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DEPARTMENT OF CLINICAL INVESTIGATION

ANNUAL RESEARCH PROGRESS REPORT

FISCAL YEAR 1989
VOLUME I

BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234

AD-A219 891



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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 1988. Report also includes known presentations and publications by the Brooke Army Medical Center staff. The research protocols described were (continued on reverse side) <i>Keywords:</i>		

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.

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FOREWORD

The Department of Clinical Investigation at Brooke Army Medical Center has completed another outstanding year. The number of protocols as well as general quality of work continues to improve. This work could not be accomplished without the continued support from the BAMC Commander, BG William L. Moore, Jr., and the DCCS, COL Daniel Rosenthal and COL Larry L. Morgenstern, as well as from respective department chiefs and program directors. Finally, a great deal of thanks needs to go to the staff of DCI which continues to turn out an exceptional product in terms of facilitating investigational activities and administrative oversight for the research efforts within BAMC.

We welcome the addition this year of Dr. Jean Johnson, clinical nurse researcher, who has joined us from the University of Texas Health Science Center School of Nursing. Dr. Johnson has already made a significant impact upon nursing research in BAMC and has gained a wide, favorable reputation throughout clinical and nursing departments.

LTC Bob Whiddon continues to provide new direction and increased support for the bone marrow rescue program as well as maintaining a number of clinical and basic microbiology protocols.

Our physiologist, Dr. John Ward, has made a significant impact on a number of studies within the animal facility and has been principally responsible for several projects making successful completion.

The past year, DCI brought several guest speakers to BAMC to speak for the professional staff of the hospital at large and this was well received and will be continued in the future.

For a long time we have fought for a new animal facility, and now it appears that this will come to fruition in FY 90. This represents the fruit of the labors of many of the people over several years.

We continue to face the same clouds on the horizon concerning budgetary and personnel constraints and some belt tightening for the future will certainly be a reality. A critical shortage of professional and support personnel exists at all levels and Department of Clinical Investigation is no exception. I believe that some innovative and creative measures may provide a minor degree of relief; however, we will strive to increase our efficiency with continued support for BAMC researchers. We will also enhance our efforts to seek extramural funding from approved federal funding agencies and military granting institutions. We are beginning to open the doors more to U.S. Army Medical Research and Development Command as well as the Henry M. Jackson Foundation.

I wish to congratulate all the members of the Department of Clinical Investigation who have provided excellent service over the past year as well as to the professional staff of BAMC who have worked long and hard hours on the research efforts and clinical projects.

I am looking forward to 1990 being even more successful as BAMC continues to assume a leading role as a major research institute of excellence in the San Antonio Biotech Community as well as in the military medical community at large.

A handwritten signature in black ink, appearing to read "RD Latham", with a stylized flourish at the end.

RICKY D. LATHAM

Major, MC

Chief, Department of Clinical Investigation

UNIT SUMMARY - FISCAL YEAR 1989

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>
Latham, Ricky D.	MAJ	61F	Chief, Cardiologist
Peace, Theopolis	COL	64B	Veterinary Lab Animal Officer
Whiddon, Robert G., Jr.	LTC	68A	Microbiologist
Danley, David L.	MAJ	68E	Immunologist
Diaz, Noel	SSG	92B3R	NCOIC
Hinds, Johnny W.	SSG	92B3	Med Lab Specialist
Jones, Sheila	SSG	92B3	Med Lab Specialist
Farooqui, Muhammed	SSG	92B2	Med Lab Specialist
Duncan, Rory D.	SGT	92B2	Med Lab Specialist
Gaines, Marlene	SGT	91T2	Animal Care Specialist
Park, Chung	SGT	91T2	Animal Care Specialist

C. Staffing (continued)

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Elysee, Victor**	SGT	92B2	Med Lab Specialist
Merrill, Gerald A.	GS11	00401	Research Immunologist
Ayala, Eleanor	GS11	00644	Medical Technologist
Grassel, Janice	GS11	00404	Biological Laboratory Technician
Ward, John A.*	GS13	00401	Research Physiologist
Johnson, Jean A.*	GS12	00610	Research Nurse
Reeb, Barbara	GS9	00644	Medical Technologist
Chapa, Isidoro	GS7	00645	Medical Technician
Williams, Dannie*	GS7	00404	Biological Laboratory 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 Aug 88; 28 Aug 89; 8 May 89

** Reassigned 10 Sep 89

D. Funding

<u>Type</u>	<u>Fiscal Year 88</u>	<u>Fiscal Year 89</u>
Civilian personnel to include benefits	Not Available	257,615.00 *
Consumable supplies	111,415.00	128,200.00
Civilian contracts to include consultants	10,200.00	13,291.00
TDY	2,690.00	
Publications	13,392.00	(N/A IMO Budget)
Noninvestment equipment (Minor MEDCASE)	-----	-----
Other OMA		
OMA Total	137,697.00	399,106.00
MEDCASE	172,600.00	95,000.00
Other		
Military	Not Available	680,215.00 *
TOTAL	310,297.00	1,174,321.00

*These figures are estimates based on a total of \$937,830.00 reported by the Resource Management Division. We have been unable to obtain a breakdown of civilian/military pay.

Protocol Disposition FY 89

	<u>Terminated</u>	<u>Transferred</u>	<u>Completed</u>	<u>Ongoing to FY 90</u>
FY 77	-		0	1
FY 78	0		0	1
FY 82	0		1	0
FY 83	1		0	1
FY 84	1		1	1
FY 85	1		0	3
FY 86	3		5	8
FY 87	11		10	23
FY 88	16		29	38
FY 89	<u>7</u>		<u>17</u>	<u>118</u>
	40		63	194

Training Protocols

	<u>Terminated</u>	<u>Completed</u>	<u>Ongoing to FY 90</u>
FY 82	2	0	0
FY 85	0	0	1
FY 86	3	0	6
FY 87	0	1	6
FY 88	0	0	1
FY 89	<u>0</u>	<u>0</u>	<u>3</u>
	5	1	17

Group Protocol Disposition FY 89

	<u>Terminated</u>	<u>Completed</u>	<u>Ongoing to FY 90</u>
SWOG	0	23	99
POG	<u>0</u>	<u>1</u>	<u>63</u>
	0	24	162

1989 COMMANDER'S AWARD WINNERS

First Place

Hemodynamic Consequences of Anesthetic Induction
with Etomidate in Hypovolemic Swine

Kevin W. Olson
Captain, MC
Anesthesia and Operative Service
Department of Surgery

Second Place

Colonic Lavage Solution (Colyte®) as a Treatment for
Chronic Constipation: A Double-Blind, Placebo Controlled Study

Richard I. Andorsky
Captain, MC
Gastroenterology Service
Department of Medicine

Third Place

Pulmonary Arterial Compliance at Rest and Exercise in Normal Man:
Application of the Three-Element Windkessel Model

David M. Slife
Captain, MC
Cardiology Service
Department of Medicine

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Brooke Army Medical Center
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DEPARTMENT OF CLINICAL INVESTIGATION

PRESENTATIONS

DEPARTMENT OF CLINICAL INVESTIGATION

- Arrington, M.E., Byers, V.L. Predictive Risk Factors Associated with Stroke Patient Falls in Acute Care Settings. World Federation of Neuroscience Nurses, Anaheim, CA, September 1989. (C)
- Butler, B. Gravitational Hemodynamics. APS/ASPET Joint Meeting, Montreal, Quebec, Canada, 9-13 October 1988. (C)
- Butler, B. Computer Analysis of Arterial Pressure Waves Recorded with Multisensor Macromanometry. Computers in Science and Teaching, Beaumont, TX, 4 March 1989. (C)
- Danley, D.L. Use of Fluorescein-5-Maleimide and Flow Cytometry to Study Sulfhydryl Groups on Candida albicans. Society of Armed Forces Laboratory Scientists, San Antonio, TX, April 1989. (C)
- Danley, D.L., Hinds, J., Grassel, J., Merrill, G. Use of Fluorescein-5-Maleimide and Flow Cytometry to Study Sulfhydryl Groups on Candida albicans. American Society of Microbiology, New Orleans, LA, 14-18 May 1989. (C)
- Johnson, J.M. Reliability of Instruments to Measure Stress in Mothers and Temperament and Behavior in 4-5 Year Olds. Translating Research Data into Clinical Applications, San Antonio, TX, 22 September 1989. (C)
- Johnson, J.M. Reliability of Instruments to Measure Stress in Mothers and Temperament and Behavior in 4-5 Year Olds. National Nursing Research Conference, Chicago, IL, 27-30 September 1989. (C)
- Latham, R.D. Gravitational Physiology III. APS/ASPET Joint Meeting, Montreal, Quebec, Canada, 9-13 October 1988. (C)
- Latham, R.D. Effects of Gravity on Central Circulatory Dynamics in the Baboon. Society of Air Force Physicians, Bethesda, MD, 2-5 March 1989 (C)
- Latham, R.D. Visiting Professor, Wenner-Gren Research Laboratory, Lexington, KY, 28 April 1989. (C)
- Merrill, G.A. Looking for Rhodanese Epitopes. Department of Biochemistry Faculty Research Seminar, University of Texas Health Science Center, San Antonio, TX, 19 September 1989. (C)

Ward, J.A. Chairman "Section IV Computers in Science and Teaching, Session I."
Beaumont, TX, 4 March 1989.

Ward, J.A. Designing an Analog Computer to Extract Heart Rate from Arterial Pressure Waves. Computers in Science and Teaching, Beaumont, TX, 4 March 1989.

Ward, J.A. Fitting a 3-Element Windkessel Model to the Systemic Arterial Tree: Analysis of Algorithms Using Digital, Analog, and in vivo Models. Computers in Science and Teaching, Beaumont, TX, 4 March 1989. (C)

DEPARTMENT OF EMERGENCY MEDICINE

Chisholm, C.D. Anesthetics. American College of Emergency Physicians Wound Care (ACEP) Course. San Antonio, TX, April 1989.

Chisholm, C.D. Skills Lab III: Layered Closure, Regional Anesthesia. ACEP Course, San Antonio, TX, April 1989.

Chisholm, C.D. Emphysematous Pyelonephritis. Grand Rounds, Portland VA Hospital, Portland, OR, April 1989.

Chisholm, C.D. Right Sided Boerhaave's Syndrome. Grand Rounds, Portland, VA Hospital, Portland, OR, April 1989.

Chisholm, C.D. Sacred Cows in Emergency Medicine. 1st Annual Controversies in Emergency Medicine Meeting, University of Texas Southwest Medical Center, Dallas TX, 9 May 1989.

Chisholm, C.D. EMS Controversies. 1st Annual Controversies in Emergency Medicine Meeting, University of Texas Southwest Medical Center, Dallas, TX, 9 May 1989.

Chisholm, C.D. Inhaled Sodium Bicarbonate in the Treatment of Chlorine Inhalation Injury. Society for Academic Emergency Medicine, San Diego, CA, May 1989.

Chisholm, C.D. Panel Moderator: Airway Control and Intraosseous Infusion in the Field. National Association of EMS Physicians, San Francisco, CA, June 1989.

Chisholm, C.D. Panel Moderator: Lidocaine, Bronchodilators and High Dose Epi in the Field. National Association of EMS Physicians, San Francisco, CA, June 1989.

Chisholm, C.D. Consensus Document Panel: A National EMS Physician Disaster Network. National Association of EMS Physicians, San Francisco, CA, June 1989.

Coleridge, S.T. Dealing with Consultants. 13th Annual Ambulatory Patient Care Conference, Willingen, West Germany, 18 October 1988.

Coleridge, S.T. Management of the Difficult Patient. 13th Annual Ambulatory Patient Care Conference, Willingen, West Germany, 17 October 1988.

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Coleridge, S.T. Emergency Department Administration. TriService Symposium in Emergency Medicine, San Antonio, TX, March 1989.

Coleridge, S.T. Consultant's Corner. TriService Symposium in Emergency Medicine, San Antonio, TX, March 1989.

Coleridge, S.T. Moderator "Abstract Presentations. TriService Symposium in Emergency Medicine, San Antonio, TX, March 1989.

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Norris, R.N. Recent Innovations in the management of Snake Envenomation. Greater San Antonio Histopathologic Society, San Antonio, TX, December 1988. (C)

Norris, R.N. Emergency Medicine Board Review Course. TriService Symposium in Emergency Medicine, San Antonio, TX, March 1989.

Rodgers, K.G. Paramedic Training: How Far and at What Cost? Emergency Medicine Grand Rounds, San Antonio, TX, January 1989.

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Simmons, J.R. Perceptions of Resident and Staff Physicians in Clinical Teaching. Present Concepts in Internal Medicine 4th Annual American College of Physicians Army Regional Meeting, San Francisco, CA, October 1988.

Simmons, J.R. Perspectives on Medical Education. Department of Medicine and Emergency Medicine Conference, Darnall Army Community Hospital, Fort Hood, TX, 10 November 1988.

Allergy and Immunology Service

Dyer, P.D. Methotrexate in the Treatment of Steroid Dependent Asthma. Aspen Allergy Conference, Aspen, CO, July 1989

Cardiology Service

Bailey, S.T. High-Fidelity Rest and Exercise Hemodynamic Effect of Beta-Blockade in Mitral Stenosis. International Symposium on Heart Failure - Mechanisms and Management, Jerusalem, Israel, 21 May 1989. (C)

Johns, J.P. Color Doppler Can Demonstrate Spontaneous Resolution of Femoral Pseudoaneurysms. International Symposium, Mayo Clinic, Rochester, Minnesota, 19 September 1989. (C)

Johns, J.P. Color Flow Doppler and Valvular Heart Disease. 4th Bi-Annual Cardiovascular Technologists Conference, El Paso, TX, September 1989. (C)

Johns, J.P. Exercise Echo. 4th Bi-Annual Cardiovascular Technologists Conference, El Paso, TX, September 1989.

Moody, J.M. Isovolumic Contraction Vanishes in Severe Exercise. JACC, February 1989. (C)

Moody, J.M. Left Ventricular Isovolumic Contraction Vanishes During Intense Severe Exercise. 38th Annual Scientific Sessions, American College of Cardiology, Anaheim, CA, March 1989. (C)

Dermatology Service

Angeloni, V.L. Frontalis-Associated Lipoma of the Forehead. American Academy of Dermatology Annual Meeting, Washington, DC, 9 December 1988.

Finder, K.A. Cutaneous Manifestation of Sweat Gland Necrosis. American Academy of Dermatology Annual Meeting, Washington, DC, 3 December 1988.

Finder, K.A. Excision of Mucocoele. American Academy of Dermatology Annual Meeting, Washington, DC, 4 December 1988.

Grabski, W.J. Razor Blade Excision of Mohs Specimens. American College of Mohs Micrographic Surgery of Cutaneous Oncology, 7 March 1989.

Heller, J.J. Granular Cell Tumor. American Academy of Dermatology Annual Meeting, Washington, DC, 4 December 1988.

Keeling, J.H. Tropical Dermatology. Global Medicine Course, School of Aerospace Medicine, Brooks Air Force Base, San Antonio, TX, 7 February 1989.

Keeling, J.H. Dermatology in a Combat Environment. Texas National Guard, Corpus Christi, TX, 24 February 1989.

Low, G.J. Radiation Induced Pemphigus. Texas Dermatology Association Meeting, Fort Worth, TX, 13 May 1989.

McCollough, M.L. Reticular Erythematous Syndrome. American Academy of Dermatology Annual Meeting, Washington, DC, 1 December 1988.

McCollough, M.L. Pseudocyst of the Auricle. American Academy of Dermatology Annual Meeting, Washington, DC, 1 December 1988.

Salasche, S.J. Prevention of Complications Near Free Margins. Southern Medical Association, New Orleans, LA, 10 November 1988.

Salasche, S.J. Aesthetic Consideration and Scar Camouflage. American Academy of Dermatology Annual Meeting, Washington, DC, 3 December 1988.

Salasche, S.J. Surgical Anatomy/Basic Surgery Course. American Academy of Dermatology Annual Meeting, Washington, DC, 3 December 1988.

Salasche, S.J. Intermediate Surgery Course Director. American Academy of Dermatology Annual Meeting, Washington, DC, 3-4 December 1988.

Salasche, S.J. Complications Seminar - Moderator. American Academy of Dermatology Annual Meeting, Washington, DC, 4 December 1988.

Salasche, S.J. Nail Surgery Seminar. American Academy of Dermatology Annual Meeting, Washington, DC, 5 December 1988.

Salasche, S.J. Management of Squamous Cell Carcinoma. American Academy of Dermatology Annual Meeting, Washington, DC, 6 December 1988.

Salasche, S.J. Surgical Pearls. American Academy of Dermatology Annual Meeting, Washington, DC, 7 December 1988.

Endocrinology Service

Newman, F. Rheology: Applications to Small Vessel Disease. Air Force Endocrine Society Meeting, San Antonio, TX, October 1988.

Newman, F. Pseudopheochromocytoma. University of Texas Health Science Center at San Antonio, January 1989.

Thomason, A. Polycystic Ovarian Disease. Wilford Hall Endocrine Society Meeting, San Antonio, TX, June 1989.

General Medicine Service

Berry, M. Quality Assurance in Ambulatory Care. Present Concepts in Internal Medicine - ACP, San Francisco, CA, 21 October 1988.

Omori, D. Pending Laboratory Tests in Discharged Patients. Present Concepts in Internal Medicine - ACP, San Francisco, CA, 21 October 1988.

Hematology-Oncology Service

Burris, H.A. Thrombotic Thrombocytopenic Purpura. Present Concepts in Internal Medicine - ACP, San Francisco, CA, October 1988.

Foulke, R.S. Autologous Bone Marrow Transplant Program at BAMC. Present Concepts in Internal Medicine - ACP, San Francisco, CA, October 1988. (C)

Nash, M.E. Gamma Interferon, a Phase I Trial. Recent Concepts in Internal Medicine - ACP, San Francisco, CA, October 1988. (C)

O'Rourke, T.J. Phase I Clinical Trial of Difluorodeoxycytidine (LY188011) Given as an Intravenous Bolus. NCI European Organization for Research and Treatment of Cancer, Amsterdam, The Netherlands, March 1989. (C)

Yoder, L. Expectations and Experience Evaluation of Oncology Patients Participating in Phase I Clinical Trials. NCI European Organization for Research and Treatment of Cancer, Amsterdam, The Netherlands, March 1989.

Zaloznik, A.J. Chemotherapy and Colorectal Cancer Quality Assurance Review. Texas Tumor Registrars Association Meeting, San Antonio, TX, October 1988.

Infectious Disease Service

Dooley, D.P., McAllister, C.K., et al. Urinary Tract Infection Due to *Hansenula*. American Society of Microbiology, New Orleans, LA, May 1989.

Dooley, D.P. *Hansenula fabiani* Prostatitis. American Society of Microbiology, New Orleans, LA, May 1989.

Longfield, R. Nosocomial Bacteremia. American College of Physicians - Army Chapter, San Francisco, CA, October 1988.

Smith, C.E. Ceftazidime Resistance Among *Pseudomonas* Isolates. American Society of Microbiology, New Orleans, LA, May 1989.

Smith, C.E. Ceftazidime Resistant Gram Negative Bacilli. American Society of Microbiology, New Orleans, LA, May 1989.

Nephrology Service

Gouge, S.F. Removal of Radiocontrast Agents by Dialysis Membranes. National Kidney Foundation/American Society of Nephrology, San Antonio, TX, December 1988.

Gouge, S.F. Diabetic Nephropathy. Regional Day in Medicine, Dwight David Eisenhower Army Medical Center, Augusta, GA, 17 March 1989.

Koenig, K. Utility of Free 1,25(OH)₂D₃ Measurements in Renal Failure. American Federation for Clinical Research, Washington, DC, May 1989.

Neurology Service

Gordon, W. Neurocardiology. Grand Rounds, University of Texas Health Science Center at San Antonio, 21 September 1989.

Halliday, A.W. The Management of Chronic Cephalgia. Texas Association of Physician Assistants Annual Meeting, San Antonio, TX, 7 October 1988.

Halliday, A.W. Clinical Considerations in Motor Neuron Disease. Grand Rounds, University of Texas Health Science Center at San Antonio, 15 December 1988.

Pulmonary Disease Service

Anders, G.T. Tuberculosis in Patients with HIV Infection: Unusual Clinical Aspects. 54th Annual Scientific Assembly of the American College of Chest Physicians, Anaheim, California, 4 October 1988. (C)

Anders, G.T. Drug Resistance in Patients with HIV Infection and Tuberculosis. Present Concepts in Internal Medicine/ 5th Annual ACP Army Regional Meeting, San Francisco, CA, 20 October 1988. (C)

Anders, Pulmonary Monokine Production in HIV-Infected Patients. American Thoracic Society, May 1989. (C)

Anders, G.T. Cytokine Elaboration by Alveolar Macrophages in HIV Infection. American Thoracic Society, May 1989. (C)

Johnson, J.E. Post-bronchodilator Response to Isoproterenol in COPD. Present Concepts in Internal Medicine/5th Annual ACP Army Regional Meeting, San Francisco, CA, 20 October 1988. (C)

Johnson, J.E. Demonstration of Reversal of Density Dependence in Washouts of Helium and Sulfur Hexafluoride in Dog Lungs. Present Concepts in Internal Medicine/5th Annual ACP Army Regional Meeting, San Francisco, California, 20 October 1988.

Peacock, M.E. Acute Post-bronchodilator Testing in COPD Patients. American Thoracic Society, May 1989. (C)

Peacock, M.E. Acute Post-bronchodilator Response in Stable COPD Patients. American Thoracic Society, May 1989. (C)

Walton, B.F. Predictive Value of Preoperative Spirometry in Thoracotomy Patients. Present Concepts in Internal Medicine/5th Annual ACP Army Regional Meeting, San Francisco, CA, 20 October 1988. (C)

DEPARTMENT OF NURSING

Anderson, F. MEGA-Code. Advanced Cardiac Life Support, Audie Morphy VA Hospital, San Antonio, TX, October 1988

Anderson, F. Publishing. Joint Military Medical Command (JMMC) Nursing Research Conference, San Antonio, TX, November 1988.

Anderson, F. The Significance of the Relationship of Total Blood Cholesterol to High Density Lipoprotein. JMMC Nursing Research Conference, San Antonio, TX, November 1988.

Callich, M.A. Supporting the Child with Cancer Who Must Undergo Frequent Intensive Procedures. Nurse Committee of the Pediatric Oncology Group, St. Louis, MO, October 1988.

Callich, M.A. Formulating the Research Queston/Hypothesis. 4th Annual Research Conference, Wilford Hall USAF Medical Center, Lackland AFB, TX, November 1988.

Dolter, K. Reliability and Validity of Pulmonary Artery Catheter Measurements. 4th Annual Research Conference, Wilford Hall USAF Medical Center, Lackland AFB, TX, October 1988.

Dolter, K. Advanced Hemodynamic Trouble Shooting. American Association Critical Nursing, Dallas, TX, November 1988.

Wehner, R. Perioperative Management of Hypertension. American Association of Nurse Anesthetists, Green Belt, MD, November 1988.

Wehner, R. Brevibloc in Clinical Practice. American Association of Nurse Anesthetists, Green Belt, MD, November 1988.

Wilson, L. Problem Identification. 4th Annual Research Conference, Wilford Hall USAF Medical Center, Lackland AFB, TX, November 1988.

Yoder, L. Abstract Review. 4th Annual Research Conference, Wilford Hall USAF Medical Center, Lackland AFB, TX, November 1988.

Yoder, L. Innovations in Oncology Nursing. Medical Surgical Conference, 7th MEDCOM, Europe, May 1989.

Yoder, L. Expectaions and Experiences of Phase I Trial Patients. Medical Surgical Convergence, 7th MEDCOM, May 1989.

Yoder, L. Monitoring to Promote Nursing. Association of Pediatric Oncology Nurses, June 1989.

Yoder, L. Autologous Bone Marrow Rescue. Methodist Hospital Bone Marrow Transplant Course, San Antonio, TX, June 1989.

Yoder, L. Biology of Cancer. Methodist Hospital Bone Marrow Transplant Course, San Antonio, TX, June 1989.

Yoder, L. Role of the Clinical Nurse Specialist. Incarnate Word College, San Antonio, TX, July 1989.

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

Maslow, A.S. The Potential Role of Bacterial Cell Wall Products in Meconium-Stained Amniotic Fluid and Subsequent Maternal and Neonatal Disease. Society of Perinatal Obstetricians, 9th Annual Meeting, New Orleans, LA, 1-4 February 1989

DEPARTMENT OF PATHOLOGY AND ALS

Beckius, M. Urinary Tract Infections Caused by *Hansenula fabianii* in an Immunocompromised Host. American Society of Microbiology, New Orleans, LA, May 1989.

Berkland, M.E. A Prospective Comparison of Three Methodologies for Quantification of CPK-MB Isoenzyme in Patients Suspected of Having Myocardial Infarcts. American Society of Clinical Pathologists, Las Vegas, NV, 25-27 October 1988.

Berkland, M.E. A Prospective Comparison of Three Methodologies for Quantification of CPK-MB Isoenzyme in Patients Suspected of Having Myocardial Infarcts. 7th National Conference, Association of Osteopathic Physicians and Surgeons, San Diego, CA, 29 March 1989.

Brown, B.F. Cerebellar Hemangioblastoma. San Antonio Society of Pathologists, San Antonio, TX, September 1989.

Kimbrell, K.A. Pleomorphic Variant of Chronic Lymphocytic Leukemia. San Antonio Society of Pathologists, San Antonio, TX, September 1989.

DEPARTMENT OF PEDIATRICS

Baker, J. The Pediatric Athlete. Pediatrics for the Practitioner Course, San Antonio, TX, June 1989.

Brien, J.H. Cephalosporin in Pediatrics. American College of Osteopathic Pediatricians, Boston, MA, May 1989

Brien, J.H. Treatment of Meningitis in Pediatrics. American College of Osteopathic Pediatricians, Boston, MA, May 1989.

Brien, J.H. Febrile Rashes and Other Timely Topics. Pediatrics for the Practitioner Course, San Antonio, TX, June 1989.

Heiman, H.S. Infant Resuscitation Techniques. Pediatrics for the Practitioner Course, San Antonio, TX, June 1989.

Inscore, S. Immediate Management of Near Drowning. Pediatrics for the Practitioner Course, June 1989.

Takao, R. Stress During Housestaff Training Years. Annual Chief Residents Retreat, Department of Family Medicine, Medical College of Wisconsin, Lake Geneva, WI, May 1989.

Takao, R. Gynecologic Examination of the Adolescent. Pediatrics for the Practitioner Course, San Antonio, TX, June 1989.

Woodall, J.B. Parenteral Lipids NS BPD, ROP & IVH. Compra, Aspen, CO, June 1989.

DEPARTMENT OF PSYCHIATRY

Grill, D. Credentialing and Licensing of Psychologists within HSC. AMEDD Combat Psychiatry Conference, Kileen, TX, 7 March 1989.

Grill, D. Panel Member of Mental Health Consultants. AMEDD Combat Psychiatry Conference, Kileen, TX, 7 March 1989.

Randle, C. The Psyciatric Day Facility at BAMC. AMEDD Combat Psychiatry Conference, Kileen, TX, 7 March 1989.

DEPARTMENT OF RADIOLOGY

Gerza, C. Mammography - What's Old and New. Present Concepts in Diagnostic Radiology AMEDD Meeting, San Antonio, TX, April 1989.

Heironimus, J. Functional Brain Imaging Using SPECT. Recent Advances in Diagnostic Imaging and Percutaneous Surgery Meeting, San Antonio, TX, April 1989.

Heironimus, J. Clinical Usefulness of SPECT Imaging. Present Concepts in Diagnostic Radiology AMEDD Meeting, San Antonio, TX, April 1989.

Sisk, L. MRI of the Knee. Present Concepts in Diagnostic Radiology AMEDD Meeting, San Antonio, TX, April 1989.

Telepak, R.J. The Curriculum Approach to Radiology. Present Concepts in Diagnostic Radiology AMEDD Meeting, San Antonio, TX, April 1989.

Timmons, J. 123-Ioamphetamine Brain Scans, Theory and Clinical Utility. Present Concepts in Diagnostic Radiology AMEDD Meeting, San Antonio, TX, April 1989.

DEPARTMENT OF SURGERY

Anesthesia and Operative Service

Castro, T. Central Nervous System and Cardiovascular Effects and Interaction Between Lidocaine and Chronic Verapamil Therapy in Awake Cats. American Society of Anesthesiologists, San Francisco, CA, 8-12 October 1988.

Culling, R.G. Rapid Tracheal Intubation with Vecuronium: The Timing Principle. American Society of Anesthesiologists, San Francisco, CA, 8-12 October 1988.
(C)

Culling, R.G. Rapid Tracheal Intubation with Vecuronium: The Timing Principle. 42d Post Graduate Assembly of Anesthesiologist, New York, NY, 10-14 December 1988.

Daniels, D.J. Combat Anesthesia. Special Forces Medics, Okinawa, 30 Aug 89.

Daniels, D.J. Combat Anesthesia. Special Forces Medics, Japan, 5 Sep 89.

Gillespie, J.H. Efficacy of Endotracheal Tube Cuff Palpation and Humidity in Distinguishing Endotracheal from Esophageal Intubation. American Society of Anesthesiologists, San Francisco, CA, 8-12 October 1988. (C)

Hecker, R.B. A Comparison of Pulse Oximeters During Helicopter Flight. Annual Meeting Southern Medical Assoc., New Orleans, LA, November 1988.

Kingsley, C.P. Ketamine Infusion: An Alternative Anesthetic Technique in the Morbidly Obese Patient. Annual International Research Society, Orlando, FL, 4-6 March 1989. (C)

Kingsley, C.P. Anesthesia in Austere Conditions. University of Texas Health Science Center, San Antonio, TX, 6 April 1989.

Kingsley, C.P. Anesthetic Practice in Burn Anesthesia. Anesthesia Department, Ufa, Russia, 20 June 1989.

Kingsley, C.P. Radiology for the Nurse Anesthetist. Academy of Health Sciences, Fort Sam Houston, TX, 29 June 1989.

Kirlangitis, J. Comparison of Bretylium and Lidocaine for the Prevention of Ventricular Fibrillation After Aortic Cross-Clamp Release During Coronary Artery Bypass Surgery. American Society of Anesthesiologists, San Francisco, CA, 8-12 October 1988. (C)

Kirlangitis, J. Comparison of Bretylium and Lidocaine in the Prevention of Ventricular Fibrillation After Aortic Cross-Clamp Release During Coronary Artery Bypass Surgery. 42d Post Graduate Assembly of Anesthesiologists, New York, NY, 10-14 December 1988. (C)

Menk, E.J. Prevention of Contamination of the Concha Humidifier. American Society of Anesthesiologists, San Francisco, CA, 8-12 October 1988. (C)

Menk, E.J. Subarachnoid and Epidural Calcitonin for the Management of Cancer Pain. 42d Post Graduate Assembly of Anesthesiologists, New York, NY, 10-14 December 1988.

Menk, E.J. Electrical Safety in the OR. University of Texas Health Science Center, San Antonio, TX, 10 May 1989.

Menk, E.J. Electrical Safety in the OR. Department of Anesthesiology, Wilford Hall USAF Medical Center, Lackland AFB, TX, 23 May 1989.

Menk, E.J. Combat Anesthesia. Special Forces, Bad Tolz, West Germany, 11-15 Jul 89.

Silverman, S.M. A Comparison of Serum Lidocaine Levels Using Two Variations of the Axillary Block. Annual International Anesthesia Research Society Meeting, Orlando, FL, 4-8 March 1989. (C)

Silverman, S.M. Combat Anesthesia. Reserve Units, Clarksville, TN, 12-14 Sep 89.

Strong, W.E. Does the Sympathetic Block Outlast Sensory Block - A Thermographic Evaluation. American Society of Anesthesiologists, San Francisco, CA, 8-12 October 1988. (C)

Strong, W.E. Ketamine Infusion: An Alternative Anesthetic Technique in the Morbidly Obese Patient. 42d Post Graduate Assembly of Anesthesiologists, New York, NY, 10-14 December 1988. (C)

Strong, W.E. Does the Sympathetic Block Outlast Sensory Block - A Thermographic Evaluation. 42d Post Graduate Assembly of Anesthesiologists, New York, NY, 10-14 December 1988. (C)

Neurosurgery Service

Backer, R.J. Transcranial Doppler Recording After Closed Head Injury: Diagnosis and Evaluation of Post-Traumatic Vasospasm. American Association of Neurological Surgeons, Washington, DC, 15- April 1989.

Ophthalmology Service

Farris, S.R. Postoperative Pressure in Standard Extracapsular Cataract Extraction. Alamo City Residents Clinical Conference (ACRCC), University of Texas Health Science Center San Antonio (UTHSCSA), March 1989.

Foster, M.S. A Review of Cataract Extractions Performed from Below, ACRCC, UTHSCSA, March 1989.

Grimes, Chronic Rhino-Orbital-Cerebral Mucormycosis. ACRCC, UTHSCSA, March 1989.

Hacker, H.D. Evaluation of Single Punctum Excision for Dry Eye Syndrome. ACRCC, UTHSCSA, 1 April 1989. (C)

Hollsten, D.A. The Ophthalmic Manifestations and Treatment of the Amniotic Band Syndrome. 19th Annual Scientific Symposium of the American Society of Ophthalmic Plastic and Reconstructive Surgeons, Las Vegas, NV, 7 Oct 1988.

Hollsten, D.A. Pediatric Lacrimal Disorders. American Academy of Ophthalmology, Las Vegas, NV, 11 October 1988.

Hollsten, D.A. Involitional Entropion/Ectropion - Can One Procedure Do All? Scheie Eye Institute, Philadelphia, PA, 10 December 1988.

Hollsten, D.A. Medial Canthal and Lacrimal Injuries, Ocular Trauma Course, Letterman Army Medical Center, February, 1989.

Kietzman, T.J. Transient Bilateral Blindness in Pre-Eclampsia. ACRCC, UTHSCSA, March 1989.

Mein, C.E. Retinoblastoma, Lecture Series for Retina, Vitreous Uveitis, Intraocular Tumors. Wilford Hall USAF Medical Center, Lackland AFB, TX, 17 October 1989.

Mein, C.E. Uveitis. Lecture Series for Retina, Vitreous, Uveitis, Intraocular Tumors. Wilford Hall USAF Medical Center, Lackland AFB, TX, 17 October 1989.

Mein, C.E. Sympathetic Ophthalmia. Ocular Trauma Course, Letterman Army Medical Center, February 1989.

Mein, C.E. Safe and Effective Local Anesthesia for Vitreoretinal Surgery. ACRCC, UTHSCSA, March 1989.

Mein, C.E. The Peripheral Retina. Alamo Tri-Service Optometric Society, 8 June 1989.

Mein, C.E. Safe and Effective Local Anesthesia for Vitreoretinal Surgery. ACRCC, UTHSCSA, 1 April 1989.

Olser, J.M. Fuch's Heterochromic Iritis. Grand Rounds University of Texas Health Science Center, San Antonio, TX, February 1989.

Olsen, J.M. Coat's Disease. Grand Rounds University of Texas Health Science Center, San Antonio, TX, February 1989.

Olsen, J.M. Downbeat Nystagmus. Grand Rounds University of Texas Health Science Center, San Antonio, TX, January 1989.

Olsen, J.M. Anterior Ischemic Optic Neuropathy. Grand Rounds Wilford Hall USAF Medical Center, Lackland AFB, TX, March 1989.

Olsen, J.M. Optic Nerve Head Drusen. Grand Rounds University of Texas Health Science Center, San Antonio, TX, March 1989.

Olsen, J.M. Pars Plana Vitrectomy Surgery Vitreous Loss During Extracapsular Cataract Extractions. ACRCC, UTHSCSA, March 1989.

Parks, S.L. Benign Mixed Tumor of the Palpebral Lobe of the Lacrimal Gland. ACRCC, UTHSCSA, March 1989.

Walker, J.D. Gonioscopy. University of Texas Health Science Center, San Antonio, TX, 4 November 1989.

Walker, J.D. Visual Fields in Glaucoma. University of Texas Health Science Center, San Antonio, TX, 4 November 1988.

Walker, J.D. Topical Glaucoma Therapy. University of Texas Health Science Center, San Antonio, TX, 16 December 1988.

Walker, J.D. Systemic Glaucoma Therapy. University of Texas Health Science Center, San Antonio, TX, 16 December 1988.

Walker, J.D. Gonioscopy. University of Texas Health Science Center, San Antonio, TX, 14 July 1989.

Walker, J.D. Primary Angle Closure Glaucoma. University of Texas Health Science Center, San Antonio, TX, 14 July 1989.

Webster, G.B. Granular Cell Tumor of the Orbit. ACRCC, UTHSCSA, March 1989.

White, W.L. Oculomotor Palsy, Facial Capillary Hemangioma, and Cerebellar Hypoplasia. A New Type of Neurocutaneous Disorder? ACRCC, UTHSCSA, March 1989.

Orthopaedic Surgery Service

Bucknell, A.L. The Spectron Enhanced Fixation System - Design Advances. Academy of Orthopaedic Surgeons. Las Vegas, NV, February 1989.

Bucknell, A.L. The Use of Titanium in Press Fit Hip Arthroplasty. Academy of Orthopaedic Surgeons. Las Vegas, NV, February 1989. (C)

Coe, J.D. Neuropathological Changes with Spinal Instrumentation. A Canine Model. 23rd Annual Meeting of the Scoliosis Research Society, Baltimore, MD, 1 October 1988.

Coe, J.D. Biomechanical Evaluation of Cervical Spinal Stabilization Methods in a Human Cadaveric Model. Cervical Spine Research Society 16th Annual Meeting, Key Biscayne, FL, 1 December 1988.

Coe, J.D. Neuropathological Changes with Spinal Instrumentation. A Canine Model. Society of Military Orthopaedic Surgeons, Williamsburg, VA, 5 December 1988.

Coe, J.D. Load to Failure Strengths of Spinal Implants in Osteoporotic Spines. A Comparison Study of Pedicle Screws, Laminar Hooks, and Spinous Process Wires. 35th Annual Meeting of the Orthopaedic Research Society, Las Vegas, NV, 6 February 1989.

Coe, J.D. Neuropathological Changes with Spinal Instrumentation. A Canine Model. Exhibited at 35th Annual Meeting of Orthopaedic Research Society, Las Vegas, NV, 8 February 1989.

Coe, J.D. Neuropathological Changes with Spinal Instrumentation. A Canine Model. American Academy of Orthopaedic Surgeons 56th Annual Meeting, Las Vegas, NV, 13 February 1989.

Coe, J.D. The Biomechanics, Histomorphometry, and Neurological Effects of Pedicle Fixation. Exhibited at American Academy of Orthopaedic Surgeons 56th Annual Meeting, Las Vegas, NV, February 1989.

Coe, J.D. 3-D Imaging for the Post-Surgical Failed Back Syndrome. Exhibited at American Academy of Orthopaedic Surgeons 56th Annual Meeting, Las Vegas, NV, February 1989.

Coe, J.D. Load to Failure Strengths of Spinal Implants in Osteoporotic Spines - A Comparison Study of Pedicle Screws, Laminar Hooks, and Spinous Process Wires. Annual Meeting of Scoliosis Research Society, September 1989.

Otolaryngology Service

Braaten, J.M. Anterior Inferior Cerebellar Artery Aneurysm. American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, LA, 24-28 September 1989.

Elledge, E.S. Papillary Cystadenoma Lymphomatosum (Warthin's Tumor): A Changing Incidence? Southern Medical Association Annual Scientific Meeting, New Orleans, LA, 6 November 1988.

Elledge, E.S. Nasal Hemangiopericytoma. American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, LA, 24-28 September 1989.

Elledge, E.S. Tonsillar Squamous Cell Carcinoma Metastatic to a Branchial Cleft Cyst. American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, LA, 24-28 September 1989.

Fraker, J.T. Oat Cell Carcinoma of the Larynx. Southern Medical Association Annual Scientific Meeting, New Orleans, LA, 6 November 1988.

Gibbons, D.R. Craniocervical Chordoma. Third Annual Mid Atlantic Resident Research Symposium, Washington, DC, 6 May 1989.

Gibbons, D.R. Spontaneous Otorrhea from Tegmen and Labryinthine Congenital Anomalies. Annual Meeting of the American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, LA, 24-28 September 1989.

Gibbons, D.R. Postoperative Postauricular Keloids. Annual Meeting of the American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, LA, 24-28 September 1989.

Hayes, D.K. Viability of Skin Flaps Subjected to Simultaneous Chemical Peel in Guinea Pigs. Third Annual Mid Atlantic Resident Research Symposium, Washington, DC, 6 May 1989. (C)

Hayes, D.K. Dermal Healing After Cemical Peel and Skin Flap. Annual Meeting of the American Academy of Facial Plastic and Reconstructive Surgery, New Orleans, LA, 21-23 September 1989. (C)

Hayes, D.K. Myxoma of the Maxilla in an Infant. Annual Meeting of the American Academy of Facial Plastic and Reconstructive Surgery, New Orleans, LA, 24-28 September 1989.

Jarchow, R.C. What's Ahead in Skin Cancer Research? American Academy of Facial Plastic and Reconstructive Surgery Symposium on Facial Skin Malignancies, San Antonio, TX, 4 November 1988.

Jarchow, R.C. Soft Tissue Course. Annual Otolaryngology Basic Science Course, Armed Forces Institute of Pathology, Washington, DC, April 1989.

Jarchow, R.C. Posterior Component of the Facelift Incision. Annual Meeting of the American Academy of Facial Plastic and Reconstructive Surgery, New Orleans, LA, 21-23 September 1989.

Jarchow, R.C. Surgical Principles of Facelift. Annual Meeting of the American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, LA, 24-28 September 1989.

Moss, J. Reconstruction of Frontal Sinus Defects. Annual Meeting of the American Academy of Facial Plastic and Reconstructive Surgery, New Orleans, LA, 21-23 September 1989.

Stambaugh, K.I. The Outstanding Ear. Fourth Annual Meeting of the American Society of Pediatric Otolaryngology, 20 May 1989.

Stambaugh, K.I. The Outstanding Ear: Its Correction. Pediatric Head and Neck Reconstruction Course, Tacoma, WA, 4-5 August 1989.

Peripheral Vascular Surgery

Olson, D.W. Catheterization Related Vascular Injuries: BAMC Experience 1984-1988. AMEDD Vascular Meeting, Bethesda, MD, 3 December 1988.

Olson, D.W. Brachiocephalic Reconstruction: BAMC Experience. AMEDD Vascular Meeting, Bethesda, MD, 3 December 1988.

Olson, D.W. Penetrating ABdominal Trauma. Postgraduate Seminar, Wilford Hall USAF Hospital, Lackland, AFB, TX, 13 April 1989.

Plastic Surgery Service

Young, R.N. The Use of Myocutaneous Flaps for Pressure Sores. South Texas Chapter of the American College of Surgeons, Temple, TX, 26-28 January 1989.

Young, R.N. The Use of Myocutaneous Flaps for Pressure Sores. Annual Military Plastic Surgery Symposium, Aurora, CO, 16-19 April 1989.

Urology Service

Boykin, W. Obliteration of the Posterior Urethra Secondary to Periurethral Teflon. James Kimbrough Urologic Symposium, Norfolk, VA, November 1988.

Hansberry, K. Prophylaxis for Thromembolic Phenomena in Urologic Surgery. James Kimbrough Urologic Symposium, Norfolk, VA, November 1988.

Rodriguez, F.R. Quality of Life in Prostate Cancer Patients. James Kimbrough Urologic Symposium, Norfolk, VA, November 1988.

Thompson, I.M. The Natural History of Prostatic Carcinoma. James Kimbrough Urologic Symposium, Norfolk, VA, November 1988.

Thompson, I.M. Idiopathic Macroorchidism. James Kimbrough Urologic Symposium, Norfolk, VA, November 1988.

Thompson, I.M. Screening for Carcinoma of the Prostate. Visiting Professor, New York University, New York, NY, December 1988. (C)

Thompson, I.M. Efficacy of Early Diagnosis of Carcinoma of the Prostate. Visiting Professore, University of Michigan, Ann Arbor, MI, December 1988.

Thompson, I.M. Vignettes in the Treatment of Carcinoma of the Prostate. Kansas City Urologic Society, May 1989.

Zeidman, E.J. Vaginal Surgery for Incontinence. William Beaumont Army Medical Center, El Paso, TX, March 1988.

Zeidman, E.J. Vaginal Sling for Treatment of Type III SUI. James Kimbrough Symposium, Norfolk, VA, November 1988.

Zeidman, E.J. Complete Urinary Obstruction Following Periurethral Polytetrafluoroethylene Injection for Urinary Incontinence. Western Section of American Urological Association, Scottsdale, AZ, March 1989.

PHYSICAL MEDICINE AND REHABILITATION SERVICE

Miley, D. The Hearing Disabled Child and His/Her Special Needs. Proprietors of Day Care Facilities, Lila Cockrell Center, San Antonio, TX, August 1989.

PREVENTIVE MEDICINE SERVICE

Longfield, J. Varicella Outbreaks in Army Recruits from Puerto Rico: Varicella Susceptibility in a Population from the Tropics. 1989 Globa Medicine Course, School of Aerospace Medicine, Brooks AFB, TX, February 1989.

Longfield, J. Prevention of Bloodborne Infections in the Occupational Setting: Surveillance Requirements and Responsibilities. Preventive Medicine Physician's Short Course, Baltimore, MD, September 1989.

Longfield, J. Varicella Vaccine: Applications in the Military. Preventive Medicine Physician's Short Course, Baltimore, MD, September 1989.

NUTRITIONAL CARE DIVISION

Freese-Kepczyk, B. Project Care and Share - Feeding the Hungry. San Antonio District Association, 15 October 1988.

Saxton, L. Health Eating Habits. Fort Sam Houston Elementary School, Fort Sam Houston, TX, 25 October 1988.

Hemingway, M. Nutrition and Dental Health. Fort Sam Houston Elementary School, Fort Sam Houston, TX, 3 February 1989

Money, E. Nutrition for Children. Day Care Workers, Fort Sam Houston Youth Activities, Fort Sam Houston, TX, 28 February 1989.

Corum, S. Low Fat/Low Salt Eating. Fort Sam Houston Elementary School, Fort Sam Houston, TX, 6 March 1989.

Hemingway, M. Good Nutrition for the Preschool Child. Nulsen Preschool, Fort Sam Houston, TX, 7 March 1989.

Guinn, E. Role of Nutrition Care Personnel in Nutrition for Patients and Hospital Staff. Girl Scout Troop 643, Fort Sam Houston, TX, 11 March 1989.

McCann, E. Cholesterol. Army Residence Community, San Antonio, TX, 13 March 1989.

Money, E. Eat Smart. American Cancer Society, San Antonio, TX, 6 April 1989.

Freese-Kepczyk, B. Use of Essential Amino Acids in Acute Renal Failure. Annual Texas Dietetic Association Meeting, San Antonio, TX, 15 April 1989.

Freese-Kepczyk, B. Use of the Metabolic Cart. Annual Texas Dietetic Association Meeting, San Antonio, TX, 15 April 1989.

Money, E. Nutritious Snacks. Alamo Heights Presbyterian Church, San Antonio, TX, 19-23 June 1989.

Money, E. Basic Four and a Whole Lot More. Fort Sam Houston Elementary School, Fort Sam Houston, TX, 10 July 1989.

Hoedebecke, S. Infant and Child Nutrition. Day Care Providers, Fort Sam Houston Day Care Center, Fort Sam Houston, TX, 11 July 1989.

Money, E. Nutrition Forum. Great American Smoke Out Conference, Austin, TX, 2 August 1989.

Saxton, L. Eat Smart. Great American Smoke Out Conference, Austin, TX, 17 August 1989.

Money, E. Evolution of Breastfeeding. Army Community Health Nurses, Fort Sam Houston, TX, 28 August 1989.

Dietetic Interns. How to Choose Lean Beef. Food Festival sponsored by American Heart Association, San Antonio, TX , 16 September 1989.

Money, E. How Smart the Southwestern Way. National Hispanic Week Activities at the Medical Museum, Fort Sam Houston, TX, 26 September 1989.

DEPARTMENT OF THE ARMY
Brooke Army Medical Center
Fort Sam Houston, Texas 78234-6200
DEPARTMENT OF CLINICAL INVESTIGATION

PUBLICATIONS

DEPARTMENT OF CLINICAL INVESTIGATION

Ayala, E., Krikorian, D. Effect of L-Lysine Monohydrochloride on Cutaneous Herpes Simplex Virus in the Guinea Pig. J. Med. Virology 28:16-20, 1989. (C)

Byers, V., Arrington, M.E., Finstuen, K. Predictive Risk Factors Associated with Stroke Patient Falls in Acute Care Setting. J. Neurosurg. Nursing, (in press). (C)

Gunn, B.A. Comparative Virulence of Human Isolates of Coagulase-Negative Staphylococci Tested in an Infant Mouse Weight-Retardation Model. J. Clin. Microbiol., March 1989. (C)

Latham, R.D., Rubal, B.J., Sipkema, P., et al. Ventricular/Vascular Coupling and Regional Arterial Dynamics in the Chronically Hypertensive Baboon: Correlation with Cardiovascular Structural Adaptation. Circ. Res., 63(4):798-811, Oct. 1988. (C)

Latham, R.D. Recently Diagnosed Idiopathic Dilated Cardiomyopathy: Incidence of Myocarditis and Efficacy of Prednisone Therapy. Am. Heart J., 4:876-882, April, 1989. (C)

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PHYSICAL MEDICINE SERVICE

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Detail Summary Sheet

Date: 25 Sep 89 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: Victor Elysee, SGT Paul M. Horowitz, Ph.D.
Key Words: <u>Aspergillus</u> sp. <u>Penicillium</u> sp.	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$946.45
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: A commercial source of two strains of Aspergillus which are potent producers of a chlorinated toxin have been found. The mechanism of chlorination is not known, but a likely mechanism involves a haloperoxidase function. These strains are to be ordered for evaluation of haloperoxidase activity.

Detail Summary Sheet

Date: 25 Sep 89	Proj No: C-18-88	Status: Ongoing
Title: Development of an Indirect Chemiluminogenic Enzyme Linked Immunoassay (CELIA) for Demonstrating Conformational Changes in a Model Protein		

Start Date 16 Dec 88	Est Comp Date:
Principal Investigator Gerald A. Merrill	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Paul M. Horowitz, Ph.D., UTHSC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 779.93
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To develop monoclonal antibodies to rhodanese, a well characterized model protein, and use these antibodies in the development of an indirect soluble chemiluminescent enzyme linked assay system.

To assess the binding affinities of anti-rhodanese monoclonal antibodies for their epitopes and demonstrate conformational changes involving the rhodanese epitopes by monitoring changes in binding affinities.

Technical Approach: An assay has been developed for evaluation of the binding affinity with which MABs to rhodanese interact with their respective epitopes. This assay is an indirect assay in which the initial step is to allow the soluble form of rhodanese being evaluated to achieve an equilibrium binding state with the soluble MABs. Equilibrium will be assumed to be achieved after 16 hours of incubation at 4°C with constant rocking. Several concentrations of the rhodanese form will be utilized; each incubated with a fixed concentration of MAB. It is essential that antigen be in excess to MAB at all antigen concentrations employed in the assay. Following this initial incubation, an aliquot of the antigen-antibody equilibrium mixture will be removed and added to 12*55 mm polystyrene tubes to which rhodanese has been immobilized. The technique for immobilizing the enzyme to the tube surface inactivated the enzyme but exposes the epitopes recognized by each of the 3 existing anti-rhodanese MABs. Incubation at this step is also at 4°C and is to allow a portion of the MAB which is not bound by rhodanese in the initial equilibrium step to bind to the immobilized rhodanese. MAB which is bound by soluble rhodanese in the first incubation is not available for binding to the immobilized rhodanese. The tubes are then washed and horseradish peroxidase labeled goat anti mouse antibody (HRPO-GAM) is added and allowed to bind to the primary MABs bound to the immobilized rhodanese. Following this step, the tubes are again washed and HRPO

C-18-88 (continued)

substrates are added. These substrates are orthophenyl diamine and peroxide for ELISA assays and luminol and peroxide for chemiluminescent assays (CELIA's).

It is essential that the equilibrium established in the first incubation is not perturbed. Thus, the period of this second incubation must be kept to a minimum so as not to allow sufficient time for extensive dissociation of the antibody-antigen complexes that formed in the initial incubation step. This equilibrium will not be sufficiently drawn toward dissociation if less than 15% of the available antibody is bound to the immobilized rhodanese. However, enough antibody must be bound to the immobilized antigen (in the absence of competition with soluble antigen) to ensure a signal to be detected which is significantly above background to allow the ability to observe a decrease in the amount of free MAB bound to the immobilized rhodanese (indicating an increased binding of the MAB to the soluble form of enzyme in the initial equilibrium incubation).

Progress: These conditions were shown to be met for each of the MABs using an assay in which several concentrations of free MAB were incubated for various times in tubes in which rhodanese was immobilized. Next the contents of the tube were transferred to a second tube with immobilized rhodanese and incubated for the same time period under the same conditions. Comparing the ELISA results of these tubes, if the difference was less than 15% and the signal was at least 10 times the background signal, then the conditions of the second assay step were acceptable. To ensure these conditions, one MAB requires an incubation time of 2 hrs at a MAB concentration of 1:5000. The other 2 MABs require an incubation step of only 15 min at MAB concentrations of 1:2000. The amount of MAB at these dilutions was determined by isolation of semipurified MABs by hydroxyappitite HPLC quantitated by densitometry of polyacrylamide gels and lowry protein determinations. Based on these results, a minimum concentration of rhodanese in the equilibrium incubation between soluble enzyme and MABs is 10 to 20 ug/ml, thus ensuring a minimum of a 10 fold excess of antigen to MAB.

The optimal pH and peroxide concentrations to obtain maximum signal to noise ratios of the CELIA assay were also determined. Comparison of urea peroxide and hydrogen peroxide was also examined with no apparent differences seen between these substrates of the HRPO with either nonspecific or specific light production.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: G-22-88 Status: Completed
 Title: Comparison of PT and aPTT Values Obtained from Standard Venipuncture and Implanted Venous Access Device Methods

Start Date 13 Jan 88	Est Comp Date:
Principal Investigator Mary E. Arrington, R.N., MSN	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Eleanor Ayala, M.T. Steven Drennan, 1LT AN Osburn Stone, CPT, AN Patricia Potts, 1LT, AN Michael E. Berkland, CPT, MC
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 _____	Results _____

Objective(s): To investigate the extent of variation in prothrombin time (PT) and activated partial thromboplastin time (aPTT) obtained from two blood sampling methods from implanted venous access devices as compared to standard peripheral venipunctures in Hematology/Oncology patients.

Technical Approach: One hundred sample sets will be studied, 50 in each group, from a convenience sample. Following a 20 ml normal saline preflush and a 5 cc discard, six serial blood volumes will be sampled from each subjects implanted venous access device (IVAD). Subjects will serve as their own controls via concurrent venipuncture. Two IVAD conditons will be studied - heparin locked IVAD's and IVAD's receiving non-heparinized infusates. Each serial volume will be tested using Pt and aPTT, as well as thrombin times as futher evidence of heparin contamination.

Progress: The findings of this and two other studies indicate that both aPTT and PT obtained from the IVAD may not be reliable for clinical use. Peripheral venipuncture would be recommended where absolute accuracy of these values are important for diagnosis and treatment. As expected, PT is less sensitive to the effect of heparin, the findings concur with others that PT values are clinically reliable obtained from the IVAD. Further study is needed for testing aPTT drawn from IVAD's with a lesser concentration of heparin flush than used in the patients studied.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-25-88 Status: Ongoing
 Title: Use of Fluorescence-Activated Flow Cytometry to Identify Bone Cells

Start Date 14 Jan 88	Est Comp Date:
Principal Investigator David L. Danley, MAJ, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Janice Grassel, M.T. Barbara Reeb, M.T.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 929.65
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the feasibility of using FACS to identify bone cells and to study their metabolic activities.

Technical Approach: In our initial study, we propose to use human or animal cell lines with known characteristics of osteoblasts: SAOS-2 (human), MT-3T3 (human, and ROS 17/2.8 (rats). They will be grown and passed under sterile conditions in the CI tissue culture facilities. To identify cell types and function, we will use a FACS 400.

Progress: Several osteoblast cell lines were cultivated for use as targets for potential bone cell markers. Of interest was the marker, alkaline phosphatase, an enzyme which appears at different levels in maturing osteoblasts. An arrangement was made to acquire sufficient quantities of purified human enzyme for the production of specific monoclonal antibodies; however, sufficient quantities have not been produced.

Detail Summary Sheet

Date: 23 Aug 88	Proj No: C-33-88	Status: Terminated
Title: Health Beliefs and Glycemic Control of Type II Diabetics		

Start Date 17 Feb 88	Est Comp Date:
Principal Investigator Mary E. Arrington, R.N., MSN	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: John Simmons, MAJ, MC
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 6 Apr 89	Results Terminated

Objective(s): To describe health beliefs specific to a diabetic population and their relationship to the glycemic control attained.

Technical Approach: The health beliefs and glycemic control of 120 accessible adult, type II diabetic patients will be studied utilizing a descriptive survey research design. The Diabetes Health Belief Scale, a demographic questionnaire and a glycosylated hemoglobin will be used as the basis for data collection.

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

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-50-88 Status: Completed
 Title: CVA Patient Falls: Intrinsic Risk Factors Profile

Start Date 2 May 88	Est Comp Date:
Principal Investigator Mary E. Arrington, R.N., MSN	Facility Brooke Army Medical Center
Dept/Svc Department of	Associate Investigators: Vicki Byers, Ph.D., RN, CNRN Kenn Finstuen, M.S., M.Ed., Ph.D.
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 _____ Results _____	

- Objective(s): 1) To identify the characteristics that are associated with CVA patients falling.
- 2) To explain the nature of the relationship among characteristics and falling.
- 3) To compare, within the patient profiles, the characteristics of CVA patients who fall with those CVA patients who do not.

Technical Approach: The procedure involved in this collaborative study was a retrospective in-patient chart audit as the method of data collection. Charts, laboratory reports, scan reports, and incident reports were reviewed and data collected using the Data Sheet-Fall Tool developed by the investigators. A 96% inter-rater reliability of the data collection tool was determined on 10 CVA fall patients prior to data collection. The independent variables include demographics, hemisphere of CVA, blood pressure, weight loss prior to fall, combination of neurological deficit, activity level at time of fall, mental status, medications, and laboratory values.

Progress: Discriminant analysis from stepwise multiple linear regressions were employed to determine significant predictors of patient falls within the control and assessment areas (mentation, motor, sensory, general status, medication, laboratory values, activity level) as well as background characteristics. All significant variables were then forced into a 16 variable risk factor equation which resulted in a $R^2 = .30$ ($F [16,296] = 7.92$ $p < .001$), a highly predictive finding. Interestingly enough, control variables of age, gender, and ethnicity in addition to stroke characteristics, medical diagnosis, and medical facility

G-50-88 (continued)

failed to discern fall from control patients. The final results indicate that stroke patients with a history of falls, with impaired decision-making, that exhibit balance problems, generalized weakness, abnormal hematocrit, and are easily fatigued should be identified for surveillance especially at night when most falls occurred.

The information obtained from incorporating fall characteristics and risk factors for falls in stroke patients could be utilized to develop a program aimed at preventing falls in acute care settings. Clinical prospective studies using precise instruments to measure mental, motor, and sensory status are needed to further examine predictive risk factors associated with stroke patient falls. Further, nursing intervention studies are needed based on precise neurological assessment criteria to explore ways to reduce falls in hospitalized stroke patients.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-12-89 Status: Ongoing
 Title: An Investigation of Cell Wall Sulphydral Groups and the Pathogenicity of Candida albicans

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator David L. Danley, MAJ, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: John Hinds, SSG Gerald A. Merrill, GS-11 Janice Grassel, GS-11
Key Words: <u>Candida albicans</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 examine the significance of sulphydral groups on the cell wall of C. albicans and the ability of this yeast to kill human monocytes or to be killed by human polymorphonuclear leukocytes (PMN).

Technical Approach: Several assays have been developed that use either spectrophotometry or fluorescence-activated cell sorting to measure cell wall sulphydral groups. By comparing the prevalence of these groups on yeast cells following phagocytosis by monocytes or PMN, we can determine whether or not they are being altered as a result of phagocytosis. Moreover, by selectively modifying these groups with chemical reagents prior to phagocytosis, we can determine their importance in mediating monocyte lysis and in maintaining the metabolic activity of the yeast cell.

Progress: An assay was developed that used fluorescence-activated flow cytometry and fluorescent reagents (fluorescein maleimide, FM) to study the sulphydryl groups on yeast cells of Candida albicans. Reduced sulphydryl groups are very prevalent on the cell wall of blastoconidia in log phase growth. FM binding is markedly reduced in yeast cells in stationary phase growth or those sitting in a nutrient free medium for 1-2 hours. Incubation of yeast cells with phagocytic cells effected a marked reduction in FM binding. However, phagocytosis was not required for this reduction, since phagocyte lysate was equally

C-12-89 (continued)

effective in blocking sulfhydryl groups. Through oxidative metabolism, viable blastoconidia continuously reduce sulfhydryl groups. When these groups are blocked with an irreversible inhibitor, such as N ethyl maleimide, the yeast cells cannot grow. Current efforts center on identifying phagocytic mechanisms that may irreversibly block yeast cell sulfhydryl groups.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-25-89 Status: Ongoing
 Title: Computer-Assisted Comparison of Data Tables Used to Identify Mycobacteria

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator Robert G. Whiddon, Jr., Ph.D., LTC, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investiation	Associate Investigators: S. V. Juchau, COL, MS Joe Martinez, GS-09
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 _____	Results _____

Objective(s): To find the most effective test method to identify mycobacteria. The test battery selected will then be used to identify clinical isolates in parallel with the current method and these identifications compared by using Pearson's correlation coefficient.

Technical Approach: Data will be collected from the literature on all tests reported to be useful in the identification of mycobacteria. This data set will be analyzed and compared to the data table currently used at BAMC to identify mycobacteria. Computer programs written by the principal investigator will be used to find the best combination of tests to be used. This optimum test battery will be compared to the one in use. The test battery selected from this process will then be used to identify clinical isolates in parallel with the current method and the results of these identifications compared by using Pearson's correlation coefficient.

Progress: The analysis of the identification table currently in use in DPALS resulted in the following:

The table contains 25 organisms challenged in 26 tests. Two separate analyses were required of 1800 paired comparisons for a total of 3600 paired comparisons among the 26 tests. At the optimum scaling value, 2% of the organism pairs do not separate. Seven tests (27%) can be eliminated and exactly the same results achieved.

A literature review combining information compiled by the International Working Group for Mycobacterial Taxonomy (IWGMT) produced a table of 22 organisms tested with 50 tests. This table had an endpoint of 77% scaling value and required 1386 paired comparisons. Since these organisms were slowly growing mycobacteria, four of which are routinely identified by gene probing, these four organisms were dropped and the table analyzed to determine the testing required to identify the remaining 18 organisms. This analysis required three separate analyses of 918 pairs for a total of 2754 paired comparisons. Of 50 original tests, 37 can be omitted and all pairs separated at an 82% scaling value endpoint. This is a reduction of 74% of the testing requirement and complete separation of all the organisms.

The IWGMT has also developed a large table for the rapidly growing mycobacteria. It consists of 57 tests and 16 organisms. This table required 720 paired comparisons and can be reduced by 44 tests (77%) and all pairs separated at a 99% scaling endpoint.

In summary, 8460 paired comparisons have been analyzed, and two resulting identification tables generated that are reduced by 74% and 77% respectively. The slowly growing mycobacteria can be identified at a scaling value of 82% and the rapidly growing mycobacteria at 99%. Of 107 tests, 81 can be eliminated for a 76% reduction in the testing requirement.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-68-89 Status: Ongoing
 Title: The Establishment of a Summary Database for the Autologous Bone Marrow Rescue Program

Start Date: 5 May 89	Est Comp Date:
Principal Investigator Robert G. Whiddon, Jr., LTC, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Richard Guidice, MAJ, MC Barbara Reeb, GS-09 Rory Duncan, SGT
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 _____	Results _____

Objective(s): To identify data elements from autologous bone marrow rescue (ABMR) patient records that should be merged with the existing laboratory data generated during bone marrow processing.

Technical Approach: This merged file will generate ad hoc and permanent reports that will document the success of this program and provide a basis of comparison with other programs. This data will serve as a Quality Assurance instrument for the program and can provide an experience summary for other laboratories that set up ABMR procedures. Questions that are expected to be answered are the number and type of blood products used with this patient population, correlations between cell counts and viability and time to engraftment, and correlations between drugs and dose and engraftment.

Progress: Fourteen of 26 targeted files have been screened and the data abstracted. No further progress has been made

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-91-89 Status: Ongoing
 Title: Development of a Standard Protocol for the Rapid Plasmid Profile
 Analysis of Bacterial Isolates

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Gerald A. Merrill	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Robert G. Whiddon, LTC, MS Guy Plunkett, III, Ph.D.
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 _____	Results _____

Objective(s): To evaluate each of several procedures for the rapid isolation of bacterial plasmids, and to select one which reproducibly yields a wide size range of bacterial plasmids from a variety of bacterial strains likely to be bacterial pathogens.

Technical Approach: Bacterial test strains will be obtained from the Area Lab with no reference to the patient source. These strains will be grown overnight at 37°C in 5 ml of LB media to obtain adequate numbers of bacteria. The initial extraction process to be evaluated will be the method described by Holmes and Quigley.

Progress: Adequate recovery of bacterial plasmids was achieved using a modification of the method of Holmes and Quigley which involves weakening of the bacterial cell wall by treatment with lysozyme and a non-ionic detergent (triton X100) followed by cell lysis with boiling. Recovery of plasmids ranging from 2.2 to 55.5 kBases was successfully achieved with this procedure. Separation of these plasmids by electrophoresis on vertical agarose gels did not provide reproducible resolution of the plasmids. Effective electrophoresis of plasmids was achieved using a submarine horizontal electrophoresis unit. A submarine

C-91-89 (continued)

electrophoresis unit and gel photography equipment to document electrophoretic results have been purchased but have not yet arrived.

Plasmid analysis was utilized to monitor a recent outbreak of methicillin resistant S. aureus at BAMC. Three distinct plasmid profiles were observed. The plasmid profile was used by infectious disease personnel to monitor the epidemiology of the spread of the resistant organisms in this facility.

• More definitive evidence of the commonality between two or more organisms having similar plasmid profiles requires the partial digestion of isolated plasmids by selective endonucleases. At this time, endonuclease digestion of plasmids has not been initiated. These studies will be conducted upon arrival of the required submarine electrophoresis system.

Detail Summary Sheet

Date: 21 Aug 89 Proj No: C-74-87 Status: Terminated
 Title: Short Term High Dose Steroids in Orthognathic Surgery

Start Date 12 Aug 87	Est Comp Date:
Principal Investigator John McLaughlin, LTC, DC	Facility Brooke Army Medical Center
Dept/Svc Department of Dentistry/Oral Surgery	Associate Investigators:
Key Words: Steroids Surgery, Orthognathic	
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): To determine the effects of high dose steroids on serum cortisol levels in oral surgery patients.

Technical Approach: Fifteen patients undergoing orthognathic and preprosthetic surgery will receive 20 mg of Decadron at the beginning of surgery and then 20 mg every two hours while they are in surgery. Postoperatively they will receive 8 mg of Decadron every six hours for 24 hours and then two intramuscular injections of 80 mg of Depo-Medrol on the morning after surgery and the following morning. Serum cortisol levels will be checked at the time of admission, immediately postoperatively on the day of surgery, postoperative day three which would correspond to maximum suppression, postoperative day frou which is after the delayed release steroid, then on a weekly basis until serum cortisol level returns to baseline.

Progress: The study has been terminated. No data collected.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-16-88 Status: Completed
 Title: Effects of Chlorhexidine Gluconate Oral Rinse Versus Normal Saline and Cepacol on the Incidence of Local Osteitis in Mandibular Third Molar Surgery

Start Date 2 Dec 87	Est Comp Date:
Principal Investigator James E. Berwick, MAJ, DC	Facility Brooke Army Medical Center
Dept/Svc Department of Dentistry/Oral Surgery	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 80	
Total Number of Subjects Enrolled to Date: 80	
Date of Periodic Review 9 Mar 89	Results Completed

Objective(s): To determine whether a chlorhexidine gluconate containing oral rinse (Peridex) used as a preoperative rinse and intraoperative lavage agent will reduce the incidence of local osteitis following mandibular third molar surgery, in comparison to similar procedures with normal saline and Cepacol and no rinse.

Technical Approach: This study compared the effectiveness of .12% chlorhexidine used as a preoperative rinse and intraoperative irrigation agent with .05% cetylpyridium and normal saline in the reduction of dry socket in mandibular third molar extractions.

Progress: The results indicate the chlorhexidine and cetylpyridium were found to be no more effective in the reduction of dry socket than intraoperative irrigation with normal saline.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-93-89 Status: Ongoing
 Title: The Occurrence of Bacteremia Associated with Osseointegrated Endosteal Implants

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator John R. Scuba, MAJ, DC	Facility Brooke Army Medical Center
Dept/Svc Department of Dentistry/Oral Surgery	Associate Investigators: John P. McLaughlin, LTC, DC William P. Mills, LTC, DC William F. Nauscheutz, CPT, MS
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 _____	Results _____

Objective(s): To determine whether states of bacteremia exist subsequent to the emplacement of intraoral implants, either immediately postoperatively or after a prolonged healing phase.

Technical Approach: Patients participating in the study will be oral and maxillofacial surgery inpatients and outpatients receiving osseointegrated endosseous intraoral implants in preparation for prosthodontic restoration of missing teeth. Four weeks after healing of intraoral tissues and loading of implants with a dental prosthesis, 22 cc. of blood will be drawn. The patient will be asked to masticate vigorously for two minutes and a second blood sample will be drawn five minutes subsequent to this. Both samples will be sent to the laboratory for aerobic and anaerobic blood culture.

Progress: This is a new study. No data are available.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-66-86 Status: Terminated
 Title: The Antimicrobial Spectrum of Fresh Water Contaminated Wounds and the Incidence of Wound Infections Associated with These Injuries

Start Date 8 Jul 86	Est Comp Date:
Principal Investigator (Singletary) Carey Chisholm, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words: Wound, contaminated Wound, infection	
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 Sep 88	Results Continue

Objective(s): 1) To identify common fresh waterborn human pathogens involved in wounds acquired in or around fresh water bodies within the state of Texas.

2) To determine the incidence of wound infections in wounds contaminated by fresh water.

3) To make recommendations for initial choice of antibiotics for wound infections caused by fresh water bacteria.

Technical Approach: Patients presenting for care to the BAMC Emergency Department with an acutely acquired (less than 24 hours) or infected wound that had been contaminated by fresh water will be studied. All wounds will be swabbed and culture swab sent for culture and antibiotic sensitivities.

Progress: This study was terminated due to data being published by another investigator.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-67-86 Status: Terminated
 Title: The Choice of Antibiotics for Marine Acquired Wound Infections

Start Date 8 Jul 86	Est Ccmp Date:
Principal Investigator (Singletary) Carey Chisholm, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words: Infection, marine acquired	
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 Sep 88 Results Continue	

Objective(s): 1) To identify the organisms responsible for infections of salt water contaminated wounds from the Texas/Gulf Coast region.

2) To determine antibiotic sensitivities for the pathogens involved in salt water exposed wound infections.

3) To make recommendations for the initial choice of antimicrobials to be utilized in treating salt water contaminated wounds pending culture results.

Technical Approach: All patients with an acutely acquired or infected wound with a history of salt water contamination will be initially eligible to participate in the study. All wounds will be swabbed for culture and sent for culture and sensitivity. If clinically indicated, debridement and/or suturing will e performed. Tetanus prophylaxis will be administered if indicated.

Progress: Data have been published by other investigators; therefore, the study is terminated.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: C-17-87 Status: Completed
 Title: Comparison of Diphenhydramine, Promethazine, and Placebo in Patients with Abdominal Pain

Start Date 10 Feb 87	Est Comp Date:
Principal Investigator Robert N. Norris, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words: Pain, abdominal	
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 6 Apr 89	Results Continue

Objective(s): 1) To evaluate the relief of abdominal pain using Diphenhydramine and Promethazine.

2) To compare the efficacy of Diphenhydramine versus Promethazine in the treatment of abdominal pain.

Technical Approach: This is a prospective randomized, double blind study of patients between the ages of 18 and 60 years who are diagnosed as having gastroenteritis. Following evaluation, the patient will be asked to rate the severity of abdominal pain using the numerical scale 1 through 5. Patients will be randomized by the coding sequence - A, B, C. Diphenhydramine, Promethazine, and normal saline will be placed in letter coded vials whose contents will be unknown to the evaluators. The evaluator will obtain 1 cc from the corresponding vial which correlates Diphenhydramine, 50 mg; Promethazine, 25 mg; or normal saline. The fluid will be administered intravenously over two minutes. The patient will be asked to evaluate the severity of the abdominal pain at 15 minutes and 30 minutes using the same numerical scale.

Progress: This study has been completed. However, the data are being analyzed by Dr. Ferguson at Fort Hood.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: C-63-87 Status: Ongoing
 Title: Role of Routine Radiographs in the Evaluation of Acute Knee Complaints
 in the Emergency Department

Start Date 25 Jun 87	Est Comp Date:
Principal Investigator MAJ Robert L. Norris, Jr.	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Peter Curka, CPT, MC
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 develop a set of high-yield criteria based on a careful history and physical examination in patients with acute knee complaints that will guide Emergency Department physicians in the ordering of knee radiographs.

Technical Approach: All patients 15 years of age and older presenting to the Emergency Department with a chief complaint of acute knee pain or dysfunction will be included in the study. A thorough history and orthopedic examination as outlined in the study form will be performed. The examining physician will then document whether or not he/she expects to find an abnormality on radiographic examination and what he/she expects that abnormality to be. Then in a retrospective manner, each case will be reviewed, comparing the examining physician's expectations and findings to the findings from the official radiologic report to determine whether the x-rays made any difference in the patient's diagnosis or management.

Progress: Data collection continues.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-73-87 Status: Ongoing
 Title: The availability of Antivenin (Crotalidae) Polyvalent and Antivenin
 (Micrurus fulvius) in Texas Hospitals Providing Emergency Medical Care

Start Date 12 Aug 87	Est Comp Date:
Principal Investigator	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Robert L. Norris, MAJ, MC
Key Words: Antivenin	
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 attempt to determine the actual supply and availability of antivenins against the venomous snakes indigenous to Texas in hospitals providing emergency medical care in the State.

Technical Approach: A questionnaire will be sent to all pharmacy directors of hospitals in the State of Texas. The pharmacy director will be asked to quantify his/her facility's antivenin supply currently in stock. Simultaneously, a questionnaire will be mailed to all directors of Emergency Departments/Emergency Rooms of hospitals in the State. They will be asked several pertinent questions regarding their facility's approach to the management of snakebite victims.

Progress: Data are being analyzed.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-89-87 Status: Ongoing
 Title: Prognostic Predictive Value of the Clinical/Hemodynamic Classification Schema of Left Ventricular Performance in Acute Myocardial Infarction Determined at the Time of Presentation and 72 Hours Post-Admission

Start Date 21 Sep 87	Est Comp Date:
Principal Investigator Brenda A. Gowsky, CPT, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Ricky D. Latham, MAJ, MC Lawrence Pupa, MAJ, MC William Wright, CPT, MC
Key Words: Infarction, myocardial	
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 Sep 88	Results Continue

Objective(s): 1) To determine the predictive value of the Killip classification in acute myocardial infarction for short term prognosis.

2) To correlate the Forrester classification documented by invasive measurements as well as noninvasive assessment of left ventricular function with the Killip classification and prognosis.

Technical Approach: Patients arriving in the Emergency Room at BAMC with a chief complaint of chest pain and/or shortness of breath will be entered into the study. It is the object of this study to correlate noninvasive Killip with the invasive monitoring of the Forrester classification and to correlate these with hospital mortality and prognosis. Residents will assess the patient and complete a questionnaire.

Progress: None due to difficulty with residents completing questionnaires as requested. Considering a retrospective review instead.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-42-89 Status: Ongoing
 Title: Comparison of Light Reflection Rheography and Venography in the
 Diagnosis of Acute Deep Venous Thrombosis

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator Timothy MacLean, MAJ, USAF, MC	Facility Brooke Army Medical Center
Dept/Svc Department of	Associate Investigators: Kevin Rodgers, CPT, MC John M. Bauman, MAJ, MC Carey Chisholm, MAJ, MC Robert Norris, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$6,000.00
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 determine the applicability of Light Reflection Rheography as a screening tool for the detection of deep venous thrombosis in the emergency department.

2) To determine the sensitivity and specificity of Light Reflection Rheography when compared to venography in the diagnosis of acute deep venous thrombosis.

Technical Approach: All patients over 18 years of age with history/physical exam suspicious for a lower extremity DVT will be eligible for the study. Once the examining physician has arranged venography, the on-call LRR physician will perform the test. The AV-1000 (an LRR), is a noninvasive test utilizing light reflection from a sensitive emitter attached to the lower calf by an adhesive ring. The patient does a set of dorsiflexion exercises and a strip chart is produced by the instrument. The affected and unaffected legs are compared. The results of venography will be compared to the results of LRR.

Progress: AV 1000 was received early August 1989. Therefore, actual study will begin in the near future.

Detail Summary Sheet

Date: 16 Oct 89 Proj No: C-84-89 Status: Ongoing
 Title: The Efficacy of Steroid Burst Therapy in Reducing Severity of an Acute Migraine Headache

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Laurel I. Kietzman, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators:
Key Words: Migraine	
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 steroid burst therapy has any significant effect in the treatment of acute migraine pain when compared with placebo.

Technical Approach: Patients will be randomly assigned to receive either steroid burst (Prednisone) or placebo for five days. At the end of five days, the patients will return to the Neurology Clinic and asked to rate the severity of their pain on a linear and verbal scale. Patients who have visited an Emergency Department or clinic because of persistent or worsening symptoms within the five day period will be graded as failures.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-123-89 Status: Ongoing
 Title: A Compound Curve Cutting Edge Needle for Skin Closure

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator Benjamin Walker, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Emergency Medicine	Associate Investigators: Thomas P. Cook, 2LT, USAR
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 _____	Results _____

Objective(s): To gather preliminary information regarding the usefulness to emergency physicians and residents of a newly designed skin closure needle.

Technical Approach: All patients with cutaneous lacerations presenting to the emergency department will be evaluated and treated in the usual manner. If wound closure is deemed necessary with either a 4-0 or 5-0 suture, a PS-2 compound curve needle with either a 4-0 or 5-0 nylon suture will be utilized to close the wound. The physicians will then be asked to fill out a questionnaire evaluating their satisfaction with the needle.

Progress: This is a new study.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-13-82 Status: Terminated
 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: Bernard P. Rehal, M.D., PAC
Key Words: Intracardiac pressure	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 9	
Date of Periodic Review 9 Mar 89	Results Completed

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: Patient enrollment has been completed. However, since the principal investigator is no longer on active duty and for two years has reported "data being analyzed," it is unlikely that any information will be received. Therefore, the study is terminated.

Detail Summary Sheet

Date: 21 Sep 89 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 (vice Salasche) William J. Grabski, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: Catherine Pollard, R.N. Martha McCullough, MAJ, MC
Key Words: Basal cell carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 168	
Date of Periodic Review n/a	Result: Open for Follow-Up

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 at the baseline and 36 month visits. History, total skin exam, and necessary biopsies are done at each visit. Laboratory data is collected at the 2 week, 3 month, 6 month, 12 month, 24 month and 36 month visit. Lateral cervical and thoracic spine films are done at 0 and 36 month visit at this point in the study.

Progress: To date, 148 patients are actively participating in the study. Of the 169 patients enrolled, 8 have died, 6 have moved from the study site, and 5 have left the study for conflicting health reasons. Twenty-eight patients are currently on medication and 116 patients have completed the 3 year medication period (4 patients are still on study but off medication due to side effects). Twenty two patients have completed the 5 year study and all except one of these patients continues to be followed every 6 months for recurrent tumors. All laboratory data and x-rays are up to date. Study is continually closely monitored by NIH, the last site visit being accomplished during May 1989.

Detail Summary Sheet

Date: 12 Oct 89	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	Facility
Ricky D. Latham, M.D., MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Cardiology	John P. Mulrow, MAJ, MC
Key Words:	Bernard J. Rubal, Ph.D.
Cardiomyopathy, congestive	Renu Virmani, MAJ, MC, AFIP
	Max Rabinowitz, M.D., AFIP
	James Baker, M.D., WRAMC
	Stephen Ramee, CPT, MC, LAMC
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost: \$3373.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 6 Apr 89	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.

Protocol has been amended to include left heart biopsy.

Progress: Results show no improvement with steroids. F/V variables are in the process of being analyzed.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-19-84 Status: Completed
 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., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Michael Cawthon, M.D., MAJ, MC Michael F. Hartshorne, M.D., MAJ, MC Joseph P. Murgu, 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: _____	
Date of Periodic Review 6 Apr 89	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 and 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: Analysis of ventriculograms revealed no specific changes. IV MUGA was 63% sensitive almost 100% predictive of significant coronary artery disease.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-73-84 Status: Terminated

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 John W. McClure, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Ricky D. Latham, MAJ, MC Bernard J. Rubal, Ph.D. Steven R. Bailey, MAJ, MC
Key Words: Catheter, left atrial	

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 28 Sep 88	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: This study was terminated due to lack of patient accrual.

Detail Summary Sheet

Date: 6 Jul 89 Proj No: C-49-85 Status: Terminated
 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., COL, 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:	
Total Number of Subjects Enrolled to Date: 20	
Date of Periodic Review 6 Jul 89	Results Terminated

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: This study was terminated due to transfer of principal investigator.

Detail Summary Sheet

Date: 13 Oct 89	Proj No: C-30-86	Status: Completed
Title: Incidence and Significance of a Presystolic "A-Wave" as Determined by Doppler Echocardiography.		

Start Date 12 Mar 86	Est Comp Date:
Principal Investigator Joseph P. Johns, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Stephen D. Hoadley, MAJ, MC
Key Words: Echocardiography, Doppler	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 1,190.16
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date: 63	
Date of Periodic Review 23 Mar 88	Results Completed

Objective(s): To assess the frequency and hemodynamic significance of a pre-systolic Doppler "A-wave", as observed in the left ventricular outflow tract.

Technical Approach: The presence of a presystolic wave has been shown in previous doppler studies of the pulmonary artery. To examine and the presence and significance of this wave in the LVOT, two approaches are being taken. (1) Noninvasive echo/doppler studies of normal patients were compared to patients with LVH. M-mode and 2-D echocardiograms from 45 NL and 18 LVH subjects were obtained along with pulsed Doppler recordings from the apical window. The sample volume was place in the LVOT within 0.5 cm of the aortic annulus. A quantitative index of hypertrophy (IH) was obtained from measurements of LV dimensions, septal and free wall thicknesses. A two-way split-plot ANOVA was performed on 12 patients from each group to assess the effect of IH and age on maximum PE velocity.

Progress: PE velocity averaged 19 ± 6 in NL and 25 ± 12 (SD) cm/s in LVH ($p=0.6$). LOT systolic velocities averaged 89 cmn/s in both groups and did not change with ave. ANOVA showed a significant increase in PE velocity with age ($P < 0.05$) but not with relative LVH ($p < 0.10$). We conclude that PE velocity is affected by age and does not represent a useful noninvasive index of LV contractile performance in hypertrophy.

Detail Summary Sheet

Date: 21 Aug 89 Proj No: C-55-86 Status: Completed
 Title: Right Heart Flow Dynamics ("Flow Dynamics in the Right Ventricular Outflow Tract" previous title)

Start Date 12 Jun 86	Est Comp Date:
Principal Investigator Joseph Johns, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Randy Condos, LTC, MC
Key Words: Ultrasound, Doppler	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 13	
Date of Periodic Review 6 Jul 89	Results Completed

Objective(s): To use Doppler ultrasound combined with high fidelity pressure measurements in the right ventricular outflow tract and proximal pulmonary artery to determine the pressure-flow relationships in that region.

Technical Approach: A complete two-dimensional and M-mode echocardiographic examination will be performed with particular attention to discovering right heart valvular disease or intracardiac shunts. Right heart catheterization with a Millar high-fidelity triple tip catheter will be performed in the standard manner. The electromagnetic flow probe will be calibrated using simultaneous Fick and thermal dilution cardiac output. This will be used to correlate with the doppler flow probe. Doppler ultrasound will be calibrated in the usual manner, ensuring that each strip chart has a "menu" with a stop-frame 2-D echo.

A two-way split-plot ANOVA was performed on 12 patients to assess the effect of Index of hypertrophy (IH) and age on maximum pre-ejection flow (PE) velocity.

Progress: Final evaluation of the data confirmed our preliminary conclusions that PE velocity is affected by age and does not represent a useful noninvasive index of LV contractile performance in hypertrophy.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-60-86 Status: Ongoing
 Title: The Natural History of HTLV-III Infection and Disease in a United States Military Population.

Start Date 25 Jun 86	Est Comp Date:
Principal Investigator C. Kenneth McAllister, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators:
Key Words: HTLV-III	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 50	
Total Number of Subjects Enrolled to Date: 500	
Date of Periodic Review n/a	Results

Objective(s): 1) To assess the impact of HTLV-III infection on fitness for duty (deployability, military readiness and retention) by systematically defining the natural disease progression in individuals with documented HTLV-III infections in the general military population (active duty, dependents and retirees).

2) To form an information basis and a study cohort upon which number other studies can be built (i.e., drug treatment of HTLV-III, etc.)

Technical Approach: Each HTLV-III infected individual will be staged according to the Walter Reed Staging Classification. The only additional requirements of individuals enrolled in this study are (1) additional information gathered from each individual as a consequence of this study will be centralized in a common data base; (2) serum and CSF will be stored at WRAIR for future testing.

Progress: All data on HIV risk factors is being recorded in ongoing fashion in Preventive Medicine bank at WRAIR.

Detail Summary Sheet

Date: 22 Sep 89	Proj No: C-74-86	Status: Ongoing
Title: Intensive Chemotherapy, Delayed Local Irradiation, Total Body Irradiation and Autologous Bone Marrow Rescue in Treating High Risk Ewing's Sarcoma		
Start Date 12 Aug 86	Est Comp Date:	
Principal Investigator Richard O. Giudice, MAJ, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Timothy J. O'Rourke, LTC, MC Paul J. Thomas, COL, MC Barbara Reeb, GS-9	
Key Words: Sarcoma, Ewing's		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: _____		
Total Number of Subjects Enrolled to Date: 1		
Date of Periodic Review 9 Sep 88 Results Continue		

Objective(s): 1) To improve disease-free survival of patients with Ewing's sarcoma having a high risk of treatment failure.

2) To test the effectiveness of intensive inducition chemotherapy, delayed RT to the primary tumor and TBI with ABMR.

3) To test the toxicity of such a regimen.

4) To test the accuracy of currently available staging techniques and monitoring techniques in recognizing residual primary and metastatic tumor.

5) To test whether tumor size independently of other variables predicts long-term disease-free survival.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: One patient enrolled on study. None enrolled during the last year.

Detail Summary Sheet

Date: 21 Sep 89 Proj No: C-94-86 Status: Terminated
 Title: Human Pyloric Response to Intraduodenal Blood: A Manometric Study

Start Date 29 Sep 86	Est Comp Date:
Principal Investigator Julian E. Armstrong, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Fred Goldner, COL, MC
Key Words:	
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 9 Sep 88 Results Continue	

Objective(s): To determine the association between the presence of blood in the duodenum and pyloric manometric response.

Technical Approach: Forty patients will be studied; 20 would be controls (normal endoscopic exam of duodenum) and 20 patients would have duodenal ulcers. All patients would undergo endoscopy exam in the standard manner. At the completion of the diagnostic exam, pyloric sphincter measurements will be made.

Progress: Five patients were studied without incident. Due to transfer of principal investigator, the project was temporarily halted, and the study kept open pending assignment of a new principal. However, no one is interested in continuing the study; therefore it is terminated.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-2-87 Status: Ongoing
 Title: Percutaneous Transluminal Valvuloplasty in Adult Mitral/Aortic Stenosis

Start Date 19 Nov 87	Est Comp Date:
Principal Investigator (vice Bailey) W. Randy Condos, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words: Stenosis, aortic Stenosis, mitral	Brent A. Grishkin, COL, MC
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 8 Nov 88	Results Continue

Objective(s): To apply the technique of percutaneous balloon dilatation of valvular aortic/mitral stenosis to a patient population at high risk of morbidity and mortality from aortic/mitral valve replacement and/or chronic anti-coagulation.

Technical Approach: All patients age 21 or older with hemodynamically proven symptomatic aortic stenosis of either calcific/degenerative or congenital etiologies or patients age 21 or older with hemodynamically proven, significant mitral valve stenosis will be eligible if they are clinically considered to be a high risk for surgical valve replacement or chronic anticoagulation. Cardiac catheterization and valvuloplasty will be performed as outlined in the study protocol.

Progress: Because of the stringent eligibility criteria for this study, patient accrual is extremely slow.

Detail Summary Sheet

Date: 21 Aug 89 Proj No: C-10-87 Status: Completed
 Title: Effect of Reducing the Total Cholesterol/HDL Cholesterol Ratio to Less than 3.0

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator Edwin J. Whitney, MAJ, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven R. Bailey, MAJ, MC Mary Dunn, MAJ, AN Stacey Adams
Key Words: Cholesterol, total Cholesterol, HDL	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 16.50
Number of Subjects Enrolled During Reporting Period: 17	
Total Number of Subjects Enrolled to Date: 17	
Date of Periodic Review 6 Apr 89	Results Continue

Objective(s): To determine the effect of reducing the TC/HDL cholesterol ratio to less than, or equal to 3.0 in patients with angiographically documented coronary artery disease.

Initial Approach: Patients who had a cardiac catheterization within 3 months and with measurable stenoses were eligible. Seventeen patients were treated with various combinations of cholestyramine and gemfibrozil or cholestyramine, gemfibrozil and niacin. Eleven patients were treated with "low dose" cholestyramine (mean dose 10.6 gm/day) and gemfibrozil (100 mg/day).

Progress: The combination of cholestyramine and gemfibrozil reduced total serum cholesterol and the total cholesterol/HDL cholesterol ratio from 272 mg/dL and 7.2 to 156 mg/dL and 4.6, respectively. The addition of "low dose" niacin (mean dose 1470 mg/day) to the combination of gemfibrozil and cholestyramine produced further reductions in total cholesterol and the total cholesterol/HDL cholesterol ratio. In the eleven patients receiving "low dose" cholestyramine, "low dose" niacin and gemfibrozil, the total cholesterol and total cholesterol/HDL ratio fell from 318 mg/dL and 9.1 to 156 mg/dL and 4.1, respectively. Only 3 of 17 patients reduced the doses or discontinued the medications during the

C-10-87 (continued)

year of follow-up. The combination of "low dose" cholestyramine, "low dose" niacin and/or gemfibrozil is well tolerated and can produce much larger reductions in serum lipids than standard doses of the drugs used individually.

Conclusion. Low dose combination therapy with niacin, gemfibrozil and cholestyramine can dramatically reduce serum lipids in patients to levels which are rarely associated with cardiovascular disease epidemiologically. It is possible that reduction in serum lipids to these levels will result in further reductions in the risk of developing atherosclerotic coronary artery disease.

Detail Summary Sheet

Date: 21 Aug 89 Proj No: G-11-87 Status: Completed
 Title: Atrial Natriuretic Peptide and Hemodynamics in Orthotopic Cardiac Transplantation.

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: John B. Copley, COL, MC John P. Mulrow, M.D.
Key Words: Transplantation, cardiac	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 6 Apr 89 Results Completed	

Objective(s): To examine the relationship of cardiac pressures, atrial natriuretic peptide levels and catecholamine levels during rest and exercise in patients with orthotopic cardiac transplantation.

Technical Approach: To assess the responsiveness of atrial natriuretic factor (ANF) in orthotopic cardiac transplantation (TX), we obtained peripheral (P) and central (PA) ANF levels at rest (R) and exercise (E) in 4 patients (pts) on a high salt diet (200 mEq sodium [NA], 80 mEq potassium). There were 3 females, a 1 male, mean age 42±16 years who were 10±3.0 months post-TX, clinically stable and free from rejection on biopsy. Medications except for immunosuppressives were stopped before study. Daily 24 hour urine collections documented NA balance and serum creatinine was less than 1.5 mg/dl in all pts. ANF determinations (pg/ml) were performed on extracted plasma. Simultaneous right and left hi-fidelity hemodynamics were obtained with P and PA ANF levels at R and E.

Progress: While ANF levels increased from P to PA at R and E, only increases from PA R to PA E (178±69 to 452±260) were significant (p<0.05). A significant increase in RA from R to E occurred (6±1 to 16±2) but did not correlate with R and E changes in PA ANF levels. We conclude ANF can respond in the TX heart to a high salt diet and exercise. Mechanisms of release of ANF are not clear.

Detail Summary Sheet

Date: 21 Aug 89 Proj No: C-12-87 Status: Terminated
 Title: Clinical and Outpatient Follow-up of Cardiac Transplantation

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator William R. Condos, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven R. Bailey, MAJ, MC Ricky D. Latham, MAJ, MC
Key Words: Transplantation, cardiac	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 6 Apr 89	Results Terminated

Objective(s): To describe the evolution and present state of the art for cardiac transplantation and to describe the clinical follow-up of patients at BAMC.

Technical Approach: Patients referred by BAMC for cardiac transplantation to institution(s) in San Antonio will return to Brooke following the immediate postoperative care at the surgical center. At each follow-up visit, the following will be obtained: ECG, urine analysis, creatinine clearance, chest x-ray, CBC, PA20, cyclosporin level and titers for cytomegalic herpes and varicella virus. Five-day ambulatory ECG monitoring, radionuclide assessment of diastolic, systolic function, and echo cardiography Doppler will be performed at appropriate intervals. Endomyocardial biopsies to detect rejection will be performed weekly for the first six weeks, monthly for the next six to seven months, and then every two to three months for life.

Progress: This study merely involves routine follow-up of cardiac transplantation. It is not felt that this warrants keeping an active protocol. Therefore, the study is terminated.

Detail Summary Sheet

Date: 29 Sep 89 Proj No: C-13-87 Status: Ongoing
 Title: Evaluation of Biventricular Performance in the Deinnervated Heart

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven R. Bailey, MAJ, MC Ares Pasipoularides, M.D., Ph.D.
Key Words: Heart, deinnervated	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date. 4	
Date of Periodic Review 6 Apr 89	Results Continue

Objective(s): To examine the following biventricular parameters in the deinner-
 vated heart at rest, volume expansion (leg raising) and submaximal dynamic exer-
 cise: (1) systolic ejection indices; (2) pressure volume loops; (3) diastolic
 indices of stress-strain; and (4) hemodynamic response to Valsalva and Mueller
 maneuvers.

Technical Approach: To evaluate the exercise (E) response in cardiac transplant
 (Tx) patients (pts) on cyclosporine, we performed right and left heart cathe-
 terization at rest (R) and supine bicycle (E) using multisensor high fidelity
 catheters. Four pts (3 females, 1 male) mean age 47+15 years, mean 10+months
 post transplant, who were clinically stable and free of rejection by biopsy were
 studied off cardiac medications.

High fidelity catheters were used to measure simultaneous aortic root pressure
 (Ao) and flow velocity and LV pressure at rest and during supine bicycle exer-
 cise (Ex). Fourier analysis of Ao and flow signals was used to calculate
 characteristic input impedance (Z_c). Diastolic decay Ao was used to determine
 systemic compliance (C) by a monoexponential model (RC).

Progress: These are post cardiac transplant patients requiring routine clinical
 catheterization. No problems have been encountered.

Detail Summary Sheet

Date: 21 Sep 89 Proj No: C-14-87 Status: Terminated
 Title: Prospective Randomized Clinical Trial of the Capillary Cloning System
 for Patients with Extensive Small Cell Lung Cancer

Start Date 15 Jan 87	Est Comp Date:
Principal Investigator Arlene J. Zaloznik, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, small cell lung	
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 6 Apr 89 Results Continue	

Objective(s): To perform a prospective randomized single agent clinical trial of the newly developed capillary cloning system.

Technical Approach: A portion of tumor will be removed and sent to the laboratory for capillary cloning to determine which drugs will or will not be effective in the treatment of small cell lung cancer.

Progress: This protocol is now closed and has been reopened as SWOG 8610.

Detail Summary Sheet

Date: 21 Aug 89 Proj No: C-37-87 Status: Completed
 Title: Phase II Study of Carbetimer in Lung Carcinoma

Start Date 18 Mar 87	Est Comp Date:
Principal Investigator Arlene J. Zaloznik, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Carbetimer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review 6 Apr 89	Results Completed

Objective(s): 1) To determine the response rate and response duration in subjects with advanced non-small cell carcinoma of the lung treated with carbetimer.

2) To define the qualitative and quantitative toxicities of carbetimer administered in a Phase II study.

Technical Approach: For inclusion in the study, all subjects must have a histologic diagnosis of recurrent or metastatic non-small cell cancer of the lung. Subjects with recurrent or metastatic non-small cell cancer of the lung must be previously untreated except for surgery and/or radiotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Eight patients from BAMC were enrolled on this study and 18 patients at other institutions. Overall the drug was tolerated with only minimal toxicity. In view of the absence of response in 17 evaluable patients, we conclude that Carbetimer as given in this study has no significant activity in non-small cell lung cancer.

Detail Summary Sheet

Date: 21 Sep 89 Proj No: C-41-87 Status: Completed
 Title: Shortening of Left Ventricular Isovolumic Contraction Time During Exercise in Normal Man

Start Date 9 Apr 87	Est Comp Date:
Principal Investigator Joe M. Moody, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Johns, MAJ, MC
Key Words:	Ares Pasipoularides, M.D., Ph.D.
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 6 Jul 89	Results Continue

Objective(s): To assess, using noninvasive tools, the relative timing of mitral valve closure and aortic valve opening at rest and during exercise in normal volunteers.

Technical Approach: Simultaneous M-mode echocardiography of aortic and mitral valves is performed during upright bicycle exercise in normal volunteers. Recordings are obtained at increasing heart rates to assess changes in MC-AO interval.

Progress: We have found that at HR > 175, isovolumic contraction time approaches zero and in some cases aortic opening precedes mitral closure.

Detail Summary Sheet

Date: 21 Aug 89 Proj No: C-42-87 Status: Ongoing
 Title: Total Systemic and Regional Aortic Compliance at Rest and with Exercise

Start Date 9 Apr 87	Est Comp Date:
Principal Investigator David Slife, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	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: 10	
Date of Periodic Review 6 Jul 89	Results Continue

Objective(s): 1) To compare compliance as determined by a three-element windkessel arterial model (using aortic input pressure and flow) at rest and with exercise, to compliance determined by the standard RC model in normal man.

2) To compare aortic compliance by each method in normal and hypertensive patients.

3) To evaluate the regional proximal aortic contribution to the total systemic capacitance.

Technical Approach: We measured simultaneous pulmonary artery pressure and flow with a multisensor micromanometer flow velocity catheter during routine cardiac catheterization in ten normal subjects to evaluate the parameters of the three-element Windkessel model: pulmonary characteristic impedance (Z_c), pulmonary vascular resistance (PVR) and pulmonary arterial compliance (cp). These values were then compared to independent calculations of these variables.

Progress: This study reports the first use of the three-element Windkessel model to describe pulmonary vascular dynamics in man. We found that the parameter estimates were appropriate both at rest and exercise. Given these findings and excellent correlations with normalized (to body weight) values in other species, we believe the compliance value from the three-element Windkessel model is a good estimate of the true value when the correlation of model to measured is $R > 0.90$. This technique offers the advantage of parameter estimation during transients and may provide a reliable in vivo method to evaluate pulmonary arterial compliance in man.

Detail Summary Sheet

Date: 19 May 89 Proj No: C-45-87 Status: Completed
 Title: Utility of Solubilized Calcium Citrate in the Management of Moderate and End-Stage Renal Failure

Start Date 9 Apr 87	Est Comp Date:
Principal Investigator (vice Lindberg) Karl Koenig, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: J. Brian Copley, COL, MC Howard M. Cushner, MAJ, MC John M. Bauman, MAJ, MC
Key Words: Renal failure, end-stage	
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 6 Jul 89 Results Completed	

Objective(s): To assess the value of solubilized calcium citrate (Super-Citracaltm) in the management of moderate and end-stage renal failure.

Technical Approach: Seventy-five to 150 adult patients of either sex with endogenous creatinine clearance ranging from 25-60 ml/min will participate in the study. Eligible participants will be randomly assigned into three groups. Patients in Group I will receive Super-Citracal 500 mg calcium three/day (with meals). Those in Group II will take calcium carbonate 500 mg calcium three/day (with meals). Patients in Group III will receive placebo medication three/day (with meals). The remainder of the study will be conducted as outlined in the study protocol.

Progress: The study is completed and the resulting paper is being written by CPT Koenig who is now assigned to William Beaumont Army Medical Center.

Detail Summary Sheet

Date: 30 Mar 89 Proj No: C-49-87 Status: Terminated
 Title: Phase II Study of Carbetimer in Advanced Breast Carcinoma

Start Date 11 May 87	Est Comp Date:
Principal Investigator Arlene J. Zaloznik, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, breast	
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 6 Jul 89 Results Terminated	

Objective(s): 1) To determine the response rate and response duration in subjects with advanced breast carcinoma treated with carbetimer.

2) To define the qualitative and quantitative toxicities of carbetimer administered in a Phase II study.

Technical Approach: To be eligible for this study, all subjects must have a histologic diagnosis of breast carcinoma. Subjects must have an estimated survival of at least 12 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed prematurely on 29 March 1989 because of poor accrual at BAMC and the other institutions involved in the study.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-52-87 Status: Ongoing
 Title: Autologous Bone Marrow Rescue in Patients with Acute Leukemia and Lymphoma Using Ex-Vivo Marrow Treatment with 4-Hydroperoxycyclophosphamide (4-HC)

Start Date 13 May 87	Est Comp Date:
Principal Investigator Richard O. Giudice, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Paul J. Thomas, COL, MC Allen Potter, LTC, MC Barbara Reeb, DAC Rory Duncan, SGT
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 900.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 14	
Date of Periodic Review 6 Jul 89 Results Continue	

Objective(s): 1) To evaluate autologous marrow rescue after intensive therapy in patients with acute leukemia and lymphoma in second remission or subsequent remission or in early relapse.

2) To study the effects of ex-vivo bone marrow purging utilizing 4-HC on malignant cells, marrow stem cells, and relationship to subsequent engraftment times.

3) To study the acute toxic effects of the preparative regimens.

Technical Approach: To be eligible for this study, all patients must have a diagnosis of acute leukemia or aggressive histology lymphoma and have relapsed after therapy. Bone marrow should be harvested when the patient is in remission.

Therapy will follow the schema outlined in the study protocol.

Progress: 1) Four adult patients and one pediatric patient enrolled to have bone marrow harvested and stored. Will transplant when they relapse.

2) Total of 14 patients harvested to date. Two adult patients have been transplanted - one with ALL who relapsed 1½ years after transplant. She is alive and in another remission. One patient with non-Hodgkin's lymphoma is in continuous complete remission.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-54-87 Status: Terminated
 Title: Left Ventricular Systolic Dynamics in Coronary Arterial Disease at Rest and in Exercise

Start Date 13 May 87	Est Comp Date:
Principal Investigator (vice Bailey)	Facility
W. Randy Condos, LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Cardiology	
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 6 Jul 89	Results Continue

Objective(s): To develop indices for LV pumping efficiency and regional wall contractility in CAD. We will quantify intraventricular pressure distributions promoting the displacement of blood in the LV chamber towards the aortic valve in the course of systolic isovolumic contraction and ejection.

Technical Approach: Twenty patients with suspected CAD will be prospectively evaluated during routine diagnostic cardiac catheterization prior to retrograde left ventriculography. All patients will undergo standard retrograde arterial catheterization from the arm using an #8 high fidelity catheter with two laterally mounted micromanometers and an electromagnetic flow sensor at the level of the proximal pressure sensor. The study will be carried out as outlined in the protocol.

Progress: Study terminated due to lack of progress.

Detail Summary Sheet

Date: 21 Aug 89 Proj No: C-57-87 Status: Terminated
 Title: Phase I Trial of Intrapleurally Administered Intron-A®

Start Date 29 May 87	Est Comp Date:
Principal Investigator (Brown) Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words:	
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 6 Jul 89 Results Terminated	

Objective(s): To determine the tolerance to and toxicity of intrapleural administration of Intron-A® in patients with malignant pleural effusions.

Technical Approach: To be eligible for this study the patient must have histologically proven diagnosis of cancer involving the pleura, as demonstrated by pleural fluid cytology or pleural biopsy positive for carcinoma or lymphoma, or histologically proven intrathoracic malignancy with a cytologically negative effusion, without other apparent etiology. The patient's malignant pleural effusion must be refractory to standard systemic therapy, or the patient's tumor must have no known effective standard therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been replaced by a study using larger doses of Alpha-Interferon.

Detail Summary Sheet

Date: 22 Aug 89	Proj No: C-58-87	Status: Completed
Title: Phase I Study of LY186641 (Sulfonylurea)		

Start Date 29 May 87	Est Comp Date:
Principal Investigator (vice Brown) Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	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: 8	
Date of Periodic Review 6 Jul 89	Results Completed

Objective(s): To determine the maximum tolerated dose (which is both predictable and reversible) of LY186641 as a single dose given every 3 weeks.

Technical Approach: In order to be eligible for inclusion in this study, all patients must have microscopically confirmed diagnosis of advanced or metastatic cancer. All patients' tumors must be refractory to all known forms of effective therapy (surgery, radiotherapy, chemotherapy) as well as other investigational agents of higher potential efficacy. Patients must have a predicted life expectancy of at least 12 weeks and a performance status less than or equal to 2.

Therapy will follow the schema outlined in the study protocol.

Progress: Since this study opened, eight patients have been treated at BAMC. Mild methemoglobinemia (10%) has been seen and no other significant toxicity.

The study was closed to further patient accrual on 29 Mar 89.

Detail Summary Sheet

Date: 2 Oct 89 Proj No: C-59-87 Status: Ongoing
 Title: Phase I Study of LY188011 (Difluorodeoxycytidine)

Start Date 29 May 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	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: 15	
Date of Periodic Review 6 Jul 89	Results Completed

Objective(s): To determine the maximum tolerated dose of LY188011 as a single dose given for 5 consecutive days with each cycle repeated every 21 days.

Technical Approach: Patients must have a microscopically confirmed diagnosis of metastatic or advanced cancer. Patients' cancers must be refractory to effective therapy (surgery, radiotherapy, chemotherapy) as well as other investigational agents of higher potential efficacy. Patients must have a predicted life expectancy of at least 12 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: At the time of annual review this study was reported as having been closed to further patient accrual. However, on 10 August, a request to reopen the study was received and subsequently approved by the Institutional Review Committee.

The study was reopened to study a less frequent dosing schedule (every two weeks) as it appears that this schedule will be more efficacious based on the MTDs observed in Phase I studies at BAMC and elsewhere.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-62-87 Status: Ongoing
 Title: Development of an Autologous Bone Marrow Rescue Program (Master Protocol)

Start Date 25 Jun 87	Est Comp Date:
Principal Investigator Richard O. Giudice, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Paul J. Thomas, COL, MC Allen Potter, LTC, MC Robert G. Whiddon, Jr., LTC MS Barbara Reeb, DAC Rory Duncan, SGT
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 11,595.00
Number of Subjects Enrolled During Reporting Period: 21	
Total Number of Subjects Enrolled to Date: 21	
Date of Periodic Review	Results

Objective(s): 1) To develop an autologous bone marrow rescue program at Brooke Army Medical Center.

2) To participate in research and clinical studies individually as well as part of the Southwest Oncology Group and Pediatric Oncology Group.

3) To establish a competent marrow rescue service for all eligible DOD patients for present clinical indications and future indications, i.e., radiation exposure.

Technical Approach: Bone marrow stem cells will be obtained by multiple bone marrow aspirations under general anesthesia. The marrow will be prepared by accepted methods and frozen for future reinfusion.

This is the master protocol for the autologous bone marrow transplant program.

Progress: Twenty-one patients have undergone bone marrow harvest and storage on this protocol over the past year. Breakdown is as follows: breast cancer, 7 patients; Hodgkin's disease, 4 patients; Non-Hodgkin's lymphoma,, 7 patients; AML, 1 patient; ALL, 1 patient; and rhabdomyosarcom, 1 patient.

Detail Summary Sheet

Date: 21 Sep 89	Proj No: C-64-87	Status: Ongoing
Title: Evaluation of Patients with Human Immunodeficiency Virus (HIV) Seropositivity Detected by Screening for the Presence and Potential Etiology of Exercise Intolerance		
Start Date 2 Jul 87	Est Comp Date:	
Principal Investigator James E. Johnson, MAJ, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: Gregg T. Anders, MAJ, MC Herman M. Blanton, MAJ, MC Eleanor Ayala, DAC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 5		
Total Number of Subjects Enrolled to Date: 43		
Date of Periodic Review 9 Sep 88 Results Continue		

Objective(s): Patients with HIV seropositivity have been noted to have exercise intolerance at an early stage when they are otherwise asymptomatic. The goals of this study are as follows: 1) To determine the prevalence of complaints of exercise intolerance and dyspnea in the study population. 2) To document whether abnormalities of exercise physiology exist in these patients complaining of exercise intolerance. 3) To evaluate these patients for potential causes of exercise intolerance such as early opportunistic pulmonary infection or lymphocytic interstitial pneumonitis (LIP).

Technical Approach: All active duty patients admitted to the HIV ward or referred to the HIV clinic for evaluation will be considered eligible for the study. These patients will be given a questionnaire on the day of admission including questions regarding exercise tolerance and dyspnea as well as previous lung, heart and muscle diseases. The response to these questions will be used for further patient selection. All participants will undergo gallium scan of the lungs, pulmonary function testing to include lung volumes and a D_LCO , cycle ergometry pulmonary exercise testing and bronchoalveolar lavage (BAL). The BAL fluid will be divided and submitted for the following: 1) staining for routine cytological evaluation (for evidence of viral infection) as well as for AFB and GMS stains; 2) culture for AFB, Fungi, CMV and HIV virus; 3) HIV antigen testing for comparison to peripheral blood titers; 4) quantitation of lymphocytes, PMN's, monocytes as well as lymphocyte subsets particularly OKT4 and OKT8.

Progress: About one fourth of the patients show exercise impairment consistent with a cardiac cause (low anaerobic threshold, low VO_2 max). No infecting organisms were found on BAL. About one-half of the patients have gallium uptake in intrathoracic nodes.

Detail Summary Sheet

Date: 12 Aug 89 Proj No: C-66-87 Status: Ongoing
 Title: Immunosuppressive Therapy for Psy Proven Myocarditis (Collaborative Study with University of Utah Medical Center and Centers for Multicenter Trial)

Start Date 2 Jul 87	Est Comp Date:
Principal Investigator Ricky D. Latham, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: William R. Condos, LTC, MC
Key Words: Myocarditis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 10 Jul 89 Results Continue	

Objective(s): To test the hypothesis that immunosuppressive therapy is beneficial in myocarditis.

Technical Approach: This is a national muticenter trial including 23 patient enrollment centers. Therapy will follow the schema outlined in the study protocol.

Progress: One subject died because of disease. Another subject was identified but declined to enter the study. Follow-up in another subject continues.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-70-87 Status: Ongoing
 Title: High Dose Busulfan with Autologous Bone Marrow Rescue

Start Date 17 Jul 87	Est Comp Date:
Principal Investigator (vice Harvey) Richard O. Giudice, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: R. Foulke, MAJ, MC Paul Thomas, COL, MC Allen Potter, LTC, MC Barbara Reeb, DAC Rory Duncan, SGT Robert G. Whiddon, Jr., LTC, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 6500.00
Number of Subjects Enrolled During Reporting Period: 6	
Total Number of Subjects Enrolled to Date: 14	
Date of Periodic Review 9 Sep 88	Results Continue

Objective(s): 1) To study the toxicities associated with the treatment of refractory malignancies, utilizing cyclophosphamide, busulfan and etoposide.

2) To evaluate the response rates and the response duration of patients treated with the above regimen.

Technical Approach: An IND for busulfan was obtained in March 1987. The protocol was amended in June to include the use of cyclophosphamide and etoposide (VP-16). Inclusion/Exclusion criteria and therapy is as outlined in the study protocol.

Progress: On the busulfan-VP 16 protocol, six additional adults have been transplanted. There have been four deaths in the peritransplant period. Two patients are alive and well without evidence of disease.

Detail Summary Sheet

Date: 21 Sep 89 Proj No: C-71-87 Status: Ongoing
 Title: Use of Clofazimine in Immunocompromised Patients for the Treatment of Infections Caused by Mycobacterium Avium-Intracellulare and Other Atypical Mycobacteria Resistant to Conventional Antituberculous Therapy.

Start Date 17 Jul 87	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC
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 9 Sep 88	Results Continue

Objective(s): To use and determine the effectiveness of the investigaitonal drug clofazimine (Lamprene®) for the treatment of infections due to Mycobacterium avium-intracellulare and other atypical mycobacteria in immuno-compromised patients.

Technical Approach: Selection of patients will be on the basis of medical history, physical examination and laboratory studies including an evaluation of immunological status. Attempts will be made to culture body fluids and or tissue specimens from patients to substantiate the presence of atypical mycobacterial infection. All mycobacterial isolates will be tested in vitro for sensitivity to clofazimine.

Progress: No subjects have been enrolled to date; however, we desire to keep this protocol open and available to patients who meet entry criteria.

Detail Summary Sheet

Date: 21 Sep 89	Proj No: C-72-87	Status: Ongoing
Title: Rifabutin (Ansamycin LM 427) CDC Protocol		

Start Date 17 Jul 87	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC
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 <u>2 Sep 88</u> Results <u>Continue</u>	

Objective(s): To determine the effectiveness of Rifabutin in the treatment of patients with disseminated M. avium complex disease, localized M. avium complex disease unresponsive to standard therapy, selected patients with rifampin-resistant M. tuberculosis, and other selected patients with mycobacterial infections.

Technical Approach: Under the compassionate release IND, Rifabutin is intended for immunocompromised patients with disseminated M. avium complex disease, patients with pulmonary MAC disease unresponsive to standard therapy, and patients with rifampin-resistant tuberculosis. Other patients with mycobacterial diseases which have not responded to standard therapy may also be eligible to receive Rifabutin. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled in this protocol to date; however, we desire to keep the study available to patients who might meet the entry criteria.

Detail Summary Sheet

Date: 21 Aug 89 Proj No: C-76-87 Status: Terminated
 Title: A Study of Patterns of Ambulatory Oxygen Saturation in Patients with Chronic Obstructive Lung Disease

Start Date 13 Aug 87	Est Comp Date:
Principal Investigator James E. Johnson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary Dis.	Associate Investigators:
Key Words: Oxygen saturation	
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 Sep 88	Results Continue

Objective(s): To determine by 24 hours ambulatory oxygen saturation monitoring if constant low flow oxygen therapy is an effective method of preventing oxygen desaturation and if oxygen desaturation occurs in patients without room air hypoxemia.

Technical Approach: Data to be collected on each patient meeting the inclusion criteria are the patient's age, sex, duration on oxygen therapy, pulmonary function, room air arterial blood gas, arterial blood gas on oxygen, hematocrit, EKG, and rate of oxygen flow. The patient will then wear an ambulatory pulse oximeter and maintain a log of daily activities. Patients that show evidence of desaturation will have a second period of ambulatory oxygen saturation monitoring. During this second period, a 24 hour Holtor monitor will be performed. The 24 hour pulse oxymeter and Holtor monitor recordings will be examined to determine if periods of desaturation are associated with dysrhythmias.

Progress: No patients have been enrolled. It is elected to terminate the study at this time.

Detail Summary Sheet

Date: 21 Sep 89 Proj No: C-88-87 Status: Ongoing
 Title: A Survey of Intracolonic Combustible Gas Compositions with Various Endoscopic Preparations

Start Date 10 Sep 87	Est Comp Date:
Principal Investigator Francis E. Peluso, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Fred Goldner, COL, MC
Key Words: Gas, intracolonic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 573.50
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 whether phosphate enema is an adequate preparation for rectosigmoid electrocautery during sigmoidoscopy, with respect to concentrations of combustible gases.

2) To determine how an oral polyethylene glycol preparation (Colyte, Edlaw Preparations) and phosphate enema (C.B. Fleet Co.) compare with respect to combustible gas concentrations in the rectum.

3) To determine how regional concentrations of combustible gases in the colon correlate with regional visual assessments of bowel preparation with polyethylene glycol.

Technical Approach: Thirty patients undergoing routine flexible sigmoidoscopy and thirty patients undergoing routine colonoscopy will be entered into the study. The standard bowel cleansing regimens for each procedure will be utilized. At colonoscopy, six gas samples will be obtained via a polyvinyl tube passed through the scope. The method of collecting gas samples during flexible sigmoidoscopy will be identical.

Progress: Study has been delayed due to equipment failure, followed by manpower shortage. We are now awaiting calibration gas and then will proceed.

Detail Summary Sheet

Date: 2 Oct 89 Proj No: C-91-37 Status: Completed
 Title: Phase I Study of LY188011 (Difluorodeoxycytidine - Seven Day Continuous Intravenous Infusion)

Start Date 21 Sep 87	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	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 9 Sep 88 Results Continue	

Objective(s): To determine the maximum tolerated dose (which is both predictable and reversible) of LY188011 as a single dose given as a 7 day continuous infusion with each cycle repeated every 28 days.

Technical Approach: Patients must have a microscopically confirmed diagnosis of metastatic or advanced cancer. The cancers must be refractory to effective therapy (surgey, radiotherapy, chemotherapy) as well as other investigational agents of higher potential efficacy.

Therapy will follow the schema outlined in the study protocol.

Progress: The study has been abandoned for now because of observations made in other Phase I studies. Namely, it has been seen that more frequent dose schedules have significant fever and flu-like symptoms at very low-dose levels relative to less frequent bolus schedules. Because of this toxicity, blood levels of drug are far below those attained on less frequent schedules and these levels are presumably less efficacious.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-11-88 Status: Ongoing
 Title: Effect of Thyroid Replacement on Lipid Profile - Differences Associated with Keeping the TSH in Low Normal as Compared to Upper Normal Euthyroid Range

Start Date 2 Dec 87	Est Comp Date:
Principal Investigator	Facility
Albert M. Thomason, COL, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Endocrinology	
Key Words:	
Euthyroid	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 9 Mar 89	Results Continue

Objective(s): To demonstrate a difference in the lipid profile of euthyroid patients treated with higher or lower doses of thyroid replacement therapy.

Technical Approach: Patients being treated with thyroid replacement would be enlisted as volunteers. Individual patients would have their TSH levels adjusted by varying their thyroid replacement dose to above 3.5 mcIU or below 1.1 mcIU/ml depending on whether the initial value was above or below the mean euthyroid value of 2.3 mdIU/ml. The patient would be maintained at the lower or higher TSH value for 3 months as determined by monthly measurements. Then, the patient's serum lipid profile (cholesterol, triglyceride, and HDL cholesterol) would be determined after a 14 hour fast x 2. Subsequently, the patient would have his dosage of thyroid replacement adjusted to keep his TSH value in the opposite end of the euthyroid range from which it was initially. After three months of stabilization of the new value of TSH level, the plasma lipid profile would be repeated. Subsequently, the patient would once again have his TSH value adjusted to a relatively higher or lower value depending on where he started initially. After another 3 month period of stabilization, lipid profile would again be obtained.

Progress: Quite surprisingly, patients have not volunteered for this program per solicitation with fliers. Will keep trying to obtain volunteers.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-14-88 Status: Completed
 Title: Atrial Fibrillatory Wave Size and Left Atrial Enlargement: An
 Echocardiographic Analysis.

Start Date 2 Dec 87	Est Comp Date:
Principal Investigator Douglas G. Ebersole, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: J. Mark Moody, LTC, MC James Gilman, MAJ, MC Joseph Johns, MAJ, MC
Key Words:	
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 9 Mar 89	Results Continue

Objective(s): To determine if atrial fibrillatory wave size correlates with left atrial size by M-mode and 2-D echocardiographic assessment.

Technical Approach: New diagnoses of atrial fibrillation or sequential patients receiving EKG's found to be in atrial fibrillation are undergoing (1) 4 minute EKG's for fibrillatory wave analysis and (2) echocardiogram to assess left atrial size.

Progress: No correlation was found between atrial fibrillatory wave size and left atrial size or volume by echocardiography.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-17-88 Status: Ongoing
 Title: Evaluation of Immunocyte Populations in Mice Infected with Coccidioides immitis (fungus)

Start Date 16 Dec 87	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: David L. Danley, MAJ, MS Rebecca Cox, Ph.D. Janice M. Grassel, M.T.
Key Words: <u>Coccidioides immitis</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): To evaluate, using flow cytometry, the immunocyte populations associated with Tissues infected with C. immitis from susceptible and resistant strains of mice.

Technical Approach: In this study we propose to identify and enumerate different immunocyte populations in the spleen and peripheral blood of DBA/2 and BALB/c mice infected intranasally with C. immitis, using a fluorescence-activated cell sorter (FACS). All animals will be maintained and infected by Dr. R. Cox and her associates at the San Antonio Chest Hospital. Animals will be infected with ten spores intranasally. At various times after infection, spleen cells, peripheral blood, and lung tissue will be recovered. A single cell suspension will be obtained from solid tissue by mincing the organs in balanced salt solution; whereas peripheral leukocytes will be assayed without separation from contaminating erythrocytes.

Progress: Initial experiments have recently been completed and results are encouraging. Gamma interferon provided significant protection against infection and mortality. More interferon has been obtained and further experiments will follow.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-19-88 Status: Ongoing
 Title: Effect of Oral Agents vs Insulin Therapy on Lipid Profile

Start Date 13 Jan 88	Est Comp Date:
Principal Investigator	Facility
Albert M. Thomason, COL, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Endocrinology	
Key Words:	
Insulin therapy	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 6 Apr 89	Results Continue

Objective(s): To demonstrate whether low density lipoprotein cholesterol and total cholesterol-high density lipoprotein cholesterol ratios are worse in Type II diabetics treated with insulin as compared to oral agents.

Technical Approach: 30 patients being treated with oral hypoglycemic agents would be enlisted as volunteers. For the first 3 months, the patient would be followed on his/her usual oral hypoglycemic agent to determine average HGB A1C and lipid profile values. Subsequently the patient would be taken off the oral hypoglycemic agent and placed on human insulin therapy in such a dosage as to keep the Hgb A1C value as near as possible to the value the patient had while being treated with oral hypoglycemic agent. After 4 months on insulin therapy, the patient's lipid profiles for the previous 3 months would be averaged to compare the lipid profile while on oral hypoglycemic therapy. Subsequently, the patient would be taken off insulin and restarted on the same dose of hypoglycemic agent as previously taken. At the end of 4 months, the patient's lipid profile would be averaged as before.

Progress: Those patients who have considered volunteering for this program could not be enrolled because they were either taking insulin or taking lipid lowering agents. Will continue trying to obtain volunteers through distribution of fliers.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-23-88 Status: Completed
 Title: Do Oral Iron Supplements Cause False Positive or True Positive Hemocult Tests? Use of Hemoquant Assays for Hemoglobin Quantification.

Start Date 13 Jan 88	Est Comp Date:
Principal Investigator Edward F. Coles, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators:
Key Words: Hemocult tests	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 3960.00
Number of Subjects Enrolled During Reporting Period: 14	
Total Number of Subjects Enrolled to Date: 14	
Date of Periodic Review	Results

Objective(s): To determine if positive Hemocult test frequently observed in patients taking various oral iron supplements is a true-positive or a false-positive reaction by simultaneous quantitation of gastrointestinal blood loss by the Hemaquant method.

Technical Approach: The study consisted of four one week periods during which a single stool sample was collected on the third, fifth and seventh days for Hemocult™ testing and HemoQuant™ assay. Standard dietary medication restrictions recommended for Hemocult™ testing were exercised throughout the study period. No iron preparations were ingested during the first and third weeks and these results served as control values. One 324 mg tablet of ferrous sulfate was ingested orally three times each day during the second week and one 324 mg tablet of ferrous gluconate was ingested three times each day during the fourth week of the study.

Progress: All 84 stool specimens collected during the two weeks of oral iron therapy were negative on Hemocult™ testing, and the results of corresponding quantitative assays for fecal blood by the HemoQuant™ method were normal and did not differ significantly from control values. The Hemocult™ test results from our study differ markedly from those of a prior study of similar design using only Hemocult™ tests and oral iron preparations. Our HemoQuant™ data confirm that oral iron preparations, in therapeutic doses, do not interfere with the HemoQuant™ assay.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-37-88 Status: Ongoing
 Title: A Comparison of Cine and DSA Quantitative Coronary Angiography

Start Date 7 Mar 88	Est Comp Date:
Principal Investigator (vice Abrams) Lee B. Padove, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/General Medicine	Associate Investigators: Steven R. Bailey, MAJ, MC Eleanor Ayala, M.T., MBA
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 _____	Results _____

Objective(s): To compare the latest automated techniques for evaluation of coronary artery stenoses to planimetry of coronary artery casts.

Technical Approach: With the consent of family members, ten cadavers wer studied. Hearts were removed and arteries selectively injected with barium latex at 10 ATM for five minutes. Biplane cineangiographic films plus digital images taken, coronary casts decalcified and sectioned.

This study has been amended to include the injection of the left and right ventricle with barium latex in order to get radiopaque casts. These casts are to be used in validation and comparison of ventriculography by DSA and cineangiography.

Progress: No reportable data are availabe due to change in principal investiga-
tor.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-47-88 Status: Ongoing
 Title: Percutaneous Recanalization of Human Coronary Arteries with Balloon-Expandable Intracoronary Grafts (BEIG)

Start Date 25 Apr 88	Est Comp Date:
Principal Investigator (vice Bailey) W. Randy Condos, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review 6 Jul 89	Results Continue

Objective(s): 1) To determine the safety of the stent by evaluating reported clinical complications associated with its placement.

2) To determine the effectiveness of the stent by evaluating patients for long-term patency rates. Patency will be compared with results reported in the literature for PTCA alone. In addition, results will be compared with follow-up of a concomitant group of control patients treated by PTCA.

Technical Approach: This study is designed as a prospective survey following placement of a Balloon Expandable Intracoronary Stent in a coronary artery. The stent will initially be implanted in patients with confirmed collateral blood flow to the distal portion of the stenotic coronary artery.

Progress: Six month catheterizations for patency in five patients will be completed shortly. One patient is doing extremely well 18 months post-implant.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-51-88 Status: Completed
 Title: Bowel Preparation for 60 cm Flexible Sigmoidoscopy

Start Date 9 May 88	Est Comp Date:
Principal Investigator Kevin L. Preston, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Francis E. Peluso, MAJ, MC Fred Goldner, COL, MC
Key Words: Sigmoidoscopy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 100	
Total Number of Subjects Enrolled to Date: 100	
Date of Periodic Review 6 Jul 89	Results

Objective(s): To evaluate the efficacy of various enema administration schedules in achieving optimal bowel preparation for 60 cm flexible sigmoidoscopy.

Technical Approach: One hundred patients undergoing flexible sigmoidoscopy for routine indications were randomized to one of three groups. Group A received one 4.5 oz Fleet™ hypertonic phosphate enema one hour prior to the procedure. Group B received two Fleet™ enemas one 1 hour prior to the procedure, and Group C, one Fleet™ enema three hours prior and a second Fleet™ enema one hour prior to sigmoidoscopy. All examinations were performed with an Olympus CF-P10S 63 cm flexible sigmoidoscope. No dietary restrictions were employed.

Progress: The results indicate the use of one Fleet™ enema one hour prior to flexible sigmoidoscopy resulted in excellent or adequate preparations in 82% of patients. Identical results were noted in Group B using two Fleet™ enemas one hour prior to the procedure. In Group C, the use of a Fleet™ enema three hours and one hour prior to sigmoidoscopy resulted in an excellent or adequate preparation in 71% of patients. Poor results were seen in 17% and 18% of patients in Group A and B, respectively, while 29% of patients in Group C had inadequate results.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-55-88 Status: Completed
 Title: Epidemiology and Clinical Data in Patients with AIDS and Mycobacterium Tuberculosis (MTb) Infection in Texas

Start Date 9 May 88	Est Comp Date:
Principal Investigator Gregg T. Anders, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: H. M. Blanton, MAJ, MC
Key Words:	
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 evaluate the occurrence of MTb infection in patients with HIV infection as well as full-blown AIDS and to assess clinical response to therapy and occurrence of drug resistance; to assess in vitro susceptibility patterns and to determine effectiveness of MTb chemoprophylaxis in HIV infected patients.

Technical Approach: We retrospectively reviewed the inpatient and outpatient records of patients with both AIDS and Mtb who had been addmitted to the San Antonio State Chest Hospital. We also worked with the Texas State Department of Health, which recently instructed physicians in the State of Texas to note the presence of AIDS on the "TB-400" forms which have been used statewide for several years to report Mtb. Fifty-one TB-400 forms were obtained for individuals with Mtb and AIDS through the state.

Progress: With the projected estimates of cases of AIDS and its association with Mtb, there is a significant risk of tuberculosis once again becoming a major cause of morbidity across the United States. In the AIDS population of our study, we found significantly greater extrapulmonary involvement than in those without AIDS. In vitro resistance to therapy does not appear to be greater with AIDS. Fourt-drug empiric therapy should be strongly considered in all patients with Mtb and AIDS in Texas and other high-resistance regions.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-60-88 Status: Completed
 Title: Hemodynamics of Aortic Stenosis

Start Date 3 Jun 88	Est Comp Date:
Principal Investigator Roger Belbel, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	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 _____ Results _____	

Objective(s): 1) To develop hemodynamic parameters obtained by invasive and noninvasive means which could be used to assess left ventricular adaptation to pressure overload.

2) To develop new indices for assessing severity of aortic stenosis.

Technical Approach: The normal correlation between measured LVET and stroke volume (SV) is absent in aortic stenosis (AS). However, it has been reported that the degree of prolongation (Δ ET) of LVET above that predicted from SV is strongly correlated with valve area (AVA). Accordingly, we tested this using micromanometric LVET (0.331 ± 0.038 s, SD), SV (80 ± 26 ml) and AVA ($1 \pm .6$ cm²) measurements on 42 patients with pure AS.

Progress: Our data indicate that there is a fair correlation ($r=0.71$) between Δ ET and AVA. There was significant improvement ($r=0.85$) when only data from patients whose measured LVET fell within ± 1 SD from the mean were used. When measured LVET exceeded 0.369 s, $r = 0.76$. However, when LVET was less than 0.293 s, $r=0.47$, indicating a poor correlation.

We conclude: Prediction of AVA using Δ ET is feasible only when measured LVET is within the range 0.370 – 0.295 s. However, such a prediction is not possible when LVET is greatly abbreviated, probably as a consequence of impaired LV performance.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-61-88 Status: Terminated
 Title: Non-invasive Estimation of Prosthetic Aortic Valve Area Using Doppler Ultrasound

Start Date 3 Jun 88	Est Comp Date:
Principal Investigator Joseph P. Johns, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	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 6 Jul 89	Results Terminated

Objective(s): To determine if Doppler ultrasound, using the equation of continuity, can accurately estimate the effective area of prosthetic valves in the aortic area.

Technical Approach: A multicenter study will be performed involving patients at WRAMC, BAMC, and FAMC. It will be a two-armed study. There will be a retrospective evaluation of patients who have undergone aortic valve replacement within the past two years at these medical centers. There will be a prospective analysis of patients undergoing valve replacement. All patients will undergo 2-D and M-mode echocardiography as well as pulsed and continuous wave Doppler echocardiography of the aortic valve.

Progress: Study terminated by principal investigator.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-67-88 Status: Completed
 Title: Evaluation of Patients with Human Immunodeficiency Virus (HIV)
 Seropositivity for the Presence of Cardiac Disease

Start Date 14 Jul 88	Est Comp Date:
Principal Investigator James E. Johnson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: Greg A. Anders, MAJ, MC Ricky D. Latham, MAJ, MC C. Kenneth McAllister, COL, MC J. William Kelly, MAJ, MC David M. Slife, CPT, MC
Key Words: HIV seropositivity	
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 23 Aug 89 Results Completed	

Objective(s): To measure directly the cardiac response to exercise in these patients in an effort to document whether or not there are abnormalities.

Technical Approach: Patients are undergoing right heart catheterization with maximum incremental exercise with expired gas analysis and mixed venous lactates.

Progress: Six of nine patients showed elevated filling pressures with exercise consistent with cardiac dysfunction.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-69-88 Status: Completed
 Title: Colonic Lavage Solution (Colyte) as a Treatment for Chronic Constipation

Start Date 14 Jul 88	Est Comp Date:
Principal Investigator Richard Andorsky, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Fred Goldner, COL, MC
Key Words: Constipation, chronic Lavage, colonic	
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 6 Jul 89 Results Completed	

Objective(s): 1) To determine if Colyte might be an effective therapy for the treatment of chronic refractory constipation.

2) To determine the appropriate dosing schedule when using Colyte as therapy for chronic constipation.

Technical Approach: Twenty four patients with chronic constipation were entered into a controlled, double-blinded, randomized, cross-over study. Each patient was given two containers, marked A and B, one containing Colyte® and the other a placebo. They drank a specified amount (8 or 16 ounces) of Solution A for five consecutive days, followed by an equivalent amount of Solution B for five consecutive days. Daily number of bowel movements and stool consistency were recorded. Group I drank 8 ounces per day of solution; Group II drank 16 ounces per day of solution. Mean stool frequency and mean stool consistency were calculated for each treatment group.

Progress: Analysis of variance results confirmed that Colyte® was superior to placebo in regard to stool frequency (8.13 ± 4.23 vs. 4.71 ± 2.47 , $p < .01$) and stool consistency (2.62 ± 0.99 vs. 1.74 ± 1.03 , $p < .05$), and that 16 ounces of Colyte® per day was superior to all other groups in regard to the measured variables. Side effects from the Colyte® were infrequent and tolerable. Our results support that Colyte® may be an effective alternative therapy in the treatment of chronic constipation.

Detail Summary Sheet

Date: 13 Oct 89 Proj No: C-71-88 Status: Ongoing
 Title: Evaluation of the Effects of Coronary Collateral Vessels on
 Exercise-Induced Wall Motion Abnormalities

Start Date 5 Aug 88	Est Comp Date:
Principal Investigator Joseph P. Johns, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators:
Key Words:	
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	Results

Objective(s): To determine the role that the degree of coronary collateraliza-
 tion has on the induction of exercise-induced wall motion abnormalities during
 exercise echocardiography.

Technical Approach: Subjects will be recruited from patients at BAMC, and the
 Audie Murphy VA Hospital, who have recently undergone cardiac catheterization
 and selective coronary cineangiography for the investigation of known or
 suspected coronary artery disease. When possible, all antianginal medications
 will be discontinued three half-lives prior to exercise testing. Upright
 bicycle exercise which allows for continuous echocardiographic imaging
 throughout exercise and during recovery will be used. All exercise echocar-
 diographic studies will be recorded on videotape for analysis.

Progress: Two subjects enrolled. No complications. Study continues to recruit
 patients.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: C-72-88 Status: Terminated
 Title: Long Term 5-Fluorouracil Infusion for Recurrent Head and Neck Cancer

Start Date 5 Aug 88	Est Comp Date:
Principal Investigator	Facility
Patrick W. Cobb, CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Hem-Oncology	Arlene J. Zaloznik, LTC, MC
Key Wor's:	
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 study the effect of a continuous infusion of 5-Fluorouracil (300 mg/m²/d) on patients with recurrent head and neck cancer.

Technical Approach: Patients will receive 300 mg/m²/d of 5-FU in a continuous infusion via central venous catheter. All patients will be placed on vitamin B6, 150 mg/d orally, to prevent and/or ameliorate palmar-plantar erythrodysesthesia. Patients with recurrent squamous cell cancer of the head and neck who are not candidates for curative treatment with radiation therapy or surgery are eligible for the study.

Progress: This study was terminated by the principal investigator due to poor patient accrual.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-74-88 Status: Ongoing
 Title: A Prospective Analysis of Cardiac Changes Related to Radiation Therapy

Start Date 5 Aug 88	Est Comp Date:
Principal Investigator William T. Wright, Jr., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: J. Mark Moody, LTC, MC Douglas Jackson, CPT, MC
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 _____	Results _____

Objective(s): 1) To assess immediate (short term) effects of mediastinal irradiation on ventricular function.

2) To assess predictors of ventricular function before and after mediastinal irradiation.

3) To establish a baseline for evaluation of late cardiac changes, to include coronary artery occlusion related to radiation.

Technical Approach: Patients will be eligible for this study who are 18 years of age or older and who are to receive irradiation to the mediastinum including any portion of the heart in the field regardless of tumor type. Patients will be stratified to one of three groups according to the amount of heart included in the radiation field receiving a minimum of 1,000 rads. Groups in which less than or equal to one-third of total heart tissue, greater than one-third, but less than two-thirds of total heart tissue, and greater than two-thirds of total heart tissue will be identified. All patients will answer a symptom questionnaire prior to initiation of testing.

Progress: Time constraints have prevented the pursuit of this study. Patient recruitment will begin in the near future.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-78-88 Status: Ongoing
 Title: Phase II Study of Patients with Primary Malignant Gliomas Treated with Intracranial Recombinant IL-2 and Autologous LAK Cells (Collaborative Study with Audie Murphy VA Hospital)

Start Date 8 Sep 88	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Arlene J. Zaloznik, LTC, MC Mark R. Keaton, CPT, MC Thomas D. Brown, M.D.
Key Words: Glioma Recombinant IL-2	
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 determine the time of disease progression and overall survival in patients with primary malignant gliomas treated with surgical resection and postoperative intracranial IL-2 and autologous LAK cells.

2) To detect preliminary evidence for objective response in those patients with measurable disease postoperatively.

3) To determine the toxicity of IL-2 and autologous LAK cells administered intracranially in this patient population.

4) To correlate in vitro biologic parameters of these patients' malignant gliomas with their clinical outcomes.

Technical Approach: Patient eligibility and therapy is as outlined in the study protocol.

Progress: An IND has been obtained and revisions in the protocol recommended by the NCI and neurosurgery completed. An initial patient is being sought.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-87-88 Status: Completed
 Title: Evaluation of Blood Flow in Full Thickness Skin Grafts Utilizing the Laser Doppler Velocimeter

Start Date 12 Oct 88	Est Comp Date:
Principal Investigator Michael J. Mulvaney, MAJ, MC	Facility brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: Stuart J. Salasche, COL, MC
Key Words: Laser Doppler Velocimeter	
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 measure cutaneous blood flow in full thickness skin grafts from the time of placement until stabilization of blood flow occurs and the graft "takes". To correlate blood flow data to observed clinical color and textue changes, as well as known physiologic changes that have been documented in full thickness skin grafts.

Technical Approach: Ten patients requiring full thickness skin grafts following cancer removal were entered into the study. The Laser Doppler Velociment (LDV) wasused to measure blood flow in the anticipated donor site, the contralateral donor site, and the forehead. Daily readings were obtained as well as pho-tographs.

Progress: This study demonstrated a a clinical pattern in Laser doppler Velocimeter readings versus time for full thickness skin grafts of the nose. Clinical observations revealed a definite series of recognizable changes which correlated with LDV measurements. Comparisonof these observations with previous histologic and physiologic studies produce a plausible model that allows the pro-cess of graft incorporation to be better understood by the clinicia. .

Detail Summary Sheet

Date: 12 Aug 89 Proj No: C-88-88 Status: Ongoing
 Title: Phase I Study of LY186641 (Sulfonylurea) Given Over 21 Days Every Four Weeks

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Hematology-Oncology Staff
Key Words: Sulfonylurea	
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 26 Sep 89 Results Continue	

Objective(s): To determine the maximum tolerated dose of LY186641 as single daily doses given in multiple courses of 21 consecutive days followed by a rest period of approximately 7 days.

Technical Approach: All patients must have a histopathologically confirmed diagnosis of advanced or metastatic cancer. Therapy will follow the schema outlined in the company protocol.

Progress: On the schedule originally studied, dose limiting toxicity was seen at the 810 mg/M² level. One patient, reported to the IRB and sponsor, had methemoglobinemia requiring treatment with methylene blue and hemolytic anemia requiring transfusion. The protocol has been modified to study a schedule of administration 5/7 days for 21 days. On this schedule entry of patients continues at 1080 mg/M² which appears to be the maximum tolerated dose on this second schedule.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-89-88 Status: Ongoing
 Title: A Randomized, Double-Blind Efficacy, Safety and Pharmacokinetic Study
 of Two Doses BMY-25801 in Patients Receiving High-Dose Cisplatin, Phase II

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Terry R. Jenkins, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words:	
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 14 Sep 89	Results Continue

Objective(s): To compare the antiemetic efficacy, safety, and pharmacokinetics of two doses of BMY-25801 in 80 chemotherapy-naive cancer patients receiving cisplatin ≥ 100 mg/m² in combination with other chemotherapeutic agents.

Technical Approach: This is a randomized double-blinded parallel phase II trial comparing the antiemetic properties of two intravenous doses of BMY-25801, 1.2 mg/kg and 6.0 mg/kg, in 80 chemotherapy-naive cancer patients treated with cisplatin or in combination with other chemotherapeutic agents. Patients will be randomly allocated to receive 3 intravenous doses of BMY-25801 at 1.2 mg/kg or 6.0 mg/kg. The study will be administered over 15 minutes; 0.5 hours before and 1.5 and 3.5 hours after the initiation of the cisplatin infusion.

Progress: A total of 13 courses of therapy have been delivered to 7 patients. There has been no significant toxicity noted. The investigational antiemetic has been completely effective in some patients while ineffective in others. However, the blinded nature of the study comparing the two dose levels makes an appraisal of the efficacy of the drug impossible.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-91-88 Status: Completed
 Title: A Randomized Double-Blind Comparison of Three Dose Levels of Intravenous GR-C507/75 in the Prevention of Nausea and Vomiting Associated with Cisplatin

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Arlene J. Zaloznik, LTC, MC
Key Words:	
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 24 Apr 89	Results Completed

Objective(s): To compare the antiemetic efficacy of three different doses of intravenous GR-C507/75 in patients receiving cisplatin for the first time; to further define the safety profile of intravenous GR-C507/75 when used as an antiemetic in patients with cancer receiving cisplatin for the first time.

Technical Approach: Male or nonpregnant females who are to receive cisplatin as a single dose of ≥ 100 mg/m² for the first time will be eligible. Therapy will follow the schema outlined in the study protocol.

Progress: Notification was recieved that this study was closed as accrual goals had been met. Ne, patients can no longer be rnolled, but patients can continue to be retreated as long as they remain eligible.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-92-88 Status: Ongoing
 Title: Domperidone (R 33,812) Compassionate Clearance Single Patient Protocol

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Eddie Starnes, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Francis E. Peluso, MAJ, MC
Key Words:	
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 9 Mar 89	Results Continue

Objective(s): To treat patients with gastric stasis who have failed conventional forms of therapy.

Technical Approach: Only patients who have failed all other forms of therapy meeting the eligibility criteria may be entered on this study. Therapy will follow the schema outlined in the study protocol.

Progress: Two patients with severe refractory symptoms of idiopathic delayed gastric emptying of solids are entered on single patient protocols for use of the experimental medication Domperidone released to them by Janssen Pharmaceutica on a compassionate clearance basis. Both individuals have enjoyed significant dramatic

C-92-88 (continued)

symptomatic improvement on the protocol with essentially no significant side-effects. Required periodic blood work and symptom score sheet with other related documentation are sent to Janssen every two months. We will continue patients on the protocol indefinitely as clinically indicated.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-3-89 Status: Completed
 Title: The Clinical Usefulness of Preoperative Spirometry in Coronary Artery Bypass Surgery

Start Date 23 Nov 89	Est Comp Date:
Principal Investigator Benjamin F. Walton, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: Gregg T. Anders, MAJ, MC
Key Words: Spirometry	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 90	
Total Number of Subjects Enrolled to Date: 90	
Date of Periodic Review	Results

Objective(s): To examine the usefulness of preoperative spirometry in predicting complications during or after coronary artery bypass grafting (CABG) and to determine characteristics which could limit the population needing preoperative screening.

Technical Approach: In order to address the clinical usefulness of preoperative spirometry, which is unclear from previous studies, we reviewed its use in the patient undergoing CABG. These patients were chosen because of the likelihood of concomitant lung disease and because the effects of the surgical procedure may predispose them to pulmonary complications during hospitalization. By a review of the records of 90 consecutive patients undergoing non-urgent CABG, we attempted to determine the predictive value of the test related to complications, if abnormal tests impact on perioperative care, and the likelihood of abnormal spirometry in this population with emphasis on finding those factors which may allow the surgeon to better choose which patients should be screened, if any.

Progress: Preoperative spirometry does not appear to be predictive of postoperative pulmonary complications in the patient population studied.

Detail Summary Sheet

Date: 25 Aug 89 Proj No: C-13-89 Status: Terminated

Title: A Double-Blind Clinical Study Comparing the Electrophysiologic Effects of Hexabrix and Isovue-370 in Left Ventriculography and Selective Coronary Arteriography

Start Date 5 Dec 88	Est Comp Date:
Principal Investigator (vice Bailey)	Facility
W. Randy Condos, LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Cardiology	J. Mark Moody, LTC, MC
Key Words:	John R. Gilman, MAJ, MC
Hexabrix	David Slife, MAJ, MC
Isovue-370	Joseph P. Johns, MAJ, MC
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 two new contrast agents, Hexabrix and Isovue-370, during left ventriculography and coronary angiography.

Technical Approach: Patients will be randomized to receive either Hexabrix or Isovue-370 during left ventriculography and coronary angiograph. A comparison between these two contrast agents will be made for the following: (1) ECG changes; (2) adverse reactions, i.e. V.T., emboli, allergic reactions, nausea, etc.; and (3) quality of cine angiogram.

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

Detail Summary Sheet

Date: 25 Aug 89 Proj No: C-17-89 Status: Ongoing
 Title: Modification of Diet in Renal Disease Study

Start Date 20 Dec 88	Est Comp Date:
Principal Investigator (vice Tapp) Steven F. Gouge, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: Dietary Staff, University of Texas Health Science Center, San Antonio
Key Words:	
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 determine if one of two therapies can slow or prevent the development of end stage renal disease in patients with chronic renal disease: 1) a diet restricted in protein and phosphorus and/or 2) one of two levels of blood pressure control (mean arterial pressure less than 107 or less than 92).

Technical Approach: Participants will be assigned to an appropriate diet programs as determined by the dietary staff at the University of Texas Health Science Center and followed on a regular basis.

Progress: Fourteen patients from BAMC have been screened. Thus far only three have opted to continue the study. This is a four year study, and there is no data yet available.

Detail Summary Sheet

Date: 25 Aug 89 Proj No: C-20-89 Status: Ongoing
 Title: Transplantation of Human Basal Cell Carcinoma to C57/BALB/C gb^J/bg^J = NU/NU (beige-nude) Mouse.

Start Date 20 Dec 88	Est Comp Date:
Principal Investigator Larry E. Becker, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: Ronald E. Grimwood, Lt Col, USAF, MC
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	Results

Objective(s): To transplant human basal cell carcinoma to the C57 beige-nude mouse, and to utilize this animal model to study aspects of the biology of BCC.

Technical Approach: Forty male Beige-Nude mice were transplanted with human BCC, (5 of which were cases obtained from Dermatology Service, BAMC) utilizing our reported subcutaneous implantation technique. Initial volume and wet weight were determined for each tumor. The tumors were measured every two weeks by calipers, with a final volume determined at 120 days at which time the tumors were harvested, weighed, and processed for routine histology. Only those tumors demonstrating typical BCC histology were included in the final data.

Progress: Thirty-two tumor sites were positive for persistent tumor at harvest. Tumor volumes declined by an average of 51% and average tumor weight by 33%. There were increased numbers of mast cells surrounding the BCC tumor lobules. These results indicate that BCC can survive for 120 days in the Beige-Nude mouse. The detectable loss of tumor volume and weight may be secondary to several factors including loss of non-viable tissue, human stromal dependence, inherent slow growth, or elaborated factors from surrounding cytotoxic cells such as mast cells.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-22-89 Status: Ongoing
 Title: Selenium Deficiency in Patients on Chronic Dialysis: Laboratory and Clinical Manifestations

Start Date 27Jan 89	Est Comp Date:
Principal Investigator David Charney, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: Steven Gouge, MAJ, MC Gerald Merrill, GS-11 Ronald Shippee, CPT, MS
Key Words: Selenium deficiency	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 70	
Total Number of Subjects Enrolled to Date: 70	
Date of Periodic Review	Results

Objective(s): To determine if patients on chronic dialysis are selenium deficient by comparing them with normal controls and patients with near-end-stage renal disease.

Technical Approach: Part 1 is designed to confirm or deny the existence of a selenium deficient population by comparing HD and PD to CRF and Control groups. Part 2 will assess the adequacy of oral replacement of senium deficiency and look at the possible effects of such repelition on two clinical entities which may be associated with deficiency states - namely, myocardial dysfunciton and LDL cholesterol elevations - without any other specific interventions designed to correct these problems. Part 3 will investigate whether there is significant loss of selenium in the dialysate (hemodialysate or peritoneal dialysate) fluid.

Progress: Although we have had difficulty recruiting patients in the chronic renal failure group, preliminary results show that only three of 33 hemodialysis patients had significantly lower plasma selenium levels than controls, and there was no significant difference in red cell glutathione peroxidase levels between the groups. This would seem to indicate a lack of selenium deficiency in our study groups. We are attempting to recruit a second cohort of dialysis patients to confirm this finding. Parts 2 and 3 of the study are on hold pending these results.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-23-89 Status: Ongoing
 Title: Retrospective Analysis of Acute Exacerbations of Chronic Renal Failure

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator	Facility
Steven F. Gouge, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Nephrology	
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 156	
Total Number of Subjects Enrolled to Date: 156	
Date of Periodic Review	Results

Objective(s): To determine the risk factors for, clinical presentations and outcomes of acute exacerbations of chronic renal failure; and to compare these variables in patients to patients with chronic renal failure without exacerbation and patients with acute renal failure without prior chronic renal failure.

Technical Approach: Records of patients with a discharge diagnosis of acute renal failure, CRF, or both during the period 1986 and 1987 will be reviewed.

Progress: We have examined records of 156 of the 247 patients. We analyzed data on the first 75 patients and found no major differences between the groups.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-24-89 Status: Ongoing
 Title: Rate Dependent Toxicity of Amphotericin B Infusion

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator David P. Dooley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC Craig E. Smith, MAJ, MC James K. Gilman, MAJ, MC
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 _____	Results _____

Objective(s): To conduct a trial to compare the relative toxicities of low versus rapid infusion of Amphotericin B (AMB).

Technical Approach: Data will be collected before, during, and after a single day's infusion of AMB. A 500 ml bag of AMB will be hung and allowed to run over either a 1 or 4 hour period. Each patient will be observed for two, and hopefully four, infusion, on two separate days. Each patient will alternately receive both speeds of infusion, with alternate patients receiving a one hour infusion on the first day and a four hour infusion on the second; versus the long, then short infusion on successive days. Subjective and objective data collected at the bedside on each patient will be tabulated.

Progress: Little or no progress has been made on this study due to shortage of nursing care personnel and rotation of principal investigator at other health care facilities.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-30-89 Status: Ongoing
 Title: The Effect of Folinic Acid in the Prevention of Leukopenia in AIDS Patients Treated with Trimethoprim/Sulfamethoxazole of Pneumocystis carinii Pneumonia

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC David P. Dooley, MAJ, MC
Key Words: Pneumonia, <u>Pneumocystis carinii</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 determine the effect of folinic acid in the prevention of leukopenia in AIDS patients treated with high does trimethoprim/sulfamethoxazole (T/S) for Pneumocystis carinii pneumonia (PCP).

Technical Approach: Patients will be randomly assigned to one of three groups to be treated with T/S for a total of 21 days. Group I will receive folinic acid, 15 mg daily; Group II will receive folinic acid only if the WBC becomes less than 3000 and Group III, the control group, no folinic acid. All patients will have serum folate, red cell folate, serum B12 level, CBC, reticulocyte count, PMN lobe count, BUN, creatinine, SGOT, SGPT, LDH, and total bilirubin obtained prior to therapy. Daily CBC, platelet counts, and PMN lobe counts will be obtained. Daily reticulocyte counts will be obtained in patients in Group II to monitor response. Patients in Groups I and II will have reticulocyte counts should the WBC becomes less than 3000 or platelet count less than 80,000. Trimethoprim and sulfamethoxazole levels will be obtained on day 3 of therapy.

Progress: No untreated PCP patients have been seen at Brooke Army Medical Center since the study opened. Six patients have been enrolled at Wilford Hall Medical Center.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-31-89 Status: Ongoing
 Title: Primary Prophylaxis with Aerosolized Pentamidine in HIV Patients at High Risk for Pneumocystis carinii Pneumonia

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC David P. Dooley, MAJ, MC
Key Words: Pneumonia, <u>Pneumocystis carinii</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 compare the efficacy of three dosage regimens of aerosolized pentamidine for primary prophylaxis in HIV patients who have been identified at high risk for the development of Pneumocystis carinii pneumonia.

Technical Approach: Patients will be randomly assigned to one of three groups: Group I will receive inhaled pentamidine 150 mg biweekly, and Group II and II will receive inhaled pentamidine 300 mg and 150 mg monthly, respectively. All patients will have baseline T-cell studies, serum immunoglobulin levels, CBC, SMA-17, urinalysis, anergy panel, ESR, pulmonary function testing, gallium scan and Technetium 99 DTPA scan prior to therapy. Laboratory follow-up will consist of CBC, SMA-17, T-cell studies, and quantitative immunoglobulins, every 3 months, and CXR every six months. Prophylaxis will be discontinued when the patient is diagnosed as having PCP or develops intolerance to the drug.

Progress: No patients have been enrolled due to equipment acquisition problems. These have recently been overcome, and patient enrollment is ready to begin.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-36-89 Status: Ongoing
 Title: A Prospective, Double Blind Study of Retrovir in Early HIV Infection

Start Date: 23 Feb 89	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC
Key Words: HIV infection	
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 _____ Results _____	

Objective(s): To evaluate the safety and tolerance of chronic administration of Retrovir in adult patients with early manifestations of ARC, including those presenting with only HIV-associated lymphadenopathy and a CD4 cell count < 500 cells/mm³, and to assess the efficacy of Retrovir therapy in the treatment of HIV disease in these patients.

Technical Approach: This will be a placebo-controlled, double-blind study to evaluate the effect of 800 mg/day of oral Retrovir on the clinical, immunologic and virologic manifestations of early AIDS-Related Complex. Patients entering this trial will have signs and symptoms consistent with early stages of the disease and CD4 cell number ≤ 500 but ≥ 200 cells/mm³. The safety and tolerance of retrovir in this population will also be evaluated. Patients will be randomized to receive either Retrovir or placebo capsules for 96 weeks. Study medicines will be administered at a dose of 200 mg every 6 hours.

Progress: Patients were enrolled and two remained on study when NIH evaluated data in June. Following data evaluation, all patients were switched over to open label AZT. These patients will continue to be followed but the blinded portion of the protocol has been terminated.

Detail Summary Sheet

Date: 28 Aug 89	Proj No: C-38-89	Status: Ongoing
Title: The Effects of Beta Blockade on Rest and Exercise Hemodynamics in Patients with Mitral Stenosis		

Start Date: 28 Feb 89	Est Comp Date:
Principal Investigator Thomas L. Ashcom, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Steven R. Bailey, MAJ, MC Joseph P. Johns, MAJ, MC
Key Words: Beta blockade Mitral stenosis	
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): 1) Obtain simultaneous left and right heart high fidelity hemodynamic pressures in patients with mitral stenosis under conditions of rest, exercise and beta blockade.

2) Study the interrelationships between valve area, cardiac output, diastolic filling period, and mitral valve gradient, systolic, diastolic function in patients with mitral stenosis under the above conditions.

3) Correlate data obtained by cardiac catheterization to non-invasive evaluation of echo-Doppler under similar conditions of rest, exercise and beta-blockade.

Technical Approach: The study will be undertaken in three different phases. The initial phase will consist of a retrospective analysis of all patients with mitral stenosis who under high-fidelity cardiac catheterization under conditions of rest and exercise. Phase II will be a prospective descriptive analysis of left and right heart high-fidelity hemodynamics in patients with mitral stenosis under conditions of rest, exercise and beta blockade. The last aspect of the study, Phase III, will utilize the echo-Doppler data and methodology verified by cardiac catheterization to study the long-term effects of beta blockade on the exercise tolerance of patients with mitral stenosis.

Progress: Six patients have been enrolled in this study. All six have undergone the noninvasive protocol, consisting of Doppler echocardiographic evaluation of mitral valve gradients at rest and during exercise with and without beta blockers. It is anticipated that an additional six patients will be necessary to complete this phase of the protocol.

C-38-89 (continued)

There have been three patients enrolled in the invasive portion of the protocol. It is anticipated that an additional five patients will be necessary.

Preliminary analysis of data suggests that in patients with severe mitral stenosis, beta blockers decrease the resting gradient at the expense of cardiac output. The decrease in cardiac output with exercise is the limiting factor with respect to their symptoms and hemodynamics.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-39-89 Status: Ongoing
 Title: Assessment of Revascularization via Coronary Artery Bypass Grafting by Dipyridamole-Thallium Scintigraphy

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator James K. Gilman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Ricky D. Latham, MAJ, MC Vincent Pearson, LTC, MC Brent Grishkin, COL, MC
Key Words:	
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	Results

Objective(s): To determine the utility of dipyridamole-Thallium scintigraphy as a noninvasive modality to assess the completeness of revascularization at coronary bypass surgery.

Technical Approach: Pre- and postoperative dipyridamole-Thallium scintigraphic studies will be performed on forty patients undergoing elective coronary artery bypass surgery. The ability of this imaging modality to demonstrate incompletely revascularized hearts will be assessed by comparing the results of dipyridamole-Thallium scintigraphy with the results of post-CABG cardiac catheterization. Patients will be followed prospectively to determine whether patients with redistribution abnormalities on dipyridamole-Thallium scintigraphy are more likely to re-present with angina or infarction in the first postoperative year.

Progress: We have enrolled five patients in the study. Two have completed all phases of data collection except the first six month follow-up visit. The remaining three have completed the first phase (CABG and pre-CABG dipyridamole study) and will return in 2-4 weeks for post CABG studies.

Detail Summary Sheet

Date: 28 Aug 89 Proj No: C-40-89 Status: Ongoing
 Title: Beat-to-Beat Analysis of Pulmonary Compliance in Normal Man at Rest and with Exercise

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator David M. Slife, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine, Cardiology	Associate Investigators: Ricky D. Latham, MAJ, MC
Key Words: Pulmonary compliance	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$6,750.00
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): 1) Analyze resting steady state compliance as determined by the three-element Windkessel model in 10 patients.

2) Compare the model-derived pulmonary characteristic impedance and pulmonary resistance with that obtained by the conventional manner at rest.

3) Compare model-derived compliance at rest to values obtained during steady state supine exercise.

4) Compare the three-element Windkessel model to a distributed model for pulmonary compliance and estimate the percentage to total compliance contributed by the pulmonary vasculature.

Technical Approach: With micromanometry technology, ten normal patients who have undergone cardiac catheterization will be identified and will be evaluated to determine pulmonary arterial dynamic variables - characteristic impedance, pulmonary vascular resistance and arterial compliance at rest and with exercise. The determination of these variables will be accomplished by two methods: the three-element Windkessel model and by traditional methods of calculating these parameters. These two methods will then be compared to evaluate the utility of the computer model in determining pulmonary arterial dynamics.

Progress: Thus far, we have not had any patients who meet the criteria for inclusion in this.

Detail Summary Sheet

Date: 24 Aug 89 Proj No: C-41-89 Status: Completed
 Title: Greater Acute Bronchodilator Response with Nebulized Agents Than with Isoproterenol Metered Dose Inhaler in Patients with Stable Chronic Obstructive Pulmonary Disease

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator Mark D. Peacock, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Internal Med.	Associate Investigators: James E. Johnson, MAJ, MC Gregg T. Anders, MAJ, MC David L. Hazlett, M.D.
Key Words: Pulmonary Disease, Chronic Obstructive	
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): The most common agent used in the assessment of the acute bronchodilator response in COPD is isoproterenol delivered by a metered-dose inhaler. The goal of this study is to determine the existence of a more effective method of assessing this response in stable patients with COPD.

Technical Approach: Records of the Chronic Respiratory Disease Ward of the San Antonio State Chest Hospital were reviewed. Standard testing with isoproterenol delivered by a metered dose inhaler (MDI) was compared to testing with a panel of medications delivered by nebulizer. The panel included metaproterenol, isoetharine, atropine, epinephrine, terbutaline, and albuterol.

Progress: All six nebulized agents elicited a greater increase in FEV₁ than did isoproterenol delivered by MDI, with significant increases being documented for four of these agents. While 15 of the 66 patients had a 15% or greater increase in FEV₁ when tested with isoproterenol, 61 responded similarly to at least one agent in the panel, and 50 responded to two or more agents. This data reveals that bronchodilator testing utilizing a panel of nebulized agents is a more sensitive indicator of acute reversibility in stable COPD than is testing with the single agent isoproterenol delivered by MDI.

Detail Summary Sheet

Date: 24 Aug 89 Proj No: C-45-89 Status: Completed
 Title: Serum Enzyme Assays in Suspected Myocardial Infarction: A Prospective Comparison of Three Methodologies for Measuring Serum MB Creatine Phosphokinase Activity

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator David Mego, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Internal Med.	Associate Investigators:
Key Words: Infarction, Myocardial	
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 diagnostic performance of three commercially available serum MB creatine phosphokinase (CK-MB) assays in suspected myocardial infarction (MI).

Technical Approach: In 196 consecutive patients admitted to the coronary care unit for exclusion of MI, three methodologies for measuring serum CK-MB were compared. All patients had three blood samples obtained serially at eight hour intervals, with determination of CK-MB by immunoinhibition assay (IIA), electrophoresis (ELP), and radioimmunoassay (RIA) on each sample. The diagnosis of MI was made by World Health Organization criteria, using CK-MB by RIA as well as standardized prospective coding of each patient's history and EKG.

Progress: By analysis of receiver operating characteristic curves, there was no significant difference in accuracy between the three CK-MB assays. The cost of the IIA was about one-fourth that of ELP or RIA, and the IIA was more rapidly performed. As compared with ELP or RIA, we conclude that a newly available immunoinhibition assay for CK-MB provides similar diagnostic accuracy and increased convenience at a greatly reduced cost.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-46-89 Status: Ongoing
 Title: Effect of Topical Minoxidil on Nail Growth

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator Larry E. Becker, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: Joseph P. Johns, MAJ, MC Ronald M. Shelton, CPT, MC
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 _____ Results _____	

Objective(s): To evaluate the effectiveness of a 5% topical solution of minoxidil versus placebo to stimulate (increase rate) of nail growth in normal volunteers.

Technical Approach: As outlined in the company protocol.

Progress: No patients have been enrolled. Request for protocol modification has been approved by the IRB. Patient enrollment will begin shortly.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-49-89 Status: Ongoing
 Title: Percutaneous Endoscopic Gastrostomy: A Three Year Experience at Brooke Army Medical Center

Start Date 20 Mar 89	Est Comp Date:
Principal Investigator Harold Sullivan, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	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 _____	Results _____

Objective(s): To review the BAMC experience with this relatively new endoscopic technique for placing a gastrostomy tube by a nonsurgical approach.

Technical Approach: All records of patients having undergone gastrostomy or percutaneous endoscopic gastrostomy since July 1986 will be reviewed. All pertinent information will be recorded. The broad categories of specific information will include indication, technique, pre-procedure blood test results, immediate and late complications, mortality, and follow-up.

Progress: The study is in the data collection phase. One hundred and three inpatient charts have been reviewed including all cases having gastrostomy listed as a procedure and all cases of gastrostomy entered into the Gastroenterology Service Database. Eight-one cases have been identified of which 70 have been reviewed. Further follow-up has been obtained telephonically in 18 cases. Once case/chart review is complete, the data will be analyzed.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-50-89 Status: Completed
 Title: Evaluation of the Float Method for Determining Adequacy of Alveolar Specimens Obtained with Transbronchial Biopsy

Start Date: 3 Apr 89	Est Comp Date:
Principal Investigator Gregg T. Anders, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: James E. Johnson, MAJ, MC H. M. Blanton, MAJ, MC Kenneth Linville, CPT, MC
Key Words:	
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 prospectively evaluate, based on histopathologic correlation, if the "float-no float" method of analysis is an adequate screen for sufficient alveolar tissue. Bedside determination by the bronchoscopist of the adequacy of specimen obtained for alveolar evaluation is largely empiric, and appears to be based upon the intuitive notion that air-containing structures (alveoli) should float in liquid medium, while non-air-containing tissue (bronchial wall) should sink.

Technical Approach: All patients selected to undergo transbronchial biopsy for clinical indications will be entered in the study until a total of 100 specimens have been analyzed. Biopsy specimens will be performed with the same biopsy forceps and suspended in 60 cc of 10% formalin. The PI will then visually inspect each specimen for determination of a) surface floatation; b) floatation between surface and bottom; and c) sinking to bottom, of each specimen. Specimens will then be submitted for histologic diagnosis, number of alveolar structures viewed microscopically per specimen. The histopathologist will estimate the percentage of the specimen made up of alveoli. The histopathologist will be blinded to the float-no float evaluation previously determined by the PI.

Progress: A total of 103 specimens from 17 patients were evaluated. Of total specimens, 39 floated, 7 suspended in mid-zone, and 57 sank to bottom. Current histopathologic evaluation, while not completed, suggests no correlation between flotation and alveolar number.

Detail Summary Sheet

Date: 13 Oct 89 Proj No: C-55-89 Status: Ongoing
 Title: Arterial Healing After Percutaneous Sheath Cannulation: Prospective Study to Determine the Natural History of Pseudoaneurysm Formation

Start Date: 3 Apr 89	Est Comp Date:
Principal Investigator	Facility
Joseph P. Johns, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Cardiology	Lawrence E. Pupa, MAJ, MC
Key Words:	Steven R. Bailey, M.D.
	Roger J. Belbel, CPT, MC
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): It is hypothesized that pseudoaneurysms may transiently develop after percutaneous arterial cannulation and may be present during the early phase of arterial healing. This study will explore this hypothesis through prospective serial echocardiographic evaluation of arteries after percutaneous vessel cannulation.

Technical Approach: The natural history of arterial healing after percutaneous vessel cannulation is poorly understood; however, complications at the arterial site rarely occur and can lead to patient morbidity. This study is designed to prospectively examine the natural history of arterial healing in a large group of patients after arterial cannulation to determine the true frequency of pseudoaneurysm formation, and to examine the hypothesis that pseudoaneurysms may spontaneously resolve in some patients. Approximately 500 patients will be studied through noninvasive ultrasound techniques which place the patient at no additional risk, and which permit serial evaluation of changes at the arterial site. This information may lead to better management of patients who develop these arterial complications.

Progress: Awaiting arrival of new equipment before patient enrollment begins.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-56-89 Status: Ongoing
 Title: Serum Levels of T4, T3, free T4, free T3, and TSH with Progressive Increments of Thyroid Hormone Replacement in Patients with no Intrinsic Capability of Producing Thyroid

Start Date: 3 Apr 89	Est Comp Date:
Principal Investigator Albert M. Thomason, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Endocrinology	Associate Investigators:
Key Words:	
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 demonstrate the effect of incremental increases of thyroid hormone on the serum thyroid hormone levels in the individual patient from the hypothyroid to the hyperthyroid state.

Technical Approach: Fifteen volunteers would be solicited among those with a history of thyroid ablation for thyroid cancer who are undergoing a total body scan after being off thyroid hormone therapy for 6 weeks. After the scan is completed the patient would be asked to return for daily blood sampling and started on a thyroid replacement dosage of 0.025 mg daily. The patient would remain on this dose until the serum T4 value shows no change over a period of 3 days. At this time the free hormone levels and the reverse T3 levels would be measured in addition to the routine thyroid studies. Then the patient would have an increment in hormone dosage of 0.025 mg and have daily measurements of thyroid functions until a new steady state of T4 level is revealed. The increments in l-thyroxine dosage would be continued until the patient reaches a serum triiodothyronine level of greater than 200 mg/dl. Thyroid dosage would subsequently be adjusted to keep the patient mildly thyrotoxic and to keep the TSH value unmeasurable, the usual level for a thyroid cancer patient.

Progress: This project was approved only recently. Suitable subjects having total body scan have not yet volunteered for this study.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-57/58-89 Status: Ongoing
 Title: The Endogenous Opioid System in Tourette Syndrome
 Neuroimaging in Tourette Syndrome

Start Date: 4 Apr 89	Est Comp Date:
Principal Investigator Sidney W. Atkinson, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Neurology	Associate Investigators: James H. Timmons, CPT, MC, Department of Radiology/Nuclear Medicine
Key Words: Tourette Syndrome	
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 effectiveness of Naltrexone in controlling the disabling movements of Gilles de la Tourette Syndrome (TS), and to assess neurotransmitter function in TS both while on Naltrexone and off medication.

To determine if abnormalities exist of function or regional blood flow in brains of patients with Gilles de la Tourette syndrome (TS).

Technical Approach: Ten patients over age 6 referred to the Pediatric Neurology Service whose clinical symptoms give them a diagnosis of TS will be studied. Each patient will serve as his own control in a double blinded cross-over control fashion with groups beginning as on medication (a) or on placebo (B). There will be a one week washout between phases. Dosages of Naltrexone will be adjusted according to weight and size and will vary from 25 mg BID to 75 mg BID. Measurement of the efficacy of Naltrexone will be done by a questionnaire to each patient. Spinal puncture will be done on all patients as part of the evaluation of the movement disorder.

Several studies have attempted to look at neuroanatomic abnormalities in TS. In one of these two patients were reported with midbrain abnormalities found on MRI. SPECT is a new technique of function brain imaging and has been successfully used to evaluate several neurologic conditions. Iofetamine has the effect of a slow intra-arterial injection and continues to reach the brain over the entire period of the scan. Therefore, patients meeting the criteria for inclusion of the above study will be referred to the Nuclear Medicine Service for scanning. 3-5 millicuries of I-123 Iofetamine will be administered IV and the imaging obtained using SPECT.

Progress: To date, no patients have been entered on this study.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-60-89 Status: Ongoing
 Title: A Pilot Trial of Late Thrombolysis and Delayed Revascularization in
 (Late) Myocardial Infarction

Start Date: 4 Apr 89	Est Comp Date:
Principal Investigator (vice Condos) Lawrence E. Pupa, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: J. Mark Moody, LTC, MC W. Randy Condos, LTC, MC John-Francis M. Hennecken, MAJ, MC James K. Gilman, MAJ, MC
Key Words:	
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	Results

Objective(s): 1) To compare the patency rate of Activase® versus placebo with acute myocardial infarction presenting 6-24 hours after the onset of symptoms.

2) To assess the efficacy (ventricular function) of acute PTCA in patients with occluded infarct arteries 6-24 hours after the onset of symptoms.

3) To determine the relationship between infarct artery patency, ventricular function, and clinical outcomes.

Technical Approach: This is a parallel group, randomized double blind placebo-controlled trial comparing Activase® with placebo. One hundred patients will be randomized to each drug treatment group. The coronary angiogram upon which the efficacy determination will be based will be the first injection of the IRA performed between 6 and 24 hours following the start of infusion. At this time left ventriculography will be performed to measure left ventricular function. If the infarct related artery is patent, the patient will be returned to the CCU for monitoring. If the vessel remains occluded the eligible patient will be randomized to either PTCA or no PTCA. A rest and exercise gated blood pool scan will be performed 4-6 weeks post-treatment. A second coronary angiogram and ventriculogram will be performed 4-6 months post-treatment.

Progress: One patient has been enrolled. No reportable data are available.

Detail Summary Sheet

Date: 28 Sep 89	Proj No: C-61-89	Status: Ongoing
Title: Comparative Efficacy and Safety of Fleet Hypertonic Phosphate Enema, Water Enema, and Colyte Enemas for Flexible Sigmoidoscopy - A Double Blind Randomized Study		
Start Date: 26 Apr 89	Est Comp Date:	
Principal Investigator Shailesh C. Kadakia, MAJ, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Charles Cohan, MAJ, MC	
Key Words:		
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 _____ Results _____		

Objective(s): To compare the efficacy and safety of Fleet Hypertonic Phosphate Enema (HPE), water enema, and Colyte enemas used as cleansing solutions for flexible sigmoidoscopy in patients who are having flexible sigmoidoscopy for screening and diagnostic evaluation.

Technical Approach: A total of 100-125 patients will be enrolled in the study. All patients should have been advised to undergo flexible sigmoidoscopy. Patients undergoing sigmoidoscopy will be required to self-administer the enema prior to the examination. Patients will be randomly assigned to one of the three enema regimens. Neither the patient nor the endoscopist will be aware of the enema regiment administered. The adequacy of bowel preparation will be graded as excellent, adequate, mediocre or poor/inadequate.

Progress: So far, 24 patients have been enrolled. The study is blinded, therefore results are not available. However, there does not seem to be any significant obvious differences in the three groups.

Detail Summary Sheet

Date: 12 OCT 89 Proj No: C-63-89 Status: Ongoing
 Title: What is the Value of Fecal Occult Blood Tests Performed at the Time of Digital Rectal Examination?

Start Date: 26 Apr 89	Est Comp Date:
Principal Investigator	Facility
Charles Cohan, MAJ, MC	Brocke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Gastroenterology	Shailesh Kadakia, MAJ, MC
Key Words:	Eddie Starnes, COL, MC
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 clinical meaning and usefulness of positive fecal occult blood tests (Hemoccult Method) discovered at the time of routine digital rectal examination.

Technical Approach: Adult patients over the age of 40 with positive hemoccult tests obtained on normal-appearing stool obtained at rectal examination will be eligible. All patients will be offered the standard of care which includes full evaluation of the lower GI tract (colonoscopy or flexible sigmoidoscopy/air contrast barium enema) and possibly the upper GI tract. Anoscopic examination will be performed within 48 hours of the digital examination. Stool Hemoccult II samples will be collected on three consecutive days in the usual maner. Hemoquant assays will be obtained on the same spontaneously passed stool specimens used for Hemoccult II testing.

Progress: To date no patients have been entered on this study.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-64-89 Status: Ongoing
 Title: Hemodynamic Response to Maximal Supine Exercise

Start Date: 5 May 89	Est Comp Date:
Principal Investigator Timothy J. Martin, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: David M. Slife, MAJ, MC James Johnson, MAJ, MC
Key Words:	
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	Results

Objective(s): To characterize the hemodynamic response to maximal supine exercise in normal human volunteers.

Technical Approach: Fifteen male or female subjects referred for cardiac catheterization and between the ages of 18 and 75 will be eligible to participate. Each subject will perform progressive supine cycle exercise while intracardiac pressures, cardiac output, and oxygen consumption are measured.

Progress: The exercise bike failed during test of one patient. Second patient had frequent ectopy and results are uninterpretable. Metabolic cart failed during test of third patient.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-70-89 Status: Ongoing
 Title: Rifampin for Infusion (Compassionate Use Protocol)

Start Date: 15 May 89	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC
Key Words:	
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 _____ Results _____	

Objective(s): To provide intravenous rifampin for "humanitarian" use on specific cases.

Technical Approach: Any patient satisfying one or more of the following criteria will be considered eligible for treatment with rifampin IV: 1) active tuberculosis where the drug cannot be taken by mouth, patients who do not tolerate oral medication, and in comatose patients (tuberculous meningitis); 2) infections with microorganisms resistant to approved antibiotics; (3) in patients with in vitro sensitivity tests positive to an approved antibiotic but who develop an allergy or exhibit an adverse reaction to that antibiotic, or whose disease is serious enough to warrant treatment with an investigational drug. Lyophilized rifampin will be reconstituted and administered according to established procedures.

Progress: One patient was enrolled and tolerated the medication without difficulty. He received the medication for too short a period to assess efficacy.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-71-89 Status: Completed
 Title: Compassionate Use Ganciclovir Therapy for Sight- or Life-Threatening Cytomegalovirus Disease in the Immunocompromised Patient (ICM 1691)

Start Date: 7 Jun 89	Est Comp Date:
Principal Investigator Craig Smith, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC Robert N. Longfield, COL, MC John W. Kelly, MAJ, MC David C. Slagle, MAJ, MC David P. Dooley, MAJ, MC
Key Words:	
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	Results

Objective(s): 1) To make intravenous (IV) ganciclovir available to immuno-compromised patients 18 years of age and over with a life-threatening or sight-threatening CMV infection, where the symptoms of disease are too severe to allow admission to a controlled clinical study of ganciclovir therapy.

2) To determine the afety and tolerance of a two to three week induction course of ganciclovir IV (5 mg/kg bid) followed by a maintenance course of ganciclovir IV (5 mg/kg daily, 7 times per week) for an indefinite duration.

3) To tabulate the patient's clinical response.

Technical Approach: The following patients are eligible for enrollment: 1) All patients previous enrolled in the compassionate use study (ICM 1257/1257A) or who have terminated from another Syntex ganciclovir study; 2) patients with AIDS and life-threatening CMV disease; 3) patients with immunodeficiencies other than AIDS, with life-threatening or sight-threatening CMV disease will be eligible for enrollment. Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been treated on this study. The FDA has approved the use of Ganciclovir in patients with cytomegalovirus disease.

Detail Summary Sheet

Date: 12 Aug 89 Proj No: C-72-89 Status: Completed
 Title: A Treatment Protocol for the Use of Intravenous Ganciclovir in AIDS Patients with Immediately Sight-Threatening CMV Retinitis (TX 303)

Start Date: 7 Jun 89	Est Comp Date:
Principal Investigator Craig E. Smith, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: C. Kenneth McAllister, COL, MC Robert N. Longfield, COL, MC J. William Kelly, MAJ, MC David P. Dooley, MAJ, MC
Key Words:	
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	Results

Objective(s): To determine the safety and efficacy of intravenous ganciclovir induction and maintenance therapy in AIDS patients 18 years of age and above with sight-threatening CMV retinitis at standard doses of 10 mg/kg/day and 35 mg/kg/week, respectively.

Technical Approach: Patients meeting the following criteria are eligible for inclusion in this study: 1) Patient must have AIDS or evidence of HIV infection by antibody by licensed tests (ELISA, confirmed by Western Blot), p24 serum antigen, and/or positive HIV culture; 2) patients must have a diagnosis of immediately sight-threatening CMV retinitis as determined by an ophthalmologist; 3) the retinitis may be unilateral or bilateral. Therapy will follow the schema outlined in the study protocol.

Progress: One patient was treated on this study. The FDA has approved the use of Ganciclovir in Aids patients with sight-threatening CMV retinitis.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-73-89 Status: Ongoing
 Title: Phase I Study of SK&F 104864-A Administered as a Single Intravenous Dose Every 21 Days

Start Date: 7 Jun 89	Est Comp Date:
Principal Investigator James G. Wall, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hem. Oncology	Associate Investigators:
Key Words:	
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	Results

Objective(s): 1) To determine the maximal tolerated dose of SK&F 104864-A given as a single dose every 21 days.

2) To determine the qualitative and quantitative toxicities of SK&F 104861-A.

3) To determine the recommended dose for SK&F 104864-A as a single dose every 21 days to be used in Phase II trials.

Technical Approach: Eligible patients will receive therapy as outlined in the study protocol.

Progress: To date, two patients have been treated at BAMC. Both patients tolerated treatment well without serious side effects. The first patient had received her initial dose at UTHSCSA. On day 9 of cycle 2 it was felt she had experienced a minor response in the size of the measurable lymph node. The second patient only recently started therapy.

A total of seven additional patients have been treated at Audie Murphy VA Hospital. One patient treated at the third dose level experienced Grade 3

C-73-89 (continued)

leukopenia and was withdrawn from study. We are currently accruing a total of three evaluable patients at that dose level before proceeding to the next dose. (Subsequent patients treated at that dose level have experienced minimal, if any, hematological toxicity.)

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-74-89 Status: Ongoing
 Title: A Phase I/II Clinical Trial to Evaluate the Safety and Efficacy of a Weekly Administration of Brequinar Sodium (DuP 785) in Combination with an Every Three Week Administration of Cisplatin in Cancer Patients with...Solid Tumors

Start Date: 7 Jun 89	Est Comp Date:
Principal Investigator Timothy J. O'Rourke, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hem. Oncology	Associate Investigators:
Key Words:	

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	Results

Objective(s): 1) To identify the maximum tolerable dose, dose-limiting toxicities and recommended dose(s) for efficacy trials of DuP 786 when administered on a once-a-week basis in combination with an every-three-week schedule of cisplatin in patients with cancer refractory to conventional therapy or in patients for whom no standard therapy exists.

2) To characterize the safety and toxicity profiles of DuP 786 plus cisplatin combination chemotherapy regimen.

3) To evaluate the clinical efficacy of the combination regimen consisting of the recommended dose of DuP 785 plus standard dose cisplatin.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Two patients entered on this study died while on study. Both of these were reported to the sponsor and the IRB. Both cases were not clearly related to a drug toxicity. Three additional patients have been entered and the study continues.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-75-89 Status: Ongoing
 Title: An Investigation of Locus of Control in Dialysis Patients
 (Collaborative Study with University of Texas Health Science Center)

Start Date: 9 Jun 89	Est Comp Date:
Principal Investigator	Facility
Steven R. Gouge, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Nephrology	
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 35	
Total Number of Subjects Enrolled to Date: 35	
Date of Periodic Review	Results

Objective(s): To investigate the locus of control of patients in renal failure.

Technical Approach: A locus of control instrument and a questionnaire will be administered to 200-300 patients presently undergoing dialysis.

Progress: This is a multicenter study and data from all centers are being analyzed.

Detail Summary Sheet

Date: 16 Oct 89 Proj No: C-82-89 Status: Ongoing
 Title: Serum Angiotensin Converting Enzyme Elevation in Patients with HIV-I Infection. A Controlled, Prospective Study

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Daniel R. Ouellette, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: Gregg T. Anders, MAJ, MC
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 _____	Results _____

Objective(s): To evaluate the use of the serum ACE level as a convenient marker and correlate for macrophage function in the progression of HIV infection.

Technical Approach: A total of 50-60 subjects will be evaluated. Study groups will be arranged into four major divisions: 1) normal controls, consisting of 12-15 active duty HIV-seronegative volunteers, 2) asymptomatic HIV-seropositive patients, 12-15 total; 3) AIDS-related complex, or ARC patients, 12-15 total; and 4) 12-15 patients with AIDS. Serum angiotensin-converting enzyme (ACE) levels will be obtained via venipuncture during the routine evaluation of study groups 2, 3, and 4. Normal volunteers will have venipuncture performed either by the PI or the staff monitor. The mean values for serum ACE will be compared among groups, and CD4 levels will be compared and correlated with ACE levels as well.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-85-89 Status: Ongoing
 Title: Introduction of TNF-alpha in Human Infection by Coccidioides immitis
 (Collaborative Study with Wilford Hall USAF Medical Center)

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator (vice Kelly) David P. Dooley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Infectious Dis.	Associate Investigators: Matthew J. Dolan, CPT, USAF MC Rebecca A. Cox, Ph.D. J. William Kelly, MAJ, MC
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	Results

Objective(s): To determine whether human infection with Coccidioides immitis results in the production of tumor necrosis factor α (TNF- α)/cachetin.

Technical Approach: Patients with coccidioidomycosis would be stratified according to extent of disease, and matched by age, race, and sex to healthy controls. Patients and controls would be phlebotomized once, and peripheral blood monocytes exposed in vitro to killed spherules. TNF- α present in culture supernatants would then be measured by RIA. Risks to patients and controls would be limited to peripheral venipuncture.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-92-89 Status: Ongoing
 Title: High-Dose Chemotherapy and Autologous Bone Marrow Rescue for Locally Advanced Breast Cancer

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Patrick W. Cobb, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hem-Oncology	Associate Investigators: Richard O. Guidice, MAJ, MC Barbara Reeb, MT Roy Duncan, SGT Robert G. Whiddon, Jr., LTC, MS
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 _____	Results _____

Objective(s): To determine the effects of high dose chemotherapy and autologous bone marrow rescue on women with advanced breast cancer.

Technical Approach: All patients meeting the eligibility criteria will receive the standard dose of Cytosan, Adriamycin, and 5-FU (FAC) with cycles repeated every 21 days as blood counts allow to complete four cycles. Choice of local control measures will be at the discretion of the patient and the physicians, and will be done six weeks after the last cycle of FAC chemotherapy. Bone marrow aspiration, cryopreservation, and storage will be done six weeks after the last course of FAC chemotherapy, or after the patient has sufficiently recovered from the local control procedure.

Progress: This is a new study. No data are available.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-98-89 Status: Ongoing
 Title: Therapy of Dialysis Hypotension with Hypertonic Saline and Dextran

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator	Facility
Stephen F. Gouge, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Nephrology	
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	Results

Objective(s): To assess the efficacy and side effects of infusing small volumes of hypertonic saline with and without Dextran in the treatment of hemodialysis-induced hypotension.

Technical Approach: This is a randomized, blinded, cross-over study of 40 patients with end-stage renal disease who undergo dialysis two or three times weekly. Three solutions will be tested: (1) 10 cc of 23% NaCl, (2) 30 cc of 7.5% NaCl, and 30 cc of 7.5% NaCl with 6% Dextran 70. When hypotension occurs during dialysis, the assigned solution shall be infused, and the BP and pulse response shall be monitored. Each patient will cross over to receive each of the three solutions during subsequent dialysis sessions in which hypotension occurs.

Progress: None. Following initial approval, it was determined that Pharmacia has an IND for Dextran 70. Therefore, the study was put on hold pending approval by Pharmacia to participate in their study.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-103-89 Status: Ongoing
 Title: Single Patient Protocol for Treatment of Systemic Mycoses with Itraconazole (R51,211)

Start Date: 2 Aug 89	Est Comp Date:
Principal Investigator	Facility
Craig E. Smith, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Infectious Dis.	C. Kenneth McAllister, COL, MC
Key Words:	J. William Kelly, MAJ, MC
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): Compassionate use of drug Itraconazole for treatment of systemic mycoses.

Technical Approach: Eligible patients must have positive culture and/or histologic findings which identify the pathogen. Dosage will be initiated on 100 mg q.d. with a meal and maintained on that dose for at least a month. If patient is unchanged or worsening, dose may be increased in 100 mg increments to a maximum of 400 mg/day. The optimal duration of treatment is unknown, but a treatment course of about one year is planned.

Progress: Patient is progressing.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-104-89 Status: Ongoing
 Title: Pilot Study to Screen Serotypes of Klebsiella species and P. aeruginosa

Start Date: 14 Aug 89	Est Comp Date:
Principal Investigator J. William Kelly, MAJ, 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: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the serotypes of Klebsiella species and P. aeruginosa that may be encountered in Study CSP 316 and to compare these serotypes to the serotypes included in both vaccines.

Technical Approach: All patients in the intensive care units will be followed for the development of infections with Klebsiella (K) and P. aeruginosa (PA). K and PA isolate will be saved and sent for serotyping. The laboratory of Dr. Alan Cross, Department of Bacterial Diseases, Walter Reed Army Institute of Research, will be designated as the Study Center. The Study Center will coordinate the receipt of cultures and will send the cultures as a large group to Dr. T. L. Pitt, at the Colindale Laboratory, London, England for serotyping.

Progress: No data are available.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-105-89 Status: Ongoing
 Title: Esophageal Dilation with Savary-Gilliard Bougies Using a Guide Wire with Markings without the Aid of Fluoroscopy

Start Date: 14 Aug 89	Est Comp Date:
Principal Investigator Shaeleesh C. Kadakia, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Gastroenterology	Associate Investigators: Charles Cohan, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 18	
Total Number of Subjects Enrolled to Date: 18	
Date of Periodic Review	Results

Objective(s): To report our experience in the use of Savary-Gilliard dilators in patients who have undergone esophageal dilation over past three years.

Technical Approach: All esophageal dilations performed with a marked guide wire will be reviewed for the collection of data.

Progress: A total of 18 patients have been dilated with the Savary Dilator system without the use of fluroscopy since the inception of this study. A total of 43 dilation sessions have been performed on these patients. No complications have occurred with any of these procedures.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-106-89 Status: Ongoing
 Title: What is the Operative Risk in Patients with Severe Pulmonary Disease?

Start Date: 14 Aug 89	Est Comp Date:
Principal Investigator John F. Theroux, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Pulmonary	Associate Investigators: Greg Anders, MAJ, MC
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 _____	Results _____

Objective(s): To determine the relationship between severity of pulmonary dysfunction (as measured by spirometry) and operative morbidity/mortality.

Technical Approach: All preoperative pulmonary function tests (PFTs) on file in the Pulmonary Disease Service will be reviewed. The inpatient records of patients with severe COPD who underwent thoracic (nonresectional) and major abdominal procedures will be reviewed. For each severe COPD patient record reviewed, the records of two patients with mild-moderate COPD, and two patients without obstruction will be reviewed. These two control groups will be matched to the severe COPD patient by operation category and by age. The frequency and types of pulmonary complications for each of the three patient categories will be determined, and differences will be analyzed.

Progress: This is a new study. It is too early to report any meaningful results.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-107-89 Status: Ongoing
 Title: Phase I Trial of Intrapleurally Administered Alpha Interferon in
 Malignant Pleural Effusions

Start Date: 14 Aug 89	Est Comp Date:
Principal Investigator	Facility
Howard A. Burris, III, CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Hem-Oncology	Timothy J. O'Rourke, LTC, MC
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	Results

Objective(s): 1) To determine the tolerance to and toxicity of intrapleural administration of Intron-A® in patients with malignant pleural effusions.

2) To determine antitumor activity of Intron-A intrapleurally as evidenced by control of pleural effusions.

Technical Approach: Treatment of eligible patients will follow the schema outlined in the study protocol.

Progress: This study is temporarily on hold pending acquisition of an IND by Schering Corporation.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-118-89 Status: Ongoing
 Title: American Andes Biomedical Research Expedition 1989

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator Winston J. Worme, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine	Associate Investigators: Jeanne DeBolt Worme
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 _____	Results _____

Objective(s): To assess the use of a battery of psychometric and performance tests at altitude and to investigate the use of a high carbohydrate diet at altitude.

Technical Approach: Twenty four volunteer climbers will make a rapid ascent of Nevado Illimani in the Andes Mountains of Bolivia. Twelve subjects will receive Diamox and Hexadrol daily. The remaining 12 subjects will receive Diamox plus placebo tablets daily. The first dose will be administered at sea level prior to ascent by plane to 12,000 feet. Subjects will continue their assigned regimen for 7 days or until the highest altitude is reached.

Progress: This is a new study.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-120-89 Status: Ongoing
 Title: LCSG 881 - A Randomized Phase II Study of Preoperative Therapy for
 Patients with Technically Unresectable Non-Small Cell Lung Cancer

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator James G. Wall, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hem-Oncology	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 _____ Results _____	

Objective(s): To collect information regarding efficacy and toxicity of various preoperative treatment programs.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-121-89 Status: Ongoing
 Title: Acute Serum Potassium Elevation After Intravenous Hypertonic Contrast in Patients with Normal, Impaired, and Absent Renal Function

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator William E. Buchanan, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Nephrology	Associate Investigators: Ronald Salmond, MAJ, MC Steve Gouge, MAJ, MC David Slife, MAJ, MC Joseph Johns, MAJ, MC James Heironimus, Lt Col, USAF MC
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 _____	Results _____

Objective(s): To determine if there is a significant elevation in serum potassium after intravenous hypertonic iodinated contrast and whether patients with impaired or absent renal function are at increased risk of more marked and persistent hyperkalemia.

Technical Approach: Subjects with normal renal function and chronic renal insufficiency will be enlisted from adult patients scheduled for nonemergent cardiac catheterization and divided into three groups. Group 1 will include patients with glomerulofiltration rate (GFR) 140-61 ml/min, Group 2 with GFR 60-10, and Group 3 with GFR <10. Precontrast blood samples will be drawn and collected by the principal investigator. Elevation in serum K after contrast within each group will be analyzed for significance. Assays plus plasma catecholamines will be performed

Progress: This is a new study.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-122-89 Status: Ongoing
 Title: A Technique for the Growth of Epidermal Sheets Obtained from Patients Undergoing Reduction Mammoplasty

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator Jerome C. Hill, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Dermatology	Associate Investigators: Ronald E. Grimwood, Lt Col, USAF MC Larry E. Becker, COL, MC William K. Becker, LTC, MC David L. Danley, MAJ, MS
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 _____	Results _____

Objective(s): To establish a technique for isolating and growing epidermal sheets from cells obtained from patients undergoing reduction mammoplasty.

Technical Approach: Discarded skin from patients undergoing reduction mammoplasty will be used for this study. Cells thus obtained will be planted on plastic tissue culture plates containing keratinocyte growth medium (KGM) which has been developed for the growth of keratinocytes. The medium will be manipulated to induce the growth of multilayer epidermal sheets by the addition of fetal calf serum, and the use of Dulbecco's modified Eagle's medium which contains an elevated concentration of calcium.

Progress: This is a new study.

Detail Summary Sheet

Date: 6 Nov 89	Proj No: C-125-89	Status: Ongoing
Title: Phase II Trial of High-Dose Busulfan and Cyclophosphamide with Autologous Bone Marrow Transplantation in Metastatic Breast Cancer		

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator Patrick W. Cobb, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Hem-Oncology	Associate Investigators: Richard O. Guidice, MAJ, MC Svetislava J. Vukelja, MAJ, MC Robert G. Whiddon, Jr., LTC, MC Barbara Reeb, MT Rory Duncan, SSG
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 _____	Results _____

Objective(s): To study the effects of high dose chemotherapy and autologous bone marrow transplantation on women with metastatic breast cancer.

Technical Approach: Ten to twenty women from 18-65 years of age who have metastatic breast cancer of cytotoxic or hormonally-resistant disease will be treated with high-dose cyclophosphamide and busulfan. The primary endpoints for this pilot study will be the complete remission rate and duration of remissions, as compared to other recent high-dose chemotherapy and ABMT regimens for breast cancer. If this regimen appears to be at least as active as published regimens and is well-tolerated, then a third drug will be added in an attempt to increase efficacy in a subsequent phase I study.

Progress: This study was approved by the Institutional Review Committee in September. It is too early to report any progress.

Detail Summary Sheet

Date: 6 Nov 89	Proj No: C-126-89	Status:
Title: HM-PAO Brain SPECT in TIA as Predictor of Ischemic Infarction		

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator Stuart E. Sinoff, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Neurology	Associate Investigators: Mary B. Hart, MAJ, MC
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 _____ Results _____	

Objective(s): To prospectively investigate the usefulness of HM-PAO Brain SPECT as a predictor of permanent cerebral infarction in transient ischemic attacks.

Technical Approach: In a prospective series of patients presenting with transient cerebral ischemia, TC-99m HM-PAO brain SPECT studies will be obtained within 72 hours (of the TIA) and follow the clinical course over a three month period. Following Tc-99m HM-PAO SPECT the patients will be followed by one of the neurologists at six weeks and three months.

Progress: This study was approved by the Institutional Review Committee in September. No reportable progress is available.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-128-89 Status: Ongoing
 Title: In vivo Validation of Catheter Mounted Piezoelectric PHONOCARDIOGRAPHIC Transducer

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator Randolph Modlin, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: James K. Gilman, MAJ, MC J. Mark Moody, Jr., LTC, MC Bernard J. Rubal, Ph.D.
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 _____	Results _____

Objective(s): To compare direct intracardiac phonocardiographic recordings to recordings derived from micromanometric pressure transducers.

Local Approach: Piezoelectric phonocatheters will be used on 50 patients going right and left heart catheterization to record intracardiac sound for comparison with signals derived from micromanometric pressure transducers. In vitro data suggests that the piezoelectric phocatheter possesses improved frequency response characteristics and better signal-to-noise ratio than data obtained from the standard Millar pressure transducer. In this preliminary study, a spectrum of cardiac pathology is sought to demonstrate the efficacy of the new catheter and identify different pathologic states that might prove fruitful for further investigation.

Progress: This study was approved by the Institutional Review Committee in September. No progress has been made.

Detail Summary Sheet

Date: 28 Sep 80 Proj No: C-48-86 Status: Completed
 Title: Animal Facilitated Therapy (AFT) in the Brooke Army Medical Center
 Pediatric Department.

Start Date 4 Apr 86	Est Comp Date:
Principal Investigator Lynn J. Anderson, MAJ, VC	Facility Brooke Army Medical Center
Dept/Svc Department of Ministry & Pastoral Care	Associate Investigators: Carolyn Randle, LTC, MC Robert VanIngen, MAJ, CH Jesse DelaCruz, LTC, AN
Key Words: Therapy, animal facilitated	
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) Determine patient and staff opinions of animal facilitated therapy before and after such therapy has been utilized.

2) Educate staff, subjects, and subjects' families of the potential values of AFT to them.

3) Evaluate specifically: (a) the distractive value of an animal to a child during a stressful exam or test, and (b) the value of an animal as a cotherapist in mental health counseling sessions.

4) Identify other potential studies for future evaluation.

Technical Approach: Subjects will be selected from children currently being treated by the BAMC Pediatric Department. They will be chosen on the basis of their desire to be involved in the program. We will evaluate the distractive value of an animal to a child during a stressful exam or procedure such as repeated withdrawal of blood samples from patients being evaluated for diabetes. It is hypothesized that the presence of an animal during those times would distract the patient from the procedure, thus making the procedure easier for the patient and also for the staff involved. The study has been expanded to include patients being seen in the Department of Psychiatry.

Progress: This program has been so successful that it is considered standard care. The human-animal bond programs offer other possibilities for helping patients with particular types of illness. For instance, the Army's first therapeutic horsemanship program for neurological patients is being considered at Fort Sam Houston. The horses, carefully selected from the recreational stable, will provide physical therapy for people in wheelchairs and stimulate balance.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-86-87 Status: Terminated
 Title: A Descriptive Study of the Effectiveness of Patient Controlled Analgesia (PCA): Morphine vs Meperidine (Demerol) in Postoperative Gynecological Patients

Start Date 9 Sep 87	Est Comp Date:
Principal Investigator Lorraine Sneed, 1LT, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators:
Key Words: Analgesia	
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 Sep 88	Results Continue

Objective(s): 1) To compare the effects of a patient controlled analgesia (morphine sulfate vs meperidine) on bowel and urinary function in postoperative gynecological patients.

2) To compare the effects of morphine vs meperidine via PCA in the incidence of nausea and vomiting in immediate postoperative gynecological patients.

3) To compare the effectiveness of morphine vs meperidine via PCA for postoperative pain management.

Technical Approach: Participants will be assigned to either the morphine or demerol group and instructed in the proper use of the PCA machine. Bedside assessments will be made of each patient every 2 hours for 12 hours and then every 4 hours for 12 hours, and then every 4 hours until completion of the study. Bedside assessments will include recording urinary output, bowel activity, incidence of nausea and vomiting and pain control.

Progress: Study terminated due to transfer of principal investigator.

Detail Summary Sheet

Date: 22 Aug 89 Proj No: C-5-88 Status: Completed
 Title: Determinants of Army Ambulatory Health Care Services Utilization by Retired Military and Their Spouses

Start Date 17 Nov 87	Est Comp Date:
Principal Investigator Richard G. Jensen, MAJ, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	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	Results

Objective(s): This study has been designed to answer the following research questions:

- 1) What is the retired military population's average annual Army ambulatory care utilization rate?
- 2) What individual, societal, health services system, and need for care factors are associated with the use of Army ambulatory care services?
- 3) What combination of determinants best profiles an individual who is at risk for being a higher than average user of Army ambulatory care services?

Technical Approach: Mailout survey sent to 496 Army retirees from list maintained by Retirement Services at Fort Sam Houston, TX. 262 surveys completed and returned.

Progress: Responses to the above questions were as follows:

- 1) 69.8% (183) considered a military facility to be their usual source of outpatient health care; 29.8% (78) considered a civilian source for their usual outpatient care.

2) Respondents whose usual source of care was military were less likely to have a regular care provider, had less health insurance, held a more positive attitude toward going to the doctor, perceived less access to care, had a less positive health outlook, care from lower military pay grades, were less likely to be employed, had slightly poorer perceived health, reported more disability days, and had a slightly less positive attitude toward self-care than those whose usual source of care was civilian.

3) Respondents categorized as high outpatient care users (i.e., those reporting 9 or more contacts) had a greater number of health conditions, poorer perceived health, poorer prior health, a less optimistic health outlook, more disability days, and a lower perceived resistance to illness than those categorized as low-users.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-32-88 Status: Terminated
 Title: The Effects of Progressive Relaxation for Stress Management Among
 Critical Care Nurses

Start Date 17 Feb 88	Est Comp Date:
Principal Investigator Paulette L. Williams, LTC, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 69.50
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To determin the effects of progressive relaxation as a stress management strategy for critical care nurses.

Technical Approach: Quasi experimental design.

Progress: The study was terminated due to transfer of principal investigator to Tripler Army Medical Center.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-36-88 Status: Terminated
 Title: Survey of Surgical and Surgeon Skin Preparation

Start Date 7 Mar 88	Est Comp Date:
Principal Investigator Louise Cuthbertson, CPT, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators: Gerald O. Greenfield, MAJ, MC Michael H. Haak, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:
Number of Subjects Enrolled During Reporting Period: 60	
Total Number of Subjects Enrolled to Date: 60	
Date of Periodic Review	Results

Objective(s): Using a survey, the various methods of surgical and surgeon's preoperative skin preparation at Brooke Army Medical Center will be assessed. The reasoning and scientific basis will be measured by the survey; these may not correlate with the literature and published standards.

Technical Approach: An anonymous survey was made of physicians utilizing the operating rooms at BAMC. They were asked to answer a variety of questions regarding various skin preparation techniques, scientific basis of choices, and personal hand washing techniques.

Progress: Study terminated due to failure to submit annual progress report.

Detail Summary Sheet

Date: 22 Sep 88 Proj No: C-59-88 Status: Completed
 Title: Reliability and Validity of Instruments to Measure Stress in Parents and Temperament and Behavior in 4-5 Year Olds

Start Date 3 Jun 88	Est Comp Date:
Principal Investigator Marianne W. Callich, MAJ, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators: Jean M. Johnson, Ph.D., UTHSC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 100	
Total Number of Subjects Enrolled to Date: 130	
Date of Periodic Review	Results

Objective(s): 1) To obtain normative data for the following instruments: a) Behavioral Style Questionnaire, b) the Child Behavior Checklist, and c) the Hassles Scale.

2) To test the internal consistency of all three instruments.

3) To obtain test-retest reliability for the Behavioral Style Questionnaire and the Hassles Scale.

4) To determine the content validity of these instruments for use with families in the San Antonio area.

Technical Approach: Subjects were mothers of 4-5 year olds who had not been hospitalized or had surgery and who were without health problems. Volunteers were obtained through ads in a weekly newspaper which has a wide circulation throughout major areas of the city. Questionnaires were mailed to subjects in response to over-the-phone inquiries, along with a letter explaining the study, a description of the incentive, and the self-assigning coding system. A second administration of two of the questionnaires 3-5 weeks later was completed by 77.6% (N=80) of the subjects.

Progress: Most of the mothers in this study worked (69.9%), had some college education (80%), and belonged to upper middle income families (60.2%); 69.9% of the children attended day care. Thirty mothers (29.9%) were from military families and 20% were Hispanic. In general, the instruments were assessed as having good reliability. Internal consistencies were $\alpha = .92$ (N=90) for the Child Behavior Checklist and $\alpha = .92$ (N=103), .95 (N=91) for the Hassles Scale. Test-retest reliability for the Hassles Scale was $r = .614$, $p = .001$. The reliability

C-59-88 (continued)

for individual temperament categories of the Behavioral Style Questionnaire ranged from - .422, .513 (rhythmicity) to - .702, .845 (approach-withdrawal). Test-retest reliability for the Behavioral Style Questionnaire ranged from $r=.641$ (persistence) to $r=.905$ (approach-withdrawal).

Mothers appeared to be mostly low stressed with the most frequent stress identified as troubling thoughts about the future. The children were found to be essentially without problem behavior with 74% scoring in the normal range. Results of the t-tests showed no significant difference on behavior problem scores between boys and girls, children from military compared to non-military families, or children who attend day care compared to those who do not. Significant differences were found between boys and girls on two of the nine temperament categories: boys appeared more active than girls and girls appeared more persistent than boys but only at time 2. A significant relationship ($p=.001$) was also found between behavior problem scores on the Child Behavior Checklist and slow adaptability ($r=.48$), negative mood ($r=.43$), and non-persistence ($r=.42$).

Conclusions: The results of the study show the instruments to have good reliability in general, when used with samples which include military and Hispanic subjects. Some temperament categories of the Behavior Style Questionnaire continue to have lower reliability and are consistent with findings using this instrument with other groups; further examination and refinement of the items for these categories may be warranted. The results also support findings of other studies about relationships of behavior problems to temperament.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-80-88 Status: Ongoing
 Title: The Impact of the Use of Active Imagery on Labor and Delivery

Start Date 8 Sep 88	Est Comp Date:
Principal Investigator Cheryl Vaiani, MAJ, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators: Penelope Ward, R.N., Ph.D. Candidate (CDR, USNR)
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 _____	Results _____

Objective(s): To determine how the use of active imagery affects labor and delivery.

Technical Approach: This two part study will evaluate the psychological progressive of couples through pregnancy and compare the results of the use of active imagery both within group and between experimental and control groups.

Progress: Patient accrual has been completed. Data are being analyzed.

Detail Summary Sheet

Date: 20 Oct 89 Proj No: C-14-89 Status: Ongoing
 Title: A Study of Selected Demographic and Psychosocial Characteristics as Predictors of Uncomplicated Recovery from Elective Surgery

Start Date 5 Dec 88	Est Comp Date:
Principal Investigator Frances Anderson, MAJ, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators: Mary Edwards, RN, MSN
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 _____	Results _____

Objective(s): To determine the value of selected patient characteristics in identifying those elective surgical patients who, after discharge from the hospital, can be expected to experience recovery with few, if any, problems as opposed to those who experience delays or interruptions in that recovery because of complications related to the surgery.

Technical Approach: Subjects will have been scheduled for one of several elective surgical procedures - cholecystectomy, abdominal hysterectomy, suprapubic prostatectomy, or bowel resection with anastomosis. Prior to surgery, subjects will be asked to complete five questionnaires about their health, their family, and themselves. After discharge from the hospital, subjects will be contacted three times by phone and asked questions about their recovery.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 30 Oct 89 Proj No: C-15-89 Status: Ongoing
 Title: Stress and Coping in Childhood Cancer: A Pilot Study.

Start Date 5 Dec 88	Est Comp Date:
Principal Investigator Marianne H. Callich, LTC, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators: Dr. Gail Hoevet, University of Texas Health Science Center, SA
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 _____ Results _____	

Objective(s): 1) To perform the preliminary work on a comprehensive delineation of stresses and positive and negative coping strategies used by parents and their children with cancer and to develop a brief, quantifiable tool to measure stress and coping which will be tested in a second study.

2) To use the information obtained to analyze the effectiveness of coping strategies and plan intervention studies aimed at maximizing the positive coping strategies thereby improving the quality of life for both children and their families during this major event.

Technical Approach: Subjects will be identified in children's cancer clinics at Brooke Army Medical Center, Wilford Hall, and Santa Rosa Medical Center. The children for this study will be male or female, between the ages of 6 and 14 with a diagnosis of leukemia, lymphomas, and malignant tumors in either the diagnosis, treatment or completion of treatment stage of illness. Appointments will be made for a home visit to separately interview the parents and the child with appropriate interview schedule. A follow-up appointment will be conducted at one week to complete the interview. A teacher who has had contact with the child for at least one term will be identified by the child and family and asked questions in relation to stress and coping strategies used by the child.

Progress: Data are being analyzed.

Detail Summary Sheet

Date: 2 Oct 89 Proj No: C-28-89 Status: Completed
 Title: Effect of Bolus Injection of Esmolol on the Physiologic Response to Laryngoscopy and Intubation

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator Caryl Gaubatz, MAJ, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators: Robert Wehner, COL, AN
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 _____ Results _____	

Objective(s): To show the effects of a bolus injection of esmolol in attenuating the physiologic response of the body to the painful stimuli of laryngoscopy and intubation.

Technical Approach: Forty four ASA I and II patients scheduled for elective surgery were studied and randomly divided into four equal groups: 1. esmolol, 1 mg/kg, fentanyl, 2 mcg/kg; 2. control - placebo; 3. esmolol, 1 mg/kg; 4 fentanyl, 3.5 mcg/kg. Syringes containing fentanyl, esmolol, and placebo were prepared by a disinterested party and diluted to a final volume of 10 cc. In all cases intubation was performed in less than 30 seconds. Heart rate, systolic blood pressure, diastolic pressure, and MAP were recorded by the second "blinded" practitioner at intubation, and every minute thereafter for five minutes.

Progress: When the data was analyzed statistically, a pattern became apparent. Groups receiving fentanyl were significantly less responsive to effects of intubation than groups not receiving fentanyl ($p < 0.001$).

Based on the results of this study, it is suggested that a combination of the two drugs might be safely used to provide protection from the stresses of induction and intubation.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: G-34-89 Status: Ongoing
 Title: Perceived Role Competency Differences Between Emergency, Intensive Care, and Medical/Surgical Army Nurse Corps Officers

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator Michael A. Calder, MAJ, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	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 _____	Results _____

Objective(s): To determine whether differences exist in how emergency, intensive care, and medical-surgical Army nurses perceive actual, ideal, and preparedness competencies of assessment and triage.

Technical Approach: This is a descriptive comparative survey of perceived role competency differences, in a convenience sample of 366 Army Nurse Corps officers. Anonymously completed emergency nurse competencies questionnaires will be analyzed using one-way ANOVA, Scheffe's post hoc comparison, and multiple regression statistical methods.

Progress: Data analysis from April 1989 input has not been interpreted. Two hundred thirty-six surveys were returned but have not been evaluated.

Detail Summary Sheet

Date: 12 Oct 89	Proj No: C-59-89	Status: Ongoing
Title: The Efficacy of an Early Cardiac Rehabilitation Program as Measured by Maximum Aerobic Capacity During Metabolic Exercise Stress Test, Left Ventricular Ejection Fraction as Measured by MUGA, Change in Lipid Profile, and Perceived Quality of Life		
Start Date: 4 Apr 89	Est Comp Date:	
Principal Investigator (vice Anderson)	Facility	
Antoinette Trafford, MAJ, AN	Brooke Army Medical Center	
Dept/Svc	Associate Investigators:	
Department of Nursing	Stacey Adams Dramiga, M.A.	
Key Words:	James Gilman, MAJ, MC	
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 if those patients who have undergone coronary artery bypass grafting entering a cardiac rehabilitation program within two weeks post surgery will have significant changes in the following clinical parameters: maximum aerobic capacity, exercise tolerance, left ventricular ejection fraction, lipid profile, and perceived quality of life.

Technical Approach: Patients will be randomized into either the control or experimental group using a random table of numbers. Both groups will undergo measurement of the following parameters: perceived quality of life, ejection fraction by MUGA, exercise tolerance as determined by treadmill, and lipid profile preoperatively, prior to discharge, and 3 months post discharge from the hospital. Those randomized to the experimental group will enter a cardiac rehabilitation program one week post discharge. They will be asked to keep a daily log of various activities to include walking, biking, arm work, stair climbing, warmups and warmdowns. The control group will not enter any form of organized cardiac rehabilitation program but will receive instructions regarding risk factor modifications and life style change.

Progress: The instrument to be used for collecting data will be: The Quality of Life Index. This instrument has good reliability and validity. Data collection will begin in the near future.

Detail Summary Sheet

Date: 6 Sep 89 Proj No: C-77-89 Status: Completed
 Title: A Study of Professional Nurses' Knowledge of the Activities of Daily Living Categories as Defined by the Workload Management System for Nursing

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Barbara J. Vendt, MAJ, AN, USAR	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators:
Key Words:	
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 determine the knowledge base of professional nurses regarding the activities of daily living (ADL categories of: self/minimal care, assisted care, complete care, and total care.

Technical Approach: A structured interview was conducted with each sample participant. The interview tool consisted of two portions, demographical information on each participant, and a test. A standard of 80% correct responses on the test portion was set in order for the score to be considered passing. This coincides with the standard used for inter-rater reliability checks performed at this facility. In addition, and 80% pass rate by the sample would indicate good understanding of the ADL categories by the sample participants.

Progress: The findings were:

1. 66.67% of the sample (20 out of 30) received a passing score (80% or higher). This was below the 80% standard.
2. The mean score was 80.8.
3. The only ADL category meeting the 80% standard was self/minimal care.

C-77-89 (continued)

4. No difference was found between military and civilian nurses.
5. Training and reading the WMSN Workbook did not positively influence scores.
6. Length of experience negatively influenced scores.
7. Every sample participant thought "answering patient questions" was included in all four ADL categories. The WMSN does not include it for self/minimal care patients.

Recommendations are as follows:

1. Nursing documentation cannot be shortened at this time.
2. Increase WMSN training, emphasizing complete, assisted, and total care.
3. Each ward should be supplied with a chart summarizing the nursing actions for each ADL category. This would assist in patient classification.
4. Nurses should be informed of the reasons for excluding "answering patient questions" from the self-minimal care category. This may avert hostility to the WMSN.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-88-89 Status: Ongoing
 Title: Evaluation of a Stress Assessment Scale as a Measurement of Stress

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Beverly J. Dreyer, CPT, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	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 _____	Results _____

Objective(s): To assess the reliability and validity of the stress related items of the Fit to Win Health Risk Assessment as a measure of stress.

Technical Approach: The design is a methodological study. It will involve the administration of questionnaires to a "normal" group, a "high stress" group, and a "low stress" group. The "normal" group will be active duty Army soldiers at the Academy of Health Sciences. This group will be used to test the reliability and concurrent validity of the items. The "high stress" group will be 25 active duty Army outpatients referred to the Psychiatric Day Facility for a stress related problem. The "low stress" group will be 25 randomly selected subjects from the "normal" group who score less than five positive answers on the General Health Questionnaire.

Progress: This is a new study. No data are available at this time.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: 7-89-89 Status: Ongoing
 Title: Differences in Mixed Venous Oxygen Saturation Related to Continuous vs. Intermittent Suctioning

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Barbara A. Goodwin, MAJ, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	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 _____	Results _____

Objective(s): To compare the differences in mixed venous oxygen saturation (SvO₂) produced immediately after continuous and intermittent endotracheal suctioning.

Technical Approach: All patients scheduled for cardiac surgery who meet the inclusion criteria will be asked to participate. Pre and post-suctioning hyperoxygenation will be administered using the ventilator. If positive end expiratory pressure (PEEP) is in use, the PEEP will be maintained throughout the suctioning procedure. At this point the first SvO₂ will be taken. The subject will receive the suction treatment. Immediately after the suction pass is completed a second SvO₂ will be taken. There will be a minimum of 30 minutes between suctioning trials to allow the SvO₂ to stabilize before the initiation of a second trial.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-90-89 Status: Ongoing
 Title: Comparison of Two Methods of Re-Warming Patients in the Post Anesthesia Care Unit

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator Laura Terriguz-Kasey, CPT, AN	Facility Brooke Army Medical Center
Dept/Svc Department of Nursing	Associate Investigators: Toni Malpass, RN Karena Tarrenet, RN
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	Results

Objective(s): To evaluate the most effective manner of re-warming patients in a postoperative setting.

Technical Approach: Each patient needing re-warming per temperature on admission to PACU and meeting the eligibility criteria for entry will be included. Each patient will be assigned a heat lamp or Bair Hugger blanket. The patient's temperature will be recorded q15 minutes. It will be taken by PACU nursing staff with a IVAC 4000. Temperatures will be taken orally or axillary depending on patient cooperation and alertness. Temperature measurements will be repeated until the temperature is adequate for discharge criteria.

Progress: This is a new study. No data are available.

Detail Summary Sheet

Date: 23 Nov 89 Proj No: C-85-88 Status: Ongoing
 Title: Hormonal and Sonographic Assessments of First Trimester Pregnancies
 Complicated by Vaginal Bleeding

Start Date 8 Sep 88	Est Comp Date:
Principal Investigator (vice Valento) Kenneth Higby, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators: Clifford C. Hayslip, LTC, MC
Key Words: Beta HCG levels	
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 value of serum progesterone, estradiol, and beta HCG levels in the assessment of complicated first trimester pregnancies, and to compare vaginal and abdominal ultrasound in the early diagnosis of abnormal pregnancies.

Technical Approach: Approximately 200 patients presenting to the GYN Clinic with vaginal bleeding and known or suspected pregnancy will be asked to participate in the study. Each patient will have serum beta HCG,, progesteron and estradiol levels drawn. The evaluating physician will perform a pelvic exam and both a vaginal and abdominal ultrasound. If an intrauterine pregnancy is confirmed by ultrasound, repeat hormonal levels and ultrasound will be repeated in 2-7 days. Patients with suspected ectopic pregnancy will also have an initial hormonal evaluation and ultrasounds performed. Those patients not undergoing immediate surgery will have repeat hormonal levels and ultrasound performed in 24-48 hours. Patients with threatened miscarriage will be followed in the same manner as described for ectopic pregnancies.

Progress: Fifty-eight women have been enrolled in the study. Twenty-seven women had normal intrauterine pregnancies, 20 had abnormal intrauterine pregnancies and 11 had ectopic pregnancies. Serum progesterone and estradiol levels in women with normal pregnancies were significantly higher than those of women with abnormal or ectopic pregnancies. Serum progesterone levels were <10 ng/ml in only 2 of 56 serum samples from women with normal pregnancies, but 39 of 52 levels in women with abnormal gestations and 21 of 25 levels in women with ectopic pregnan-

C-85-88 (Continued)

cies were <10 ng/ml. Serum estradiol levels were <200 pg/ml in 3 of 55 samples in women with normal pregnancies, 43 of 51 samples in women with abnormal intrauterine and 22 of 26 samples in women with ectopic pregnancies. Serum estradiol and progesterone levels appear to be a valuable adjunct in evaluating women during the first trimester.

Detail Summary Sheet

Date: 28 Sep 89	Proj No: C-43-89	Status:
Title: Inter-Observer Variation in the Classification of Endometriosis		

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator Clifford G. Hayslip, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Endometriosis	
Accumulative MEDCASE Cost: \$15,104.00	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 reproducibility of the Amerivan Fertility Society classification scores in assessing the severity of endometriosis found at the time of diagnostic laparoscopy by different observers.

Technical Approach: Twenty women undergoing diagnostic laparoscopy for infertility and endometriosis will be studied. A VHS video camera will be used to systematically record the pelvic findings at the time of laparoscopy. The pelvic findings will be evaluated at laparoscopy: (1) anterior peritoneum, (2) right round ligament, (3) right broad ligament, (4) right tube, (5) right ovary, (6) uterus, (7) left round ligament, (8) left tube, (9) left ovary, (10) cul-de-sac and uterosacral ligaments. The pelvic findings on each patient will be recorded and saved on standard VHS cassettes. The video cassettes of the 20 patients will be reviewed by three groups of physicians. Each member will be asked to score each patient on the basis of the AFS revised classification for endometriosis.

Progress: No patients have been enrolled to date because VHS video camera and recorder have not arrived. Equipment should arrive by late September or early October.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-102-89 Status: Ongoing
 Title: The Effect of Human Surfactant Treatment of Hyaline Membrane Disease on the Incidence of Pneumothorax. (Collaborative Study with Keesler USAF Hospital)

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator	Facility
Arthur S. Maslow, LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Obstetrics and Gynecology	
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 _____	Results _____

Objective(s): To determine the incidence of pneumothorax in infants with HMD who receive replacement surfactant, as compared with historical controls.

Technical Approach: Amniotic fluid will be collected at the time of delivery by cesarean section. The fluid will be sent to Keesler USAF Medical Center where surfactant will be removed from the amniotic fluid and processed in their laboratory. The final surfactant product is used to treat infants with hyaline membrane disease.

Progress: This is a new study.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-124-89 Status: Ongoing
 Title: To Compare the Effects of Continuous Versus Cyclic Continuous Estrogen-Progestin Therapy on Fasting Serum Lipoproteins in Postmenopausal Women

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator	Facility
Eduardo R. Raez, CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Obstetrics-Gynecology	Clifford C. Hayslip, LTC, MC
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	Results

Objective(s): To compare the effects of continuous versus cyclic hormonal replacement therapy on the fasting serum lipoprotein profiles (FLP) of postmenopausal women.

Technical Approach: One hundred postmenopausal patients routinely seen at the GYN clinic will be asked to participate in the study. Women who have been on cyclic ERT, women taking Premarin only, and women on no hormonal replacement will be the three study groups. Patients on cyclic ERT, will have baseline FLP drawn on days 1, 15 and 25 of the month. At this time these patients will be switched to continuous therapy, and their FLP rechecked after two months in continuous therapy. Patients on Premarin alone, and postmenopausal patients on no therapy will be asked to have a single baseline FLP performed prior to entering the study. At this time they will be placed on three months of cyclic therapy, followed by three months of continuous therapy. FLP will be performed on these patients in a similar manner on days 1, 15 and 25 of the third month of cyclic therapy, and at random a single time after two months of continuous therapy.

Progress: This is a new study.

Detail Summary Sheet

Date: 21 Sep 89	Proj No: C-65-86	Status: Ongoing
Title: Identifying Pathogenic Coryneform Bacteria		

Start Date 8 Jul 86	Est Comp Date:
Principal Investigator S. Vern Juchau, COL, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology/Microbiology	Associate Investigators: Robert G. Whiddon, Jr., LTC, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 883.28
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To investigate a means of identifying and separating coryneform bacteria that can be isolated from the human body.

2) To attempt to correlate identified groups with normal flora or pathogenic potential.

3) To provide clinical microbiologists and physicians with a tool to better interpret the significance of the isolation of a gram-positive, non-spore forming bacillus which does not fall into one of the groups of known primary pathogens.

Technical Approach: The major focus of this study will be to classify coryneform bacteria of human origin on the basis of cellular fatty acids with the aid of a gas-liquid chromatography. Profiles of ATCC strains of human coryneforms will be constructed to serve as a data base to which clinical isolates will be compared.

Progress: The microbial identification system which characterizes microbes on the basis of their cellular fatty acids was obtained. Fourteen strains of coryneform bacteria have been analyzed and the results look promising. Work will continue in the next year to the extent that a database library should be developed for the development of taxonomic relationships.

C-65-86 (continued)

Various biochemical identification schemes have been tested on 42 strains of coryneform bacteria. A computer program developed by LTC Whiddon was used to ascertain the best test combination, and that combination has been tested on most of the strains. This information along with the cellular fatty acid profiles will help to determine true taxonomic relationships among the coryneform bacteria and practical methods for identification.

Detail Summary Sheet

Date: 9 Nov 89 Proj No: C-45-88 Status: Terminated
 Title: A Brief Analysis of the Role of Simultaneous DNA Flow Cytometry on
 Routine EndoPAP® Endometrial Sample

Start Date 29 Mar 88	Est Comp Date:
Principal Investigator Donald H. Gale, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators: Hansa B. Raval, COL, MC
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 _____ Results _____	

Objective(s): 1) To assess a simple method of specimen collection that will enable simultaneous correlation between cytology and DNA analysis.

2) To determine the role of DNA analysis in Cytologically difficult cases.

Technical Approach: Flow cytometric evaluation performed on many of the 47 original samples. Technical difficulties limited early samples usefulness and one computer problem (dumped data) eradicated additional findings. Currently, however, 15 samples are under evaluation for correlation and clinical utility.

Progress: Study terminated due to failure to submit annual report.

Detail Summary Sheet

Date: 22 Aug 89 Proj No: C-64-88 Status: Ongoing
 Title: Rapid Laboratory Detection of Mycoplasmosis Using a Radiometric Device

Start Date 14 Jul 88	Est Comp Date:
Principal Investigator William Nauschuetz, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	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 _____	Results _____

Objective(s): 1) To determine if Mycoplasma pneumoniae can be detected from clinical specimens using a system by which the pathogen is selected and detected by the evolution of ¹⁴C-labelled CO₂ from medium containing ¹⁴C-labelled glucose.

2) To determine if the amount of liberated ¹⁴C-labelled CO₂ allows sufficient sensitivity such that growth of the M. pneumoniae is detected significantly faster than allowed by conventional isolation techniques.

3) To mold this detection system into one which is compatible with the BACTEC Blood Culture Instrument, which is a common microbiology laboratory tool, found in a significant percentage of clinical laboratories.

Technical Approach: To develop a system by which SP4 medium will be made to include ¹⁴C-labelled glucose, as well as ampicillin, fungizone, crystal violet and thallium acetate to inhibit other bacterial, mycotic, and mycoplasmal species found in respiratory systems.

Progress: BACTEC bottles containing the SP4 medium with ¹⁴-C labelled glucose were seeded with Mycoplasma pneumoniae, incubated and read daily on the BACTEC reader. Cultures seeded with as few as 50 organisms were easily detectable within 10 days, as the radiometric readings progressed from 0 to approximately 200 within that period.

C-64-88 (continued)

Arrangements have been made with the Department of Emergency Medicine, such that patients with symptoms similar to those of mycoplasmosis will be cultured to rule out mycoplasmosis using the reference culture method, and also with the BACTEC/SP4 bottles. Clinical evaluations will be initiated in early October to coincide with the natural rise of mycoplasmosis cases.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-67-89 Status: Ongoing
 Title: A Comparison of Enzyme-Linked Immunoassay and Papanicolaou Stain versus Cell Culture for Detecting Chlamydial Trachomatis Cervical Infections

Start Date: 5 May 89	Est Comp Date:
Principal Investigator Bradley N. Harper, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pathology	Associate Investigators: S. Vern Juchau, COL, MS Margit Gerardi, CPT AN Phillip L. Day, LTC, MC Helen Viscount, 1LT, MS
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 410	
Total Number of Subjects Enrolled to Date: 410	
Date of Periodic Review	Results

Objective(s): 1) To compare the Chlamydiazyme test versus cell culture in the diagnosis of Chlamydia trachomatis infections in young asymptomatic females.

2) To determine the positive predictive value of intracellular inclusions for Chlamydia trachomatis infections.

Technical Approach: We propose that 500 consecutive female patients seen at the Troon Medical Clinic have a Chlamydiazyme swab submitted in addition to the PAP smear and culture swab that is routinely submitted. After 500 specimens have been processed, the sensitivity of Chlamydiazyme will be assessed versus the culture. If this test is of equal sensitivity, the cell culture can be discontinued. As a follow-on study, a correlation between cytologic criteria suggestive of Chlamydia infection versus culture/Chlamydiazyme findings would be performed.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 28 Sep 89 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: 10	
Total Number of Subjects Enrolled to Date: 98	
Date of Periodic Review 6 Jul 89 Results Continue	

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: Due to nonavailability of a pediatric dietitian, the diet portion of the study has been on hold. A new pediatric dietitian has been assigned and help in that part of the study will be sought. The measurement of Na/K ATPase has been completed. No difference in the enzyme values between the obese and the non-obese children was noted. However, a technical error in the measurement of the enzyme has not been entirely ruled out. It appears that glucagon levels following a stimulation are lower in obese children; other investigators have

C-34-85 (continued)

reported low glucagon levels in obese subjects. We will compare a subset of obese children who have low levels with those showing higher values to determine if the difference between the two is related to the degree of obesity, regional distribution of fat, glucose intolerance, or the insulin response.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-21-86 Status: Ongoing
 Title: A Comparison of High Frequency Oscillatory Ventilation and Conventional Ventillation in the Management of Respiratory Distress Syndrome in Infants Less Than 1750 Grams. (Collaborative Study with Wilford Hall USAF Hospital)

Start Date 19 Mar 86	Est Comp Date:
Principal Investigator Howard Heiman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Jan Carter, MAJ, MC John Woodall, COL, MC
Key Words: Syndrome, respiratory distress	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 470.00
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 12	
Date of Periodic Review 6 Apr 89	Results Continue

Objective(s): To evaluate the efficacy of using high frequency oscillatory ventilation (HFOV) in the management of respiratory distress syndrome (RDS) in premature infants, as compared to using the conventional neonatal ventilation (CV) therapy of intermittent mandatory ventilation and continuous distending pressure.

Technical Approach: The study population will consist of premature infants less than 33 weeks gestational age, less than 1750 grams birth weight, and less than 24 hours of age who require mechanical ventilation for treatment of RDS. Patients will be separated into four categories by birth weight and then randomly assigned to one of three treatment groups: CV only, HFOV initially followed by CV, or HFOV only.

Progress: This study will resume as soon as the investigators complete the training in high frequency oscillatory ventilation.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-22-86 Status: Ongoing
 Title: Prophylactic Intravenous Immunoglobulin in High Risk Neonates.
 (Collaborative Study with Walter Reed Army Medical Center)

Start Date 26 Feb 86	Est Comp Date:
Principal Investigator (vice Wiswell) Jan Carter, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Leonard E. Weisman, LTC, MC
Key Words: Neonate, high risk	John Woodall, COL, MC Howard Heiman, MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 7	
Total Number of Subjects Enrolled to Date: 32	
Date of Periodic Review 9 Mar 89	Results Continue

Objective(s): To evaluate, in a double blind manner, the effectiveness, compared to an albumin placebo, of IVIG in preventing infectious disease and/or reducing morbidity and mortality in the high risk neonate.

Technical Approach: Participants will be given one of two medications. One will contain antibody to Group B streptococci and the other will contain human albumin and sugar. One dose of the medication will be given by vein over a one hour period. 2 cc. of blood will be drawn before the medicine is given, immediately after it is given, and at one, two, and eight weeks later. Babies will be followed over an 8 weeks period for evidence of infection.

Progress: No adverse reactions have been observed.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-40-87 Status: Completed
 Title: Surfactant Production by Bacteria

Start Date 8 Apr 87	Est Comp Date:
Principal Investigator Chandra M. Tiwary, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words:	Sheila Jones, SSG
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$481.30
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a Results _____	

Objective(s): To measure the surface tension lowering activity of pathogenic, non-motile bacteria and compare the same with that of motile pathogenic bacteria.

Technical Approach: Surfactant (SR) was measured by the surface tension lowering property on water by the bacteria (BC). SR secretion was determined by measuring it in the medium growth in the BC and in an extract containing sonicated BC which represented SR in the body of BC.

Progress: SR was absent in *S. typhimurium* and *N. sicca* and their secretions. Although present in secretions, SR was absent in the bodies of *H. paraphrophilus*, *P. aeruginosa* and *N. gonorrhoeae*. Inhibitory substance(s) present in the body of some BC (*p. mirabilis*, *Sh. sonnei*, *Strep. pyogenes* and *Staph. aureus*) presented the full activity of SR until higher volumes of the bacterial extract were used. SR is secreted in the medium by *P. mirabilis*, *Sh. sonnei*, *N.G.*, *Staph. epidermidis*, and *Strep pyogenes* in varying amounts. The production and secretion of SR by various BC is not uniform.

Detail Summary Sheet

Date: 2 Oct 89 Proj No: C-79-87 Status: Ongoing
 Title: Appetite and Pectin

Start Date 9 Sep 87	Est Comp Date:
Principal Investigator Chandra M. Tiwary, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Victor Elysee, SGT
Key Words: Appetite Obesity	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 650.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 23	
Date of Periodic Review 9 Sep 88	Results Continue

Objective(s): To assess the role of pectin in suppression of hunger in obese children.

Technical Approach: Subjects will be obese children (ages 6-18) attending the pediatric clinic. All subjects will be studied twice at least 3 days apart. Subjects will be given either orange juice or orange juice with pectin. The child will be asked to describe the degree of hunger on a scale of 1 to 20, giving a rating of 1 if most full and 20 if very hungry. The same scale will be used to rate hunger every hour for four hours. At the end of four hours, the child will be given ice cream and again asked to rate hunger. Saliva production will be measured on three times - before drinking the juice, 4 hours after drinking the juice, and 1/2 hour after eating the ice cream.

Progress: Twenty three obese children completed the two day study. Each child ingested a prescribed amount of orange juice with and without pectin.

Conclusion: The pectin made a marginal difference in decreasing the appetite of children although in some children the change was large. The appetite varied in the same child on the two different days. The children felt hungry at their specific lung time and when that time passed, they felt less hungry. This conclusion is being analyzed. We plan to study an additional seven patients to complete the study.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-24-88 Status: Ongoing
 Title: Ceftriaxone for Outpatient Management of Suspected Occult Bacteremia

Start Date 13 Jan 88	Est Comp Date:
Principal Investigator James H. Brien, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Robert L. Norris, Jr., MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 24	
Total Number of Subjects Enrolled to Date: 44	
Date of Periodic Review 6 Apr 89 Results Continue	

Objective(s): To determine the effectiveness of Ceftriaxone in the outpatient management of children three to thirty-six months of age with suspected occult bacteremia.

Technical Approach: Children are randomized to receive either Ceftriaxone IM or Augmentin PO with ongoing follow-up until fever and illness is resolved.

Progress: The study is progressing as expected. Currently there are > 300 patients enrolled from all participating medical centers. Goal is about 1000.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-43-88 Status: Completed
 Title: An Analysis of Adolescent Suicide Gesture Patients at Brooke Army Medical Center

Start Date 29 Mar 88	Est Comp Date:
Principal Investigator Carla Iavarone, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Richard Takao, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 9	
Date of Periodic Review 6 Apr 89	Results Continue

Objective(s): To gather information that may subsequently be helpful in formulating an intervention plan in order to reduce the frequency of adolescent suicide gestures.

Technical Approach: Persons 18 years of age and younger who have been admitted to BAMC Pediatrics for having committed a suicide gesture during the course of the study or within the previous five years will be eligible for the study. Objective data will be collected by review of the inpatient chart and if necessary by phone or personal interview. The cases will be carefully scrutinized to determine if any identifiable pattern or similarities exist.

Progress: Study results reveal that 60% of the patients were female, with the peak incidence occurring at 15 to 16 years of age. Caucasians comprised 50% of the study group, 30% were hispanic, and 20% were other nationalities. A history of substance abuse or child abuse was obtained in at least one-half of all cases. Only 20% were failing a class at the time of the incident, and 30% had been seen by a psychiatrist in the past. Ingestion was the mode of gesture in all cases, with aspirin or acetaminophen implicated in nearly one-half of ingestions. The most common precipitating factor for the suicidal event was parental conflict.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-90-88 Status: Ongoing
 Title: Phase I Study of Piritrexim in Children with Advanced Leukemia and Solid Tumors (A Multicenter Study under the Direction of Dr. Thomas E. Williams, Santa Rosa Childrens Hospital)

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator (vice Thomas) Allen R. Potter, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia	Timothy J. O'Rourke, LTC, 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 _____	Results _____

Objective(s): To define the maximum tolerated dose and the dose limiting toxicity when Piritrexim capsules are administered orally to children in a daily x 5 schedule repeated every three weeks.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Thusfar, no patients have been eligible to enter this study. However, it remains open to future patients who meet the criteria for entry.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-96-89 Status: Ongoing
 Title: A Practical Microtechnique for Protime, Partial Thromboplastin Time and Fibrinogen in the Neonate

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator Sheryl J. Morris, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators: Howard Heiman, MAJ, MC Jan Carter, MAJ, MC
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 _____	Results _____

Objective(s): To evaluate a new microtechnique for determining protime, partial thromboplastin time, and fibrinogen.

Technical Approach: At presentation of labor, the obstetrical service obtains permission for delivery. Inclusive is utilization or disposal of aby tissue or blood products. The general practice is disposal of the placenta and cord blood, thus this study would utilize that which is normally disposed and thus not interfere or predispose the patient to any danger or harm. The cord blood will be divided into three paired specimens. The experimental sample will consist of 1.3 ml of blood, 0.15 ml of sodium citrate, and the standard sample of 2.7 ml blood and 0.3 ml sodium citrate. The samples will then be sent to the laboratory.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 21 Sep 89 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 Hartshorne) James D. Hieronimus, LTC, USAF MC	Facility Brooke Army Medical Center
Dept/Svc Department Radiology/Nuclear Medicine	Associate Investigators: James H. Timmons, CPT, MC
Key Words: Adrenal scan	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 12	
Date of Periodic Review 8 Sep 89	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: Inadequate data are available for analysis from our center alone. Complete research project data collected at Nuclear Medicine Service, Letterman Army Medical Center.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-47-89 Status: Ongoing
 Title: Evaluation of ¹³¹I-miBG (¹³¹I-meta-iodobenzylguanidine sulfate) in Patients Suspected of Having Pheochromocytoma, Paraganglioma or Medullary Hyperplasia

Start Date 20 Mar 89	Est Comp Date:
Principal Investigator James D. Heironimus, Lt Col, USAF, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Radiology/Nuclear Med.	Associate Investigators: Vincent D. Pearson, LTC, MC
Key Words:	
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	Results

Objective(s): To evaluate the use of ¹³¹I-miBG as an aid in the diagnosis, evaluation, and localization of pheochromocytomas, paraganglioma, neuroblastoma and/or adrenal medullary hyperplasia.

Technical Approach: Patients suspected of having pheochromocytoma, paraganglioma or medullary hyperplasia will be eligible. If upon careful consideration of the clinical history, examination and laboratory findings the patient is considered to have reasonable suspicion (>5% possibility) of any of the above conditions, they will be included for study by ¹³¹I-miBG scintigraphy.

Progress: Both studies negative with no contradictory laboratory/pathology data.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-62-89 Status: Ongoing
 Title: Evaluation of the Effects of Treatment with 0.075% Topical Capsaicin in Patients with Reflex Sympathetic Dystrophy Using Three Phase Bone Scintigraphy

Start Date: 11 Apr 89	Est Comp Date:
Principal Investigator	Facility
Mary Hart, CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Radiology/Nuclear Med.	Stuart Sinoff, MAJ, MC
Key Words:	Emil Menk, MAJ, MC
Reflex sympathetic dystrophy	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review	Results

Objective(s): 1) To assess the efficacy and safety of topically applied capsaicin cream 0.075% in the treatment of pain symptoms of reflex sympathetic dystrophy (RSD) or causalgia.

2) To assess if the treatment of superficial pain results in the improvement of or reversal of concurrent bone pathology.

3) To assess the usefulness of bone scintigraphy in predicting responses to treatment with capsaicin.

4) To assess the usefulness of bone scintigraphy as an objective indicator of response to capsaicin cream.

Technical Approach: Up to 15 patients with chronic RSD or causalgia will be entered into this clinical trial. Symptom severity and disability will be assessed through the physicians global evaluation and visual analogue scale. Pretreatment assessment will include three phase radionuclide bone scanning. The patients will receive 20 mCi of 99m Technetium MDP intravenously and rapid sequence blood flow studies of the affected and contralateral limb. Each patient will receive four 1.5 ounce tubes of capsaicin cream. Capsaicin cream will be applied four times daily for the duration of the study.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 1 Nov 89 Proj No: C-108-89 Status: Ongoing
 Title: Evaluation of Interstitial Lymphoscintigraphy with Radioactive Technetium Antimony Trisulfide Colloid (99m Tc-Sb₂S₃) for Lymphedema, Internal Mammary and Excised Malignant Melanoma Lymphoscintigraphy

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator	Facility
James D. Heironimus, Lt Col, USAF MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Radiology/Nuclear Med.	Vince Pearson, LTC, MC
Key Words:	Mayola W. Boykin, MAJ, MC
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 effectiveness of radioactive Tc99m Antimony Trisulfide Colloid in imaging lymph nodes.

Technical Approach: Patients will be selected and referred to Nuclear Medicine Service primarily by the Surgery and Oncology Clinic. Both extremities (both arms or both legs) of patients with lymphedema will be injected with Tc 99m Sb₂S₃. Imaging will be performed using a low energy, parallel collimated Anger camera. Views will include hands or feet and liver, with markers applied to localize the liver and major joints on the images.

Progress: This is a new study.

Detail Summary Sheet

Date: 2 Oct 89 Proj No: C-21-78 Status: Ongoing
 Title: Clinical Study of Intraocular Lenses.

Start Date February 1978	Est Comp Date:
Principal Investigator (vice Walker) Calvin E. Mein, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Arthur T. Glover, MAJ, MC Donald A. Gagliano, MAJ, MC John D. Walker, COL, MC
Key Words: Intraocular lens Cataract extraction	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 404	
Total Number of Subjects Enrolled to Date: 2535	
Date of Periodic Review 3 Apr 88	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: Intraocular lenses are implanted according to the company protocol.

Progress: Lens implant results have been excellent. No adverse reactions to any implants have been detected.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-12-83 Status: Terminated
 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 cholecystolithiasis 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: This study was terminated due to retirement of principal investigator.

Detail Summary Sheet

Date: 21 Sep 89 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 (vice Aspinall) Donald R. Bender, LTC, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators:
Key Words: High frequency hearing levels	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 32	
Total Number of Subjects Enrolled to Date: 32	
Date of Periodic Review 9 Sep 88 Results Continue	

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: Data has been gathered on the ultrasound exposed group. We are in the process of scheduling the remainder of the subjects in the control group.

Detail Summary Sheet

Date: 21 Sep 89 Proj No: C-1-86 Status: Ongoing
 Title: Continuous Intra-Arterial Chemotherapy for Advanced Refractory Pelvic Malignancies Employing an Implantable Infusion System

Start Date 28 Oct 85	Est Comp Date:
Principal Investigator(vice Rodriguez) Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Francisco Rodriguez, COL, MC Richard O. Giudice, MAJ, MC Michael Hartshorne, MAJ, MC Marvin Walker, MAJ, MC
Key Words: Infusion System, implantable	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 Mar 89	Results Continue

Objective(s): To determine the efficacy of continuous infusion of intraarterial chemotherapeutic agents for pelvic malignancies utilizing an implantable infusion system (Porta-Cath)®.

Technical Approach: Patients with advanced pelvic malignancies are eligible. After analysis of feeding tumor vessels from the digital subtraction angiography, a decision will be made as to which hypogastric vessel supplies the majority of the tumor. An oblique, lower quadrant incision will be made on the appropriate side and the hypogastric artery and its proximal branches will be dissected extraperitoneally. The lumen will be dilated and the catheter directed into the hypogastric artery. The tip of the catheter will be placed immediately above the highest vessel off which tumor vessels arise.

Progress: Only one patient has entered this study due to strict eligibility criteria. That patient was unable to continue on-study due to inability to place the Porta Cath. Nevertheless, we request to keep the study open for any future patients with advanced drug and surgically-refractory pelvic malignancies.

Detail Summary Sheet

Date: 21 Sep 89 Proj No: C-52-86 Status: Completed
 Title: Correlation of Sperm ATP-dependent Bioluminescence and Sperm Motility.

Start Date 12 May 86	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Gerald Merrill, GS11
Key Words: Sperm motility	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$400.00
Number of Subjects Enrolled During Reporting Period: 25	
Total Number of Subjects Enrolled to Date: 25	
Date of Periodic Review _____ Results _____	

Objective(s): To establish an association between sperm ATP concentrations as determined by bioluminescence and sperm motility.

Technical Approach: This protocol will utilize the discarded semen for bioluminescence analysis.

Progress: The findings included a somewhat linear relationship between bioluminescence and motility except in a subset of patients who had no motility but good bioluminescence. In these patients with low or no motility, it appears that a defect in energy - motility coupling is present.

Detail Summary Sheet

Date: 21 Sep 89 Proj No: C-73-86 Status: Completed
 Title: Comparison of External Pneumatic Compression Boots and Embolex in
 Prophylaxis Against Deep Vein Thrombosis

Start Date 12 August 1986	Est Comp Date:
Principal Investigator (vice Hansberry) Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Oncology	Associate Investigators: John M. Bauman, MAJ, MC Francisco Rodriguez, COL, MC
Key Words: Thrombosis, deep vein	
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 9 Sep 88	Results Continue

Objective(s): To compare the efficacy and complication rates of external pneumatic compression (EPC) boots and the drug Embolex in preventing lower extremity venous thrombosis in patients undergoing open urologic procedures.

Technical Approach: Adult male patients 40 years of age and older scheduled for open urologic procedures are eligible. Patients will be assigned to one of three treatment groups according to a table of random numbers. Group I will receive Embolex 2 hours before and every 12 hours during the post-operative period. Group II will have external pneumatic compression of the calves achieved by inflatable boots. EPC will be applied during induction of anesthesia and continued until the patient is ambulatory at least three times a day. Controls will wear Ted hose pre- and post-operatively.

Progress: Thromboembolic phenomena occurred in 20% of patients treated with TED hose, in 12.5% of patients treated with external pneumatic compression boots and in 8% of patients treated with Embolex.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-87-86 Status: Ongoing
 Title: LCSG 853 - A Clinical Trial in Patients with Stage II and III Completely Resected Non-Small Cell Lung Cancer Comparing Chemotherapy (CAT) versus No Therapy Following Surgery...

Start Date 8 Sep 86	Est Comp Date:
Principal Investigator (vice Grishkin) James Ameika, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators: Greg Bowman, LTC, MC Dennis Moritz, LTC, MC Robert Johnson, MAJ, MC
Key Words: Cancer, non-small cell lung	
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 9 Sep 88	Results Continue

Objective(s): 1) To compare combination chemotherapy (CAP given at 4-week intervals for 4 cycles) as an adjuvant to surgery to prolong disease-free interval and survival with no immediate adjuvant treatment following complete resection of stage II and III non-small cell cancer of the lung.

2) To compare combination chemotherapy (CAP) administered immediately post-operatively in prolonging survival in these patients with delayed combination chemotherapy administered at the time of systemic recurrence in the no-treatment control group.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No new patients have been enrolled.

Detail Summary Sheet

Date: 21 Sep 89 Proj No: C-3-87 Status: Ongoing
 Title: Radical Retropubic Prostatectomy and Orchiectomy for Stage C Carcinoma of the Prostate

Start Date 19 Nov 87	Est Comp Date:
Principal Investigator John Brizzolara, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Prostate Carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 9 Mar 89	Results Continue

Objective(s): To determine the efficacy of combined hormonal and surgical therapy for carcinoma of the prostate.

Technical Approach: Patients eligible for entry into the study will either be placed on Leupron therapy, one injection per day for two months, or undergo bilateral simple orchiectomy. Eight weeks following orchiectomy, radical prostatectomy will be performed.

After post-hormonal manipulation studies are obtained, patients will undergo staging pelvic lymphadenectomy. Postoperative treatment shall be in accordance with standard procedures.

Progress: Three additional patients have been entered into this study. Two patients did not down-stage (clinically) their tumors and have subsequently been treated with external beam radiotherapy. One patient exhibited downstaging of his tumor and is scheduled for radical retropubic prostatectomy. The only adverse complication to leuprolide thus far has been one patient who developed a possible decrease in auditory acuity and is currently being evaluated by ENT Service at BAMC.

Detail Summary Sheet

Date: 12 Aug 89 Proj No: C-32-87 Status: Completed
 Title: LCSG 821 - A Randomized Comparative Trial of Lobectomy versus Limited Resection for Patients with Cancer of the Lung

Start Date 2 Mar 87	Est Comp Date:
Principal Investigator Brent A. Grishkin, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators:
Key Words: Lobectomy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 5	
Total Number of Subjects Enrolled to Date: 19	
Date of Periodic Review 6 Apr 89	Results Completed

Objective(s): 1) To determine if limited pulmonary resection (wedge resection or segmental resection) for peripheral T₁N₀M₀ non-small cell lung cancer is as effective as lobectomy in preventing recurrence of disease.

2) To compare morbidity and mortality of limited resection with that of standard lobectomy.

3) To compare postoperative pulmonary function with regard to type of procedure employed.

Technical Approach: Eligible patients must have a presumed diagnosis of non-small cell carcinoma of the lung (squamous cell, adenocarcinoma or large cell). The patient must be a candidate for lobectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: Of the nineteen patients enrolled on this study, one is deceased, four are alive without recurrence, and fourteen were registered but not randomized.

Detail Summary Sheet

Date: 2 Oct 89	Proj No: C-46-87	Status: Ongoing
Title: LCSG 862 - Immunohistochemical Analysis of Lung Cancer		

Start Date 9 Apr 87	Est Comp Date:
Principal Investigator (vice Grishkin) Greg T. Bowman, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators:
Key Words:	
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	Results

Objective(s): 1) To ascertain the predictive value of a series of immuno-histochemical markers for response and survival in a previously studied patient population on whom data on routine prognostic factors, response, survival and toxicity is known.

2) To ascertain whether patterns of disease presentation are correlated with specific markers for cell surface and cytoskeletal proteins.

3) To ascertain if the pattern of loss of markers used to define the small cell "variant" cell lines and specimens is predictive of improved response in non-small cell patients.

Technical Approach: Data collection and registration are as outlined in the study protocol.

Progress: Study applicable only to patients also on LCSG 853 protocol (C-87-86). The two participants enrolled on this study are now deceased.

Detail Summary Sheet

Date: 21 Sep 89 Proj No: C-50-87 Status: Ongoing
 Title: Chromosomal Analysis of Genitourinary Neoplasms

Start Date 11 May 87	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Eric J. Zeidman, MAJ, MC Kurt L. Hansberry, CPT, MC Isidoro Chapa, GS-7
Key Words: Karyotype	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 10,253.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 45	
Date of Periodic Review _____	Results _____

Objective(s): To correlate tumor karyotypes with patient data, tumor stage and grade, and clinical course of the disease.

Technical Approach: At the time of removal of a genitourinary tumor, a small piece of tumor tissue will be sent for karyotyping. The technique for karyotyping will employ the coverslip method. Chromosomal banding will include standard techniques for G-banding, Q-banding (fluorescence), and C-banding. Photographs will include intact banded metaphase plates. Karyotyping will be performed by cutting individual chromosomes from photographs and identifying according to standard nomenclature.

Progress: Thus far, review of karyotypes reveal that transitional cell carcinoma has a variety of deletions and trisomies, primarily of chromosome 11 and 9. Prostate tumors and patients with BPH seem to have very little change in cytogenetic evaluation.

Detail Summary Sheet

Date: 22 Aug 89	Proj No: C-65-87	Status: Completed
Title: Trauma Score		

Start Date 2 Jul 87	Est Comp Date:
Principal Investigator R. Duane Cook, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/General Surgery	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): This study will compare the TRAUMA SCORE and CRAMS (Circulation, Respiration, Abdomen, Motor, Speech) SCALE as predictors of outcome and triage instruments in major trauma, and will also serve to document the present state of trauma care at BAMC.

Technical Approach: The study population will be comprised of all patients brought to the BAMC Emergency Department because of major trauma who are either admitted, transferred to another hospital, or die prior to admission. After stabilization of the patient, a checklist will be completed by a physician involved in the resuscitation to record information regarding the patient's pre-hospital and emergency department condition and care. Each patient will be scored according to both the TRAUMA SCORE and the CRAMS SCALE. Following disposition, the final diagnoses, procedures, complications and ultimate outcome will be obtained to complete each patient's file.

Progress: The study was designed to extend over a two year period, with the first six months serving as a pilot study. During the pilot study phase, 130 patients were seen in the Emergency Department. One hundred-thirteen (87%) were males, with only 17 females. The average age of the entire group was 28.8 years. The most frequent dispositions from the ER were the operating room (30%), and to Beach Pavilion for CT scanning (30%). Twelve percent were

C-65-87 (continued)

admitted directly to one of the two surgical intensive care units. Eleven percent were transferred to another hospital, and twelve patients (9%) died before leaving the Emergency Department.

In addition to 14 patients transferred directly from the ER, 8 other patients were either transferred later or left against medical advice for a total of 22. Of the 108 patients in whom ultimate outcome could be determined, there were 85 survivors and 23 deaths, for a total mortality of 21.3%.

When categorized by the Trauma Score, 62 patients (57%) had scores of 15 or 16 with no deaths. There was an incremental increase in mortality in patients with scores of 14 to 10, and no survivors in the 14 patients with scores of 9 or less. The CRAMS score distribution varied somewhat in that there were not as many patients at the high end of the scale. There were no deaths in the 36 patients (33%) with scores of 9 or 20. Again, an incremental increase in mortality was present from scores 8 to 5, with no survivors in the group with scores of 4 or less.

This report supports the findings of other published series that demonstrate a correlation between both the Trauma Score and CRAMS Scale with survival.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-90-87 Status: Ongoing
 Title: Opti-Fixtm Hip Prosthesis (Multicenter Study)

Start Date 21 Sep 87	Est Comp Date:
Principal Investigator Allen L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators:
Key Words: Prosthesis, hip	
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 9 Sep 88	Results Continue

Objective(s): To prove safety and efficacy of the use of porous surfaces (with stability afforded by biologic fixation instead of bone cement) by statistical comparison to similar patient populations of like cemented components and other published data.

Technical Approach: Patients requiring total hip replacement will be asked to participate in this study. If they agree, the Opti-Fixtm will be implanted as outlined in the study protocol.

Progress: One ye : follow-up on all ten patients shows early excellent results, based upon the modified Harris Hip Scale (Rating System). There have been no complications.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-1-88 Status: Completed
 Title: Fully Coated Porous Polysulfone Titanium Alloy (TI-6AL-4V) Hip
 Prosthesis

Start Date 13 Nov 87	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators:
Key Words: Hip prosthesis	
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 9 Mar 89	Results Continue

Objective(s): To determine (1) whether the prostheses may be stabilized by biological fixation into the porous surface material of the femoral component without the use of bone cement; and (2) whether the stability of the prostheses will occur and whether it will be equal to or superior to the stability afforded by methods currently used with other hip prostheses.

Technical Approach: As outlined in the company protocol.

Progress: Patient enrollment has been completed. The study remains open for follow-up only.

Detail Summary Sheet

Date: 12 Oct 89	Proj No: C-2-88	Status: Terminated
Title: Bone Conduction Implantable Device		

Start Date 17 Nov 87	Est Comp Date:
Jesse Moss, LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/Otolaryngology	John Ribera, CPT, MS
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 _____	Results _____

Objective(s): To determine the feasibility of implanting bone conduction devices in patients with mild to moderate conductive hearing loss in comparison to benefits from conventional hearing prostheses.

Technical Approach: This will be a single blind study available to 30 patients with conductive hearing losses which cannot be ameliorated through existing surgical procedures or conventional hearing aids.

The XOMED Audiant device will be implanted into the mastoid bone. After the incision is healed, the sound transmitter with the external coil will be applied over the magnet.

Progress: This study was terminated due to inability to obtain the XOMED Audiant device.

Detail Summary Sheet

Date: 6 Aug 89 Proj No: C-3-88 Status: Terminated
 Title: Comparison of Trigger Point Injections Using a Local Anesthetic with and without a Steroid in the Treatment of Myofascial Pain Syndrome.

Start Date 17 Nov 87	Est Comp Date:
Principal Investigator William E. Strong, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Emil J. Menk, MAJ, MC Timothy Hansen, CPT, MC
Key Words: Syndrome, myofascial pain Trigger point	
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 Mar 89 Results Continue	

Objective(s): 1) Compare the therapeutic effects of injecting a trigger point with Marcaine alone or Marcaine with Kenalog.

2) Compare the duration of effect when injecting a trigger point with Marcaine alone or Marcaine with Kenalog.

3) Compare pain of injection of a trigger point using Marcaine alone and Marcaine with Kenalog.

Technical Approach: Patients with diagnosis of myofascial pain syndrome who are referred to the Pain Clinic will be recruited for the study. After information sheet is completed, subjects will be randomly assigned to one of two treatment groups. Patients will be placed in the supine position on the examination table, and dolormeter will be used to monitor the amount of pressure on trigger point required to reproduce maximal discomfort. Group I will receive 10 cc, 0.5% Marcaine, and Group II 10 cc, 0.5% Marcaine with 20 mg Kenalog. Patients will be asked to mark a Visual Analog Scale (VAS) and a pressure reading will be taken at various times during the investigation.

Progress: This study is terminated due to failure to submit annual progress report.

Detail Summary Sheet

Date: 21 Sep 89 Proj No: C-7-88 Status: Completed
 Title: The Time Principle in the Induction of Anesthesia.

Start Date 1 Dec 87	Est Comp Date:
Principal Investigator Douglas Culling, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Emil J. Menk, MAJ, MC Robert E. Middaugh, MAJ, MC
Key Words: Timing principle	
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 Mar 89	Results Continue

Objective(s): To determine if a single large bolus of a nondepolarizing neuromuscular blocking drug, if given using the timing principle, will produce reliable relaxation for intubation within 60 seconds after the induction of anesthesia.

Technical Approach: Patients were randomly assigned to one of three groups. Groups differed only in the vecuronium dose administered during induction with group A receiving .1 mg/kg, group B .15 mg/kg, and group C .2 mg/kg. All groups received reglan and ranitidine preoperatively. Routine monitoring included pulse oximetry and mass spectrometry. The degree of neuromuscular blockade was visually estimated via train of four using a Digi Stim II nerve stimulator after the patient lost consciousness. After pre-oxygenation, all patients were given midazolam IV. One minute later level of consciousness was assessed, and the appropriate bolus of vecuronium was given. At the onset of clinical weakness, as judged by hand grip or decreased ventilatory effort, patients were asked to cough and then received sodium pentothal. Six seconds later patients were intubated and clinical conditions during intubation graded.

Progress: All groups were similar in terms of age, weight, and sex. Intubation scores were uniformly excellent. There was no significant difference between groups for onset time of clinical weakness. There was, however, a significant difference between groups for the time required for the return of twitch. Additionally, this was found to correlate with increasing age. Commonly patients exhibited a hemodynamic response to intubations with elevations of both heart rate and blood pressure.

G-7-88 (continued)

In the present study, timing the administration of a single moderate sized bolus of vecuronium to the onset of clinical weakness provided consistently excellent intubating conditions at 60 seconds. From a pharmacodynamic standpoint this method of administration seems logical. The "timing principle" may provide the optimal method of administration of current nondepolarizing muscle relaxants for rapid sequence intubations.

Detail Summary Sheet

Date: 12 Oct 89	Proj No: C-10-88	Status: Ongoing
Title: C-Reactive Protein, Erythrocyte Sedimentation Rate, and White Blood Count in Aseptic Loosening of Total Joint Components		

Start Date 2 Dec 87	Est Comp Date:
Principal Investigator Henry G. Chambers, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Allan L. Bucknell, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 391.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 9 Mar 89	Results _____ Continue _____

Objective(s): To prospectively evaluate the efficacy of these blood tests in the evaluation of pre- and postoperative revision total joint patients.

Technical Approach: All patients who enter the hospital for a revision total joint arthroplasty will have a CRP, ESR, and WBC level drawn at the time of initial routine preoperative evaluation. These will be repeated immediately postoperatively, on postoperative days 1 thru 5, at 6 weeks, at 3 months and at 6 months. Should an infection be suspected clinically, a CRP level will be drawn at that time as well.

Progress: Patient accrual has been completed. The study remains open for data analysis.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-12-88 Status: Ongoing
 Title: The Effect of Bone Allograft in Total Joint Replacement on C-Reactive Protein, Erythrocyte Sedimentation Rate, and White Blood Cell Count.

Start Date 2 Dec 87	Est Comp Date:
Principal Investigator	Facility
Henry G. Chambers, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/Orthopaedics	Allan L. Bucknell, COL, MC
Key Words:	
Bone allograft	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost: 135.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To prospectively evaluate the efficacy of these blood tests in the evaluation of patients undergoing total joint replacement with bone allograft.

Technical Approach: All patients who enter the hospital for a total joint arthroplasty in whom an allograft is planned will have a CRP, ESR, and WBC level drawn at the time of initial routine preoperative evaluation. These will be repeated immediately postoperatively, on postoperative days 1 thru 5, at 6 weeks, at 3 months and at 6 months. Should an infection be suspected clinically, a CRP level will be drawn at that time as well.

Progress: Patient accrual has been completed. The study remains open for data analysis.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-20-88 Status: Ongoing
 Title: LCSG 871 - Centralized Non-Small Cell Lung Cancer Specimen Repository
 and DNA/RNA Bank

Start Date 13 Jan 88	Est Comp Date:
Principal Investigator (vice Grishkin) James Ameika, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators: Dennis Moritz, LTC, MC Greg Bowman, LTC, MC Robert Johnson, MAJ, MC
Key Words: Non-small cell lung cancer	
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 _____	Results _____

Objective(s): To provide the LCSG tissue repository with specimens of non-small cell lung cancer and adjacent normal tissue from previously untreated patients who are undergoing resection of lung cancer.

Technical Approach: Patients with non-small cell lung cancer, who have not received prior treatment, who undergo resectional therapy, will be invited to participate. At the time of operation, if sufficient tissue is available, portions of the primary tumor and adjacent normal lung tissue will be processed as outlined in the study protocol.

Progress: We are on schedule with follow-up reports. Three patients are deceased. Accrual of data continues.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-21-88 Status: Completed
 Title: Evaluation of Stress Fractures with Dual Photon Absorptiometry

Start Date 13 Jan 88	Est Comp Date:
Principal Investigator Michael H. Haak, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Gerald Q. Greenfield, MAJ, MC Michael F. Hartshorne, MAJ, MC
Key Words: Fractures, stress	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 50	
Date of Periodic Review n/a Results _____	

Objective(s): To evaluate dual photon absorptiometry, a relatively new diagnostic technique for quantiative evaluation of bone mineral content, in patients with stress fracture injury.

Technical Approach: Utilizing bone densitometry - evaluate stress fracture sites and compare to uninjured side, also evaluate systemic bone mineral density by checking L5 spine.

Progress: Regional bone density data in the area of stress fractures were not different from non-fractured unions in same subject. The spinal bone density (systemic bone density) was significantly decreased compared to age, sex, race, height, and weight in matched controls.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-26-88 Status: Terminated
 Title: Physio-Stim™ Pulsed Electromagnetic Field Therapy System

Start Date 17 Feb 88	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators:
Key Words:	
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 6 Apr 89 Results Terminated	

Objective(s): To determine the effectiveness and safety of the Physio-Stim™ Electromagnetic Field Therapy System in the treatment of ununited fractures of long and short bones and failed arthrodeses.

Technical Approach: Patients meeting the criteria for inclusion in this study will be randomly assigned to receive either daily treatment using the Physio-Stim™ Therapy System or standard therapy. Patients assigned to the Physio-Stim™ Therapy System group will be asked to apply it over the fracture area 8 hours a day for six months. Patients in the standard therapy group will continue treatment program of non-weight bearing, elevation, and physical therapy.

Progress: This study was terminated by American Medical Electronics.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-27-88 Status: Terminated
 Title: Evaluation of Continuous Positive Airway Pressure (CPAP) as an Adjunct to Respiratory Therapy After Spinal Surgery

Start Date 17 Feb 88	Est Comp Date:
Principal Investigator Michael H. Haak, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	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 _____	Results _____

Objective(s): To test the benefits of CPAP following spine surgery and correlate its use with respiratory function and postoperative complications.

Technical Approach: Use continuous positive airway pressure as an adjunct to respiratory therapy in patients undergoing spine fusion.

Progress: This study was terminated due to difficulties in enrolling patients and in coordinating availability of ICU beds.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-28-88 Status: Ongoing
 Title: In vivo Monitoring of Reconstructed Hip Joints During Walking

Start Date 17 Feb 88	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: James A. Davidson, M.S. Henry G. Chambers, MAJ, MC Michael H. Haak, CPT, MC
Key Words: Reconstructed hip joint	
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 6 Apr 89	Results Continue

Objective(s): To determine the activity the activity associated change in temperature in vivo for total hip replacement arthroplasty.

Technical Approach: A thermocouple will be placed in the hip joints of patients who have received a total hip arthroplasty with either a cobalt-chrome hip or a ceramic head to evaluate if there is any change in hip temperature.

Progress: This study has been delayed due to technical problem with the monitors.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-29-88 Status: Ongoing
 Title: Evaluation of Arthroplasty-Associated Bone Density Change with Dual Photon Absorptiometry.

Start Date 17 Feb 88	Est Comp Date:
Principal Investigator	Facility
Michael H. Haak, CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/Orthopaedic	Allan L. Bucknell, COL, MC
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 6 Apr 89	Results Continue

Objective(s): To evaluate the bone mineral density and associated strength of bone in patients undergoing total hip replacement arthroplasty.

Technical Approach: Evaluate by sequential bone densitometry patients undergoing uncemented hip arthroplasty and evaluate bone density associated with certain prosthesis designs.

Progress: Preliminary study showed that positioning of the legs for sequential scanning created a 10% error. A leg holding device was designed and fabricated and new trials are under way to determine if the positioning error has been eliminated.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-30-88 Status: Ongoing
 Title: Functional Evaluation of Morbidity with Upper Extremity Arterial Catheterization

Start Date 17 Feb 88	Est Comp Date:
Principal Investigator Michael H. Haak, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Richard Jansen, CPT, MS William Wright, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 277.55
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 20	
Date of Periodic Review	Results

Objective(s): To evaluate the morbidity associated upper extremity arterial catheterization with prospective subjective and objective functional upper extremity evaluation of patients receiving elective cardiac catheterization.

Technical Approach: Patients undergoing catheterization will have pre-cath and interval evaluation of upper extremity function.

Progress: Initial evaluation of 20 subjects showed a transient dysfunction in relation to grip strength and sensation which resolved in approximately three months. Those with technical complications showed longer term morbidity in terms of upper extremity function.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-35-88 Status: Completed
 Title: Evaluation of Luque Interpeduncular Segmental Fixation in Spinal Injury

Start Date 7 Mar 88	Est Comp Date:
Principal Investigator Gerald O. Greenfield, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Michael H. Haak, CPT, MC
Key Words:	
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 6 Apr 89	Results Continue

Objective(s): To review the BAMC experience with the Luque Interpeduncular Segmental Fixation System by assessment of pre- and postoperative radiologic evaluations and interim/long term results.

Technical Approach: Review operative reports, narrative summary and final radiographs utilizing Luque Interpeduncular Segmental Fixation System.

Progress: The initial ten patients had review of pre- and post-operative radiographs, evaluation of intraoperative technique, and assessment of complications. Indications were for traumatic and degenerative disorders; intraoperative technique was facilitated by utilization of cannulated screws, a feature not found in other pedicle fixation systems. There was one complication of incorrect plate placement, and one episode of the screw exiting the pedicle. All patients were immobilized in an external orthosis for four months postoperatively.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-38-88 Status: Ongoing
 Title: Bone Density Changes with Compression Plating of Fractures

Start Date 7 Mar 88	Est Comp Date:
Principal Investigator Rick D. Compton, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Michael H. Haak, CPT, MC Edwin Melendez, COL, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 9	
Date of Periodic Review 6 Apr 89	Results Continue

Objective(s): Patients undergoing removal of compression plates after treatment of fractures will undergo bone densitometry of involved and uninvolved sites. Bone density changes will be plotted versus time since plating for various bones to quantify plate associated bone density loss.

Technical Approach: Dual photon absorptiometry will be utilized after plate removal to determine if bone density can be associated with plating of fractures as compared to the uninjured side.

Progress: Continuing to enroll patients.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-39-88 Status: Ongoing
 Title: EVALUATION of Constituents in the Synovial Fluid of Reconstructed Hips

Start Date 29 Mar 88	Est Comp Date:
Principal Investigator Henry G. Chambers, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Allan L. Bucknell, COL, MC
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 6 Apr 89	Results Continue

Objective(s): Evaluation of constituents in the synovial fluid of reconstructed hips.

Technical Approach: Twenty patients with reconstructed hips will have samples of synovial fluid collected. Each sample will be evaluated for hyaluronic acid, cholesterol, and glucose concentration.

Progress: Patient accrual has been completed. Data has been forwarded to Emory University for analysis.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-52-88 Status: Ongoing
 Title: Multiclinic Trial of Fibrillar Collagen/Calcium Phosphate Ceramic (COLHAP)

Start Date 9 May 88	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Henry G. Chambers, MAJ, MC
Key Words:	
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 6 Jul 89 Results Continue	

Objective(s): To determine the efficacy (functional and roentgenographic results) and benefits of COLHAP bone marrow (CBGS) when used for grafting procedures of long bones; to determine the safety of COLHAP (the incidence of significant device-related reactions); and to compare the efficacy and safety of COLHAP with standard autografting procedures.

Technical Approach: As outlined in the company protocol.

Progress: Annual review of this protocol was conducted by the company in May 1989. The results support CBGS both clinically and radiographically as an equivalent graft material to autogenous bone graft. The incidence and type of adverse effects combined with evidence of clinical/radiographic fracture healing suggest that CBGS will be shown to be safe and effective as a bone graft substitute in acute fracture management.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-53-88 Status: Completed
 Title: Is the Sodium Pentothal Test Valid?

Start Date 9 May 88	Est Comp Date:
Principal Investigator (vice Hansen) Roger L. Wesley, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Richard E. Emery, CPT, MC Emil J. Menk, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 10	
Total Number of Subjects Enrolled to Date: 20	
Date of Periodic Review 6 Jul 89 Results Completed	

Objective(s): To assess the effectiveness of the sodium pentothal test in differentiating somatic from psychogenic pain.

Technical Approach: Healthy (ASA I or II) patients with known neurologic compromise and with reproducible clinical findings (i.e., radiculopathy with pain and positive straight leg raise test) are tested in the operating room as they are being induced with sodium pentothal. They are given a painful stimuli - an achilles pinch, and a straight leg raise, and the response to both recorded. The patients are induced with incremental doses of IV sodium pentothal until a response to voice command and a lid lash reflex is lost. The patients are then given the same painful stimulus, and again, a straight leg raise test is performed with responses recorded.

Progress: This study involved examining patients with diagnostically proven lesions correlating with low back and radicular pain under what Winne terms "heavy sedation." Our expectation was that if this is a valid test, all of our patients would show a negative test - that is, respond to an SLR test with a grimace and/or a withdrawal response. In fact, 95% of the patients did so. Our study confirms that the pentothal test has a sensitivity of 95%.

C-53-88 (continued)

We conclude that heavy penbtothal sedation does not obliterate a painful response to straight leg raising in patients with discogenic radiculopathy. Thus, the pentothal pain test may be utilized as sensitive test to more efficiently select or identify those patients with organic causes for radicular pain in whom a reproducible finding such as a positive SLR is present. It may serve as a useful test to eliminate psychosocial variables in the diagnosis of low back pain, and should allow us to more efficiently select those patients who may benefit from surgical intervention.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-54-88 Status: Completed
 Title: Clinical Usage of Atracurium

Start Date 9 May 88	Est Comp Date:
Principal Investigator Charles P. Kingsley, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Richard Peterson, CPT, MC
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 _____	Results _____

Objective(s): To contribute the clinical experience of the usage of the muscle relaxant Atracurium at BAMC to a nationwide data base.

Technical Approach: In an effort to assemble a large data base on the clinical usage of the drug, Atracurium, Burroughs-Wellcome has asked 200 institutions to collect data on initial dosages, total dosage, and reversal requirements for 50 patients. This data will be pooled and analyzed using appropriate statistical tests.

Progress: This study has been completed and the data pooled .

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-57-88 Status: Terminated
 Title: VitaPatch Pin Protection Device, Phase I and II

Start Date 3 Jun 88	Est Comp Date:
Principal Investigator George Harrington, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Gerard Pennington, CPT, MC
Key Words:	
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 6 Jul 89	Results Terminated

Objective(s): Phase I - To evaluate Vitapatch™, a new skin dressing which contains antibiotics.

Phase II - To evaluate the safety and effectiveness of a new protection device, called VitaPatch. The effectiveness will be evaluated in terms of differences in the rate of bacterial colonization/infection, site appearance, convenience of use, and patient comfort as compared with established protocol.

Technical Approach: Phase I - After obtaining culture samples of the skin, patches (4 with antibiotic, 6 without) are placed on the abdomen. At the end of 24 hours, 48 hours, and 5 days two patches will be removed from each side of the abdomen and a culture taken.

Phase II - Patients requiring pin placement to assist healing of a fracture will be asked to participate. At the time of pin placement half of them will be covered with VitaPatch and half will receive standard treatment. The patches will remain in place for 72 hours, unless drainage requires prior removal. At the time of removal, all pin sites will be cultured for bacterial contamination and checked for signs of infection.

Progress: This study was terminated by the company.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-62-88 Status: Terminated
 Title: Short Term Evaluation of the Safety and Efficacy of Topically Applied Capsaicin in Pain Associated with Postherpetic Neuralgia

Start Date 13 Jun 88	Est Comp Date:
Principal Investigator Emil J. Menk, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 13	
Total Number of Subjects Enrolled to Date: 13	
Date of Periodic Review	Results

Objective(s): This is a six-week, double-blind, vehicle controlled multi-center clinical trial to evaluate the clinical safety and efficacy of topically applied 0.075% capsaicin cream for the relief of the pain of chronic postherpetic neuralgia.

Technical Approach: Patients who have had the pain of postherpetic neuralgia for greater than six months are invited to participate in this double-blind study to evaluate the efficacy of topically applied 0.075% capsaicin cream.

Progress: Three out of thirteen patients dropped out of the study due to inability to tolerate the burning of the cream upon application. Of the ten completers, five received capsaicin and five received placebo. One patient on capsaicin reported feeling slightly better while one patient on placebo reported complete remission.

Efforts to obtain the statistical analysis of the results of this study from the company have been fruitless. Because of this the study was terminated.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-63-88 Status: Ongoing
 Title: Long Term Evaluation of the Safety and Efficacy of Topically Applied Capsaicin in Pain Associated with Postherpetic Neuralgia

Start Date 13 Jun 88	Est Comp Date:
Principal Investigator Emil J. Menk, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 9	
Total Number of Subjects Enrolled to Date: 9	
Date of Periodic Review 6 Jul 89	Results Ongoing

Objective(s): This is a long term (up to 12 months), open-label, multi-center clinical trial to evaluate the clinical safety and efficacy of topically applied 0.075% capsaicin cream for the relief of the pain of postherpetic neuralgia.

Technical Approach: For those patients that do not gain relief from the blinded short term evaluation, they are invited to participate in the long term, open-label study to evaluate the efficacy of topically applied 0.075% capsaicin cream.

Progress: Nine patients with postherpetic neuralgia have been enrolled in this long term study of topical capsaicin. All patients were enrolled after completing the corresponding short term study. Although no data analysis has been done, some patients do report continued pain relief with chronic application. No unanticipated side effects have been observed or reported.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-65-88 Status: Terminated
 Title: Local Anesthesia for Retinal Detachment Surgery

Start Date 14 Jul 88	Est Comp Date:
Principal Investigator Calvin E. Mein, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	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 _____	Results _____

Objective(s): To determine the safety and effectiveness of local anesthesia for retinal detachment surgery.

Technical Approach: Patients 18 years of age and older scheduled to undergo retinal detachment surgery will be eligible for the study. Rather than blindly penetrate the retrobulbar space with a sharp needle as is present accepted practice, the proposed technique utilizes a direct subtenon approach with a blunt irrigation needle.

Progress: No patients have been enrolled on the study and it was decided to no longer pursue the project.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-66-88 Status: Ongoing
 Title: Lacrimal Pump Quantification

Start Date 14 Jul 88	Est Comp Date:
Principal Investigator William L. White, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: A. Tyrone Glover, M.D. Arthur Buc'ner, M.D.
Key Words:	
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 9 Sep 89	Results Complete

Objective(s): To utilize dacryoscintigraphy to quantitate the rate that passage of tears through the lacrimal drainage system is influenced by blinking.

Technical Approach: Volunteers with no history of lacrimal drainage problems will undergo two dacryoscintigrams. One study will be done with the eyes closed and the other with the patient blinking normally. The lacrimal flow rates will be calculated and the difference between the two will represent the amount that tear flow is influenced by blinking.

Progress: Results are being analyzed.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-68-88 Status: Completed
 Title: Non-Thermal Pulsed High Peak Power Electromagnetic Energy (Diapulse™) in the Treatment of Ankle Sprains

Start Date 14 Jul 88	Est Comp Date:
Principal Investigator Henry G. Chambers, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Gerard Pennington, CPT, MC
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 _____	Results _____

Objective(s): To assess the effects of Diapulse™ on the edema and rehabilitation time after ankle sprains.

Technical Approach: Patients will receive treatment in a blinded manner to determine efficacy of Diapulse in the rehabilitation of ankle sprains.

Progress: The Diapulse™ has been shown to be extremely effective in reducing the swelling associated with Grade II and III sprains.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-70-88 Status: Completed
 Title: The Ideal Test Dose for Detection of Subarachnoid Injection in Spinal Anesthesia

Start Date 5 Aug 88	Est Comp Date:
Principal Investigator Gary S. Baxter, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Douglas Culling, MAJ, MC Emil Menk, MAJ, MC
Key Words: Test dose Continuous spinal anesthesia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 120	
Total Number of Subjects Enrolled to Date: 120	
Date of Periodic Review 6 Jul 89 Results Completed	

Objective(s): To determine the minimum concentration of local anesthetic required to detect evidence of subarachnoid injection in a reasonable amount of time during attempted epidural anesthesia, yet in a small enough dosage not to produce a high or total spinal in a parturient.

Technical Approach: A peripheral IV was placed and a continuous spinal catheter was inserted in the L3-L4 or L4-L5 interspace which freely aspirated CSF. Catheters were inserted approximately 2 cm in the subarachnoid space. Patients then received one of three solutions in a 2 ml volume to which had been added 15 mcg of epinephrine. Group I received 0.5% hyperbaric bupivacaine, Group II received 0.5% isobaric bupivacaine and Group III received 1.5% isobaric lidocaine. Loss of sensation to cold and pinprick and the dermatomal level corresponding to the catheter insertion site were assessed over a ten minute period. A final level to loss of sensation to cold and 50 Htz tetanus was determined at the conclusion of the minute study period.

Progress: Patients in two of the three study groups failed to give evidence of subarachnoid block at five and as late as ten minutes with wide variability in the levels obtained. All patients receiving 0.5% hyperbaric bupivacaine developed evidence of spinal block in less than five minutes with no high spinals and minimal variation in the final level obtained. Based on an absence of reports of high or total spinal anesthesia, these results would suggest that the administration of 2 ml of 0.5% hyperbaric bupivacaine as a test dose for epidural anesthesia is a safe and sensitive indicator of accidental subarachnoid injection in all patients to include the obstetrical population.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-73-88 Status: Terminated
 Title: Marital Enrichment Aural Rehabilitation Program for the Hearing Impaired

Start Date 5 Aug 88	Est Comp Date:
Principal Investigator (vice Aspinall) John E. Ribera, CPT, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Kenneth Aspinall, COL, MS
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 _____ Results _____	

Objective(s): 1) To investigate marital discord as a significant factor in the noncompliant use of hearing aids.

2) To introduce communication strategies to current traditional aural rehabilitation programs.

3) To create a screening program to be used by audiologists in identifying and referring those hearing impaired couples needing marital counseling.

Technical Approach: Subjects 50 years of age and older with a history of noise exposure and bilateral high frequency hearing loss will be eligible for the study. Subjects will be randomly assigned to experimental and control groups. A four week, 2½ hour per week, aural rehabilitation program and marital enrichment program will be given to the experimental group. The control group will receive a traditional aural rehabilitation program during the same time span. A three month follow-up will be conducted for both the experimental and control group to identify the extent to which the hearing aid has been utilized and the extent to which communication skills have been maintained.

Progress: This study was terminated due to transfer of principal investigators.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-75-88 Status: Completed
 Title: A Closed-Jaw Method of Orotracheal Intubation using the "Lightwand"
 Transillumination Technique

Start Date 5 Aug 88	Est Comp Date:
Principal Investigator Timothy Castro, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Michael Matson, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 23	
Total Number of Subjects Enrolled to Date: 23	
Date of Periodic Review 6 Jul 89 Results Completed	

Objective(s): 1) To assess the success rate of lightwand guided orotracheal intubation in patients whose mandibles are maintained in a closed position.

2) To determine the time required for lightwand guided intubation using the closed-jaw technique.

3) To compare the results of this study to prior studies that utilized lightwand guided orotracheal intubation with initial jaw positioning and tongue grasp.

Technical Approach: In this study, a modification of the lightwand intubation technique was used to achieve orotracheal intubation of 23 healthy patients with simulated clinched jaws under general anesthesia. All patients had previously had their wisdom teeth extracted.

Progress: All intubations were successful and there were no complications. Intubation times were 8 ± 4 seconds for anesthesiologists experienced in lightwand intubation and 24 ± 13 seconds for physicians not experienced at lightwand intubation. We concluded that the required for intubation was experience related.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-76-88 Status: Ongoing
 Title: Double-Blind, Multicenter, Placebo Controlled Clinical Trial to Evaluate the Efficacy and safety of Ha-1A Human Monoclonal Antibody in Patients with Severe Gram-Negative Sepsis/Gram-Negative Septic Shock

Start Date 29 Aug 88	Est Comp Date:
Principal Investigator (vice Ducey) Michael Lamiel, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/SICU	Associate Investigators:
Key Words:	David L. Danley, MAJ, MS
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 30 Sep 89	Results Continue

Objective(s): To determine the efficacy of Ha-1A monoclonal antibody in reducing the mortality and/or direct morbidity of gram-negative sepsis as compared to a placebo group; to determine the impact that Ha-1A has on patient benefit; to determine the impact that HA-1A has on laboratory parameters/clinical signs associated with sepsis; and to determine the safety and potential for immunogenicity of Ha-1A monoclonal antibody administration in patients presenting with the clinical syndrome of gram negative sepsis.

Technical Approach: Eligible patients will be randomized to receive either the HA-1A or placebo (human albumin). Therapy will follow the schema outlined in the study protocol.

Progress: Four patients have been enrolled to date. Data and patient records have been reviewed and validated by Centocor.

Detail Summary Sheet

Date: 12 Oct 89	Proj No: C-77-88	Status: Ongoing
Title: Storz Intraocular Lens Clinical Trial		

Start Date 29 Aug 88	Est Comp Date:
Principal Investigator Calvin E. Mein, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Donald A. Hollsten, LTC, MC Arthur Glover, MAJ, MC
Key Words: Intraocular lens	
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	Results

Objective(s): To determine postoperative visual acuity of patients receiving an intraocular lens; to measure the occurrence and time course of postoperative ocular complications and adverse reactions for intraocular lens implan subjects; to measure the occurrence of postoperative lens related complications for the intraocular lens implan group; and to measure subgroups within the implant study population that are at "high risk" for the development of particulr complications, as compared to the historical control group.

Technical Approach: As outlined in the company protocol.

Progress: Twelve patients were enrolled in the Storz IOL safety adjunct study. All patients have done well with no adverse reactions noted. At the present time, these lenses are no longer being used.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-79-88 Status: Ongoing
 Title: Collaborative Ocular Melanoma Study

Start Date 8 Sep 88	Est Comp Date:
Principal Investigator Donald A. Hollsten, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators:
Key Words: Melanoma	
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 Sep 89	Results Continue

Objective(s): 1. To determine the efficacy of enucleation versus plaque irradiation in the treatment of medium size ocular melanomas.

2) To determine the efficacy of enucleation without pre-operative external radiation versus enucleation combined with pre-operative external radiation in the treatment of large ocular melanomas.

3) To determine the clinical course and community treatment standards in the treatment of small ocular melanomas.

Technical Approach: As outlined in the Collaborative Group protocol. The principal investigator will serve as the enucleating surgeon on this study.

Progress: This is a very tightly controlled study with strict criteria for entry. Also intraocular choroidal melanomas are rare tumors, further limiting numbers. We have had three patients with choroidal melanomas who underwent enucleation during the last 12 months. None of the patients met the eligibility criteria. At best we anticipate one to two enrollments per year.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-86-88 Status: Completed
 Title: Comparison of the Effectiveness of Lidocaine 1.5 mg/kg, 2.25 mg/kg, and 3 mg/kg in the prevention of Ventricular Fibrillation After Aortic Cross-Clamping.

Start Date 12 Oct 88	Est Comp Date:
Principal Investigator Kay Karasek, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: William Goglin, MAJ, MC Charles J. Kingsley, MAJ, MC Kevin Olson, CPT, MC
Key Words: Lidocaine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 32	
Total Number of Subjects Enrolled to Date: 32	
Date of Periodic Review 6 Jul 89	Results Completed

Objective(s): To study the dose of lidocaine most beneficial in reducing the incidence and severity of ventricular fibrillation after aortic cross-clamping during surgery for myocardial revascularization.

Technical Approach: Thirty two adult patients undergoing coronary artery bypass surgery were randomized to one of three groups. Group I received 1.5 mg/kg lidocaine, Group II received 2.25 mg/kg lidocaine, and Group III received 3 mg/kg lidocaine approximately five minutes prior to the release of the aortic cross clamp. At 15 minutes, 30 minutes and one hour post release of the aortic cross-clamp, blood was drawn for lidocaine assays.

Progress: Plasma lidocaine levels for all groups were within the reported therapeutic range. The incidence of ventricular fibrillation after cardiac reperfusion was: 1.5 mg/kg - 70%, 2.25 mg/kg - 40%, 3.0 mg/kg - 42%. Although, the incidence of ventricular fibrillation was lower with higher doses, it was not statistically significant. The number of operative distal anastomoses did correlate significantly with the occurrence of ventricular fibrillation. Preoperative ejection fraction and systemic blood pressure at the time of aortic cross-clamp release also correlated; however, statistical significance was not reached.

C-86-88 (continued)

It would appear that a dose of 2.25 mg/kg or 3 mg/kg of lidocaine may be more efficacious than 1.5 mg/kg in preventing ventricular fibrillation after aortic cross clamp release.

Detail Summary Sheet

Date: 24 Aug 89 Proj No: C-1-89 Status: Terminated
 Title: Treatment of Refractory Ulcers in Epidermolysis Bullosa Using Cultured Epidermal Autografts

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Jesse Moss, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Ronald E. Grimwood, Lt Col, USAF MC
Key Words: Epidermolysis bullosa	
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	Results

Objective(s): To successfully harvest and culture epidermal kartinocytes from an epidermolysis bullosa patient and develop a multilayer epidermal autograft to be used to cover nonhealing erosions.

Technical Approach: The purpose of this study will be to isolate and grow epidermal autografts from cells obtained from a suction blister on a patient with Epidermolysis Bullosa. The cells thus obtained will be planted on plastic tissue culture plates containing kartinocyte growth medium (KGM) which has recently been developed for the growth of keratinocytes. We will attempt manipulations of the media to induce the growth of multilayer epidermal sheets which may be transplanted onto nonhealing eroded areas on the same patient.

Progress: Attempts to grow the epidermal sheets were unsuccessful. Therefore, this study has been replaced by protocol #C-80-89.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-2-89 Status: Ongoing
 Title: Incidence of Asymptomatic Varicocele in Fertile Men

Start Date 22 Nov 89	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Timothy Dixon, CPT, MC Eric S. Zeidman, MAJ, MC Kurt Hansberry, MAJ, MC Francisco R. Rodriguez, COL, MC
Key Words: Varicocele	
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 asymptomatic varicocele in a group of men with proven fertility.

Technical Approach: All men requesting bilateral scrotal vas ligations for contraception will be eligible for inclusion. Patient will undergo vasectomy in a routine fashion. Prior to vasectomy, Doppler examination will be performed of the left and right spermatic cords. Patients will be first examined recumbent during comfortable respirations. Then they will be asked to perform a valsalva maneuver, and if a venous whir is detected, will be designated as possessing varicocele by this test. Following venous Doppler, scrotal ultrasound will be performed. If, on valsalva, scrotal ultrasound detects veins within the spermatic cord of 3 mm or greater, a ultrasound-detected varicocele will be scored. Immediately prior to vasectomy, standard semen analysis will be performed to quantitate semen motility, morphology, and total count.

Progress: Thus far, one patient has been accrued on-study. This patient had an asymptomatic varicocele by doppler examination.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-4-89 Status: Terminated
 Title: Screening for Adenocarcinoma of the Prostate: A Prospective, Randomized Study with Multiple Endpoints

Start Date 22 Nov 89	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Eric J. Zeidman, MAJ, MC Francisco R. Rodriquez, COL, MC
Key Words: Adenocarcinoma, 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 ultrasound examination of the prostate is efficacious in reducing morbidity and mortality from carcinoma of the prostate in a screening function.

Technical App. Patients will be randomized into two groups - rectal examination alone ; al examination with transrectal ultrasound. Patients will initially fill general questionnaire. A urinalysis will be obtained and they will undergo , flowmetry. If abnormalities are detected either by rectal examination or , rectal ultrasound, prostate biopsy may be required. This will be performed off-protocol.

Progress: This study was terminated due to the fact that the National Cancer Institute will shortly release an RFA for centers requesting to participate in a screening study. For this reason, the principal investigator requests to close thi study and will apply for funding to participate in the NCI study, when released.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-5-89 Status: Terminated
 Title: Intravesical Hyperthermia for Superficial Transitional Cell Carcinoma of the Bladder

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Eric J. Zeidman, MAJ, MC
Key Words: Carcinoma, transitional cell	Francisco R. Rodriguez, COL, MC
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	Results

Objective(s): To investigate whether hyperthermia can control superficial transitional cell carcinoma and will do so with less morbidity than currently available therapies.

Technical Approach: Ten patients from the Urology Clinic population will be offered entry into this study. Urine cultures will be obtained from all patients. Those with positive cultures will be treated with appropriate antibiotics. A cystometrogram will be performed in all patients to determine bladder capacity and to determine intravesical pressure at 80% of bladder capacity to dictate filling pressure during therapy. Hyperthermic treatment will be performed once weekly for four weeks. Hyperthermic perfusion will be performed at 43°C for one hour at the intravesical pressure through a 22F, 5cc balloon, 3-way foley catheter. Patients will undergo cystoscopy at 2, 4, and 6 weeks following initiation of therapy.

Progress: One patient has been treated with intravesical hyperthermia. without complication. Serial cystoscopies revealed that bladder tumors were unaffected by the hyperthermia. Since initiation of the protocol, a series of patients from Europe have been reported in whom hyperthermia was employed. Only a small fraction of patients responded to therapy - a significantly lower response rate than conventional therapy.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-6-89 Status: Ongoing
 Title: Comparison of 2-Suture versus 4-Suture Bladder Neck Suspension in the Treatment of Stress Urinary Incontinence

Start Date 22 Nov 89	Est Comp Date:
Principal Investigator Eric J. Zeidman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: William Boykin, CPT, MC Ian M. Thompson, MAJ, MC Kurt Hansberry, MAJ, MC Timothy Dixon, CPT, MC Francisco R. Rodriguez, COL, MC
Key Words: Incontinence, stress	
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 n/a	Results

Objective(s): To determine the success (as measured by the absence of postoperative incontinence and the presence of normal postoperative micturition) of two different bladder neck suspension techniques in the treatment of stress urinary incontinence associated with hypermobility and malposition of the bladder neck.

Technical Approach: Twenty adult females with objective stress urinary incontinence associated with bladder neck hypermobility and mild cystocele will be randomized into two groups. One group will undergo a traditional 2-suture bladder neck suspension with the two sutures placed at the level of the bladder neck incorporating the medial edge of the endopelvic fascia., pubocervical fascia and vaginal wall minus the epithelium. The second group will undergo a 4-suture bladder suspension with the additional two sutures placed at the level of the bladder base incorporating vaginal wall minus the epithelium, pubocervical fascia and the anterior extension of the cardinal ligaments.

Progress: Too few patients have been studied to draw any conclusions.

Detail Summary Sheet

Date: 25 Sep 89	Proj No: C-7-89	Status: Ongoing
Title: Comparison of the Effectiveness of Bretylium 5 mg/kg, 10 mg/kg, and 15 mg/kg in the Prevention of Ventricular Fibrillation After Aortic Cross-Clamping		
Start Date 22 Nov 88	Est Comp Date:	
Principal Investigator Kevin W. Olson, CPT, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: William Goglin, MAJ, MC Brent O. Grishkin, COL, MC Charles P. Kingsley, MAJ, MC	
Key Words: Fibrillation, ventricular		
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 determine the optimal dose of bretylium tosylate to reduce the incidence of ventricular fibrillation after aortic cross-clamp release during myocardial revascularization surgery.

Technical Approach: Thirty adult patients of either sex undergoing elective coronary artery bypass surgery will be randomized to receive 5 mg/kg, 10 mg/kg, or 15 mg/kg of bretylium tosylate just prior to aortic cross clamp release. Data concerning the frequency of fibrillation, time of its occurrence and requirements for additional antidysthythmic therapy will be compared between groups.

Progress: No reportable results are available at this time.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-8-89 Status: Ongoing
 Title: The Effect of Volume in Tetracaine Spinal Anesthesia

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Richard B. Hecker, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Charles P. Kingsley, MAJ, MC
Key Words: Anesthesia, spinal tetracaine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 96	
Total Number of Subjects Enrolled to Date: 96	
Date of Periodic Review n/a	Results

Objective(s): To determine if a specific volume of fluid injected into the subarachnoid space, with a fixed dosage of hyperbaric tetracaine based on the patient's height, will affect the average maximal dermatomal spread of anesthesia.

Technical Approach: Sixty patients will receive 2, 3, or 4 cc total volume of tetracaine. Dosage will be determined according to height and will be administered in a reproducible fashion by the staff member supervising the anesthetic. The resident will be blinded to the total volume and will determine maximum dermatomal spread of anesthetic.

Progress: Data collection has been completed for the without epinephrine division. Approximately 11 patients are needed for study in the with epinephrine division. When this phase is completed statistical analysis will be done.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-9-89 Status: Ongoing
 Title: A Comparison of Interpleural Bupivacaine, Epidural Morphine and Systemic Narcotics in Post-Thoracotomy Pain

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Richard E. Peterson, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: William E. Strong, CPT, MC Charles P. Kingsley, MAJ, MC
Key Words: Pain, post-thoracotomy	
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): 1) To compare the effectiveness of interpleural bupivacaine with two commonly utilized methods of pain control.

2) To determine the ease of administration of the interpleural catheter.

3) To provide information as to the benefits of interpleural bupivacaine on postoperative pulmonary function.

Technical Approach: Forty-five patients undergoing thoracotomies will take part in the study, with 15 patients in each group. All patients will undergo pulmonary function testing prior to surgery as well as bedside spirometry post-surgery. A preoperative baseline room air arterial blood gas will be obtained on all patients. Patients will be randomized to one of three groups - Group I, parenteral narcotics; Group II, epidural morphine, Group III interpleural bupivacaine. Patients who do not receive at least 50% reduction in their level of pain within one hour will be considered failures. If either the epidural morphine or the interpleural regional anesthesia techniques are deemed a failure by the attending anesthesiologist, then that technique will be abandoned and parenteral narcotics will be substituted.

Progress: It appears that interpleural bupivacaine is less effective in controlling postoperative thoracotomy pain than is epidural narcotic. However, there is a moderate degree of analgesia from interpleural bupivacaine which may decrease supplemental narcotic requirements. There seems to be little advantage in improving postoperative pulmonary function as determined by pO₂, pCO₂, FVC, and chest x-ray.

Detail Summary Sheet

Date: 28 Sep 89 Proj No: C-10-89 Status: Completed
 Title: Comparison of Punctal Excision versus Medical Therapy in Dry Eye Syndrome

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Henry D. Hacker, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Donald Hollsten, LTC, MC
Key Words: Syndrome, dry eye	
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	Results

Objective(s): To evaluate surgical therapy (punctal excision) versus medical treatment in patients with severe dry eye syndrome to determine if definitive surgery results in significant clinical improvement.

Technical Approach: The inferior puncta of fourteen eyelids in eight patients were excised. Pre- and postoperative findings were compared based on the symptoms and physical findings of each patient. Patients were followed for change in eye discomfort, frequency of tear replacement medication used, and episodes of keratitis manifested by pain and photophobia.

Progress: All patients reported symptomatic improvement the day after surgery and continued to do well after suture removal 8-10 days later. Two patients discontinued tear medication entirely, while the mean frequency of tear use decreased by 56% for the remaining patients. In general, while all patients reported relief from dry eye symptoms the majority of patients continued to require tear supplements albeit at a reduced frequency. In summary, punctal excision offers definitive occlusion of the lacrimal canaliculus while at the same time allows the physician to evaluate patient response to this form of therapy.

Detail Summary Sheet

Date: 9 Nov 89 Proj No: C-11-89 Status: Ongoing
 Title: Sleep Deprivation, Stress and Vagal Tone

Start Date 22 Nov 88	Est Comp Date:
Principal Investigator Jeffrey Priest, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Charles P. Kingsley, MAJ, MC Donald Fox, CPT, MC Dennis Gilstad, M.D., Ph.D. John A. Dillinger, Ph.D.
Key Words: Sleep deprivation Stress Vagal tone	
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 determine the effects of sleep deprivation (two hours or less in a continuous twenty-four hour period of time) and stress on respiratory sinus arrhythmia.

Technical Approach: Individuals who are sleep deprived or engaged in stressful mental and psychomotor activity will be studied. Vagal tone as measured by RSA will be correlated with salivary cortisol levels, a known predictor of stress. Anesthesia residents will provide baseline ECG recordings and salivary samples. Following periods of sleep deprivation, and prior to and after oral presentation, the same parameters will be measured. Respiratory sinus arrhythmia (vagal tone) and salivary cortisol levels will be examined for correlation of changes due to stress or sleep deprivation.

Progress: To date the majority of data has been obtained regarding the vagal tone data and serum cortisol data. Significant differences in stressed/non-stressed cortisol levels are becoming apparent. However, vagal tone calculations do not at this time appear to be significantly different between the stressed/non-stressed groups. Preliminary results show lack of correlation between vagal tone values and stress represented by serum cortisol levels. Further data analysis will continue.

Detail Summary Sheet

Date: 12 Oct 89	Proj No: C-16-89	Status: Ongoing
Title: Argon Laser Photocoagulation in the Treatment of Pseudophakic Cystoid Macular Edema		

Start Date 20 Dec 88	Est Comp Date:
Principal Investigator Susan L. Parks, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Ophthalmology	Associate Investigators: Calvin E. Mein, LTC, MC
Key Words: Laser, argon photocoagulation Cystoid macular edema	
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	Results

Objective(s): To compare observation vs argon laser photocoagulation in the treatment of pseudophakic cystoid macular edema (CMS).

Technical Approach: Fifty patients will be selected who have had CME for greater than six months and have vision worse than 20/40. The patients will be randomly assigned to treatment or observation. Vision, photos, and flurescein angiograms will be taken on each patient. Both groups will be followed at periodic intervals for up to tow years in which vision will be retested and fluorescein angiograms repeated. Improvement in vision in the treatment group will be seen sa a positive result faving the use of laser photocoagulation in aphakic CME.

Progress: We have only enrolled three patients - two to treatment and one to observation. Laser therapy was only done in August 89, waiting for two month follow-up. Control patient has botten better without therapy.

Detail Summary Sheet

Date: 25 Sep 89	Proj No: C-18-89	Status: Ongoing
Title: The Metabolic Effects of Epidural Anesthesia		

Start Date 20 Dec 88	Est Comp Date:
Principal Investigator Richard B. Hecker, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Richard D. Culling, MAJ, MC Joseph P. Ducey, MAJ, MC
Key Words: Epidural anesthesia	
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 compare the metabolic effects of lumbar dural anesthesia (when combined with light general anesthesia) with general anesthesia intraoperatively and during the early postoperative period.

Technical Approach: The subject population will include the ASA physical status classification one through four adult patients who are scheduled for elective abdominal surgery, and who are candidates for placement of a lumbar epidural catheter. This will be a prospective study involving 30 surgical patients. The patients will be randomly assigned to one of two groups. Group one will receive lumbar epidural anesthesia combined with a "light" anesthetic. Group two patients will receive standard inhalational agent plus narcotic anesthesia. The metabolic effects of these anesthetic regimes will be analyzed by indirect calorimetry and serum cortisol determinations.

Progress: Currently used indirect calorimeter unable to accurately analyze data when used in conjunction with the inhalational agents (e.g. isoflurane). Protocol may have to be modified to eliminate indirect calorimetric analysis during the actual delivery of inhalational anesthesia.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-19-89 Status: Ongoing
 Title: Respiratory Sinus Arrhythmia Analysis: A Potential Anesthetic Depth Monitor

Start Date 20 Dec 88	Est Comp Date:
Principal Investigator Eric Lefever, LT, MC, USN	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Charles P. Kingsley, MAJ, MC Don J. Daniels, MAJ, MC Emil Menk, MAJ, MC Dennis Gilstad, M.D., Ph.D., COL, USAFR John A. Dillinger, Ph.D. (Southwest Research Institute)
Key Words: Arrhythmia, respiratory sinus	
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 correlation exists between depth of general anesthesia and vagal tone as determined by computer analysis of respiratory sinus arrhythmia.

Technical Approach: 70 healthy ASA Class I or II adult volunteers undergoing elective surgery will be randomized to receive one of seven standard anesthetic regimens. Enflurane, Halothane, and Isoflurane with spontaneous and controlled ventilation will be used. Patients whose ventilation is controlled will receive vecuornium as a muscle relaxant. A final group will receive nitrous oxide and fentanyl in addition to Isoflurane and vecuronium. EKG will be recorded for later analysis of respiratory sinus arrhythmia. Respiratory wave form, blood pressure oxygen saturation, end-tidal CO₂ and inhalational agent concentration will be recorded. The effects of anesthetic agents on respiratory sinus arrhythmia will be analyzed.

Progress: Equipment and personnel are now coordinated. Data collection will begin in the near future.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-21-89 Status: Terminated
 Title: Ketamine-Midazolam-Vecuronium as a Continuous Intravenous General Anesthesia for the Traumatized Patient

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator	Facility
Don J. Daniels, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/Anesthesiology	
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 _____	Results _____

Objective(s): To determine if a continuous intravenous infusion utilizing ketamine, midazolam and vecuronium will provide adequate anesthesia in the acutely traumatized patient safely, with regards to preservation of hemodynamics, adequate relaxation, ease of use, adequate intraoperative analgesia and amnesia, and adaptability to changing intraoperative events.

Technical Approach: The subject population will be 100 acutely traumatized patients age 19-50 years requiring immediate resuscitative surgery. Because this is strictly a descriptive study, no controls will be studied. Each subject will be assigned a trauma number and the following information recorded on a data information sheet: height, weight, relevant medical history, extent of injuries, pertinent lab values, time of incital injury, surgical incision time, and if available, estimated preoperating room blood loss. Anesthesia will be induced with midazolam, 1 mg/kg, ketamine and vecuronium, 0.10 mg/kg, using a rapid sequence technique. The patient will be visited 24 hrs postop and questioned in regard to intraoperative awareness, occurrence of dreams or hallucinations, and the occurrence of nausea and vomiting. Complications such as death, its time in relationship to surgery, and cause if known will be recorded.

Progress: No patients have been entered in this study due to the requirement that no civilians with no military affiliation may be used as investigational subjects. Unfortunately, >95% of traumatized patients presenting to BAMC for surgical treatment are non-military dependent civilians. This in effect prevents the investigation of useful, easily utilized, almost no risk anesthetic technique. Therefore, the study was terminated.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-26-89 Status: Ongoing
 Title: Study of Risk Factors in Prostate Disease

Start Date 27 Jan 89	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Randall E. Harris, Ph.D., M.D. American Health Foundation, New York
Key Words: Prostate disease	Eric J. Zeidman, MAJ, MC Francisco R. Rodriguez, COL, MA
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 various risk factors for the development of prostatic disease.

Technical Approach: This study is designed as a case-control study of patients with carcinoma of the prostate, patients with benign prostatic hyperplasia, and control patients without evidence of prostatic disease. A questionnaire will be employed to assess risk factors including diet, occupation, medications, activity, smoking, alcohol, sexual history, family history, and voiding pattern. This questionnaire will be administered by a trained epidemiologic interviewer to 100 patients in each group. Additionally several serum steroid and lipid assays will be employed.

Progress: Age-matched samples are being accrued. The study will probably be completed in approximately one year.

Detail Summary Sheet

Date: 25 Sep 89	Proj No: C-27-89	Status: Completed
Title: The Use of the "Light Wand" for Rapid Sequence Intubation.		

Start Date 30 Jan 89	Est Comp Date:
Principal Investigator Paul D. Mongan, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Robert D. Culling, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 80	
Total Number of Subjects Enrolled to Date: 80	
Date of Periodic Review	Results

Objective(s): To investigate the use of light wand guided orotracheal intubation for rapid sequence intubations and compare the success and time required to direct laryngoscopy and visualized intubation.

Technical Approach: The subject population will be 80 ASA 1 and 2 patients scheduled for elective surgery. The patients will be randomly assigned to light wand or laryngoscopy groups. Success and time required will be analyzed.

Progress: The results indicate that all light wand groups had faster intubation times than the direct laryngoscopy control group. There were no unsuccessful intubations in any group and no complications or difficulties.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-29-89 Status: Ongoing
 Title: Does BCG Bacteremia Occur After Intravesical BCG Administration?

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Craig Smith, MAJ, MC Eric Zeidman, MAJ, MC Francisco Rodriguez, COL, MC S. Vern Juchau, COL, MS
Key Words:	
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	Results

Objective(s): To determine if BCG bacteremia occurs frequently following intravesical administration of BCG.

Technical Approach: Patients undergoing BCG instillation will be eligible for this study. Patients will be placed on BCG therapy at the discretion of their primary urologic surgeon. Prior to each instillation, a urinalysis is routinely obtained and, if abnormal, the urine is cultured and the instillation postponed. Ten patients will be studied. Blood cultures will be obtained on treatments 1, 3, and 6.

Progress: Thus far, all blood cultures have revealed no evidence of BCG bacteremia.

Detail Summary Sheet

Date: 28 Aug 89 Proj No: C-32-89 Status: Ongoing
 Title: Effects of Blood Transfusion on the Metabolic Rate as Measured by Indirect Calorimetry

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator (vice Byrne) James M. Lamiell, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/SICU	Associate Investigators:
Key Words: Calorimetry, indirect	Joseph P. Ducey, MAJ, MC Glen E. Gueller, SFC
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	Results

Objective(s): To determine the effects of blood transfusion on oxygen utilization in the critically ill patient in various clinical settings and to compare the measurement of oxygen consumption by two different techniques.

Technical Approach: Indirect calorimetry will be performed on each patient using a metabolic measurement cart which involves rapid sampling of inspired and expired gases combined with respiratory gas flow. This will be performed at four different intervals: (1) prior to transfusion, (2) during transfusion, (3) immediately post-transfusion, and (4) 12-24 hours post-transfusion. Metabolic measurements will be made for 12 minutes each time. CBC and SMA-6 will be obtained prior to and post-transfusion.

Progress: The principal investigator, Dr. Byrne, has been transferred to Eisenhower Army Medical Center. However, we plan to continue with physician investigators presently assigned. The equipment to perform the study is in the SICU's and requires minimal expenditures.

Detail Summary Sheet

Date: 12 Oct 89	Proj No: C-33-89	Status: Completed
Title: LCSG 884 - Assessment of Thirty Day Operative Morbidity for Surgical Resections in Lung Cancer		

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator Brent A. Grishkin, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of	Associate Investigators:
Key Words:	
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	Results

Objective(s): 1) To determine the complication rate of surgery for the treatment of bronchogenic carcinoma.

2) To identify clinical factors measurable in the preoperative period that may predict those individuals at risk for the development of postoperative problems.

3) To develop a predictive index of postoperative morbidity/mortality.

Technical Approach: All patients undergoing thoracotomy for primary pulmonary bronchogenic carcinoma will be entered into the study, with preoperative pulmonary assessment and operative techniques reported within 72 hours of operation, and with a 30-day postoperative report subsequently submitted.

Progress: This study has been closed to new entries. However, we are on schedule with follow-up, summaries and reports. One patient is deceased.

Detail Summary Sheet

Date: 28 Aug 89 Proj No: C-35-89 Status: Ongoing
 Title: Limited Intercarpal Joint Fixation: Techniques and Biomechanical Study
 Using Cadaver Model

Start Date 21 Feb 89	Est Comp Date:
Principal Investigator Edwin Melendez, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$1,320.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To develop a technique of intercarpal joint fixation using a cadaver model.

Technical Approach: Cadaver specimens consisting of forearm, wrist, and hand will be used. Techniques for fixing the scapho-trapezium-trapezoid joint and the scaphocapitate joints will be studied. The techniques will be divided into those that immobilize the joint through transarticular techniques and those that immobilize the joint through extraarticular techniques.

Progress: The cadaver specimens have been received, and the study will start in the near future.

Detail Summary Sheet

Date: 28 Aug 89	Proj No: C-37-89	Status: Completed
Title: Evaluation of Stroke Mechanics to Shoulder Pain in the Swimmer		

Start Date: 28 Feb 89	Est Comp Date:
Principal Investigator Harry L. Warren, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	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 _____	Results _____

Objective(s): To determine what factors are associated with shoulder pain in competitive swimmers.

Technical Approach: Sixty-seven subjects completed a survey reporting general characteristics and swimming history. Symptom history was elicited to include history of any swimming related shoulder pain, duration of pain, functional impact of pain upon sports activity, presence of pain now, and aggravation of pain by particular type of swimming activity. Each subject was given a clinical examination by a physician. Stroke attributes were assessed by direct visual observation from the pool deck augmented where feasible by underwater qualitative video analysis.

Progress: Pain was present in 16% of the subjects. Forty-four percent of the subjects reported aggravation of their symptoms related to particular aspects of their swim training. Pain present during and after workout, constantly or at night was reported by 51%. Symptoms interfered with training was present in 53%, and 4% had to completely halt their training due to shoulder pain. While 13% of the study population manifested a positive apprehension sign, this included symptomatic and asymptomatic swimmers. Likewise, many of the subjects

C-37-89 (continued)

demonstrated capsular laxity manifested as subluxation. These findings did not correlate to a significant degree with symptomatology. However, their presence in a substantial portion of the subject group is suggestive of the possibility that "secondary" impingement may play a role in shoulder impingement in swimmers.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-48-89 Status: Completed
 Title: Extended Follow-up of Stage D1 Adenocarcinoma of the Prostate

Start Date 20 Mar 89	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 21	
Total Number of Subjects Enrolled to Date: 21	
Date of Periodic Review	Results

Objective(s): To assess the results of various modes of therapy of stage D1 adenocarcinoma of the prostate in patients exposed to prolonged follow-up.

Technical Approach: All patients with histologic evidence of stage D1 adenocarcinoma of the prostate are eligible for review. Patients must have been diagnosed on or before December 1, 1980. A standardized form for data retrieval is used to assess date of biopsy, grade of biopsy, clinical stage, number of nodes involved, initial treatment, time to development of local progression, time to development of metastatic disease, time to hormonal therapy, and time to death of disease.

Progress: Data reveal that prolonged survival is not uncommon in patients with minimal pelvic nodal involvement with tumor.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-51-89 Status: Ongoing
 Title: Evaluation of the Falling Meniscus Sign in Identifying the Epidural Space

Start Date: 3 Apr 89	Est Comp Date:
Principal Investigator (vice Perry) Stephen Gates, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Timothy Castro, MAJ, MC
Key Words:	
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 evaluate the reliability of the falling meniscus sign in identifying the epidural space.

2) To evaluate the value of the falling meniscus sign as a teaching aid in the instruction of epidural catheter placement by medical personnel.

Technical Approach: This study will consist of 40 patients who will be having epidural catheters placed for anesthetic purposes. Once the skin and interspinous area are anesthetized, the Touhy needle will be placed in the corresponding (1) supraspinous ligament, (2) paraspinal muscle, (3) epidural space identified by the loss of resistance technique and epidural blockade secondary to anesthetic agent given in incremental dosage. In each of these locations a K-53 catheter extension will be connected to the needle and filled with normal saline. The catheter extension will be raised above the level of the needle and observed for a falling meniscus of fluid. Also an epidural catheter will be passed through the needle when it is felt to be in the epidural space and filled with normal saline. The catheter will be raised above the level of the needle and the hump of the catheter observed for a falling meniscus of fluid. If the meniscus falls freely, the test will be interpreted as positive.

Progress: The principal investigator, MAJ A. T. Perry, has been transferred. Recruitment of patients will begin shortly.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-52-89 Status: Ongoing
 Title: A Prospective, Randomized Study of Balloon Dilatation vs. Transurethral Resection of the Prostate for Benign Prostatic Hyperplasia

Start Date: 3 Apr 89	Est Comp Date:
Principal Investigator Eric J. Zeidman, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 6,094.00
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review _____ Results _____	

Objective(s): To determine the relative benefits of balloon dilatation vs TURP for BPH.

Technical Approach: A total of 40 patients will be enrolled in the study. Patients will be randomized into two arms: Arm I - standard TURP, Arm II - balloon dilatation. Patients will undergo preoperative urodynamic evaluation with pressure flow studies. A Questionnaire concerning sexual history and urinary symptoms will be administered. Patients will be seen two weeks following their procedure at which time uroflowmetry is performed. Patients are then followed on an every 3 month basis for one year. At 3, 6 and 12 months of follow-up, complete pressure-flow urodynamic measurement is performed. Efficacy of the two treatment modalities will be compared as follows: 1) symptom score, 2) uroflowmetry, 3) treatment failures, treatment side effects, and repeat procedures.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 25 Sep 89	Proj No: C-53-89	Status: Ongoing
Title: A Comparison of Arterial Oxygen Partial Pressures Achieved with Intermittent Flow Oxygen (IF) from a Demand Oxygen Controller and Continuous Flow Oxygen (CF)		
Start Date: 3 Apr 89	Est Comp Date:	
Principal Investigator Charles P. Kingsley, MAJ, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Joseph P. Ducey, MAJ, MC William Strong, CPT, MC Linda Strezlecki, LTC, AN	
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 _____ Results _____		

Objective(s): Animal studies and human studies in chronically ill patients have shown that intermittent flow oxygen delivered by a demand oxygen controller (DOC) maintains arterial oxygen tensions at values that are equal to those values with continuous flow oxygen (CF). Twenty five postoperative patients for pulmonary surgery will be studied in a randomized crossover design.

Technical Approach: Twenty five adult patients scheduled for pulmonary surgery requiring routine arterial catheter placement and postoperative intensive care admission will be enrolled in the study. A randomized crossover design with each patient serving as his own control will be employed to evaluate the arterial oxygen partial pressures achieved with intermittent oxygen therapy from a demand oxygen controller compared to continuous flow oxygen at comparable flow rates. Arterial blood gases will be drawn at 30 minute intervals, and total oxygen use will be recorded. Continuous pulse oximetry will insure adequate oxygen delivery.

Progress: Patient enrollment will begin in the near future.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-54-89 Status: Completed
 Title: A Comparison of Three Techniques for Rapid Sequence Induction of Anesthesia

Start Date: 3 Apr 89	Est Comp Date:
Principal Investigator Sanford M. Silverman, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Douglas Culling, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 60	
Total Number of Subjects Enrolled to Date: 60	
Date of Periodic Review	Results

Objective(s): To determine any differences in intubating conditions between the timing principle, the priming principle, and rapid sequence technique with succinylcholine.

Technical Approach: Sixty ASA class 1 and 2 patients will be randomized into one of three groups. Group A will receive succinylcholine as muscle relaxant in standard rapid sequence fashion. Group B (priming group) will receive a priming dose of vecuronium followed by an intubating dose of the same. Group C (timing group) will receive a large bolus of vecuronium. After demonstration of weakness to hand grip or any clinical evidence of weakness, timing patients will be induced with sodium pentothal. All patients will receive sodium pentothal as the final induction agent. In addition, all patients will receive midazolam before any other drug in the induction sequence. The adequacy of muscle relaxation for endotracheal intubation will be evaluated by a blinded individual using established criteria. This individual will perform the intubations. The remainder of the anesthetic administered will be routine. Differences in intubating conditions among the three groups will be analyzed.

Progress: There was a significant difference between groups with respect to intubation score (ANOVA $p = 0.028$). There was a significant difference between priming and succinylcholine (Mann-Whitney U; $p = 0.009$). No significance between timing + succinylcholine ($p = 0.173$) or timing + priming ($p = 0.157$). There were no differences in demographic characteristics between the groups.

C-54-89 (continued)

Conclusions: The timing principle offers a viable alternative to succinylcholine + the priming principle. The priming principle is associated with 20-40% incidence of bucking or coughing during endotracheal intubation. This is unacceptable for a patient with an open eye injury or increased ICP.

Timing patients did not have the same degree or incidence of bucking. We believe this technique offers advantages over priming. However, this study also confirms that succinylcholine is still the "gold standard" for intubation (rapid sequence) and yields uniformly excellent intubation conditions. However, in cases where succinylcholine is contraindicated, timing offers a viable alternative.

Detail Summary Sheet

Date: 13 Nov 89 Proj No: C-65-89 Status: Ongoing
 Title: Review of Keller Bunionectomy Procedures

Start Date: 5 May 89	Est Comp Date:
Principal Investigator	Facility
Harlan Stratton, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/Orthopaedics	Henry Chambers, MAJ, MC
Key Words:	
Accumulative CASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 100	
Total Number of Subjects Enrolled to Date: 100	
Date of Periodic Review	Results

Objective(s): 1) To determine if the Keller bunionectomy procedure is successful in relieving forefootpain, improving cosmesis, allowing use of normal footwear, and to what degree it is able to improve the overall function in patients with the hallux valgus deformity.

2) To define the failure rates and mode of failure of the Keller bunionectomy.

3) To determine if the continued clinical usage of the Keller bunionectomy is indicated based on subjective and objective data collected from patients on whom this procedure has been performed.

Technical Approach: The last 100 consecutive adult patients who have had a Keller procedure at BAMC will be evaluated. A patient questionnaire will allow subjective, i.e. patient, evaluation of the surgical results. Objectively the patient will be examined for cosmesis, mobility and pin in the interphalangeal joint, pain or stiffness with metatarsalphalangeal joint motion, residual inflammation on medial metatarsal, residual hallux valgus deformity, pronation of the hallux, plantar callosities of the lesser metatarsals, and pressure distribution under the foot by use of the Harris foot mat.

Progress: Data collection completed. Statistical analysis is underway.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-66-89 Status: Ongoing
 Title: Evaluation of the Effect of Postoperative Wound Drainage Reinfusion Using the Solcotrans Orthopaedic Drainage/Reinfusion System in Reducing the Need for Whole Blood Transfusion.

Start Date: 5 May 89	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Michael B. Simpson, CPT. MC
Key Words:	
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 evaluate the efficacy of reinfusion of postoperative wound drainage in decreasing the need for whole blood transfusion in patients with significant sanguineous postoperative drainage.

Technical Approach: Patients undergoing total joint arthroplasty will be eligible. Wound drainage will be collected for a total of six hours. At the end of that time the amount of drainage in the container will be noted. If greater than 350 ml are present, the Solcotrans system will be configured for reinfusion and a new collection using will be connected to the drainage tube. For collection volumes from 150-350 ml, the system will be configured for reinfusion and a standard Hemovac suction container will be attached to the drainage tubes. Amounts less than 150 ml will not be reinfused. An aliquot of blood will be collected from each Solcotrans unit configured for reinfusion and submitted for CBC, aerobic and anaerobic cultures.

Progress: Data accumulation continues.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-69-89 Status: Completed
 Title: Long-Term Mortality from Transurethral Resection of the Prostate

Start Date: 5 May 89	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Mark Hooten, CPT, MS Ken Finstuen, Ph.D.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 90	
Total Number of Subjects Enrolled to Date: 90	
Date of Periodic Review	Results

Objective(s): To determine the mortality associated with TURP in a case-control method.

Technical Approach: From the data generated from a previous report from the Urology Service at BAMC, 30 men who were noted in the screening clinic to have significant symptoms of prostatism and who underwent TURP will be identified. Two case-controls will be selected from the overall population of men with BPH who did not undergo TURP, will be selected for each patient undergoing TURP. All patients will be evaluated for survival and treatment-related complications to a study close date pf 1 April 1989.

Progress: The multivariable analysis reveals TURP to play only a small role in overall patient survival with other factors, including hypertension, smoking, ASCVD, being significant factors in survival.

Detail Summary Sheet

Date: 25 Sep 89	Proj No: C-76-89	Status: Ongoing
Title: Thyro-Glossal Duct Cyst (TGDC)		

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator David K. Hayes, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	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 _____	Results _____

Objective(s): To characterize the presentation of true thyroglossal duct cyst that may aid in establishing the diagnoses.

Technical Approach: All inpatient medical records of patients with an admission or discharge diagnosis or operative diagnosis of TGDC will be reviewed. Attempts will be mde to contact all subjects who underwent a surgical procedure to obtain current information on their postoperative course and recurrence of the cyst.

Progress: All charts available have been reviewed. Postoperative follow-up information is being collected.

Detail Summary Sheet

Date: 16 Oct 89 Proj No: C-78-89 Status: Ongoing
 Title: Respiratory Sinus Arrhythmia Analysis During Spinal Anesthesia Evaluation of Vagal Tone in Relation to Anesthetic Levels

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Jeff Baeuerle, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	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 _____	Results _____

Objective(s): To investigate the relationship between vagal tone (as determined by computerized respiratory sinus arrhythmia analysis) and dermatomal level of spinal anesthesia.

Technical Approach: The electrocardiogram of adult patients undergoing surgical procedures with spinal anesthesia will be recorded on magnetic tape for computer analysis of R-R interval variation. This beat to beat variability may be altered in patients with spinal anesthesia as a result of altered autonomic tone. Patient care and management will not be altered in any way. Computer analysis of the taped ECG signal will be performed at Southwest Research Institute.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-79-89 Status: Ongoing
 Title: Comparison of Equipotent Doses of Bupivacaine and Tetracaine in Spinal Anesthesia

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Don J. Daniels, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	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 _____	Results _____

Objective(s): To compare the adequacy and duration of equipotent doses of bupivacaine and tetracaine in pregnant females requesting spinal anesthesia for cesarean section.

Technical Approach: One hundred healthy parturients will be studied in a randomized, double blind fashion. After prehydration, 10 mg of either tetracaine or bupivacaine in 7.5% dextrose will be placed subarachnoid at the L3-L4 level via a 25 gauge spinal needle. The onset will be evaluated by loss of cold sensation at the distribution of the lateral cutaneous nerve. Sensory function will be tested at two minute intervals by pinching the skin with Allis forceps until the sensory level is seen to stabilize. Motor blockade will also be assessed.

Progress: ACOG recently changed repeat C-section criteria. Due to this change repeat C-sections are not routinely scheduled in the OR. Also, due to this change no patients have been studied at BAMC. An attempt to use "failure to progress" patients so far has been unyielding either due to complicating fetal distress, patient desire or prior placement of an epidural for labor.

Detail Summary Sheet

Date: 16 Oct 89 Proj No: C-80-89 Status: Ongoing
 Title: Treatment of Refractory Ulcers in Epidermolysis Bullosa Using Cultured Epidermal Allografts

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Jesse Moss, LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators:
Key Words: Epidermolysis bullosa	
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 isolate and grow epidermal allografts from cells obtained from a skin biopsy performed on the parent of a child with junctional epidermolysis bullosa.

Technical Approach: A small piece of skin will be obtained from the upper buttock area. The cells thus obtained will be planted on plastic tissue culture plates containing Keratinocyte Growth Medium (KGM) which has recently been developed for the growth of keratinocytes. Attempts will be made to manipulate the media to induce the growth of multilayer epidermal sheets which will be transplanted onto nonhealing eroded areas on the child with junctional epidermolysis bullosa.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-81-89 Status: Completed
 Title: Reliability of Rectal Examination of the Prostate

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 52	
Total Number of Subjects Enrolled to Date: 52	
Date of Periodic Review	Results

Objective(s): To determine the reliability of rectal examination of the prostate based upon examinations of multiple observers in patients with ostensibly normal examinations, patients with enlarged prostates, and patients with examinations suspicious of cancer of the prostate.

Technical Approach: This pilot study will objectively determine the inter-observer reliability of rectal examination for determination of prostatic size, based upon the objective standard of ultrasound examination of the prostate.

Progress: The data reveal that digital rectal examination, as currently employed, has significant inter-observer variation and is not reproducible. However, the data reveal that this test can be taught to urology residents to improve the reproducibility.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-86-89 Status: Ongoing
 Title: The Effects of Topical Oral Clindamycin Antibiotic Rinses on Bacterial Content of Saliva in Healthy Human Subjects

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator E. Scott Elledge, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Otolaryngology	Associate Investigators: Kweon I. Stambaugh, LTC, MC Robert G. Whiddon, Jr., LTC, MS Eleanor F. Ayala, MT Sheila K. Jones, SSG
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 _____	Results _____

Objective(s): To compare the bacterial contents of oral cavity saliva in healthy human adult subjects before and after using an oral rinse containing the antibiotic clindamycin versus a control rinse of normal saline.

Technical Approach: An initial saliva sample will be obtained by having the subject expectorate into a sterile specimen container. The sample will be plated on TSA with 5% sheep blood agar for aerobic culture. From this same sample an equivalent amount will be plated on chocolate agar for anaerobic culture and immediately placed into a Gas Pak system. After 30 minutes, the subject will be given 30 cc of sterile normal saline to be used as an oral rinse for a total of 10 seconds. A second saliva sample will then be plated on TSA and chocolate agar for aerobic and anaerobic culture. Ten subjects will be given 30 cc. of clindamycin mouthwash solution prepared by dissolving the contents of a 150 mg capsule into 250 cc sterile normal saline. Additional saliva samples will be taken 2 and 4 hours later in the same manner as before. The second group of ten subjects will use another 30 cc normal saline as before, with additional samples taken at the same 1 and 4 hour intervals.

Progress: This is a new study. Patient enrollment has just begun.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-87-89 Status: Ongoing
 Title: Lung Cancer Study Group Protocol NC3: Registry of Patients with T₁N₁ Disease Only.

Start Date: 10 Jul 89	Est Comp Date:
Principal Investigator (vice Grishkin) James A. Ameika, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Cardiothoracic	Associate Investigators: Greg Bowman, LTC, MC
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 _____ Results _____	
Objective(s): To maintain a registry of patients with T ₁ N ₁ Disease only.	

Technical Approach: All patients who are found to be T₁N₁ staged clinically and surgically will be potential candidates if patient eligibility criteria are met.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 17 oct 89 Proj No: C-94-89 Status: Ongoing
 Title: Use of Intravenous Ismelin® in Patients with Reflex Sympathetic Dystrophy, Causalgia, or Raynaud's Phenomenon/Disease

Start Date: 16 Jul 89	Est Comp Date:
Principal Investigator William Strong, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Anesthesiology	Associate Investigators: Emil Menk, MAJ, MC Douglas Cumming, MAJ, MC Timothy Castro, MAJ, MC
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 _____	Results _____

Objective(s): To provide guanethidine monosulfate on a compassionate use basis and review the safety of sympathetic blockade caused by the intravenous administration of guanethidine monosulfate in an isolated limb affected by reflex sympathetic dystrophy (RSD), causalgia, or Raynaud's phenomenon/disease.

Technical Approach: Patients meeting the criteria for inclusion in the study will undergo complete history and physical examination, electrocardiogram, laboratory evaluations and urinalysis. Bier Block with Ismelin® IV and lidocaine 0.5% will be accomplished. The number and frequency of the treatments will be determined on an individual basis. One month later patients will be asked to return for follow-up evaluation.

Progress: This is a new study. No data are available.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-95-89 Status: Ongoing
 Title: Effect of the Use of Perioperative Antibiotics on the Incidence of Wound Infection Following Mastectomy

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator Steven B. Olsen, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/General Surgery	Associate Investigators: Daniel P. Otchy, MAJ, MC
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	Results

Objective(s): To prospectively analyze the effect of perioperative antibiotic use on the incidence of wound infection following mastectomy.

Technical Approach: The subject population will include all females who present to the General Surgery Service from August 1989 to December 1990. The subjects will be randomized to one of two double-blinded groups; the first group will receive intravenous antibiotics in a standard perioperative regimen consisting of a dose preoperatively and postoperative doses for 24 hours postoperatively, and the second group will receive intravenous doses of saline at the same times when antibiotics would normally be administered. The incidence of wound infections and other infective complications will be monitored during the hospital stay and at follow-up visits.

Progress: This is a new study.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-97-89 Status: Ongoing
 Title: I.V. Fluid Administration and the Occurrence of Urinary Retention
 (Spinal and General Anesthesia)

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator	Facility
Ralph A. Hartman, CPT, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/Anesthesiology	Timothy Castro, MAJ, MC
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	Results

Objective(s): To determine if the amount of intravenous fluids a patient receives peri-operatively has an effect on the incidence of urinary retention.

Technical Approach: Patients meeting the inclusion criteria will be randomized to one of two groups. Prior to institution of anesthesia, patients will receive either one-fourth (Group A) or one-half (Group B) of their calculated fluid deficit, then placed on their calculate maintenance infusion for the remainder of the anesthetic. The incidence of urinary retention as based on (1) the urge to but inability to urinate or (2) a volume of more than 400 cc obtained from in and out catheterization 3-4 hours postoperatively, will be determined postoperatively.

Progress: This is a new study. No data are available at this time.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-99-89 Status: Ongoing
 Title: Hyperbaric Oxygen Therapy in the Treatment of Non-Healing Diabetic Lower
 Extremity Lesions. (Collaborative Study with Hyperbaric Medicine Division,
 School of Aerospace Medicine, Brooks AFB)

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Robert M. Ingle, Jr., COL, USAF MC
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 _____	Results _____

Objective(s): To investigate the role of intermittent hyperbaric oxygenation in
 diabetic wound healing.

Technical Approach: All patients will receive the best standard of conventional
 care. Meticulous debridement of wounds will be done whenever indicated, and
 wound care will be standardized as much as possible. Patients will be ran-
 domized into the oxygen group (90 minutes of 100% oxygen at 2.4 atmospheres
 absolute [ATA] daily) or the control group (90 minutes of 8.75% oxygen at 2.4
 ATA daily, which is equivalent to breathing air at sea level). Patients will
 undergo 20-40 treatments in the hyperbaric chamber. If a major surgical proce-
 dure is planned, 5-10 treatments will be given preoperatively if possible.

Progress: Thus far, no patients have been entered on the study.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-100-89 Status: Ongoing
 Title: Pilot Study of Quality of Life Questionnaire of Prostatic Disease

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator Ian M. Thompson, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	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 _____	Results _____

Objective(s): To determine the ease of use of the prostate-specific Quality of Life (QOL) questionnaire and to identify any internal inconsistencies or difficulties with patient understanding of the questionnaire.

Technical Approach: Ten adult males with diagnosed diseases of the prostate will complete the QOL questionnaire. An administration checklist will be completed. Final data, including only patient identification number and disease process will be forwarded to Dr. Moynour at the Fred Hutchinson Cancer Research Center in Seattle for analysis.

Progress: This is a new study. No data are available.

Detail Summary Sheet

Date: 17 Oct 89 Proj No: C-101-89 Status: Ongoing
 Title: Hyperbaric Oxygen Therapy as an Adjuvant in the Treatment of Chronic Refractory Osteomyelitis. (Collaborative Study with Hyperbaric Medicine Division, School of Aerospace Medicine, Brooks AFB)

Start Date: 1 Aug 89	Est Comp Date:
Principal Investigator Allan L. Bucknell, COL, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedic	Associate Investigators: Robert M. Ingle, Jr., COL, USAF MC
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 _____	Results _____

Objective(s): To determine and document in a controlled fashion the effectiveness of hyperbaric oxygen (HBO) therapy in the adjuvant treatment of chronic refractory osteomyelitis (CROM).

Technical Approach: All patients will receive the best standard of conventional care. Baseline data to be collected: CBC and platelet count; ESR (beginning and end); bone biopsy through non-infected tissue and bone culture; magnified views and tomograms if needed; bone scan, Gallium scan and CT scan. Patients will be randomized into the oxygen group (90 minutes of 100% oxygen at 2.4 atmospheres absolute [ATA] daily) or the control group (90 minutes of 8.75% oxygen at 2.4 ATA daily, which is equivalent to breathing air at sea level). Patients will undergo 10-20 treatments followed by a further surgical procedure designed to permanently eradicate the infection, excluding amputation. Intravenous antibiotics will be administered for 4-6 weeks after appropriate culture and sensitivity reports. Postoperatively, hyperbaric treatments will be given for a total of 40-60 treatments before and after surgery.

Progress: Thus far, no patients have been entered on the study.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-115-89 Status: Ongoing
 Title: Treatment of Metastatic Renal Cell Carcinoma with Cimetidine: A Phase II Trial

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator MAJ Ian M. Thompson	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Arlene J. Zaloznik, LTC, MC M. Ernest Marshall, M.D.
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 _____	Results _____

Objective(s): 1) To evaluate the likelihood of response in order to assess whether this regimen should be advanced to further studies.

2) To evaluate and qualitative and quantitative toxicities of this regimen administered in a phase II study.

Technical Approach: All patients will receive cimetidine, 400 mg orally four times daily. There will be no dose reduction or escalation within this trial. Patients experiencing significant CNS toxicity will be removed from study. Any other toxicities requiring cessation of therapy will be documented.

Progress: This is a new study.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-116-89 Status: Ongoing
 Title: Evaluation of the Effect of Postoperative Wound Drainage Reinfusion Using the Solcotrans Orthopaedic Drainage/Reinfusion System in Reducing the Need for Whole Blood Transfusion in Spinal Fusion Patients

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator Jeffrey D. Coe, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Michael B. Simpson, CPT, MC Allan L. Bucknell, COL, MC
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 _____ Results _____	

Objective(s): To evaluate the efficacy of reinfusion of postoperative wound drainage in increasing the need for whole blood transfusion in spinal fusion patients with significant sanguineous postoperative drainage.

Technical Approach: Wound drainage will be collected for a total of six hours. At the end of that time the amount of drainage will be noted. If greater than 350 ml are present, the system will be configured for reinfusion and a new collection unit will be connected to the drainage tube(s) in a sterile fashion and again placed under constant suction. For collection volumes from 150-350 ml the system will be configured for reinfusion and a standard Hemovac suction container will be attached to the drainage tubes. Amounts less than 150 ml will not be reinfused. An aliquot of blood will be collected from each Solcotrans unit configured for reinfusion and submitted for CBC, aerobic and anaerobic cultures.

Progress: This is a new study.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-117-89 Status: Ongoing
 Title: Pitfalls of Spinous Process Wiring in the Cervical Spine

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator	Facility
Jeffrey D. Coe, MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Surgery/Orthopaedics	Michael B. Simpson, CPT, MC
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 _____	Results _____

Objective(s): To study the safety of a presumably "fail-safe" method for internal fixation of the cervical spine used in posterior cervical spinal fusions for various indications including trauma, degenerative disorders, reconstructive situations, and inflammatory disorders that result in cervical instability.

Technical Approach: Three subaxial cervical spine specimens from cadavers used in anatomy courses at the Academy of Health Sciences will be used. All three spines will have trans-spinous wires passed at the C2-C7 levels. Two spines will have these wires passed after using the "towel clip" method of creating the holes; one specimen will have the holes created as close to the base of the spinous process as the towel clips permit and the other will have the holes created more posteriorly over the mid-portion of the spinous process. The third specimen will have the holes created with a high speed cutting instrument with a right-angle attachment. The hole placement will be varied on the lateral surfaces of the spinous processes, taking care to observe where these surfaces blend into the posterior surfaces of the cervical lamina. The course of all the trans-spinous wires will be observed and axial radiographs and photographs will be taken.

Progress: This is a new study.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-119-89 Status: Ongoing
 Title: Shoulder Impingement Syndrome: Response to Conservative Treatment and the Predictive Value of Some Associated Clinical and Radiographic Findings

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator Michael B. Simpson, CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: Dale C. Young, MAJ, MC
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 _____	Results _____

Objective(s): To prospectively study the response of shoulder impingement syndrome to conservative and operative treatments currently utilized at Brooke Army Medical Center

Technical Approach: History, physical examination, radiographs of the involved shoulder and cervical spine, and an impingement test will be obtained at the initial visit. Conservative therapy will be initiated to include a Physical Therapy, a program of home therapy and, a non-steroidal anti-inflammatory agent (NSAIA). The patient would next be seen approximately six weeks following the initial evaluation. At that time a repeat history and physical examination would be done. Patients who are responding well to conservative treatment would be continued on that program. Those who fail to respond will then receive a single injection of Dexamethasone mixed with Xylocaine into the involved subacromial bursa. Patients who either continue to have severe symptoms after three months of conservative therapy, who demonstrate a loss in motion, or who have persistent severe functional impairment will be offered surgical intervention.

Progress: This is a new study.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-127-89 Status: Ongoing
 Title: A Randomized Prospective Study of Lumbar Spinal Fusions with and without Transpedicular Screw-Plate Fixation

Start Date: 31 Oct 89	Est Comp Date:
Principal Investigator Jeffrey D. Coe, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Orthopaedics	Associate Investigators: William C. Lauerman, MAJ, USAF MC James E. Cain, MAJ, USAF MC Kevin P. Murphy, CPT, MC
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 _____	Results _____

Objective(s): To compare the results of spinal fusion with and without the use of transpedicular instrumentation in the lumbar spine.

Technical Approach: In a multi-center study to be performed by the Orthopaedic Surgery Services of the Joint Military Medical Commander of San Antonio, a randomized prospective study will be performed in patients undergoing lumbar spinal fusions. The study group will undergo transpedicular instrumentation with Steffee (VSP) bone plates and screws and the control group will undergo fusion without instrumentation. A total of 100 patients will be entered into the study (approximately 30 to 40 at BAMC). The primary goal of the study is to determine if there is a difference in subjective pain relief, fusion rates, and complication rates between the study group (instrumented and fused) and the control group (uninstrumented and fused).

Progress: This study was approved by the Institutional Review Committee in September. No reportable progress is available.

Detail Summary Sheet

Date: 22 Sep 89 Proj No: C-58-88 Status: Ongoing
 Title: Joint Mobilization Plus Active Range of Motion Exercises versus H0me
 Active Range of Motion Exercises in the Treatment of Adhesive Capsulitis

Start Date 3 Jun 88	Est Comp Date:
Principal Investigator Carol J. Johnson, 1LT, SP	Facility Brooke Army Medical Center
Dept/Svc Physical Medicine & Rehabilitation Svc	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 5	
Total Number of Subjects Enrolled to Date: 12	
Date of Periodic Review 6 Jul 89	Results Continue

Objective(s): To compare the effectiveness of joint mobilization plus active range of motion (AROM) exercises versus a home AROM exercise program.

Technical Approach: Male and female patients, 40-70 years of age, with a diagnosis of frozen shoulder are randomly assigned to one of two treatment groups. Group A receives joint mobilization three times a week as well as a daily home exercise program. Group B is on a home exercise program only (wand, pendulum, towel stretch, wall climbing, etc.). Subjects will discontinue joint mobilization when functional AROM is restored (150° flexion, 130° abduction, 60° internal and external rotation). Shoulder AROM measurements are being taken initially, at 2 weeks, 1 month, 2 months and 3 months.

Progress: The study is progressing without complications; however, the progression is slow due to a lack of patients with a diagnosis of adhesive capsulitis.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-42-88 Status: Ongoing
 Title: Evaluation of Routine Human Immunodeficiency Virus (HIV) Screening Program in Hospitalized Patients.

Start Date 29 Mar 88	Est Comp Date:
Principal Investigator Jenice N. Longfield, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Preventive Medicine Service	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1205	
Total Number of Subjects Enrolled to Date: 1205	
Date of Periodic Review 6 Apr 89	Results Continue

Objective(s): To assess the impact of implementing a routine HIV screening program in hospital admissions in a tertiary care hospital in an area of low prevalence for the HIV infection.

Technical Approach: Evaluate implementation of routine screening of hospital admission on selected medicine and surgery wards via a questionnaire requiring data from chart review. Subsequent correlation with laboratory test results and laboratory statistics. Outcome variables include acceptance rate for screening by nonactive duty patients, rate of positive test results, hospital day when results become available, etc. Outcome variables will be categorized by ward, service, and demographic characteristics.

Progress: There have been 1144 study subjects enrolled for analysis after deletion for duplicate hospitalizations. Preliminary data analysis indicates: eliminated duplicate admissions, analyzed for demographic characteristics, active duty status, status of consent for HIV testing and results of serological analysis on those civilians consenting has been completed. Analysis for multiple variables pending and planned in near future.

Detail Summary Sheet

Date: 25 Sep 89 Proj No: C-44-89 Status: Terminated
 Title: Assessment of Risk Factors for HIV Infection Among Active Duty U.S. Army Personnel with Documented Recent HIV-Antibody Seroconversion

Start Date 28 Feb 89	Est Comp Date:
Principal Investigator Jenice N. Longfield, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Preventive Medicine 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 _____ Results _____	

Objective(s): 1) To assess demographic and behavioral determinants associated with new HIV infections.

2) Risk factors and their relative significance as determinants of HIV infection will be assessed by comparing medical, demographic, and behavioral histories of active duty personnel recently infected with HIV, with histories of individuals who have not seroconverted over a similar time period.

Technical Approach: The study will be conducted using a case-control design. Controls will be randomly selected HIV-Ab negative active duty personnel at the same posts where cases occur, and will be matched to each case on: age, race/ethnicity, grade category, and length of service in the Army. All active duty personnel with confirmed HIV-Ab seroconversion will be eligible for inclusion in this study.

Progress: Neither MAJ Longfield nor the Preventive Medicine Service is involved as a co-investigator or in anyway providing direction of this study. The study is wholly under the control of Walter Reed Army Institute of Research and the Centers for Disease Control. The only involvement of BAMC is to contact the randomly selected participants, inform them of the study, and provide to them the name and telephone number of the interviewer.

Detail Summary Sheet

Date: 12 Oct 89 Proj No: C-83-89 Status: Ongoing
 Title: Measles Contacts: Immune Response to Post Exposure Immunization

Start Date: 12 Jun 89	Est Comp Date:
Principal Investigator Jenice Longfield, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Preventive Medicine Service	Associate Investigators:
Key Words:	
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 evaluate measles antibody immune status of contacts pre- and post- vaccination relative to subsequent disease attack rates.

Technical Approach: Multiple outbreaks of measles in the United States in 1989 have demonstrated the failure to eradicate this disease using current immunized guidelines. This prospective followup of exposed contacts with antibody evaluation pre- and post- measles (re-) immunization will provide scientific data useful for future outbreak control and immunization guidance for both civilian and military personnel.

Progress: IgM have been run. Results of such a small number will be held until more enrollments are obtained. If disease recurs thifall/winter, the investigators plan to continue the protocol.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-81-88 Status: Completed
 Title: A Measurement of Lumbar Intervertebral Distraction Produced During
 Portable Static Pelvic Traction

Start Date 8 Sep 88	Est Comp Date:
Principal Investigator Thomas F. Hartz, 2LT, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: David P. Klauber, 2LT, SP Michael G Ryder, 2LT, SP Monte S. Wilson, 2LT, SP Charles L. Truwit, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 44	
Total Number of Subjects Enrolled to Date: 44	
Date of Periodic Review 6 Jul 89	Results Completed

Objective(s): To determine the effectiveness of the Granburg E-Z Tract in the production of lumbar intervertebral distraction and the potential value of this device in a home environment.

Technical Approach: Subjects assigned to the Experimental Group (n=25) each received 10 minutes of ramped pelvic traction while supine. The maximum tractional force, equal to 70% of the subject's body weight, was applied for eight minutes. The Control Group subjects were also placed in the supine position on the x-ray table for 10 minutes, but received no traction. Laberal roentgenograms were taken of every subject at zero minutes supine and at the completion of the 10th minute. These radiographs were used to measure anterior and posterior changes in disc space at levels L3-L4, L4-L5, and L5-S1.

Progress: The data revealed that no distraction occurred within the Control Group, with the exception of the anterior L5-S1 disc space. However, within the Experimental Group, distraction occurred posteriorly across all measured levels, with concurrent narrowing anteriorly across all levels, except L5-S1A.

The results indicate that simply lying supine does not cause intervertebral distraction within the lumbar spine. The results further indicate that the Granbert E-Z Tract® is capable of producing supine tractional forces of sufficient magnitude to produce posterior lumbar intervertebral distraction.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-82-88 Status: Completed
 Title: The Effect of Verbal vs. Recorded Positive Motivational Messages on Quadriceps Femoris Peak Torque Values.

Start Date 8 Sep 88	Est Comp Date:
Principal Investigator Melanie R. Carlone, ENS, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Laurie J. George, 2LT, SP Lori S. Ryan, 1LT, SP
Key Words: Isokinetic exercise	
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 6 Jul 89	Results Completed

Objective(s): To investigate the effect of direct verbal versus recorded positive motivational messages on the dependent variable of peak torque produced by the quadriceps femoris muscle group using isokinetic exercise.

Technical Approach: Forty subjects were randomly assigned to two groups: 20 received the verbal message the first week followed by the recorded message seven days later; 20 received the reverse order. The subjects were seated in the standard position for knee extension and flexion on the the Cybex II isokinetic dynamometer. The subjects performed 35 seconds of extension/flexion in the presence of a direct motivational message or a similar prerecorded message.

Progress: The difference in foot-lbs of torque for the direct session and foot-lbs of torque for the recorded session was analyzed using a Students t-test. The direct motivational message resulted in significantly higher ($p < .0005$) average torque values than did the recorded message.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-83-88 Status: Completed
 Title: A Comparison of Orthodromic and Antidromic Sensory Nerve Conduction Latencies and Amplitudes for the Median and Ulnar Nerves

Start Date 8 Sep 88	Est Comp Date:
Principal Investigator Kelly Ayote, 2LT, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: Andrew Priest, 2LT, SP
Key Words: Sensory nerve conduction	Don Hansen, 2LT, SP Lanny Boswell, ENS, SP
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 6 Jul 89	Results Completed

Objective(s): To compare the effects of different neural conduction measurement techniques (i.e. orthodromic and antidromic) upon the dependent variables of nerve conduction latency and amplitude values in the median and ulnar nerves.

Technical Approach: Neural conduction values were obtained from right and left arms of 20 healthy adults. Sensory latencies and amplitudes were obtained using OD and AD ring electrodes, OD Roth, and OD and AD palmar techniques. Skin temperature of the wrist and hand was maintained above 32° Celsius. Room temperature was maintained at a constant 28° Celsius.

Progress: Orthodromic ring and OD Roth latencies for both median and ulnar nerves were on the average 0.2 msec faster than AD ring latencies. This difference was determined to be statistically significant ($P < .0013$); however, the clinical significance is questionable. Orthodromic ring and OD Roth amplitudes were significantly smaller ($p < 4.416E-7$) than AD ring amplitudes. Palmar OD and AD latencies and amplitudes were essentially equivalent. Orthodromic ring and OD Roth techniques produced similar latency and amplitude values. This study validates the use of standardized values in electrophysiology labs for latencies, whether OD or AD techniques are employed.

Detail Summary Sheet

Date: 23 Aug 89 Proj No: C-84-88 Status: Completed
 Title: Effects of Ice and Recovery Time on Maximal Involuntary Torque Production Using the Electrostim 180

Start Date 8 Sep 88	Est Comp Date:
Principal Investigator Jan W. Durst, 2LT, SP	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: David Gohdes, 2LT, SP Wendy Ward, 2LT, SP Kevin Workman, 2LT, SP
Key Words:	
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 6 Jul 89	Results Completed

Objective(s): To investigate the effects of ice application and recovery time upon the dependent variable of involuntary peak torque production of the quadriceps femoris.

Technical Approach: Twenty subjects completed the study. Each subject served as his own control. Data were collected with respect to maximum current tolerated during electrical stimulation and the maximum involuntary isometric torque production at pre treatment, immediately post treatment and 90 minutes post treatment time intervals.

Progress: Although statistically inconclusive, observed trends suggest that the anesthetic effects of ice allowed the treatment group to tolerate a greater intensity of current. However, possibly due to the effects of ice on tissue conductivity, an increase in involuntary isometric torque production across time was not observed. Results also suggest a wide variation in subjective response to electrical stimulation.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-109-89 Status: Ongoing
 Title: Cold Conduction Through Various Casting Media

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator 2LT Bryan L. Boyea	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: 2LT Colleen E. Beven CPT William C. Byers 2LT Brent S. Ferguson
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 _____ Results _____	

Objective(s): To quantify the conduction of col through moist plaster casting, fiberglass casting, and Gel-O-Casts by determining the absolute temperature change beneath each media.

Technical Approach: Thirty-five active duty Army male volunteers, 18-31, will be studied. The three casting media will be made into circular discs which will fit into a framework that allows direct skin contact with the casting material. The subjects will be positioned prone and thermistors will be centered beneath each disc. A bag of ice slush will be placed directly over this framework. The cold application will last 40 minutes followed by 15 minutes of observation, during which the rewarming rate beneath each disc will be monitored. Tempature changes will be continuously monitored using a computer assisted analog to digital recorder.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-110-89 Status: Ongoing
 Title: A Correlation Study Comparing Three Methods of Measuring Hamstring
 Muscle Length as Compared to Sacral Angle Measurement

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator	Facility
2LT Anne D. Parson	Academy of Health Sciences
Dept/Svc	Associate Investigators:
Physical Therapy Section	2LT Donna M. Vargas
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 _____	Results _____

Objective(s): To determine whether or not a correlation exists between straight leg raise measures of hamstring muscle length and sacral angle in the long sit position.

Technical Approach: Fifty caucasian active duty military soldiers ranging in age from 18-30 will be asked to participate in the study. Hamstring length will be measured in four positions: (1) SLR test with flat back; (2) SLR test with natural lumbar curve; (3) SLR test with opposite hip and knee flexed; and (4) Sacral angle measure with the long sit test. Testing will be conducted over a period of no more than six weeks with 30 minutes being allotted for testing each subject.

Progress: This is a new study,

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-111-89 Status: Ongoing
 Title: Effects of Gender and Foot Dominance on Neural Conduction in Human Subjects

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator	Facility
Ens Gregory M. Stearne	Academy of Health Sciences
Dept/Svc	Associate Investigators:
Physical Therapy Section	2LT Patrick J. Duffy
Key Words:	2LT Cathy L. Frola
	2LT Steven P. Snider
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 investigate the effects of gender and foot dominance upon the dependent variable of neural conduction.

Technical Approach: Twenty male and twenty female subjects, 21 to 35 years of age, will be asked to participate. Neural conduction latencies and amplitudes will be measured using surface electrodes, utilizing a Cadwell 5200A electromyograph and stimulator. Data will be analyzed using an F-test from ANOVA at .05 level of significance.

Progress: This is a new study.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-112-89 Status: Ongoing
 Title: The Effect of Portable Static Pelvic Traction on Lumbar Intervertebral Distraction with Subject in 90/90 Positioning

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator CPT Patricia I. Fitzgerald	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: CPT Sarah J. Pierre 2LT Rachel K. Evans MAJ Gary Dier CPT Ronald Shippee
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 _____	Results _____

Objective(s): To determine whether the Granberg EZ Tract® portable traction unit is capable of producing the lumbar intervertebral distraction.

Technical Approach: Thirty healthy active duty U.S. Army males will be randomly assigned to either an experimental or control group. The subjects in the experimental group will each receive ten minutes of ramped pelvic traction while supine with the knees and hips in 90° of flexion. Maximal traction force, equal to 70% of the subjects body weight, will be applied for 8 minutes. Control group subjects will be placed in the traction harness in an identical position for 10 minutes but will receive no traction. While wearing the harness and lying supine in the desired position, lateral and cone-down roentgenograms will be taken of every subject at 0 minutes and 10 minutes. These radiographs will be used to measure anterior and posterior changes in disc spaces at levels L3-4, L4-5, and L5-S1.

Progress: This is a new study.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-113-89 Status: Ongoing
 Title: The Use of Therapeutic Levels of Ultrasound Over Costochondral Articulations and Its Effect on the Electrical Activity of the Heart as Measured by Electrocardiograph

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator 2LT Clard D. Heath	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: 2LT Dona L. Muger 2LT Ellen P. O'Keefe 2LT D. Paulson MAJ David M. Slife
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 _____	Results _____

Objective(s): To determine if therapeutic levels of ultrasound applied to costochondral articulations will result in a change in the electrical activity of the heart as measured by surface scalar electrocardiogram.

Technical Approach: Fifty health male active duty military personnel, ages 21-30, will be asked to participate. Each subject will act as his own control. After determining that the subject's electrocardiogram is normal, he will be given an ultrasound treatment superficially over the 2nd-5th costal cartilages. An electrocardiogram will be administered at one-minute intervals throughout the ultrasound treatment, as well as immediately after the termination of the ultrasound application. The electrocardiogram will be monitored for any possible changes throughout the course of treatment.

Progress: This is a new study.

Detail Summary Sheet

Date: 6 Nov 89 Proj No: C-114-89 Status: Ongoing
 Title: Analysis of Eight Crutch Measurement Techniques as Compared to Ideal Crutch Length

Start Date: 8 Sep 89	Est Comp Date:
Principal Investigator 2LT Dawn M. Bauer	Facility Academy of Health Sciences
Dept/Svc Physical Therapy Section	Associate Investigators: 2LT David C. Finch 2LT Karen P. McGough
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 _____	Results _____

Objective(s): To determine which of eight crutch measurement techniques is most accurate to obtain ideal crutch length.

Technical Approach: The height of 120 active duty military personnel, 60 males and 60 females between the ages of 18 and 50, will be measured. A clinically experienced physical therapist will determine each subject's ideal crutch length. The investigators will then determine the subject's cruth length using one of the following methods: 1) axillary fold to heel, 2) olecranon to tip of middle finger, 3) olecranon to tip of little finger, 4) 77% of height, 5) height minus 16 inches, 6) 77% of wingspan, 7) wingspan minus 16 inces, and 8) comparison to "crutch hole chart".

Progress: This is a new study.

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