therapy. As per protocol, patient will be restaged following the third course of therapy.

Detail Summary Sheet

Date: 27 Sep 85 Proj No: C-51-85 Status: Ongoing
 Title: Cardiovascular Monitoring in Patients Receiving Gamma Interferon.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator Gregory G. Friess, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Thomas D. Brown, M.D., CPT, MC Juan C. Garcia, M.D., CPT, MC Michael Hartshorne, M.D., MAJ, MC Michael Cawthon, D.O., MAJ, MC John Bauman, M.D., CPT, MC
Key Words: Interferon, Gamma Cardiovascular monitoring	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 12	
Total Number of Subjects Enrolled to Date: 12	
Date of Periodic Review n/a	Results

Objective(s): 1) To assess cardiovascular state in oncology patients pre- and post-treatment with gamma interferon.

2) To assess initial cardiac rhythm and possible disturbances over extended treatment with gamma interferon.

Technical Approach: Continuous Holter monitoring pre- and during treatment with Gamma interferon is being assessed in patients with advanced malignancies.

Progress: To date a variety of rhythm disturbances have been detected of unknown significance. No cardiomyopathic disturbances identified. This study continues to accumulate patients with no conclusions reached as yet.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-52-85 Status: Ongoing
 Title: A Randomized Controlled, Prospective Study of a Percutaneous J-Wire Exchange Technique for Safety and Efficacy.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator David S. Goya, M.C., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/General Medicine	Associate Investigators: David L. Grisell, M.D., CPT, MC Gregg T. Anders, M.D., CPT, MC C. Kenneth McAllister, M.D., LTC, MC Harvey M. Richey, M.D., MAJ, MC John L. Carpenter, M.D., COL, MC
Key Words: J-wire exchange	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate percutaneous J-Wire exchange technique for (1) safety and (2) risk of infection during prolonged central venous catheterization in the critical care setting.

Technical Approach: Patients agreeing to participate in the study will be randomized to one of two arms according to a table of random numbers. Even digits: j-Wire exchange technique will be performed every 72 hours or less; odd digits: new central venous access will be obtained every 72 hours or less. For new access on either arm of the study, baseline cultures will be obtained. For the J-Wire exchange technique, two blood cultures will be obtained through the old catheter and the catheter tip will be semiquantitatively cultured by the technique described by Maki et al.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 27 Sep 85 Proj No: C-53-85 Status: Ongoing
 Title: An Open Label Study to Evaluate the Use of MK-421 in Patients with Congestive Heart Failure (CHF) Who are Intolerant of Captopril.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator	Facility
Steven R. Bailey, M.D., MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Cardiology	William E. Craig, M.D., LTC, MC
Key Words:	
Congestive Heart Failure	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review n/a	Results

Objective(s): 1) To provide MK-421 for humanitarian use in patients who are intolerant of captopril and who have been demonstrated to require a converting enzyme inhibitor for optimal medical therapy of their CHF.

2) To record the efficacy and safety of MK-421 in patients with CHF who have been demonstrated to be intolerant of captopril, or are unresponsive to other vasodilators and who require a converging enzyme inhibitor for optimal medical therapy.

Technical Approach: After medical history and complete physical examination, eligible patients will receive enalapril 4 times a day by mouth. They will be followed at weekly intervals for the first four weeks and then at bi-weekly intervals.

Progress: Emergency approval was obtained to enter one patient on the study. No other patients have required enalapril since the study was approved.

Detail Summary Sheet

Date: 26 Aug 85 Proj No: C-54-85 Status: Ongoing
 Title: Rifampin for the Treatment of Serious Infections Caused by Gram-Negative Bacilli, Especially P. aeruginosa.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator Rodney A. Michael, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department Medicine/Infectious Disease	Associate Investigators: Clifton A. Hawkes, M.D., MAJ, MC C. Kenneth McAllister, M.D., LTC, MC David Looney, M.D., MAJ, MC
Key Words: <u>P. aeruginosa</u>	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To investigate the clinical efficacy of the use of rifampin as an adjunct to standard therapy (aminoglycoside plus extended-spectrum penicillin) for serious infections caused by gram-negative bacilli, especially those caused by P. aeruginosa.

Technical Approach: Hospitalized patients with suspected or documented infection with a gram-negative bacillus, especially P. aeruginosa, will be sought for admission to the study. Patients with the following infections will be considered for inclusion: 1) Bacteremia and a syndrome compatible with an infectious process, with or without a known primary focus of infection; 2) Endocarditis accompanied by a compatible clinical syndrome and documented with blood cultures; 3) Meningitis documented by appropriate CSF abnormalities and positive CSF cultures; 4) Urinary tract infection accompanied by fever, evidence of systemic toxicity and positive urine culture; and 5) Pneumonia, accompanied by appropriate clinical syndrome and documented by sputum gram stain, sputum culture, and new pulmonary infiltrate.

Progress: This study will start as soon as the IND is obtained.

Detail Summary Sheet

Date: 30 Sep 85 Proj No: C-56-85 Status: Ongoing
 Title: Significance of Hypotension During a Graded Exercise Stress Test.

Start Date 16 Aug 85	Est Comp Date:
Principal Investigator Doreen Saltiel, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/General Medicine	Associate Investigators: Stephen D. Hoadley, M.D., MAJ, MC Bernard J. Rubal, Ph.D.
Key Words: Hypotension	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To identify the subset of medically treated patients falsely diagnosed as having severe coronary artery disease by the criteria of hypotension on a graded exercise stress test.

Technical Approach: In order to evaluate the significance of hypotension during a graded exercise stress test, we reviewed 3,994 unselected GXT's over the period April 1982 through May 1985. A significant hypotensive response was defined as a blood pressure drop exceeding 10 mmHg.

Progress: Eighty-two patients were found to have a hypotensive response. Of those 82 patients, 45 underwent cardiac catheterization and coronary angiography. Of those who underwent cardiac catheterization, three subgroups were defined. Group I: Those with surgical disease defined as a coronary artery obstruction greater than 70% in the following distribution: (a) Three vessel coronary artery disease; (b) left main; and/or (c) proximal LAD. Group II: Those patients who had significant coronary artery disease, but did not meet the criteria stated above. Group III: Those with no significant coronary artery disease. Of the 47 patients who underwent cardiac catheterization and coronary

C-56-85 (continued)

angiography, 22 patients were in Group I, 10 were in Group II, and 15 were in Group III. If the hypotensive response is used to predict the need for surgery, then the positive predictive value is 47%.

In an attempt to separate Group I patients from those in Group III, the total extent of blood pressure drop was analyzed. Those in Group I had a mean blood pressure drop of $21 \text{ mm} \pm 11 \text{ mm}$, and those in Group III had a mean blood pressure drop of $19 \pm 10 \text{ mm}$. There was no significant difference between these values; therefore, the amount of blood pressure drop does not predict the need for surgery. When the incidence of hypotension in patients with surgical coronary artery disease (Group I) was compared to nonsurgical patients (Group II + Group III), no significant differences were found. However, when the incidence of hypotensive response was compared between patients with coronary artery disease (Group I + II), to those without (Group III), a significant difference was noted (Chi-square = 6.14, $p < 0.05$).

Our findings support the current thinking that a hypotensive response is predictive of significant coronary artery disease.

Detail Summary Sheet

Date: 30 Sep 85 Proj No: C-57-85 Status: Ongoing
 Title: Double-Blind Crossover Study of the Antiemetic Efficacy of High-Dose Haloperidol versus High-Dose Metoclopramide.

Start Date 16 Aug 85	Est Comp Date:
Principal Investigator Irwin L. Levey, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Kenneth L. Beougher, MAJ, MS Gregory G. Friess, M.D., MAJ, MC Sharon S. DeRuvo, CPT, AN Annette Etnyer, CPT, AN
Key Words: Antiemetic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 7	
Total Number of Subjects Enrolled to Date: 7	
Date of Periodic Review n/a	Results

Objective(s): 1) To assess the efficacy of haloperidol, dexamethasone plus diphenhydramine in prevention of chemotherapy-induced nausea and emesis.

2) To compare these results in a randomized double-blind crossover study to the "standard" antiemetic regimen currently used at BAMC (i.e., metoclopramide, dexamethasone and diphenhydramine).

Technical Approach: Technical approach as described in the initial proposal has been functional. The only problem encountered has been reliable timing of therapy and subsequent follow-up interviews.

Progress: Seven patients have been enrolled with evaluable data obtained from five of these. The remaining two patients did not complete therapy because of administrative problems. To date, both treatment arms have been well-tolerated and no clear preference has been expressed by the subjects.

Detail Summary Sheet

Date: 22 Oct 85	Proj No: C-60-85	Status: Ongoing
Title: Phase I Study of the Oral Administration of Menogaril in Patients with Advanced Cancer (Collaborative Study with University of Texas Health Science Center)		
Start Date 9 Sep 85	Est Comp Date:	
Principal Investigator Thomas D. Brown, M.D., CPT, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Kenneth L. Beougher, MAJ, MS Geoffrey R. Weiss, M.D., UTHSCSA	
Key Words: Cancer, advanced		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: _____		
Total Number of Subjects Enrolled to Date: _____		
Date of Periodic Review <u>n/a</u> Results _____		

Objective(s): 1) To determine the maximally tolerated dose (which is both predictable and reversible) of menogaril given orally every 4 weeks.

2) To determine the qualitative and quantittative toxicities of menogaril given orally.

3) To determine the recommended oral dose for menogaril to be used for initial clinical trials.

4) To determine the basic pharmacokinetics of menogaril by study of plasma and urinary levels of the agent in man.

5) To collect information about anti-tumor effects of menogaril if an anti-tumor effect is observed.

Technical Approach: Eligible patients must have a microscopically confirmed diagnosis of metastatic cancer and a life expectancy of at least 12 weeks. Only patients with solid tumors will be eligible for the study. Patients tumors must be refractory to all known forms of effective therapy as well as other investigational agents of higher potential efficacy.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-63-85 Status: Ongoing
 Title: Hemodialysis of Acute Renal Failure (ARF): Optimization of Dialysis and Nutritional Support

Start Date 10 Sep 85	Est Comp Date:
Principal Investigator John B. Copley, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: Charles J. Foulks, M.D., MAJ, MC Howard M. Cushner, M.D., MAJ, MC
Key Words: Renal failure, acute	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): 1) To determine the most efficient means to dialyze acute renal failure patients with respect to selection and operation of dialyzers under circumstances which would be expected in future military conflicts.

2) To determine the most appropriate means of nutritional support (amounts, substrate composition) to minimize morbidity and maximize survival.

Technical Approach: This is a prospective study to be conducted by three Army MEDCENS (WRAMC, BAMC, and FAMC). Adult patients with ARF will be initially stratified by urine volume (oliguric vs. non-oliguric). Patients in each group will then be randomly assigned into one of two groups (total of four groups). Each group will undergo one four-hour dialysis to define optimal dialysis parameters, and then receive dialysis according to a pre-established schedule. All patients will receive total parenteral nutrition with 1 gram/kg/day of protein. Regimen A will consist of 47 kcal/kg/d of non-protein calories. Regimen B will consist of 79 kcal/kg. Patients will be randomly assigned to either Regimen A or Regimen B and will complete both regimens during the study.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 10 Oct 85	Proj No: C-68-85	Status: Ongoing
Title: Correlation and Comparison of Blood Cultures from Indwelling Central Venous Catheters and Peripheral Venipuncture Sites in the Febrile Patient in a Special Care Setting		
Start Date 27 Sep 85	Est Comp Date:	
Principal Investigator Gregg T. Anders, M.D., CPT, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Gen. Medicine	Associate Investigators: John L. Carpenter, M.D., COL, MC C. Kenneth McAllister, M.D., LTC, MC David S. Goya, M.D., CPT, MC David L. Grissell, M.D., CPT, MC Harvey M. Richey, M.D., MAJ, MC	
Key Words: Cultures, Blood		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 0		
Total Number of Subjects Enrolled to Date: 0		
Date of Periodic Review n/a		Results

Objective(s): To quantify and statistically correlate the relationship between peripheral and central cultures in the critically ill, febrile patient.

Technical Approach: This study will analyze the data obtained from patients enrolled on the study C-52-85.

Progress: This is a new study.

Detail Summary Sheet

Date: 21 Aug 85 Proj No: C-29-84 Status: Completed
 Title: Women's Descriptions of the Impact of Their Husbands' Debilitating Illnesses (Cancer) on Their Important Roles.

Start Date 12 Apr 84	Est Comp Date:
Principal Investigator Annette Etnyre, R.N., CPT, ANC	Facility Brooke Army Medical Center
Dept/Svc UTHSC San Antonio, School of Nursing	Associate Investigators: Peggy Richardson, R.N., Ph.D.
Key Words: Debilitating illness	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 14	
Total Number of Subjects Enrolled to Date: 14	
Date of Periodic Review	Results

Objective(s): To examine the impact of a husbands' debilitating illnesses on women's assessments and evaluations of their important roles and role responsibilities.

Technical Approach: Fourteen married women ranging in age from 26 to 66 were interviewed once using a semi-structured interview guide designed to elicit both elaborative and forced-choice responses. The women were asked to rank-order their important roles, to identify changes in role responsibilities, and to evaluate their present role demands and role performances.

Progress: Overall, the women's lives were characterized by considerable change in role responsibilities. In their wife roles, demands for both expressive and instrumental functioning increased. In other roles, demands were generally described to be stable or decreasing. Women indicated their present role demands were more acceptable than worrisome to them and that they were able to deal with their important roles as "well" most of the time. However, dealing "well" with important roles often meant suppressing sad, fearful, and angry emotions. While many of the women maintained hope that their lives would continue

C-29-84 (Continued)

to be manageable, they foresaw that greater demands would be imposed on them by the progressive consequences of their husbands illnesses. The women's leadership in the family appears to be a major contributing force in keeping the family together and functioning at an extremely difficult time.

Detail Summary Sheet

Date: 21 Aug 85 Proj No: C-35-84 Status: Completed
 Title: The Effects of Perceived Changes in Important Relationships on Expectations for Recovery During a Gynecologic Cancer Illness.

Start Date 21 Jun 84	Est Comp Date:
Principal Investigator Linda Yoder, R.N., CPT, ANC	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators: Peggy Richardson, R.N., Ph.D.
Key Words: Gynecologic cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 16	
Date of Periodic Review	Results

Objective(s): To determine how the gynecologic cancer patient's expectations for recovery are affected by her perceptions of change in relationships with important others during her illness.

Technical Approach: Sixteen women ranging in age from 21 to 73 were interviewed once using a semi-structured interview guide designed to elicit both elaborative and forced choice responses. The women were asked to rank order their important relationships, to identify if these relationships remained stable or changed after the gynecologic cancer diagnosis; to identify how the relationships changed in terms of closeness, communication and task-sharing; to evaluate the relationships; and to anticipate how the relationships would be one year from the time of the interview. Visual inspection of the data distributed by frequencies and standardized using percentages revealed trends and themes.

Progress: Findings indicate that the women believed husbands to be the most important persons in their lives, with children ranking second and peers and parental figures occupying the subsequent ranks. Overall, the women described their various important relationships as changing rather than stable, and they indicated that feelings of closeness and effective communication were of greater importance than was the attempt of others to help them with their household chores or occupational tasks. They described the need to feel supported in their efforts to maintain their roles, especially the roles of wife and mother.

C-35-84 (Continued)

The woman's feelings about her prognosis and her assessments of important relationships appear related. Typically the women believed they would recover from their cancer illnesses and they described sharing supportive relationships with others. The overall themes expressed by the women were: 1) the importance of recovery within their changing important relationships; 2) a desire to return to previous role functioning; 3) a positive prognosis; and 4) a willingness to submit to any treatment plans necessary in order to recover from their gynecologic cancer illness.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-31-85 Status: Completed
 Title: A Study of Hope in Critically Ill Patients.

Start Date 26 Feb 85	Est Comp Date:
Principal Investigator Frances Dee Anderson, MAJ, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators:
Key Words: Ill, critically	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 10	
Total Number of Subjects Enrolled to Date: 10	
Date of Periodic Review	Results

Objective(s): To determine what factors critically ill patients identify as affecting their level of hope, with specific attention to what nursing actions influence the same.

Technical Approach: This study employed an open-ended semi-structured interview technique which was placed on audiotape. Data was analyzed through the use of content analysis. Coding categories were established and specific nursing actions which affected the patient's level of hop, as identified by the patients, were made.

Progress: Areas identified as influencing the patient's level of hope were amount of nurse-patient contact, patient input into the decision making process regarding treatment, and support from co-sufferers (other patients). Family support was not identified by patients as influencing their level of hope in this study.

Detail Summary Sheet

Date: 21 Oct 85	Proj No: C-6-83	Status: Completed
Title: Intravenous Piperacillin Sodium vs Penicillin-G in Combination with Gentamicin Sulfate and Clindamycin for Postoperative Gynecological and Postpartum Infections.		
Start Date 10 Nov 82	Est Comp Date:	
Principal Investigator (vice Mark) Averell H. Sutton, M.D., CPT, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:	
Key Words: Postpartum infections		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: _____		
Total Number of Subjects Enrolled to Date: _____		
Date of Periodic Review 8 Nov 84 Results Continue		

Objective(s): To compare with clinical efficacy and cost of a new semi-synthetic Penicillin (Piperacillin) used alone versus that of Penicillin-G, Gentamicin Sulfate and Clindamycin.

Technical Approach: When a potential study patient became febrile, she was evaluated by the operating surgeon or by the resident on duty at night. Routine laboratory evaluation included an initial CBC, urine culture, urinalysis, blood cultures, serum creatinine, indirect Coomb's, liver functions and cultures from abscess fluid or peritoneal fluid or uterine washings if possible or appropriate. Peak and trough levels of gentamicin and piperacillin were obtained when appropriate and indicated. Selected patients were treated with either 5 million units of aqueous penicillin-G every 6 hours plus gentamicin every 8 hours or piperacillin alone every 6 hours.

Progress: Twelve patients were assigned to the piperacillin group and seventeen to the penicillin-gentamicin group. Ten of twelve patients treated with piperacillin were considered therapeutic successes. Twelve of seventeen patients on penicillin and gentamicin had resolution of symptoms after adding clindamycin. Fifteen of seventeen patients were coded as treatment successes.

It was concluded that piperacillin may be as effective as penicillin and gentamicin therapy for gynecological/obstetrical infections as well as being less toxic.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-18-83 Status: Ongoing
 Title: A Double Blind Comparative Study of Ritodrine vs Terbutaline on Arresting Premature Labor.

Start Date 3 Mar 83	Est Comp Date:
Principal Investigator (vice Jirak) Arthur H. Schipul, Jr., M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Premature labor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 48	
Date of Periodic Review 9 Apr 85	Results Continue

Objective(s): To compare the effectiveness of two beta-2 specific receptor agonists on arresting premature labor.

Technical Approach: Ritodrine or Terbutaline are administered in a blinded fashion to randomized patients in premature labor. Measures of outcome include delay of delivery by 48 hours. Observation of side effects include: incidence of maternal/fetal tachycardia, hypotension, tremor, headache, etc., need for discontinuation of therapy secondary to side effects.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-50-83 Status: Completed
 Title: A Survey of Women Concerning Their Labor and Delivery Experiences.

Start Date 16 Jun 83	Est Comp Date:
Principal Investigator Roger L. Wallace, D.O., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators: Peggy Richardson, Ph.D.
Key Words: Delivery experiences Birthing room	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 91	
Date of Periodic Review n/a	Results

Objective(s): 1) To describe the demographic characteristics of women utilizing the labor, delivery, and recovery care facilities at BAMC from Oct 1982 thru May 1983.

2) To identify women's thoughts and feelings about their labor, delivery, and recovery experiences.

3) To determine the differences between women who use traditional labor and delivery care facilities and women who use birthing room facilities.

Technical Approach: Information is obtained retrospectively through questionnaires. Initial information gathered is to attempt to determine: how well women are prepared for childbirth (perceptions of the real-life event vs. expectations) and what effect does formal childbirth preparation (i.e. Lamaze) have on the process. Part three of the objectives will be assessed in a prospective fashion.

Progress: Data analysis is in progress. At this time, no differences are apparent between the women using the labor and delivery rooms compared to women using the birthing room. For all women, an inability to anticipate their labor and delivery experiences seems to result in a lowered sense of self esteem regarding the childbearing outcome.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-11-84 Status: Ongoing
 Title: Rapid Diagnosis of Vaginal Candidiasis.

Start Date 13 Mar 84	Est Comp Date:
Principal Investigator Phyllis F. Yohe, D.O., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators: James M. Mullins, M.D., CPT, MC Gordon O. Downey, M.D., MAJ, MC
Key Words: Candidiasis, vaginal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To develop a prototype assay to diagnose vaginal candidiasis.

Technical Approach: Patients with a clinical diagnosis of vaginal candidiasis are enrolled in the study. Vaginal cultures are sent to UTHSCSA for capsular antigen identification and for use in developing a rapid diagnostic test for vaginal candidiasis in conjunction with work done by Dr. Mark Weiner, UTHSC.

Progress: This study will be started in the near future.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-46-84 Status: Ongoing
 Title: The Evaluation of the Efficacy of the Masterson Aspirator in Outpatient Endometrial Biopsy.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Ralph Boling, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators: Bruce Rajala, M.D., CPT, MC Gordon Downey, M.D., MAJ, MC
Key Words: Masterson aspirator	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 26	
Total Number of Subjects Enrolled to Date: 26	
Date of Periodic Review 11 Sep 85	Results Continue

Objective(s): To examine the efficacy of a new instrument (Masterson Aspirator) for outpatient endometrial biopsy.

Technical Approach: The Masterson aspirator is compared to the Novak biopsy curette in outpatient endometrial biopsy. Patients are randomized to attempted biopsy with either instrument and failure to obtain tissue is treated by D&C.

Progress: No significant difference between the Masterson aspirator and the Novak curette has been noted. There have been no adverse effects.

Detail Summary Sheet

Date: 30 Sep 85 Proj No: C-64-83 Status: Terminated
 Title: In vitro Demyelination and Remyelination of Cultured Mammalian Central Nervous Tissue.

Start Date 10 Aug 83	Est Comp Date:
Principal Investigator Roby P. Joyce, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators: Debra J. Krikorian, Ph.D., CPT, MSC
Key Words: Mammalian central nervous tissue	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 3,600.71
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review n/a	Results

Objective(s): To establish the capability of studying demyelination and remyelination of mammalian central nervous tissue in vitro at Brooke Army Medical Center.

Technical Approach: Myelinated neuronal cultures will be exposed to EAE sera to investigate the process of demyelination at the EM level. The EAE sera will be removed and remyelination observed at the EM level in vitro.

Progress: Project is terminated due to technical problems with the methodology being used and due to a lack of time and personnel to pursue the project.

Detail Summary Sheet

Date: 20 Aug 85 Proj No: C-4-84 Status: Ongoing
 Title: In vivo Efficacy of Frozen Platelets.

Start Date 19 Dec 83	Est Comp Date:
Principal Investigator Roby P. Joyce, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC Michael F. Hartshorne, M.D., MAJ, MC Robert C. Allen, M.D., Ph.D., MAJ, MC Duane Broussard, M.D., CPT, MC
Key Words: Platelets, frozen	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 8 Nov 84	Results Continue

Objective(s): To evaluate the in vivo function of frozen platelets by transfusion into thrombocytopenic patients.

Technical Approach: Technically, our ability to harvest, freeze, store and thaw platelets has been a total success using the protocol developed by Dr. Valeri's laboratory.

Progress: Autologous plateletpheresis products have been harvested and frozen for future use by several BAMC leukemics. To date, none of these patients has required platelet transfusion therapy; therefore, we have been unable to document the efficacy of this product. The in vivo function of frozen platelets is being studied by Dr. Valeri at the Naval Blood Research Laboratory, Boston, and FDA approval for the routine use of frozen platelets is anticipated by early 1986.

Detail Summary Sheet

Date: 1 Oct 85 Proj No: C-62-85 Status: Ongoing
 Title: Comparison of Serum Unconjugated Bilirubin Measurements in Neonates by the Kodak Ektachem 700 and the DuPont ACA III.

Start Date 10 Sep 85	Est Comp Date:
Principal Investigator(vice Harper) Michael E. Berkland, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology/Pediatrics	Associate Investigators: Margaret Strieper, D.O., CPT, MC
Key Words: Bilirubin	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a/	Results _____

Objective(s): To determine if a consistent mathematical relationship exists between the values derived from serum unconjugated bilirubin as measured by the different methodologies of these two auto-analyzers.

Technical Approach: All patients admitted to the Newborn Nursery during a 90 day period will have 2 cc. of blood drawn at 2 and 48 hours postpartum. This blood will be placed into separate 1 cc. containers and transported to the STAT chemistry lab. These two samples would then be run during the same shift, the results collected, and the values compared.

Progress: This is a new study.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-19-83 Status: Ongoing
 Title: Comparison of Efficacy of Theophylline Administered by Continuous Infusion vs Bolus for Status Asthmaticus.

Start Date 3 Mar 83	Est Comp Date:
Principal Investigator William H. Parry, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Status asthmaticus	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 Apr 85	Results Continue

Objective(s): To determine which of two methods of IV Theophylline administration is more effective in reversing status asthmaticus.

Technical Approach: Theophylline will be administered in a double-blind fashion, i.e. initially all patients will receive a bolus of 6 mg/kg over 20 minutes. One-half of the patient population, chosen at random, will receive a bolus of 5 mg/kg every 4 hours; the other half will receive a continuous infusion of 1 mg/kg per hour of Theophylline after the initial bolus. The study will end at 24 hours.

Progress: The principal investigator has had difficulty in finding time to enroll patients on this study. However, it is anticipated that the study will start within the next six months.

Detail Summary Sheet

Date: 21 Aug 85 Proj No: C-34-84 Status: Completed
 Title: An Explanatory Study of the Exceptional Family Member Program.

Start Date 10 May 84	Est Comp Date:
Principal Investigator Robert H. Gemmill, MAJ, MSC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Lewis F. Gold, M.D., LTC, MC
Key Words: Exceptional family member program	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 65	
Total Number of Subjects Enrolled to Date: 65	
Date of Periodic Review	Results

Objective(s): 1) To describe characteristics of the exceptional family member population.

2) To study how Army active duty personnel with exceptional family members perceive the Exceptional Family Member Program.

Technical Approach: A questionnaire was developed, pretested, and distributed to active duty Army soldiers with exceptional family members who were eligible to be enrolled in the EFM Program at Brooke, Madigan, and William Beaumont Army Medical Centers.

The sample of 65 active duty Army soldiers had 161 children and 76 of these were exceptional children. The soldiers had been in the military for an average of 9.7 years, and a majority of them identified themselves as career soldiers.

Progress: Exceptional family members were young, 91% were at or below age 11, had about a 25% chance of being adopted or being under legal guardianship, and experienced both chronic medical and educational problems. They tended to be multihandicapped and obtained the majority of their medical and health related services from the federal government.

C-34-84 (Continued)

Recommendations:

1. Persuasive or normative power techniques in combination with utilitarian strategies be employed to increase participation in the EFM Program and to enhance the existing positive perception toward the program
2. Specific educational strategies be employed during the implementation of the EFM Program
3. A comprehensive involuntary referral or "child find" procedure be implemented to ensure that all eligible family members have an opportunity to be enrolled in the program
4. The package of questionnaires used to evaluate exceptional family members be modified
5. Additional research be conducted on the EFM Program recipients
6. All Army community and family programs and policies be studied.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-69-84 Status: Ongoing
 Title: Beta-thromboglobulin Levels in Adolescent Females with and without Use of Oral Contraceptives.

Start Date 13 Sep 84	Est Comp Date:
Principal Investigator (vice Day) Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Beta-thromboglobulin	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$2,292.43
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 11 Sep 85	Results Continue

Objective(s): Beta-thromboglobulin will be measured in normal adolescent female controls and in their age-matched peers on oral contraceptives.

Technical Approach: Blood for Beta-thromboglobulin levels will be obtained at the time of routine blood work on 25 females between the ages of 14-19 years of age, prior to beginning oral contraceptives. The same amount will be drawn from 25 age-matched controls not on oral contraceptives during routine physicals at the Adolescent Medicine Clinic.

Progress: Results of initial blood levels in adolescents prior to beginning oral contraceptives were variable. Unfortunately, no follow-up blood levels have been obtained - either 2^o to machine (gamma counter) malfunction or - more likely - 2^o to the adolescents being uninterested in donating more blood.

The study will continue after some revisions. It is planed to have a single person draw the blood to assure accuracy and reproducibility of the results.

Detail Summary Sheet

Date: 22 Apr 85 Proj No: C-70-84 Status: Completed
 Title: Evaluation of the Serum Lead Levels in the Children of the Military Community of Fort Sam Houston.

Start Date 13 Sep 84	Est Comp Date:
Principal Investigator Wilson Torres, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Terry E. Pick, M.D., LTC, MC
Key Words: Lead levels, serum	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 69	
Total Number of Subjects Enrolled to Date: 69	
Date of Periodic Review n/a	Results

Objective(s): To determine if there is risk of lead intoxication in the children of the military community and establish a screening program that could be utilized in efforts to prevent plumbism in children assigned to this area.

Technical Approach: Blood samples were drawn and analyzed for serum lead levels. Patients ranged in age from 1-14 years.

Progress: Forty-four of the sixty-nine patients tested had lead levels of less than 5 mcg/dl. Twenty-one were in the range of 5-9 mcg/dl and four were above 10 mcg/dl. These are all below what is considered the toxic range level. Close analysis of the population tested showed the group of children with levels above 10 mcg/dl were from the on-post housing area. However, these are old buildings that have been previously tested by Preventive Medicine and found to have an elevated content of lead.

Detail Summary Sheet

Date: 22 Jul 85 Proj No: C-71-84 Status: Terminated
 Title: Normal Lymph Node Size in Children.

Start Date 13 Sep 84	Est Comp Date:
Principal Investigator Reginald H. Moore, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Terry E. Pick, M.D., LTC, MC
Key Words: Lymph node	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To establish baseline normals for lymph node sizes in children based on age variation as well as variations in anatomical location of these nodes.

Technical Approach: Children ages 1 to 18 with reasonable palpable nodes will be included in the study. Lymph node measurement will be taken as part of the routine physical examination.

Progress: Project terminated due to transfer of principal investigator.

Detail Summary Sheet

Date: 21 Aug 85 Proj No: C-2-85 Status: Completed
 Title: The Use and Reliability of Oximetry in Sick Neonates

Start Date 14 Nov 85	Est Comp Date:
Principal Investigator Charles Hankins, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Thomas E. Wiswell, M.D., MAJ, MC
Key Words: Oximetry	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To assess the reliability of various simplified oximeters in neonates utilizing alternate sites of attachment and comparing to concurrent blood gas samples.

Technical Approach: Consecutive admission requiring oxygen therapy with a wide range of birth weight, gestational ages, and diagnoses were admitted to the study protocol. Simultaneous arterial measurements and oximeter values were obtained. When available, transcutaneous pO₂ measurements were also recorded.

Progress: Current data shows an optimistic correlation to arterial sample saturations and oximeter saturations within a clinically significant window of saturations of 80-95%. In addition, there has been a greater correlation between arterial and oximeter saturation as compared to arterial and transcutaneous pO₂'s.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-34-85 Status: Ongoing
 Title: Effect of Dietary Modifications on Weight Change in Obese Children with Different Insulin Responses to Glucose and Leucine Challenge.

Start Date	Est Comp Date:
Principal Investigator Chandra M. Tiwary, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Regina Marshall, R.N. Isidoro Chapa Elizabeth A. Milner, 1LT, MS
Key Words: Children, obese	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 15	
Total Number of Subjects Enrolled to Date: 15	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine if specific dietary modifications can result in improved weight reduction in certain categories of obese children.

2) To develop a profile for these children by identifying common characteristics according to their insulin responses to tolerance testing.

Technical Approach: Eligible patients will have a complete history, physical, CBC, SMAC-20, oral glucose tolerance test (1.75 gm/kg, max. 100 gms); and oral leucine tolerance test (150 mg/kg). Subjects will be classified into elevated and normal insulin groups in accordance with their insulin response to glucose and leucine challenges. All participants will receive dietary instructions and will be provided with behavior modification instructions.

Progress: No subject has completed the study which lasts 15 weeks for each. Due to unavailability of fluorometer, we could not measure the red cell Na/K ATPase. Another technique has recently been described, although it does not measure ATPase enzyme, measures the Na/K activity but requires a flame photometer which if available locally could be used. We therefore need a fluorometer or a flame photometer.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-36-85 Status: Ongoing
 Title: Effect of Hydration on Short Term Memory in Adults.

Start Date 29 Apr 85	Est Comp Date:
Principal Investigator Chandra M. Tiwary, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Memory, short term	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): To determine if 1) short term memory is influenced by the hydration status of a subject; and 2) any change in memory function can be correlated with a variation in plasma vasopressin level.

Technical Approach: Thirty healthy volunteers will be selected. Each subject will be tested on two separate occasions with hydration status as the only difference. For one of the two trials, each subject will be asked not to drink any fluids or eat after 2000 hours the night before. In the morning, a venous blood sample will be taken for measurement of vasopressin and osmolality. This will be followed by psychological testing. For the other trial, the subject will report at 0800 and will be given water to drink - a "water load" (20 ml/kg in 30 minutes. Again at 0900 the venous blood sample will be taken and memory testing will be done as described.

Progress: The study has not started due to inability to obtain the services of a psychologist to participate in the study.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: C-47-85 Status: Ongoing
 Title: Evaluation of Adrenocorticotrophic Hormone (ACTH) in the Prevention of Cancer Chemotherapy Induced Nausea and Vomiting in Children.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Adrenocorticotrophic hormone (ACTH)	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review Results	

Objective(s): 1) To evaluate the effectiveness of ACTH in decreasing nausea and vomiting in children undergoing cancer chemotherapy.

2) To evaluate the toxicity of ACTH and thorazine in this setting.

Technical Approach: This is a multi-center, double blinded, randomized crossover study with patients serving as their own control. Patients undergoing at least two courses of identical cancer chemotherapy will be randomized at the beginning of the study to receive either of two combinations of antiemetics - (1) ACTH with thorazine, or (2) placebo with thorazine. Patients will then receive the other combination prior to their next course of chemotherapy. Extent of nausea, vomiting, side effects, and patient preference will be measured and compared between the two combinations of antiemetics.

Progress: This is a new study. No reportable data are available.

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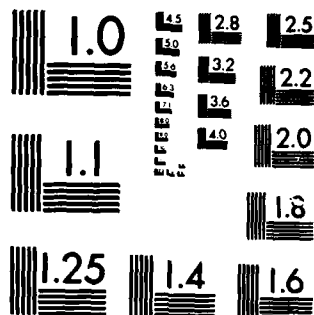
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Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-69-85 Status: Ongoing
 Title: Fever Response to Antipyretics Correlated with Etiology of Fever

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator	Facility
Martin E. Weisse, M.D., CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Pediatrics	
Key Words:	
Fever	
Antipyretics	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): To compare the fever response to acetaminophen seen in bacterial and viral infections.

Technical Approach: Patients with a temperature of 102° or greater, who have not received antipyretics within 3 hours, will be given Tylenol, 15 mg/kg, and temperature rechecked in 60 minutes. Cultures, as appropriate, will be taken. Data will be subject to statistical analysis with respect to fever response and bacteremia, and positive bacterial cultures other than blood, positive viral identification from any source, and hematologic values.

Progress: This is a new study.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-72-85 Status: Ongoing
 Title: Clinical Evaluation of a New Pulse Oximeter in the Sick Neonate.

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Charles T. Hankins, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Thomas E. Wiswell, M.D., MAJ, MC
Key Words: Oximeter, pulse	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): To evaluate reliability and possible superiority of a newly developed pulse oximeter in the management of oxygen therapy in the intensive care nursery.

Technical Approach: A study of 20 sick neonates requirement oxygen therapy will be developed. At time of routine arterial blood gas, a reading from oximeter (Biox 3700), previous oximeter (Biox IIA), and transcutaneous pO₂ monitor will be recorded within 15 seconds.

Progress: This isa new study.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-73-85 Status: Ongoing
 Title: Prospective Study of Chlamydia Infection in Neonates and Infants of Carrier Mothers Using Culture and EIA Techniques.

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Charles T. Hankins, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Thomas E. Wiswell, M.D., MAJ, MC Summers W. Taylor, M.D., CPT, MC
Key Words: Chlamydia infection	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a Results	

Objective(s): 1) To determine Chlamydia trachomatis infection rate in BAMC Obstetric population.

- 2) To determine transmission rate of Chlamydia to neonates.
- 3) To evaluate morbidity of infants at risk for Chlamydia infecitons.
- 4) To compare Elisa technique to culture technique in nasopharynx, conjunctiva, and rectum for detection of Chlamydia trachomatis.

Technical Approach: At time of speculum examination upon admission to the labor suite, chlamydia culture and EIA will be obtained n the mother. Infants will have nasopharynx, rectum, and conjunctiva swabs for culture and EIA within 24 hours of birth while in nursery. Only infants of positive mothers or infants who are positive in the nursery will have follow-up cultures at 2 and 16 weeks or prn with the development of symtpoms.

Progress: This is a new study.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-74-85 Status: Ongoing
 Title: Routine Screening for Neonatal Hyperviscosity

Start Date 27 Sept 85	Est Comp Date:
Principal Investigator Thomas E. Wiswell, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: J. Devn Cornish, M.D., MAJ, USAF MC
Key Words: Hyperviscosity	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): To determine the range of blood viscosities in newborn infants.

Technical Approach: 500 consecutive neonates born at Brooke Army Medical Center will be enrolled into the study. Viscosity measurements will be taken: a) from cord blood; b) from each infant at 2 hours of age; and c) from each infant at 24 hours of age.

Progress: This is a new study.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-68-84 Status: Terminated
 Title: A Medical Inpatient Group Treatment Program to Improve Coping with Hospital Stress.

Start Date 13 Sep 84	Est Comp Date:
Principal Investigator John B. Powell, Ph.D., CPT, MSC	Facility Brooke Army Medical Center
Dept/Svc Department of Psychiatry	Associate Investigators:
Key Words: Hospital stress	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 11 Sep 85	Results Terminated

Objective(s): To determine if a group treatment program for medical inpatients can improve patient's ability to cope with hospital- and illness-induced psychological distress.

Technical Approach: Subjects for inclusion in this study will be hospitalized patients on Wards 43G and 43H. The group treatment program will be open to all patients, whether they volunteer for the study or not. The group treatment program is designed to produce significant psychological improvement in those variables shown to be most related to illness.

Progress: Study was terminated due to difficulty in getting sufficient numbers of patients to maintain participation in group treatment. Difficulties were due to low referral rate, rapid turnover of ward patients, and resistance of patients to confronting psychological issues in a group format.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-79-84 Status: Ongoing
 Title: Biofeedback Treatment of Patients with Irritable Bowel Syndrome (IBS).

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator John B. Powell, Ph.D., CPT, MSC	Facility Brooke Army Medical Center
Dept/Svc Department of Psychiatry/Psychology	Associate Investigators: Fred Goldner, M.D., COL, MC
Key Words: Irritable bowel syndrome	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 11 Sep 85	Results Continue

Objective(s): To determine if abdominal pain in patients with IBS can be significantly reduced by treatment in a structured program of biofeedback and stress management procedures.

Technical Approach: Patients with IBS will be asked to attend one group session and two individually-scheduled EMG biofeedback sessions weekly, for four weeks. The group sessions will be designed to teach stress management and relaxation skills, with the individual sessions designed for practice and reinforcement of those skills. Participants will be asked to practice at home with a tape of relaxation exercises.

Progress: Although the treatment program is now functioning, we are waiting for enough willing patients to be screened and referred for treatment.

Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-12-77 Status: Ongoing
 Title: Intravenous Administration of I¹³¹ (NP 59) for Adrenal Evaluation of Imaging.

Start Date 15 Nov 76	Est Comp Date:
Principal Investigator (vice Bunker) Michael F. Hartshorne, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department Radiology/Nuclear Medicine	Associate Investigators:
Key Words: Adrenal scan	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 8 Nov 84	Results Continue

Objective(s): Clinical evaluation of NP 59 as a diagnostic agent for the detection of adrenal-cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

Technical Approach: This study will be performed on 50 patients after complete evaluation by the Endocrinology Service. The radiopharmaceutical will be administered by slow IV injection with a dose of 1mCi in adults and 15mCi/kg in children. Lugol's solution, 5 drops twice daily starting one day before injection and continuing for two weeks, will be used to block thyroid uptake of radioiodine. Images will be obtained on the 4th, 7th, and 11th day following injection using scintillation camera.

Progress: During the period 1 Sep 84 through 30 Sep 85, no studies were performed. Although no usage has been demonstrated, we do wish to continue our status as authorized users under the current protocol should diagnostic need for the product arise.

etail Summary Sheet

Date: 25 Sep 85 Proj No: C-58-83 Status: Ongoing
Title: Evaluation of Indium Oxine In-III Labeled Cellular Blood Components

Start Date 10 Aug 83	Est Comp Date:
Principal Investigator (vice Bunker) Michael F. Hartshorne, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Radiology/Nuclear Med.	Associate Investigators: Alfred J. Landry, R.Ph., MAJ, MSC
Key Words: Labeled cellular blood components	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 138	
Total Number of Subjects Enrolled to Date: 218	
Date of Periodic Review 11 September 1985 Results Continue	

Objective(s): To evaluate the clinical usefulness of Indium Oxine labeled cellular blood components in infections, vascular, and platelet disorders.

Technical Approach: A series of 200 volunteers, consisting of active duty, retired, and appropriate dependent personnel, will be injected with a maximum of 500 uCi of Indium-111 labeled to either autologous or homologous cellular blood components. Clinical indications for requesting Indium-111 WBCs or platelets will be those normally applied to confirm or rule out inflammatory disease/ abscess (WBC) or thrombosis/thrombocytopenia (platelet). The dose will be administered IV. Imaging with a gamma camera will usually commence within 24 hours.

Progress: No adverse reactions have been noted. The protocol was initially approved to study 200 patients. A request to amend the protocol to allow the procedure to be performed on an additional 300 patients was approved by the FDA.

Detail Summary Sheet

Date: 30 Sep 85	Proj No: C-35-85	Status: Ongoing
Title: Platelet Deposition at Coronary Angioplasty Sites: Effect of Anti-Platelet Regimen and Predictive Values of Platelet Scanning.		

Start Date 29 Apr 85	Est Comp Date:
Principal Investigator	Facility
John M. Bauman, M.D., CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department Radiology/Nuclear Medicine	Michael F. Hartshorne, M.D., MAJ, MC
Key Words:	Michael A. Cawthon, D.O., MAJ, MC
Platelet scanning	Alfred A. Landry, R.Ph., MAJ, MS
Angioplasty	Richard Schatz, M.D., MAJ, MC
	Steven Bailey, M.D., MAJ, MC
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 5	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review n/a	Results

Objective(s): 1) To assess the effect of an anti-platelet regimen on platelet deposition in coronary angioplasty sites.

2) To assess the predictive value of platelet deposition in coronary angioplasty sites with regard to subsequent restenosis of the vessel.

Technical Approach: The presence or absence of platelet deposition at the angioplasty site will be used to compare the regimens, with absence being the optimum finding. Assessment of risk of early restenosis will be based on relative occurrence between the protocols, as determined by repeat cardiac catheterization or autopsy verification.

Progress: All studies were negative for intracoronary thrombus. No adverse reactions noted.

Detail Summary Sheet

Date: 4 Oct 85 Proj No: C-21-78 Status: Ongoing
 Title: Clinical Study of Intraocular Lenses.

Start Date February 1978	Est Comp Date:
Principal Investigator (vice Bode) John D. Walker, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Donald Griffith, M.D., COL, MC
Key Words: Intraocular lens Cataract extraction	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 224	
Total Number of Subjects Enrolled to Date: 778	
Date of Periodic Review 9 Apr 85 Results Continue	

Objective(s): To establish the safety and effectiveness of this device for use in human subjects according to guidelines recommended by the Food and Drug Administration ophthalmic advisory panel.

Technical Approach: Pursuant to protocols approved by the FDA, all have selected suitable patients for insertion of both posterior chamber and anterior chamber intraocular lenses. Using standard surgical techniques, these lenses were inserted as part of a cataract operation.

Progress: In the last year, as in previous years, approximately 224 lenses were implanted under the guidelines of the FDA. In the past year, no inherent problems were encountered.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-41-81 Status: Completed
 Title: Hearing Levels in Otherwise Healthy Children Who Were Exposed to
 Ultrasound While Fetuses.

Start Date 15 Jun 81	Est Comp Date:
Principal Investigator Leonard Brown, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Robert Sawyer, M.D., COL, MC
Key Words: Ultrasound	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 15	
Total Number of Subjects Enrolled to Date: 30	
Date of Periodic Review 13 Jun 85	Results Revise Protocol

Objective(s): To measure hearing levels in otherwise healthy children who underwent diagnostic ultrasound in utero.

Technical Approach: Hearing levels of children exposed to in utero ultrasound were compared to those who received no ultrasound exposure. History and physicals were performed on each patient at the time of their audiometric evaluations.

Progress: There was apparent difference between the right and left ears and patients with three or more ultrasounds noted in the control group. The control group difference between right and left ears was just over one decibel while the difference in the study group was seven decibels. The difference between the total number of ears examined was 9.5 decibels as previously noted. Although the study population was small, the possibility of additional hearing loss with each ultrasonography exposure is of concern. While not statistically significant with this patient number, the greatest change in hearing levels between 8 and 12 KHZ appeared to be in patients who received ultrasonography during the

C-41-81 (continued)

third trimester. This data suggests two risk factors to be of concern during ultrasonography: 1) exposure during third trimester and 2) multiple exposures.

This protocol has been revised and will be continued as protocol #C-70-85.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-20-82 Status: Ongoing
 Title: Long-Term Effect of Orthoptics on the Fusional Vergences.

Start Date 16 Feb 82	Est Comp Date:
Principal Investigator (vice Kotulak) Mark D. Cooney, O.D., CPT, MSC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Optomtry	Associate Investigators: David B Gorski, O.D., CPT, MS
Key Words: Orthoptics	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 11	
Total Number of Subjects Enrolled to Date: 40	
Date of Periodic Review n/a	Results

Objective(s): To determine the long-range efficacy or permanency of orthoptics as a treatment modality for strabismus.

Technical Approach: Eligible service members and their dependents who have been diagnosed as having binocularity problems and for whom Orthoptics has been determined to be of benefit are enrolled in BAMC's Visual Therapy Program. If the patient completes the visual therapy regime directed by clinic personnel and is found to have satisfied accepted historical functional cur criteria, they are enrolled in the Investigational Study.

The patients positive or negative fusional reserve is recorded on index cards and they are called for further measurement of this same datum according to a predetermined follow-up schedule. The long-range efficacy of Orthoptics is to be determined by a 100 subject field.

Progress: Insufficient subjects have been enrolled to report results. It must be pointed out that, while many patients do not satisfy accepted criteria for functional cure, they are nonetheless helped immensely; that is, symptoms are frequently eliminated completely and visual function greatly improved.

Detail Summary Sheet

Date: 22 Jul 85 Proj No: C-41-82 Status: Terminated
 Title: Color Defects in Glaucoma.

Start Date 7 Jul 82	Est Comp Date:
Principal Investigator (vice Bode) John D. Walker, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Jonas Moses, SP4
Key Words: Glaucoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To assess the relationship between glaucoma and color vision defects. Primary emphasis will be on the correlation of early color vision defects with other signs of glaucoma, such as visual field changes and optic disc changes. The prognostic significance of color vision defects in the early glaucoma and ocular hypertensive groups will also be evaluated.

Technical Approach: None

Progress: Terminated due to loss of interest by principal investigator.

etail Summary Sheet

Date: 25 Sep 85 Proj No: C-12-83 Status: Ongoing
 Title: Is Routine Intraoperative Cholangiography (IOC) a Useful Adjunct to Cholecystectomy?

Start Date 6 Jan 83	Est Comp Date:
Principal Investigator Daniel Rosenthal, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/General Surgery	Associate Investigators:
Key Words: Intraoperative cholangiography	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To determine if routine IOC significantly alters the management of patients with cholecystólithiasis by demonstrating at operation the presence of unsuspected stones in the biliary tree.

Technical Approach: All medical centers using routine IOC will be asked to participate. On a quarterly basis, they will be asked to report the number of IOCs performed, number of normals, what was done, and the number of minutes added to the procedure.

Progress: About 250 reports have been received. The study will remain open until 500 cases have been entered.

Detail Summary Sheet

Date: 3 Oct 85 Proj No: C-52-83 Status: Ongoing
 Title: Effect of 1% Phenylephrine Nose Drops on Otitis Media and Serous Otitis.

Start Date 16 Jun 83	Est Comp Date:
Principal Investigator (vice Webb) Harold R. Wright, M. D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Terry E. Pick, M.D., LTC, MC Michael L. Lepore, M.D., LTC, MC Sylvester G. Ramirez, M.D., CPT, MC
Key Words: Otitis media Serous otitis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 13 Jun 85	Results Continue

Objective(s): To test the effect of phenylephrine nose drops on the course of otitis media and serous otitis.

Technical Approach: Patients, ages 3-8 years, with acute onset otitis media or serous otitis, will be included in the study. All patients will receive antibiotic therapy. Patients not allergic to penicillin will receive Amoxacillin, and those allergic to penicillin will receive Septra. Patients assigned to Group A will receive 1% phenylephrine nose drops four times a day for two weeks. Patients assigned to Group B will receive a saline nose drop solution prepared by the pharmacy four times a day for two weeks. If at the end of two weeks the tympanogram shows no evidence of clearing, the code will be broken and another form of therapy instituted.

Progress: This study was recently transferred to a new investigator; no progress has been made.

Detail Summary Sheet

Date: 10 May 85 Proj No: C-62-83 Status: Completed
 Title: Intravitreal Injection of Beta-Lactam Antibiotics.

Start Date 10 Aug 83	Est Comp Date:
Principal Investigator Mary A. O'Hara, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Donald D. Bode, M.D., COL, MC Clayton L. Hadick, D.V.M., CPT, VC
Key Words: Endophthalmitis Intravitreal antibiotics	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 709.43
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a/	Results _____

Objective(s): To determine the toxicity of two beta-lactam antibiotics when administered intravitreally in rabbits.

Technical Approach: Cefoperazone is injected into the vitreous of Dutch belted rabbits in varying concentrations. As a control, saline is also injected into several eyes. Toxicity is then determined over a 6 week period with exams of the eyes and ERG's. At the end of this period, the animals are sacrificed and the eyes examined histopathologically.

Progress: The toxicity segment of the study has been completed, and the drug has been found to be very non-toxic when injected intravitreally. ERG's and histopathology demonstrated toxic changes at doses approaching solubility limit, but no toxicity at lower doses.

Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-63-83 Status: Ongoing
 Title: Dose-Response Relationship of Cyclophosphamide in Murine Transitional Cell Carcinoma.

Start Date 10 Aug 83	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Donald Lamm, M.D. C. Ritchie Spence, M.D., COL, CM Edward J. Shumski, M.D., LTC, MC William Gregory, SP5 Clayton L. Hadick, D.V.M., CPT, VC
Key Words: Carcinoma, transitional cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To determine if Cyclophosphamide can prevent tumor growth in doses in which it has been previously demonstrated that no agents effectively inhibit growth of murine transitional cell carcinoma.

Technical Approach: Animals were anesthetized and received 0.1cc of a suspension of 1×10^4 tumor cells into the right lateral thigh. Each group received either cyclophosphamide or saline intraperitoneally. Animals were checked every three days for tumor presence and followed for four weeks.

Progress: This study has not been performed. It is anticipated that it will start within the next three months.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-5-84 Status: Terminated
 Title: Adjuvant Portal Venous Infusion of High Risk Colon Cancer.

Start Date 19 Dec 83	Est Comp Date:
Principal Investigator Kendall Reed, D.O., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/General Surgery	Associate Investigators: J. Dean McCracken, M.D., COL, MC
Key Words: Infusion, portal venous	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 8 Nov 84	Results Continue

Objective(s): To determine if the long-term infusion of the portal venous system with Floxuridine (FUDR) via a totally implantable pump for continuous infusion or intermittent portal venous infusion via an implantable catheter will prevent or eradicate microscopic hepatic metastases in patients undergoing curative resection of colon carcinoma which have extended through the entire thickness of the bowel wall (Duke's B₂) or involve regional nodes (Duke's C₁ and C₂).

Technical Approach: Eligible patients will be randomized to one of three treatment programs. Program #1 consists of placement of the Infus-A-Port catheter plus follow-up. Program #2 consists of implanting the Infusaid pump followed by continuous treatment with the chemotherapy drug, FUDR, for one year. Program #3 consists of placement of the Infus-A-Port catheter and injection of the chemotherapy drug 5-FU daily for 5 days and then repeated every 28 days for one year.

Progress: This study was never begun because of recent reports of biliary sclerosis using only minimal dosages of FUDR. It was felt by this investigator that the risks outweighed the potential benefits of this study.

Detail Summary Sheet

Date: 3 Oct 85 Proj No: C-12-84 Status: Ongoing
 Title: Microbiological Analysis of Aspirate Fluid Taken During Extraction of Cataracts.

Start Date 13 Mar 84	Est Comp Date:
Principal Investigator	Facility
William F. Prestowitz, M.D., CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/Ophthalmology	Donald D. Bode, M.D., COL, MC
Key Words:	
Cataracts	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 9 Apr 85	Results Continue

Objective(s): To ascertain (a) how frequently bacteria are introduced into the anterior chamber of the eye during cataract surgery; (b) when bacteria are present in the aspirate fluid, how many patients subsequently develop infection; (c) which species of bacteria are most frequently introduced into the anterior chamber and which species are most frequently opportunistic pathogens in the site.

Technical Approach: During surgery for cataract removal, sterile saline is used to irrigate the anterior chamber. This fluid will be collected and examined for bacteria.

Progress: Logistical problems with specimen processing have resulted in deferment of study pending solution of difficulties.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-15-84 Status: Ongoing
 Title: Evaluation of Lung Water Changes in Post Coronary Bypass Patients
 Receiving Hetastarch.

Start Date 16 Mar 84	Est Comp Date:
Principal Investigator (vice Cohen) Robert A. Helsel, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Thoracic	Associate Investigators: Richard M. Briggs, M.D., MAJ, MC James B. Peake, M.D., COL, MC Harold D. Head, M.D., COL, MC
Key Words: Bypass, coronary	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 9 Apr 85	Results Continue

Objective(s): 1) To answer whether postoperative use of Hetastarch (Hespan®) in coronary artery bypass graft surgery patients causes increased extravascular lung water as compared to patients treated in standard manner with blood, crystalloid solution and albumin.

2) To determine whether there are differences in extravascular lung water in either of the above groups as compared to patients treated with blood and crystalloid alone.

Technical Approach: Eligible participants will be assigned to one of three groups. All groups will have surgery conducted in the same manner and all will be given blood as needed. One group will receive additional albumin, one will receive Hetastarch and one will receive crystalloid solution (dilute salt water) as needed to support blood pressure. Other blood tests and measurements will be the same as those required for all open heart surgery patients.

Progress: This study has not been started due to lack of the lung-water computer which is due to be purchased through MEDCASE. The Institute of Surgical Research has one but attempts to borrow it have not been successful as it is currently in use. Until such time as the computer (lung-water) is obtained, the study will remain on hold.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-17-84 Status: Ongoing
 Title: Esophageal Doppler: A Non-Invasive Method for Detection of Venous Air Embolism During Lumbar Laminectomy.

Start Date 16 Mar 84	Est Comp Date:
Principal Investigator Paul E. Casinelli, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Curtis Baysinger, M.D., MAJ, MC Steven I. Schmidt, M.D., CPT, MC William J. Reynolds, M.D., Ph.D., LTC, MC
Key Words: Laminectomy, lumbar Esophageal doppler Venous air embolism	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 9 Apr 85	Results Continue

Objective(s): To investigate the efficacy of the esophageal doppler device in detecting the occurrence of venous air embolism during lumbar laminectomy, and to determine the incidence of venous air embolism during lumbar laminectomy.

Technical Approach: The investigators have continued to have problems getting a working Doppler probe. They believe this has been remedied and the study will start in the near future.

Progress: No reportable data are available.

Detail Summary Sheet

Date: 4 Oct 85 Proj No: C-38-84 Status: Completed
 Title: Postoperative Pain Differential Between Electrocautery and Suture Ligation in Tonsillectomy.

Start Date 21 Jun 84	Est Comp Date:
Principal Investigator Jesse Moss, Jr., M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Michael L. LePore, M.D., COL, MC Donald J. Wittich, M.D., MAJ, MC
Key Words: Tonsillectomy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 45	
Total Number of Subjects Enrolled to Date: 45	
Date of Periodic Review 12 Jul 85	Results Continue

Objective(s): To determine which of the two generally accepted methods of obtaining hemostasis, i.e., electrocautery or suture ligation, causes less postoperative pain.

Technical Approach: After routine tonsillectomies in ASA I patients, hemostasis is achieved with suturing on one side and cauterizing on the other side. At one week and ten days after surgery, patients are asked if one side hurts more than the other side.

Progress: Most patients reported that the cautery hurts most at one week.

Detail Summary Sheet

Date: 26 Aug 85 Proj No: C-40-84 Status: Ongoing
 Title: Comparison and Calibration of the Gates Method for Glomerular Filtration Rate and the Tauxe Method for Effective Renal Plasma Flow Determination with Standard Inulin and Para-Aminohippurate Clearances.

Start Date 21 Jun 84	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Departments of Surgery/Radiology	Associate Investigators: John M. Bauman, M.D., CPT, MC Michael F. Hartshorne, M.D., MAJ, MC Michael A. Cawthon, D.O., CPT, MC William H. Howard, III, M.D., CPT, MC C. Ritchie Spence, M.D., COL, MC
Key Words: Glomerular filtration rate (GFR) Effective renal plasma flow (ERPF)	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 169.76
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 13 Jun 85 Results Continue	

Objective(s): 1) To accurately determine the values for GFR and ERPF in 15 patients with predetermined ranges of renal functional impairment.

2) To obtain values for GFR and ERPF in the same patients through current techniques employed in the Nuclear Medicine Clinic.

3) To compare the accuracy of the Nuclear Medicine techniques as employed at this institution with the accepted standards, and correct the mathematical derivations thereof, as necessary, in order to provide improved patient care.

Technical Approach: Patients undergo a standardized renogram followed by simultaneous inulin and PAH clearances.

Progress: Thus far, in patients studied, there have been no side effects or complications of the study. It was determined by the reference laboratory that inulin and PAH assays would be batched and for this reason, urine and blood specimens are currently frozen, awaiting adequate numbers prior to shipping for assays.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-41-84 Status: Ongoing
 Title: Establishment of Human Urothelial Tissue Culture and Investigation of Carcinogenic Effects of Known Urothelial Carcinogens.

Start Date 21 Jun 84	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Debra J. Krikorian, Ph.D., CPT, MSC James B. Rounder, M.D., CPT, MC C. Ritchie Spence, M.D., COL, MC Edward J. Shumski, M.D., LTC, MC
Key Words: Carcinogens Tissue culture	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1,316.83
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To establish a line of normal urothelial cells (human in tissue culture) to allow further investigation of the effect of various carcinogens in vitro.

Technical Approach: A small piece of surgically excised normal human urothelium is preserved in tissue culture medium after the performance of an indicated urologic surgical procedure. This is then dissected using sterile microscopic technique and urothelial cells cultured. Cell lines are observed for morphologic changes.

Progress: Two cultures of urothelial tissue were established and one subculture was preserved for several months before it became contaminated. Techniques for continuing the culture line were established during this period. It is anticipated that in the next few months, another attempt at tissue growth will be performed.

Detail Summary Sheet

Date: 21 Aug 85 Proj No: C-42-84 Status: Completed
 Title: Impact on Clinical Stage of Prostate Carcinoma of Routine Screening.

Start Date 21 Jun 84	Est Comp Date:
Principal Investigator James B. Rounder, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Julius L. Teague, M.D., CPT, MC Ian M. Thompson, M.D., CPT, MC C. Ritchie Spence, M.D., COL, MC
Key Words: Carcinoma prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine if routine screening for carcinoma of the prostate impacts on the staging distribution of the disease within the screened population.

Technical Approach: The impact of routine screening with digital rectal examinations for carcinoma of the prostate on stage distribution of the disease were assessed in the primary treatment population of Brooke Army Medical Center. Two, five-year periods were compared: 1974-1978, prior to onset of routine screening, and 1979-1983, during the period of routine screening.

Progress: Clinical stage distribution of prostate cancer during the period prior to onset of routine screening was not significantly different from national averages. Routine screening during the second period significantly increased the percent of those patients with clinically curable carcinoma of the prostate. Pathological staging upstaged many patients in both series. Digital rectal examinations can thus have significant impact on early detection of carcinoma of the prostate but cannot be interpreted as a panacea for this disease.

Detail Summary Sheet

Date: 9 Sep 85 Proj No: C-45-84 Status: Terminated
 Title: The Value of Preoperative Sulfur Colloid Marrow Scintigraphy in the Treatment of Acute Fractures of the Femoral Neck.

Start Date 17 Jul 84	Est Comp Date:
Principal Investigator Stephen Norwood, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Michael F. Hartshorne, M.D., MAJ, MC Lida Crook, M.D., MAJ, MC
Key Words: Scintigraphy, sulfur colloid Fracture, femoral neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 20 Aug 85 Results Terminated	

Objective(s): 1) To determine the usefulness of preoperative sulfur colloid marrow scintigraphy in the evaluation of acute fractures of the femoral neck.

2) To determine whether the method of sulfur colloid scintigraphy is successful in determining subsequent avascularity.

Technical Approach: Sulfur colloid marrow scintigraphy will be performed within 48 hours of fracture of the femoral neck prior to treatment of the fracture. Patients will be asked to return for follow-up evaluations for two years.

Progress: This study was terminated because of several factors. First, they were unable to get the scans accomplished without disruption to the normal care of the patient. Because there are so many planning factors for the surgery on these patients, it was difficult to get other residents to participate in the counselling and arrangements for the study. Secondly, problems arose in the handling of operative specimens of femoral heads labelled with tetracycline. Some specimens were not received as study material and were not handled as such. Finally, the availability of nuclear medicine facilities after hours and on weekends was limited and prevented the performance of the scans on a majority of potential study candidates.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-63-84 Status: Completed
 Title: Double Blind Reference Control Study Comparing the Efficacy of
 CHEMOLASE® and Chymodiactin® in the Treatment of Back Pain and Leg Pain Due to
 Lumbar Disc Disease.

Start Date 10 Sep 84	Est Comp Date: 1 Oct 85
Principal Investigator Allan L. Bucknell, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Lloyd A. Youngblood, M.D., LTC, MC
Key Words: Lumbar disc disease	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 5	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review 11 Sep 85	Results Continue

Objective(s): To compare the efficacy of two chymopapain preparations,
 CHEMOLASE® and Chymodiactin®, in the treatment of low back pain due to lumbar
 disc disease.

Technical Approach: Patients will be randomly assigned to either the CHEMOLASE®
 or Chymodactin® group. The study was conducted as outlined in the company pro-
 tocol.

Progress: There was no statistical difference between the two preparations.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-66-84 Status: Ongoing
 Title: Fiberoptic Laryngoscopy and the Incidence of Sore Throat After General Anesthesia.

Start Date 13 Sep 84	Est Comp Date:
Principal Investigator Richard K. Baumgarten, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words: Fiberoptic laryngoscope	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 11 Sep 85	Results Continue

Objective(s): To determine if fiberoptic laryngoscopy prevents sore throat.

Technical Approach: Patients scheduled for elective surgery where intubation is expected to last less than one and one-half hours will be eligible for the study. A standardized postoperative interview will be utilized to identify postoperative sore throats and their severity.

Progress: The principal investigator has been transferred to Germany. No data are available. The study remains open pending the appointment of a new P.I.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-72-84 Status: Ongoing
 Title: Outpatient Intra-Arterial Digital Subtraction Angiography in the
 Evaluation of Patients with Atherosclerotic Peripheral Vascular Disease.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Bruce M. Elliott, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/General Surgery	Associate Investigators: Michael J. Huggins, M.D., MAJ, MC
Key Words: Angiography, digital subtraction	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 34	
Total Number of Subjects Enrolled to Date: 34	
Date of Periodic Review 11 Sep 85	Results Continue

Objective(s): To determine the safety, feasibility, and accuracy of outpatient intra-arterial angiography using digital subtraction angiographic technology in patients with known atherosclerotic peripheral vascular disease who otherwise would undergo conventional angiography.

Technical Approach: Patients who would routinely be scheduled for elective admission for conventional angiography will be offered outpatient intra-arterial digital subtraction angiography. Routine x-ray and blood studies will be obtained prior to the date of the scheduled arteriogram. Arteriography will be performed in the Digital Subtraction Angiography Suite utilizing the standard Seldinger technique. Upon completion of the angiogram, the patient will be observed in the Recovery Room for two hours. If there are no complications, the patient will be discharged.

Progress: Thirty-four patients have agreed to participate in this study. Recruitment has been less than initially anticipated primarily because of the relatively rigid selection criteria for entry, as well as a substantial amount of out of town patients referred via the air evac system.

Twenty-six of the initial 34 patients had arch and carotid studies performed and 12 required selective carotid injections for adequate diagnostic quality. Two patients were hospitalized immediately following the angiogram for complications. One patient sustained a minor stroke which cleared within 30 days

C-72-84 (continued)

following a selective carotid injection. The other patient was admitted for confusion following the angiogram which had cleared by the patient arrived on the ward. An additional patient was admitted for urgent carotid endarterectomy when a critical stenosis was discovered on the angiogram.

Eight patients had aorta and run-off angiograms performed for aneurysm or occlusive disease without complications. The current protocol has not caused any unusual hardship or delay in treatment in the first 34 patients. The preliminary results are encouraging, and with proper angiographic technique, it is as diagnostically accurate as conventional angiographies.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-75-84 Status: Ongoing
 Title: The Chronic Administration of Diltiazem and the Cardiovascular Responses to High Dose Fentanyl Anesthesia and Coronary Artery Surgery in Man.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Curtis L. Baysinger, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Alan Zablocki, M.D., MAJ, MC Jerry Epps, M.D., CPT, MC Charles Kingsley, M.D., CPT, MC Brent Grishkin, M.D., LTC, MC
Key Words: Anesthesia,	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 20	
Total Number of Subjects Enrolled to Date: 20	
Date of Periodic Review 11 Sep 85	Results Continue

Objective(s): To investigate the cardiovascular effects of the prior administration of diltiazem in patients anesthetized with fentanyl-diazepam-pancuronium-oxygen anesthesia during coronary artery bypass surgery.

Technical Approach: Thirty male patients taking diltiazem for greater than 30 days who will undergo coronary artery surgery will be asked to participate and will be randomized to two groups of 15. The control group will be patients who are not taking diltiazem and present for coronary artery surgery. Group I will have their diltiazem withheld over the 24 hours prior to surgery. Group II will have their diltiazem continued up until surgery. Both patients with good and poor left ventricular function will be studied.

Progress: Have randomized patients to two groups. Results are not statistically significant as yet.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-76-84 Status: Ongoing
 Title: H₁ and H₂ Antagonists and Protamine Sulfate Administration Following Cardiopulmonary Bypass.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Curtis L. Baysinger, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Charles Kingsley, M.D., CPT, MC Jerry Epps, M.D., CPT, MC Brent Grishkin, M.D., LTC, MC
Key Words: Bypass, cardiopulmonary	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 50	
Total Number of Subjects Enrolled to Date: 50	
Date of Periodic Review 11 Sep 85 Results Continue	

Objective(s): To investigate the cardiovascular effects following protamine reversal of heparin effect post cardiopulmonary bypass with and without the use of H₁ and H₂ histamine antagonists.

Technical Approach: Sixty patients scheduled to undergo coronary artery and valvular surgery will be randomized to one of four groups. All patients will receive protamine in a dose calculated from a protamine titration, at a rate of 100 mg/min via an infusion pump. Groups I and III will receive the protamine through the proximal port of the Swan Ganz catheter, groups II and IV through a left atrial line. Groups III and IV will also receive 4 mg/kg of cimetidine and 1 mg/kg of diphenhydramine during cardiopulmonary bypass. The data obtained from patients on chronic calcium blocker therapy will be compared to the data obtained from those not taking calcium channel blockers.

Progress: Fifty patients have been randomized. No trends have been identified. Results are close to statistical significance.

Detail Summary Sheet

Date: 29 Jul 85	Proj No: C-77-84	Status: Completed
Title: Can Nondepolarizing Muscle Relaxants Produce Intubating Conditions as Rapidly as Succinylcholine?		

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator	Facility
Richard K. Baumgarten, M.D., MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/Anesthesiology	Jerry Brown, D.O., CPT, MC
Key Words:	
Succinylcholine	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 51	
Total Number of Subjects Enrolled to Date: 51	
Date of Periodic Review	Results

Objective(s): To replace succinylcholine for rapid sequence intubation of the trachea.

Technical Approach: Fifty-one adult ASA Class 1, 2, or 3 patients were studied. One of three muscle relaxants was used, either atracurium or vecuronium in divided doses or succinylcholine. Time until successful intubation was accomplished was recorded.

Progress: Priming sequences of atracurium and vecuronium compared favorably with succinylcholine. For rapid sequence induction in the cooperative patient, the priming sequence provides good to excellent intubation conditions with non-depolarizing relaxants while retaining the ability to reverse after all but the shortest surgical procedures.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-78-84 Status: Ongoing
 Title: The Effects of Atracurium and Vecuronium on Intraocular Pressure and the Time Required for Intubation.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator	Facility
William J. Evans, M.D., CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/Anesthesiology	Mark H. Cook, M.D., CPT, MC
Key Words:	
Pressure, intraocular	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 16	
Total Number of Subjects Enrolled to Date: 16	
Date of Periodic Review 11 Sep 85	Results Continue

Objective(s): 1) Do these drugs affect intraocular pressure? If so, how much?

2) How soon after induction of anesthesia can a patient be intubated when these drugs are used?

3) Can these drugs be safely and effectively used in ophthalmologic surgery; in particular, in repair of penetrating globe injuries and in glaucoma surgery?

Technical Approach: Intraocular pressure and the time required for intubation of 60 patients undergoing general anesthesia for elective nonocular surgery will be measured. Patients will be assigned to one of three groups: Group I will serve as controls and will receive succinylcholine for intubation; Group II will receive atracurium; and Group III will receive vecuronium. Groups II and III will be used to compare time to intubate with Group I. Prior to induction of anesthesia, the ophthalmology resident will record the patient's intraocular pressure.

Progress: Few subjects have been enrolled than anticipated due to the logistical problems of two hospitals. However, preliminary results are encouraging.

Detail Summary Sheet

Date: 21 Aug 85 Proj No: C-1-85 Status: Completed
 Title: Etomidate as an Anesthetic Agent for Cardioversion.

Start Date 14 Nov 84	Est Comp Date:
Principal Investigator Jerry L. Brown, D.O., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Robert E. Middaugh, M.D., CPT, MC William J. Reynolds, M.D., LTC, MC
Key Words: Cardioversion	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 30	
Total Number of Subjects Enrolled to Date: 30	
Date of Periodic Review	Results

Objective(s): To establish that Etomidate is an effective and safe anesthetic for cardioversion.

Technical Approach: The effects of the induction (0.15 - 0.2 mg/kg) and maintenance (0.05 - 0.1 mg/kg) of anesthesia with Etomidate were studied in 30 patients undergoing elective or urgent cardioversions. The effects on SBP and MAP, spontaneous ventilation, time to recovery, and incidence of dysrhythmias were noted.

Progress: No patient developed hypotension, all maintained spontaneous ventilation (save one requiring intubation because of NPO status), and no ventricular dysrhythmias were noted. The average time to recovery was 11.8 minutes. The incidence of pain on injection and myoclonus were found to be markedly reduced by prolongation of injection time to 60 seconds. Etomidate produced anesthesia for cardioversion characterized by stable cardiovascular performance, without ventricular dysrhythmias, maintenance of spontaneous ventilation and excellent amnesia.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-5-85 Status: Ongoing
 Title: Localization of the Distribution of Regional Anesthetics.

Start Date 15 Jan 85	Est Comp Date:
Principal Investigator Emil J. Menk, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: John M. Bauman, M.D., CPT, MC Robert E. Middaugh, M.D., CPT, MC Curtis L. Baysinger, M.D., MAJ, MC Michael A. Cawthon, D.O., MAJ, MC William J. Reynolds, M.D., LTC, MC Michael F. Hartshorne, M.D., MAJ, MC
Key Words: Anesthetic, regional	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 30	
Total Number of Subjects Enrolled to Date: 30	
Date of Periodic Review n/a	Results

Objective(s): To define the area and extent of flow of anesthetics during regional blockades.

Technical Approach: Approximately 10 patients will be evaluated utilizing the following techniques: axillary, interscalene, stellate ganglion, intercostal nerve, and epidural blockade. Patients will be brought to the Nuclear Medicine clinic for injection and imaging whenever possible. Standard doses and volumes of the local anesthetics routinely used will be employed, as well as strict aseptic technique. Each group of 10 patients will receive the anesthetic as a single bolus injection, and the other will receive 10 cc boluses with serial imaging after each bolus.

When bone scanning is felt to be indicated to better define the anatomy of flow, injection of the MDP will take place approximately 3-4 hours prior to imaging and injection of the anesthetic agent/DTPA mixture.

Progress: Significant results noted by study are: 1) Distal digital pressure on the extremity makes a significant difference in anesthetic flow in the axillary block; 2) Anesthetic flow in the stellate ganglion block may extend as low as a T₄ level with a 15 cc volume; 3) There are four distinct anesthetic flow patterns when using a continuous intercostal block via a catheter; and 4) Exercise after injection through a paravertebral catheter may significantly alter anesthetic flow.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-6-85 Status: Ongoing
 Title: Perioperative Myocardial Infarction in Patients Undergoing Peripheral Vascular Surgery.

Start Date 15 Jan 85	Est Comp Date:
Principal Investigator William K. Goglin, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Curtis L. Baysinger, M.D., MAJ, MC John W. Culclasure, M.D., CPT, MC Bruce M. Elliott, M.D., MAJ, MC
Key Words: Infarction, myocardial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 76	
Total Number of Subjects Enrolled to Date: 76	
Date of Periodic Review	Results

Objective(s): 1) To prospectively investigate the incidence of perioperative myocardial infarction as determined by cardiac enzymes and electrocardiography in patients undergoing anesthesia and non-cardiac vascular surgery for the complications of peripheral vascular disease.

2) To demonstrate if there is a significantly greater number of myocardial infarctions as measured enzymatically as compared to those detected by clinical and electrocardiographic means only.

Technical Approach: All study patients will have a routine EKG performed as part of the usual preoperative evaluation. When the patient presents to the operating room, blood for MB CPK assay will be obtained. Immediately postoperatively and each morning for five days and EKG for interpretation by the cardiology service will be obtained. Additionally, MB CPK assays immediately postoperatively and twice a day for five days will be done. Additional EKGs and laboratory tests may be done more frequently as deemed necessary.

Progress: CPK-MB results and EKG corroboration suggest that the usefulness of this test in screening for preoperative myocardial infarction in patients who do not have complaints of chest pain is low.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-7-85 Status: Ongoing
 Title: Endotracheal Intubation Utilizing a Blind Oro-Tracheal Intubation Device.

Start Date 15 Jan 85	Est Comp Date:
Principal Investigator (vice Schwartz) Robert E. Middaugh, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words: Intubation, endotracheal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To define the limits and incidence of successful endotracheal intubation utilizing a newly developed blind-oro-tracheal intubator.

Technical Approach: Patients undergoing surgical procedures requiring oro-tracheal intubation will be included. Patients will have intravenous access and appropriate monitoring established in accordance with anesthetic standards prior to intubation. The head and neck will be maintained in the neutral position and the blind-oro-tracheal intubator device inserted into the oral cavity with the right hand while utilizing the standard chin lift maneuver with the left hand. The device is inserted such that the distal obturator end rests in the hypopharynx just distal to the glottic opening as indicated by the insertion guide on the intubation device.

Progress: Since change in principal investigators, no data are available. The study will be started in the near future.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-8-85 Status: Terminated
 Title: A Multi-Center Study for the Evaluation of a Combined Protocol for Rehabilitation of the hand Following Flexor Tendon Repair.

Start Date 15 Jan 85	Est Comp Date:
Principal Investigator William Milnor, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Jimmy A. Chow, M.D., LTC, MC Sam Dovel, 1LT, MS Joseph Jackson, M.D., LTC, MC John M. Provost, M.D., COL, MC
Key Words: Tendon, flexor repair	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To officially document the functional results of surgical repair of laceration of flexor tendons of the hand followed by standard postoperative rehabilitation regimen of controlled motion exercises of the fingers.

Technical Approach: None.

Progress: Since the method used in this study is not considered experimental, the study was terminated.

Detail Summary Sheet

Date: 27 Sep 85 Proj No: C-12-85 Status: Ongoing
 Title: Clinical Study of GORE-TEX® Polytetrafluoroethylene (PTFE) Prosthetic Ligament.

Start Date 15 Jan 85	Est Comp Date:
Principal Investigator Keith L. Markey, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators:
Key Words: Ligament, prosthetic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): To demonstrate that the GORE-TEX® expanded polytetrafluoroethylene (PTFE) prosthetic ligament is effective in its intended use (maintenance of joint stability) and that this device presents no potential serious risk to the health, safety, or welfare of the patient.

Technical Approach: None. FDA has temporarily stopped this study.

Progress: None.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-22-85 Status: Ongoing
 Title: Systematic Evaluation of Recurrent Nephrolithiasis.

Start Date 5 Feb 85	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: C. Ritchie Spence, M.D., COL, MC
Key Words: Nephrolithiasis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To determine if a systematic evaluation of nephrolithiasis with tailored therapeutic techniques can reduce incidence of stone disease.

Technical Approach: This is a two-part analysis of the importance of metabolic evaluation for nephrolithiasis. One part will compare the incidence of stone recurrence within a population of stone formers who did not undergo metabolic evaluation. The second part of the study will perform calcium-loading tests on stone formers in an attempt to categorize those with hypercalciuria. They will then be treated appropriately and compared with the historical controls.

Progress: Data sheets and forms for this protocol are being made at this time. It is anticipated that the protocol will begin within the next 3 months.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-23-85 Status: Ongoing
 Title: Upper Limits of Normal of Prostatic Acid Phosphatase: A Poor Prognostic Indicator in Carcinoma of the Prostate.

Start Date 5 Feb 85	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: C. Ritchie Spence, M.D., COL, MC
Key Words: Carcinoma, prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To determine if values of prostatic acid phosphatase within the upper limits of normal may reflect bulky or locally metastatic disease.

Technical Approach: This is a retrospective review of all those patients with adenocarcinoma of the prostate who underwent surgical staging of the disease. Preoperative prostatic acid phosphatase levels will be compared with final surgical stage to determine if a high-normal level of this enzyme may be a predictor of higher-stage disease.

Progress: This review is on-going with subject accession finished. Results are forthcoming.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-24-85 Status: Ongoing
 Title: Determination of Normal Alphafetoprotein Range in Normal Men Over the Age of 50.

Start Date 5 Feb 85	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Edward J. Shumski, M.D., LTC, MC C. Ritchie Spence, M.D., COL, MC
Key Words: Alphafetoprotein	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To determine if a difference exists in the range of normal values of alphafetoprotein in older men.

Technical Approach: Serum samples for AFP determination will be obtained from healthy volunteers referred to the Urology Service for non-testicular disease processes. All patients will be screened by history for potential liver disease or systemic complaints. Two groups of patients will be evaluated. One group will be men between the ages of 20 and 35 and second group between ages 50 and 70. Thirty patients will be evaluated in each group. All assays for AFP will be performed by the radioimmunoassay technique.

Progress: This protocol has not yet been performed.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-25-85 Status: Terminated
 Title: A Double Blind Comparison of Sensorcaine (Bupivacaine Hydrochloride) Solution 0.5% with 8% Glucose and Tetracaine 0.5% Solution with Glucose as a Spinal Anesthetic for patients Undergoing Cesarean Section.

Start Date 5 Feb 85	Est Comp Date:
Principal Investigator Linda Ornelas Wilson, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Richard K. Baumgarten, M.D., MAJ, MC Luis R. Robles, M.D., CPT, MC
Key Words: Cesarean section	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To assess and document the effectiveness and safety of Sensorcaine as a long acting spinal anesthetic in parturient patients.

Technical Approach: None.

Progress: No patients from BAMC were entered into the study prior to completion of the study by the investigators at the University of Texas Health Science Center.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-30-85 Status: Completed
 Title: Can Nondepolarizing Muscle Relaxants Produce Intubating Conditions as Rapidly as Succinylcholine? Phase II

Start Date 26 Feb 85	Est Comp Date:
Principal Investigator(vice Baumgarten) Charles E. Carter, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words: Muscle relaxants	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 34	
Total Number of Subjects Enrolled to Date: 34	
Date of Periodic Review n/a	Results

Objective(s): To determine if the muscle relaxants curare, atracurium and vecuronium act quickly enough to be used for emergency surgery.

Technical Approach: Thirty-four ASA Class 1, 2 or 3 patients were studied. One of three regimens were used - vecuronium-vecuronium; curare-vecuronium; and a pentothal control group.

Progress: For rapid sequence induction in the cooperative patient, the priming sequence using the vecuronium-vecuronium combination offers good to excellent intubation conditions. The curare vecuronium combination also offered good to excellent intubation conditions with the exception of two patients in which poor intubation conditions were found. The pentothal control group was limited to four patients after discovering poor intubating conditions in two patients and inability to intubate in the other two patients.

Detail Summary Sheet

Date: 23 Aug 85 Proj No: C-41-85 Status: Ongoing
 Title: Evaluation of Various Techniques of Septoplasty and Total Nasal Septal
 Reconstructive Surgical Procedures Utilizing Rhinometric Studies.

Start Date 29 Apr 85	Est Comp Date:
Principal Investigator Michael L. LePore, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators:
Key Words: Rhinomanometry	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

- Objective(s): 1) To utilize anterior rhinometric principles in the preoperative assessment of patients prior to nasal surgery.
- 2) To utilize anterior rhinometric principles in the postoperative evaluation of patients who have had either septoplasty surgery and/or total nasal septal reconstructive surgery.
- 3) Compare the rhinometric results with the surgical techniques to gain more information which may help us elucidate the intranasal deformities most likely to be improved by intranasal surgery, and which technique may be used in similar circumstances to achieve the best results.

Technical Approach: All patients who undergo nasal surgery will have anterior rhinomanometry performed according to presently accepted methods. Patients will have intranasal photography performed to help in the evaluation. Photography will be performed prior to use of local intranasal decongestants (1% neosynephrine) and after its use as is performed in rhinometric studies. All patients will have their visible anatomic deformities mapped out preoperatively and intraoperatively. Six weeks after surgery, anterior rhinomanometry will again be performed to ascertain objectively the results of the surgical procedure. The patient's subjective impression concerning the result will be noted. Six months after surgery and one and two years after, the patient will be asked to return for another rhinomanometric examination.

Progress: This study will start as soon as the Automated Rhinomanometric Equipment is received.

Detail Summary Sheet

Date: 26 Aug 85 Proj No: C-55-85 Status: Ongoing
 Title: Clinical Trial Evaluating the Postoperative Portal Vein Infusion of 5-Fluorouracil and Sodium Heparin in Patients with Resectable Adenocarcinoma of the Colon.

Start Date 25 Jul 85	Est Comp Date:
Principal Investigator Kendall Reed, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/General Surgery	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Infusion, portal vein	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To evaluate the efficacy of postoperative 5-FU portal hepatic infusion in patients with Dukes A, B and C adenocarcinoma of the colon.

Technical Approach: All patients with a potentially curable adenocarcinoma as documented by barium enema or endoscopic biopsy will be eligible for randomization. Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 30 Sep 85 Proj No: C-58-85 Status: Ongoing
 Title: Cervical Epidural Anesthesia for Shoulder Surgery.

Start Date 16 Aug 85	Est Comp Date:
Principal Investigator Alan D. Zablocki, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Curtis L. Baysinger, M.D., MAJ, MC Edward E. Harte, M.D., MAJ, MC Charles P. Kingsley, M.D., CPT, MC Allen L. Bucknell, M.D., LTC, MC Reginald D. Williams, M.D., COL, MC
Key Words: Anesthesia, cervical epidural	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 5	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review n/a	Results

Objective(s): To investigate the use of cervical epidural anesthesia for operations on the shoulder and determine whether it will provide adequate anesthesia and operating conditions with all of the advantages of other regional techniques with additional benefits and fewer complications.

Technical Approach: Approximately 25-30 patients undergoing shoulder operations will be studied. Those refusing to participate will be placed in a control group in which general anesthesia will be used.

Progress: Four out of five provided good to excellent operating conditions. In one patient, the technique was abandoned due to repeated intravascular placement of the epidural catheter.

Detail Summary Sheet

Date: 26 Aug 85 Proj No: C-59-85 Status: Ongoing
 Title: Multicenter Trial of Cryotherapy for Retinopathy of Prematurity.

Start Date 16 Aug 85	Est Comp Date:
Principal Investigator	Facility
Christine L. Burns, M.D., LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/Ophthalmology	
Key Words:	
Cryotherapy	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the safety and efficacy of cryotherapy of the peripheral retina in severe retinopathy of prematurity (ROP) to prevent progression of the acute disease to severe grades of cicatricial retrolental fibroplasia.

Technical Approach: Prospective data will be accumulated from infants who are at risk for developing stage 3+ ROP. Those who reach that stage will be eligible for randomization in the cryotherapy study.

Progress: This is a new study.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-61-85 Status: Ongoing
 Title: Heated Humidification versus the Closed Circuit for Temperature Maintenance

Start Date 10 Sep 85	Est Comp Date:
Principal Investigator William K. Goglin, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words: Humidification	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To determine if heated humidification warms patients more effectively than closed circuit anesthesia.

Technical Approach: A randomized crossover design will be utilized with the patient serving as his own control. Long operations with a relatively constant cold stress will be chosen (ex. radical neck dissection, tympanoplasty, craniotomy, and extensive oral surgery). Temperature will be monitored by Foley catheter temperature, pharyngeal temperature, and airway temperature. Treatment will be administered for alternate one hour periods with initial treatment chosen randomly. During the humidifier treatment, the airway temperature will be adjusted at 39°C and a 5 liter fresh gas flow used. During the closed circuit treatment, the humidifier will be removed from the circuit and basal flows will be used. Temperatures will be recorded at the beginning, midpoint and end of each interval.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-70-85 Status: Ongoing
 Title: High Frequency Hearing Levels in Otherwise Healthy Children Exposed to Three or More In Utero Diagnostic Ultrasounds

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Leonard W. Brown, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Kenneth B. Aspinall, LTC, MS Michael L. Lepore, M.D., COL, MC
Key Words: High frequency hearing levels	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): 1) To establish a normal value for high frequency hearing thresholds in children.

2) To compare a control group of healthy children with "normal" hearing threshold to a group of healthy children exposed to three or more in utero ultrasounds.

Technical Approach: This study is a continuation of study C-41-81.

A minimum of 50 otherwise healthy children between 3-6 years of age for each of two groups will be examined for high frequency hearing thresholds. The first group will consist of children exposed to three or more in utero ultrasounds, and the second group will consist of children without a history of ultrasound exposure. The primary frequencies to be studied are between 10-20,000 Hz.

Progress: This is a new study.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-71-85 Status: Ongoing
 Title: The Effects of a Constant Infusion of Etomidate and Sufentanil on
 Somatosensory Evoked Potentials in Neurosurgical Patients.

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Alan D. Zablocki, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Curtis L. Baysinger, M.D., MAJ, MC Jerry Epps, M.D., CPT, MC Lloyd Youngblood, M.D., COL, MC
Key Words: Somatosensory potentials	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): To determine the effects of a total intravenous anesthetic technique utilizing a constant infusion of etomidate and sufentanil on the intraoperative monitoring of somatosensory evoked potentials during neurosurgical procedures.

Technical Approach: Twenty adult patients undergoing elective intracranial or spine operations will be asked to participate. Induction of anesthesia will be accomplished in the standard fashion. Somatosensory evoked potentials will be monitored with the Nicolet* CA-1000 multichannel signal averager. Sites for recording electrodes for both modalities will be measured using the International 10-20 System. A set of baseline measurements will be obtained prior to induction of anesthesia. A second set will be obtained 10 minutes post-induction and a third set 30 minutes post-induction. Each measurement will be reproduced at least once and superimposed to eliminate artifact.

Progress: This is a new study.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-75-85 Status: Ongoing
 Title: Management of Acute Renal Colic

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator C. Douglas Corrie, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: R. Daniel Goff, M.D., MAJ, MC
Key Words: Renal colic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the type of narcotic and its route of administration that is most efficacious in managing acute renal colic as determined by length of time in the ER, final disposition, and patient's subjective opinion of the experience.

2) To determine whether a regular dosing schedule or an as-needed use of narcotics after the patient leaves the ER is better for continuing control of pain.

3) To define treatment parameters that would predict the need to admit the patient for prevention of recurrent renal colic leading to return to the ER and subsequent admission.

Technical Approach: Patients seen in the ER for renal colic would be put into six different groups on a random basis. The groups would be in the IM Demerol, low Dose Morphine and high dose Morphine with prn and every four hour Percocet subgroups of the primary three groups. The response of the patients to these six groups would be compared for length of time in ER, degree of pain relief, patient satisfaction with pain relief, need for subsequent return to the ER or admission and ability of patients to perform their usual duties and functions.

Progress: This is a new study.

Detail Summary Sheet

Date: 10 Oct 85	Proj No: C-76-85	Status: Ongoing
Title: Assessment of the Value of Brain Scans (BS) and Computerized Axial Tomograph (CT Scans) in the Management of Patients with Transient Ischemic Attacks (TIAS) and Cerebral Infarcts with Transient Signs (CITS)		
Start Date 27 Sep 85	Est Comp Date:	
Principal Investigator Manuel F. Ramirez, M.D., MAJ, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Surgery/Vascular Surgery	Associate Investigators: Bruce M. Elliott, M.D., MAJ, MC John M. Bauman, M.D., CPT, MC Charles F. Hales, M.D., MAJ, MC	
Key Words: Transient Ischemic Attack		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 0		
Total Number of Subjects Enrolled to Date: 0		
Date of Periodic Review n/a Results		

Objective(s): To assess teh value of both the Brain Scan (BS) and Computerized Axial Tomography (CT Scan) in the management of patients with TIAS or ClTs.

Technical Approach: All patients who present to the Peripheral Vascular Service with symptoms of TIAs, either hemispheric or non-hemispheric in nature, and those with ophthalmological findings of Hollenhorst plaque or retinal artery branch occlusion will be accepted into the study. Once a clinical diagnosis of TIA is made, then further non-invasive evaluation with both BS and CT scan with contrast will be performed.

Proress: This is a new study.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-78-85 Status: Ongoing
 Title: Impact of Smoking on Stage and Grade of Transitional Cell Carcinoma of the Urinary Bladder

Start Date 27 Spe 85	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words: Transitional cell carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a Results _____	

Objective(s): To determine the impact of smoking and its quantitative amount on the stage, grade, and incidence of bladder cancer.

Technical Approach: The records of the most recent 100 patients with a diagnosis of transitional cell carcinoma of the bladder or renal pelvis will be assessed. Three independent variables will be assessed: +/- - history of smoking; pack years of smoking; and history of toxin exposure.

Progress: This is a new study.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-79-85 Status: Ongoing
 Title: Update on Routine Screening for Adenocarcinoma of the Prostate

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Edward Mueller, M.D., CPT, MC
Key Words: Adenocarcinoma of prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To review the results of the screening clinic for carcinoma of the prostate (CAP) from January 1979 to August 1985.

Technical Approach: The records of all patients who have been seen in the Urology Screening clinic will be assessed through the Urology Clinic convenience file. Records will be reviewed for results of examinations, biopsies, clinical and pathological staging, and patient follow-up.

Progress: This is a new study.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-80-85 Status: Ongoing
 Title: Complications of Adjunctive Radiotherapy for Surgical Stage C Carcinoma of the Prostate

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Julius Teague, M.D., CPT, MC C. Ritchie Spence, M.D., COL, MC
Key Words: Stage C Carcinoma of Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review n/a	Results

Objective(s): To review the complications of radiotherapy given to patients with surgically-staged stage C carcinoma of the prostate (CAP).

Technical Approach: All patients with the diagnosis of surgically-staged, stage C CAP will be identified. Using the records of the Tumor Registry, operative records of the Urology Service, and operative schedules, it is anticipated that patients treated over the past 10-12 years may be assessed. Patient records will be reviewed for pathology, clinical staging, surgical staging, postoperative complications, radiotherapy and portals, and complications after radiotherapy.

Progress: This is a new study.

Detail Summary Sheet

Date: 30 Sep 85 Proj No: C-25-84 Status: Complete
 Title: Body Composition Determinations on Physically Active Soldiers.

Start Date 12 Apr 84	Est Comp Date:
Principal Investigator Madeleine S. Rose, MAJ, AMSC	Facility Brooke Army Medical Center
Dept/Svc Nutrition Care Division	Associate Investigators: James H. Anderson, Jr., M.D., LTC, MC
Key Words: Army weight control program	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 557.97
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review 13 Jun 85	Results Completed

Objective(s): 1) To review and test the procedures used in the Army Weight Control program on 108 male soldiers with a possible outcome being the revision of the procedure and/or standards for evaluating obesity as defined by AR 600-9.

2) Examine metabolic adjustments during weight loss in 20 overweight and 20 overweight/obese soldiers on either an 800 Kcal mixed or 800 Kcal ketogenic diet.

Technical Approach: Volunteers underwent the following tests: Body volume measurement, residual volume measurement, alcohol dilution test, whole body liquid scintillation counting, 24-hour urine collection and x-ray of left shoulder.

One hundred thirty-five soldiers were tested in Phase I to determine the best equation for predicting percent body fat (%BF) for different ethnic and age groups. Water displacement measurement of body volume was used as the standard for testing 21 anthropometric equations selected from the literature.

Progress: When the overweight soldiers were divided by race, the Army equation correlation coefficients were 0.37, $p < 0.01$; 0.29, NS; and 0.50, $p < 0.05$ for the White, Black, and Hispanic groups, respectively. The quadratic equations produced higher correlations of 0.57, 0.55, and 0.64 for the three ethnic groups, respectively. When the subjects were divided into age groups, the Jackson and Pollock quadratic equations were overall the best predictors of %BF even though other linear equations had high correlations for the White subjects < 35 years and for the Hispanic subjects ≥ 35 years. Of the 21 equations, the best predictors of %BF were the quadratic equations of Jackson and Pollock.

C-25-84 (continued)

But, even the quadratic equations had low correlations compared to the 0.80-0.90 correlation coefficients with the original populations. Results indicated that new quadratic equations need to be derived based on this overweight population.

In Phase II, eight overweight subjects were placed on calorie restricted diets and tested five times in 23 days to determine changes in body weight, water, fat, and protein. The different dietary levels did not result in any significant interactions among the variables. There was a significant interaction ($p < 0.01$) for all variables, for body weight ($p < 0.001$), and for body fat ($p < 0.05$) between the 5 test days. When the interaction between the 5 test days and the dietary levels were examined, there was a significant interaction ($p < 0.05$) for all variables. Body water ($p < 0.01$) was the influencing variable.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-77-85 Status: Ongoing
 Title: Nitrogen Balance in Pediatric Patients Undergoing Autologous Bone Marrow Transplantation

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Elizabeth Milner, 1LT, MS	Facility Brooke Army Medical Center
Dept/Svc Directorate of Nutrition Care	Associate Investigators: Steve Thomas, MAJ, AN Terry E. Pick, M.D., LTC, MC Walter H. Harvey, M.D., MAJ, MC
Key Words: Bone Marrow Transplantation, Autologous	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine N balance in pediatric patients receiving autologous bone marrow transplantation.

2) To assess changes in body composition.

3) To correlate the above with recovery and transition from parenteral to enteral feeding.

Technical Approach: 24 hour urine collections will be obtained twice a week during hospital course to determine optimum versus negative nitrogen balance. SMAC 20 for serum albumin, BUN and creatinine will also be done.

Progress: This is a new study.

Detail Summary Sheet

Date: 3 Oct 85 Proj No: C-32-85 Status: Ongoing
 Title: Benzodiazepine Drug Monitoring Program.

Start Date 26 Feb 85	Est Comp Date:
Principal Investigator John R. Downs	Facility Brooke Army Medical Center
Dept/Svc Pharmacy Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review n/a	Results

Objective(s): To observe the use and effects of benzodiazepine anxiolytic medications in a customary use situation.

Technical Approach: The study population will consist of outpatients enrolled in participating pharmacies. Individuals in the study population will have had a prescription filled in the participating pharmacy for one of the eligible benzodiazepine anxiolytic medications.

Progress: This study has not started.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-67-84 Status: Terminated
 Title: Community Health Nurses, Boundary Spanning, and Stress.

Start Date 13 Sep 84	Est Comp Date:
Principal Investigator Mary M. Hoke, MAJ, ANC	Facility Brooke Army Medical Center
Dept/Svc Preventive Medicine	Associate Investigators:
Key Words: Community Health Nurse	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 11 Sep 85 Results Terminated	

Objective(s): To identify the relationship between the community health nurse's boundary spanning activities, role conflict, and role ambiguity.

Technical Approach: A questionnaire will be mailed to community health nurses at each MEDDAC.

Progress: The study was terminated due to transfer of principal investigator.

etail Summary Sheet

Date: 25 Jul 85 Proj No: C-53-84 Status: Completed
 Title: A Comparison of Anthropometric Formulas in Black Versus White Females.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Johanna Gabbard, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Elizabeth Canaveri, 2LT, AMSC
Key Words: Body fat	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 61	
Total Number of Subjects Enrolled to Date: 61	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To evaluate the accuracy of the Army's current method for predicting percent body fat in both black and white females.

2) To determine the most accurate existing anthropometric formula for predicting percent body fat in each of the two populations studied.

Technical Approach: Two racial populations (white n = 35, black n = 26) between 18 and 25 years of age were examined. Anthropometric measurements were taken from eight skinfold sites, five circumferences, and two diameters. Percent body fat values, determined by volumetric weighing, were used as the standard value for comparison purposes to seven existing anthropometric formulas.

Progress: From the results of the comparisons, it appears that the use of the seven popular anthropometric formulas to predict percent body fat in black women are not accurate indicators, and are accurate in only three of the formulas in white women. The Durnin and Womersley formula is questionable in its accuracy to predict percent body fat in either population, particularly since it overestimates percent body fat more than any other formula.

Detail Summary Sheet

Date: 25 Jul 85 Proj No: C-54-84 Status: Completed
 Title: Measurement of Peak Torque, Endurance, and Power After Use of Isotonic and Isokinetic Ergometers.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Carol Dabill, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Jody McGuire, 2LT, AMSC
Key Words: Ergometer, isotonic Ergometer, isokinetic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 17	
Total Number of Subjects Enrolled to Date: 17	
Date of Periodic Review	Results

Objective(s): To quantify and compare specific conditioning effects of isotonic and isokinetic bicycling programs.

Technical Approach: Subjects chosen from the Army population were randomly assigned to Monark® or Fitron® bicycles. Subjects completed a six-week training program of aerobic cycling three times per week, maintaining age-adjusted target heart rates. Subjects were tested before and after training on the Cybex II® dynamometer to assess levels of peak torque, power and endurance. Relative changes in these parameters were then analyzed for each group.

Progress: Results demonstrated that the isotonic group had greater net increases in both endurance and peak torque, measured at a speed of 180 degrees per second, than the isokinetic group. The increases, however, were not statistically significant. Net decreases in power and peak torque, measured at a speed of 60 degrees per second, were found in both groups. Although no significant differences were found in the training effects measured in this study, further study testing a larger population may enable researchers to document statistically significant changes in the test parameters.

Detail Summary Sheet

Date: 25 Jul 85 Proj No: C-55-84 Status: Completed
 Title: Validation of the Long-Sitting Test on Subjects with Iliosacral Dysfunction.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Terry Bemis, CPT, AMSC	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Monte Daniel, 2LT, AMSC
Key Words: Iliosacral dysfunction	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 51	
Total Number of Subjects Enrolled to Date: 51	
Date of Periodic Review	Results

Objective(s): Validation of the long sitting test as an indicator of abnormal mechanisms of rotation of the innominate on the sacrum.

Technical Approach: Fifty-one subjects between the ages of 18 and 37 were assigned to either an experimental group or control group through a screening procedure. The 30 subjects in the control group had even posterior superior iliac spine (PSIS) heights and negative standing and sitting flexion tests. The 21 subjects in the experimental group had uneven PSIS heights, positive standing flexion tests and negative sitting flexion tests. Measurements were taken of the change in the subjects' malleoli as they moved from a supine to a sitting position. Additional supplemental and confirmational tests were then administered.

Progress: This study suggests that the long sitting test is an accurate method of predicting iliosacral dysfunction. However, the test should be used alone, but in conjunction with other confirmational data for an accurate diagnosis.

etail Summary Sheet

Date: 25 Jul 85 Proj No: C-56-84 Status: Completed
 Title: Investigation of Possible Contributing Factors to Hamstring Flexibility.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Mary Rossi, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Barbara Wax, 2LT, AMSC
Key Words: Hamstring	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 64	
Total Number of Subjects Enrolled to Date: 64	
Date of Periodic Review	Results

Objective(s): To determine if age, sex, leg dominance and certain anthropometric measurements, Q-angle, calcaneal varus/valgus and hip flexion/extension, can be considered predictors of hamstring flexibility.

Technical Approach: Thirty males and thirty-four females participated in this study. Age, sex, leg dominance, and the following anthropometric values were measured in both limbs: calcaneal varus/valgus, Q-angle, and range of active hip flexion/extension. Passive straight leg raise was measured in both limbs to assess hamstring flexibility.

Progress: For predicting right lower limb hamstring flexibility, sex and active hip flexion were the only statistically significant test values. Only sex was determined to be significant as a predictor of hamstring flexibility in the left over limb. The results of a descriptive statistical analysis of the data were unremarkable.

Detail Summary Sheet

Date: 25 Jul 85 Proj No: C-57-84 Status: Completed
 Title: The Effect of Stretching and Submaximal Warm-ups for Isokinetic Testing.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Carol D. Ross, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Heidi A. Heckel, 2LT, AMSC
Key Words: Testing, isokinetic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 46	
Total Number of Subjects Enrolled to Date: 46	
Date of Periodic Review	Results

Objective(s): To determine whether stretching, submaximal contractions, or a combination of the two will increase mean peak torque in isokinetic testing on the Cybex II.

Technical Approach: Subjects were required to attend two test sessions: one for six maximal contractions at 60°/second and another for performance of a warm-up routine followed by six maximal contractions at 60°/second.

Progress: A T-test performed on peak torque values within each group for flexion and extension revealed a statistically significant change at $\alpha = .05$ only for the extension component of the stretching warm-up group. An analysis of variance was performed on the differences within each group for flexion and extension values. No statistically significant differences were found. The results appear to indicate that these three warm-ups do not have a clinically significant effect on peak torque values in isokinetic testing.

Detail Summary Sheet

Date: 25 Jul 85 Proj No: C-58-84 Status: Completed
 Title: Contrast Baths vs. Cold Water Immersion: A Comparison of Vasomotor Response.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Gregg A. Forlini, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Mary J. Gamba, 2LT, AMSC
Key Words: Response, vasomotor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 15	
Total Number of Subjects Enrolled to Date: 15	
Date of Periodic Review	Results

Objective(s): 1) To observe and compare vasomotor response and blood flow changes in the posterior tibial artery induced by ice water immersion or contrast bath therapy..

2) To further examine the possible occurrence of cold-induced vasodilation.

3) To compare vasomotor response in the ankle using various contrast bath therapy regimen.

Technical Approach: Blood flow changes were measured objectively during a five minute - two minute contrast bath protocol. The changes were measured within each minute of the contrast bath using the ATL Pulsed Ultrasonic Doppler/Flow Analyzer.

Progress: Significant increases in blood flow occurred as a result of each hot water immersion whereas no significant decreases occurred as a result of cold water immersion. Blood flow measurement before and after the contrast bath was not significantly different. No significant changes was seen between pretest and post-test blood flow measurements.

etail Summary Sheet

Date: 25 Jul 85 Proj No: C-59-84 Status: Completed
 Title: Systemic Levels and Systemic Effects of Ten Percent Hydrocortisone
 Induced Topically Using Phonophoresis.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Ramona C. Horton, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators:
Key Words: Phonophoresis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 25	
Total Number of Subjects Enrolled to Date: 25	
Date of Periodic Review	Results

Objective(s): 1) To determine the level of hydrocortisone that enters the systemic circulation after 10 treatments of phonophoresis with 10% hydrocortisone.

2) To determine if the phonophoretic induction of hydrocortisone show any of the presently known side effects of hydrocortisone drug therapy.

Technical Approach: Blood cortisol levels were monitored for early and cumulative changes. The 25 subjects had blood drawn initially to set individual baseline cortisol levels. The subjects were given a total of 10 phonophoresis treatments every other day throughout a 3 week period. Twelve subjects used a 10% hydrocortisone cream as a coupling medium for the ultrasound, and 13 subjects used a hydrocortisone cream lacking the steroid. Additional blood samples were drawn 1 hour following the first treatment and one day after the tenth treatment.

Progress: The results revealed an average decrease in blood cortisol levels after 1 and 10 treatments for both the control and test groups. A comparison between the test and control groups showed that none of the decreases were statistically significant. It was determined that phonophoresis using 10% hydrocortisone is a safe method for delivering an antiinflammatory to the subcutaneous tissue without the risk of the drug passing into the systemic circulation.

Detail Summary Sheet

Date: 25 Jul 85 Proj No: C-60-84 Status: Completed
 Title: Attitudes Toward the Use of Stress Management Techniques to Augment Physical Therapy.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Kathy Branton, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators:
Key Words: Stress management	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): Attempt to gather information about physical therapists' attitudes or beliefs, which may influence their willingness to adopt specific treatment approaches.

Technical Approach: Subjects were asked to complete three survey instruments: 1) Stress Management Questionnaire, 2) The Rokeach Dogmatism Scale and 3) the Bem Sex-Role Inventory.

Progress: Ninety-six of the 124 surveys mailed were returned - 40 females (75.9%) and 56 males (78.9%). A chi-square analysis revealed no statistically significant relationship between the research variables. Although the majority of therapists reported having limited experience in the use of stress management techniques, nearly 40% indicated an interest in learning more about the topic, while another 43% were supportive of the use of these methods to augment traditional treatment programs.

Detail Summary Sheet

Date: 25 Jul 85 Proj No: C-80-84 Status: Completed
 Title: Electro-Acuscope 80: Effectiveness in Treating Exercise-Induced Muscle Soreness.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Larry L. Loomis, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Bradley D. Pearson, 2LT, AMSC
Key Words: Electro-Acuscope 80	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 19	
Total Number of Subjects Enrolled to Date: 19	
Date of Periodic Review	Results

Objective(s): 1) To determine whether treatment with the Electro-Acuscope 80 can decrease functional limitations secondary to exercise-induced muscle soreness, based on Cybex II endurance tests.

2) To determine whether subjectively rated muscle soreness following exercise can be significantly decreased with Acuscope treatments.

Technical Approach: Subjects were divided into two groups. All subjects performed a Cybex II wrist extensor endurance test followed by an exercise bout designed to create muscle soreness. Over a three day period the experimental group was treated with the Electro-Acuscope 80 while the other group received placebo treatments. The subjects completed subjective pain rating scales at 24 hour intervals. Following the final treatment, all subjects repeated the Cybex II endurance test. Comparisons were made between the groups for subjective pain ratings and also for mean percent change in peak torque values and number of repetitions completed during the Cybex II endurance tests.

Progress: Statistical significance was shown for the 24 hour and 48 hour pain ratings which possibly support the use of the Electro-Acuscope for management of pain disorders. No statistical significance could be shown for the 72 hour pain rating or for either of the objective measurements.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-64-85 Status: Ongoing
 Title: A Correlation Study Between Abdominal and Hip Flexor Muscle Strength and the Ability to do Push-Up and Sit-Up exercises

Start Date 10 Sep 85	Est Comp Date:
Principal Investigator William Bowler, CPT, AMS	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Jennifer Finley, 2LT, AMS Margaret Meadows, 2LT, AMS Robin Thompson, 2LT, AMS
Key Words: Muscle, abdominal Muscle, flexor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine possible statistical correlations between an individual's maximum abdominal muscle strength, hip flexor muscle strength, number of regulation Army push-ups accomplished, number of regulation Army sit-ups and number of curl-ups performed.

Technical Approach: Sixty to seventy-five subjects will be enlisted for this study. The five factors under consideration are 1) number of regulation Army push-ups accomplished in two minutes, 2) number of regulation Army sit-ups accomplished in two minutes, 3) number of curl-ups accomplished in two minutes, 4) abdominal muscle strength, and 5) hip flexor muscle strength. Each of the five factors will be tested on four separate days no less than 72 hours apart. The measurement of the hip flexor msucle strength and abdominal muscle strength will be tested on the same day.

Progress: This is a new study.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-65-85 Status: Ongoing
 Title: Alteration of Maximum Quadriceps Muscle Torque Post Anterior Cruciate Ligament Injury Using the Lenox Hill Brace

Start Date 10 Sep 85	Est Comp Date:
Principal Investigator John W. Brautigam, 2LT, AMS	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Gerald J. Dybel, 2LT, AMS Mark D. King, 2LT, AMS Bruce R. wills, 2LT, AMS
Key Words: Injury, anterior cruciate ligament	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the differences between a knee with anterior cruciate ligament laxity with and without a Lenox Hill derotation brace using the uninjured leg as a control.

Technical Approach: Subjects will consist of 20 volunteer military personnel who are at least one year post-anterior cruciate ligament repair or injury. Subjects must have a Lenox Hill derotation knee brace and a history of unilateral anterior cruciate ligament injury with a present laxity of at least 5 mm., as measured by the Lachman's strain gauge device. A manual evaluation of the subject's knee joints will be conducted. The subject will continue on to the next phase of the study which includes the positioning and familiarization to the KIN-COM. The uninjured leg, the injured leg without a brace, and the injured leg in a Lenox Hill derotation brace will be tested in random order. The subjects will then perform five sets of three repetitions. The first two sets will be submaximal for the purpose of familiarization to the KIN-COM. Three maximal contractions will then be performed in each of three conditions selected randomly.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-66-85 Status: Ongoing
 Title: Q-Angle Differences: A Factor in Peak Torque Occurrence in Isokinetic Knee Extension Range of Motion

Start Date 10 Sep 85	Est Comp Date:
Principal Investigator Leanne K. Lyon, 2LT, AMS	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Laurence N. Benz, 2LT, AMS Kevin K. Johnson, 2LT, AMS Agnes C. Ling, 2LT, AMS
Key Words: Q-angle differences	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To investigate the effect of quadriceps-angle (Q-angle) on isokinetic peak torque occurrence within knee extension range of motion.

Technical Approach: Tests of straightening the knee utilizing knee flexion/extension Cybex II exercise device will be done to measure strength. The Cybex II will only provide resistance to movement if the person exercising maintains the proper speed. Five submaximal repetitions of knee extension/flexion will be performed before actual testing begins. After the practice session, there will be a one-minute rest, followed by the actual testing session. A three minute rest period will be given before the next session for a different testing speed. Torque values for the testing speeds of 30, 60, 180 degrees/second will be calculated by the Cybex computer.

Progress: This is a new study.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-67-85 Status: Ongoing
 Title: Gravity Inversion: Effect on Common Carotid Artery Blood Flow

Start Date 10 Sep 85	Est Comp Date:
Principal Investigator T. Scott VanDenHengel, 2LT, AMS	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Scott Underwood, 2LT, AMS Vern Essenberg, 2LT, AMS Dorian Deverill, 2LT, AMS
Key Words: Gravity inversion	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the effect of a fully inverted position (head ninety degrees below horizontal with the body suspended by the ankles) on common carotid artery blood flow (ml/sec).

Technical Approach: For each subject four measurements will be taken. The measurements include common carotid artery blood flow, brachial artery blood pressure, heart rate, and intraocular pressure. Each participant will be involved in all three of the following procedures. Each procedure will consist of a particular inversion period; including zero minutes of inversion (0), two minutes of inversion (2), and four minutes of inversion (4). For each procedure the subject will have his ankles fastened by inversion boots to the base of a Gravity Guidance System. Group 0 will be placed in a horizontal position in the Gravity Guidance System and the above measurements taken after three minutes of zero inversion. For the (2) group, the subject will be attached to the Gravity Guidance System and inverted slowly so that the complete inversion will take 60 seconds. Measurements will be taken following two minutes of complete inversion. The (4) group will also be attached and lowered in the same manner as the (2) group. The four measurements will be taken after four minutes of complete inversion.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-17-85 Status: Ongoing
 Title: A Comparison of the Effects of Thiopental and Etomidate on the Cardiovascular System in ASA I Category Patients During the Induction of General Anesthesia.

Start Date 21 Jan 85	Est Comp Date:
Principal Investigator Debra K. Baggott, CPT, ANC	Facility Darnall Army Community Hospital
Dept/Svc School of Anesthesiology Nursing	Associate Investigators: Myron D. Sanders, CPT, ANC Martha J. Skipper, CPT, ANC
Key Words: Cardiovascular System Thiopental Etomidate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To compare the effects of Thiopental and Etomidate on heart rate and blood pressure during induction of general anesthesia.

Technical Approach: Participants will be randomly assigned to receive either Etomidate or Thiopental as an induction agent. A single dose will be used to induce general anesthesia. Blood pressure and heart rate monitoring equipment will be used during the entire testing procedure.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: C-33-85 Status: Completed
 Title: Transconjunctival Oxygen Monitoring During Helicopter Transport.

Start Date 26 Feb 85	Est Comp Date:
Principal Investigator Bernard A. Susavage, D.O., MAJ, MC	Facility Darnall Army Community Hospital
Dept/Svc Department of Emergency Medicine	Associate Investigators: Thomas M. Stein, M.D., CPT, MC
Key Words: Monitoring, oxygen	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine that transconjunctival oxygen tension $P_{c_jO_2}$ when measured by the Orange I Eyelid O_2 Monitoring System is independent of altitude to 5000 feet during helicopter transport.

Technical Approach: The Orange I Eyelid Oxygen Monitoring System was used to measure $P_{c_jO_2}$ at the right upper eyelid against the palpebral conjunctiva. $P_{c_jO_2}$ was recorded every 5 minutes for at least 30 minutes prior to loading the subject into the helicopter and readings recorded every 5 minutes while in the helicopter. Concomitant altitude, ambient temperature, and conjunctival temperature were recorded with each reading. The data generated was analyzed using a Repeated Measurements Design model.

Progress: The principal investigators reported that there was no difference between baseline measurements and those taken at 3,000 feet. However, an unexplained finding was that when they returned to the ground baseline readings did not return to normal.

Detail Summary Sheet

Date: 27 Sep 85 Proj No: C-39-85 Status: Ongoing
 Title: A Comparison of Traditional Suturing Versus Skin Stapling for the Primary Closure of Lacerations in an Outpatient Population.

Start Date 29 Apr 85	Est Comp Date:
Principal Investigator Joseph A. Wilkinson, M.D., CPT, MC	Facility Darnall Army Community Hospital
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words: Laceration, closure	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 39	
Total Number of Subjects Enrolled to Date: 39	
Date of Periodic Review n/a	Results

Objective(s): To compare and contrast traditional suturing and skin stapling concerning time for closure, infection rates, cosmesis, and patients acceptance in the outpatient setting.

Technical Approach: Wound closure will be determined by a random table assigning the patient into the suture or staple group. After the coapting materials have been removed, i.e. 12 weeks after injury, the wounds will be photographed. The photographs will then be assigned to groups according to cosmetic results without those viewing the photographs knowing which wounds had been sutured and which had been stapled.

Progress: We have had a greater than anticipated wound infection rate which we attribute to inadequate wound preparation by some of the corpsmen. This problem seems to be resolved. There have been only minor wound infections as complications. The follow-up and statistical analysis remains to be done once the fiftieth wound is closed.

Detail Summary Sheet

Date: 10 Oct 85 Proj No: C-48-85 Status: Ongoing
 Title: Treatment of Mammalian Bites.

Start Date 10 Jun 85	Est Comp Date:
Principal Investigator Daniel J. Dire, M.D., CPT, MC	Facility Darnall Army Community Hospital
Dept/Svc Department of Emergency Medicine	Associate Investigators: Steve Walker, D.O., MAJ, MC
Key Words: Bite, mammalian	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 69	
Total Number of Subjects Enrolled to Date: 69	
Date of Periodic Review n/a	Results

Objective(s): 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 bits 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: Sixty-nine patients have been randomized into treatment groups with an infection rate of 5.8%. This is lower than expected.

Detail Summary Sheet

Date: 25 Sep 85 Proj No: C-65-83 Status: Ongoing
 Title: Perinatal Hyperviscosity.

Start Date 10 Aug 83	Est Comp Date:
Principal Investigator (Gierbolini) Richard H. Meidell, M.D., MAJ, MC	Facility Darnall Army Hospital
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Hyperviscosity	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review 11 Sep 85	Results Continue

Objective(s): To test the hypothesis that maternal and neonatal blood viscosities are correlated.

Technical Approach: Blood viscosity is done using an LVT-microviscometer.

Progress: The previous investigator, MAJ Jose I. Gierbolini, is no longer in the Army. The study has been taken over by MAJ Meidell but no data are available at this time.

Detail Summary Sheet

Date: 22 Oct 85 Proj No: C-30-84 Status: Completed
 Title: The Relationship of Emotional Stress to Plasma Cortisol Levels in Patients Undergoing Surgical Removal of Third Molars.

Start Date 17 Apr 84	Est Comp Date:
Principal Investigator Richard L. Parsons, D.D., MAJ, DC	Facility Darnall Army Community Hospital
Dept/Svc Dental Clinic #6	Associate Investigators: Durwood E. Bach, D.D., MAJ, DC Theodore H. Heid, D.D., COL, DC Walter F. Rigdon, D.D., COL, DC
Key Words: Cortisol levels	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 29	
Total Number of Subjects Enrolled to Date: 29	
Date of Periodic Review	Results

Objective(s): To attempt to quantify emotional anxiety in dental patients undergoing surgical removal of impacted maxillary and mandibular third molars and to determine its relationship to plasma cortisol levels.

Technical Approach: Patients who are treatment planned for the elective removal of two homolateral, impacted third molars and who agree to participate in the study serve as subjects. Serum cortisol is assayed at three different times: 24 hours pre-op (baseline), immediately pre-op and 15 minutes post-op. At these three times the State-Trait Anxiety Inventory (Y-1) is also administered to quantify emotional anxiety which will be correlated with serum cortisol values to determine if there is a relationship.

Progress: The protocol has been completed; however, no reportable data is available.

Detail Summary Sheet

Date: 26 Sep 85 Proj No: C-33-84 Status: Completed
 Title: A Comparison of Patient Preference for Pulp Testers.

Start Date 10 May 84	Est Comp Date:
Principal Investigator Karl K. Harris, D.D., MAJ, DC	Facility Darnall Army Hospital
Dept/Svc Department of Dentistry/Clinic #6	Associate Investigators: W. Richard Liggett, D.D., LTC, DC George P. Barnes, D.D., COL, DC Theodore H. Heid, D.D., COL, DC Walter F. Rigdon, D.D., COL, DC
Key Words: Pulp tester Caries	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): To compare the Digital Automatic Pulp tester and the Dentotest Pulp tester for patient preference.

Technical Approach: The subjects were tested on paired teeth with both instruments (2 readings each instrument, for a total of 4 readings). The order of instrument use was on an alternating basis. The subjects were asked to indicate when a sensation was felt, and the instrument was removed and the reading recorded. After recording of the 4 readings, the subjects were asked if they had any subjective preference for either instrument.

Progress: Nineteen of twenty subjects tested expressed a subjective preference for the Digital Automatic Pulp tester.

Detail Summary Sheet

Date: 22 Aug 85 Proj No: C-13-85 Status: Ongoing
 Title: Comparison of Two Instructional Methods on Blood Cortisol Levels in the Educational Setting.

Start Date 15 Jan 85	Est Comp Date:
Principal Investigator Cecil B. Drain, MAJ, MS	Facility Texas A&M University
Dept/Svc	Associate Investigators:
Key Words: Cortisol	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine whether a systematic or non-systematic instructional strategy has an impact on blood cortisol levels in students in the post-secondary higher education setting.

Technical Approach: Students in an undergraduate course will be divided into two groups. Control measurements of blood cortisol, pulse and blood pressure will be taken. One group (experimental) will be taught how to write a behavioral objective by a professor using a non-systematic instructional strategy, and the other group (control) will be taught by the same professor on how to write a behavioral objective using a systematic instructional strategy. A test will be given at the conclusion of the instruction, and post-treatment measurements will be taken of blood cortisol, pulse and blood pressure.

Progress: No reportable data are available at this time.

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