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<td>JAMES H. ANDERSON, JR., M.D. Major, MC</td>
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<td>Performing Organization Name and Address</td>
<td>Department of Clinical Investigation Brooke Army Medical Center Fort Sam Houston, Texas 78234</td>
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<td>Abstract (Continue on reverse side if necessary and identify by block number)</td>
<td>Subject report identifies the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee, the Human Use Committee, and the Laboratory Animal Use Committee and registered with the Department of Clinical Investigations during Fiscal Year 1981. Report also includes known presentations and publications by the Brooke Army Medical Center staff. The research protocols described were conducted under the provisions of AR 40-38, as amended, Clinical (continued on reverse side)</td>
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Block 19. Key Words
Southwest Oncology Group
Gynecology Oncology Group
Polycythemia Vera Study Group
Pediatric Oncology Group

Block 20. Abstract

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.
FOREWORD

"When I use a word," Humpty Dumpty said, in rather a scornful tone, "it means just what I choose it to mean - neither more nor less."

"The question is," said Alice, "Whether you can make words mean so many different things."

"The question is," said Humpty Dumpty, "Which is to be master - that's all." (Carroll, L. Through the Looking Glass, 1871)

Although we are confronted at times with "distinctions" (meaning "whose budget?") between clinical investigation and medical research, it is of more importance to clearly define the lack of difference between high quality patient care and active clinical investigation. Despite recognition of this concept by medical organizations and hospital accreditation groups (eg., JCAH), the general public and the bureaucracy controlling the purse strings often perceives research as unnecessary, a diversion of time from patient care, and an acceptable area from which to trim the budget. It is easy looking backwards to justify the time and money spent by clinical investigators such as Walter Reed, Roger Brooke, and William Beaumont. Their medical research produced the best patient care, not only for the subjects of their investigations, but for society as a whole. It is more difficult to look forward.

"The political ambience of our time compels the scientific community to seek firm grounds for receiving a share of public resources. It might be far more realistic, however, as well as useful, for all parties to agree that, after all, we really can't measure these things with any precision and that the most difficult segment to measure, basic research, isn't so expensive that we can't afford to run on the principle that it should be kept reasonably plump." (Greenberg, D.S. Washington report. N. Engl. J. Med. 301:1456, 1979)

It thus becomes our responsibility to become master of the words "clinical investigation" and to assure their meaning is clearly understood as being synonymous with continuous improvement in the quality of patient care. Clinicians must assume active roles in formulating policies regulating research and educating those in control of financial resources as well as the general public. Often the public's perception of benefit to the patient and society overshadows the scientific merit or medical importance of any clinical investigation. With the current emphasis on patients assuming greater responsibility for decisions regarding their health care, it is imperative that the positive contributions of medical research to improved quality of care be made clear to patients and society.

BAMC has been fortunate in having a command leadership that is outstanding in its support of clinical investigations. There has been a growth in the number of active protocols (as well as their quality), the number of publications and presentations, the Department of Clinical Investigation staff available to support research, and facilities, especially the new Laboratory Animal Research and Training Center. The real credit for the work presented in this volume belongs to the clinical investigators (from principal investigators to laboratory technicians) who have devoted their time and talents to increasing medical knowledge and quality of care. Equally important are the patient volunteers who freely consented, sometimes without direct benefit to themselves, to participate in gathering new knowledge and providing a base for improved patient care.
UNIT SUMMARY - FISCAL YEAR 1981

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.

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

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E. Progress (continued)

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F. Problems

Most of our problem areas remain the same though there has been some encouraging progress in some areas. Our biggest problem continues to be adequate laboratory and administrative space. At the time the department moved into its present facilities, there were five assigned personnel occupying approximately 1850 square feet of space to work on 12 in-house protocols. At the present time, there are 23 assigned personnel working on 50 protocols in the same 1850 square feet. The addition of more equipment during the year has cut down on available work space.

Our desperate need for an animal facility was lessened somewhat by obtaining an old barracks-type building that was scheduled for destruction. Although it does not meet AALAC standards, it gives the department some capability for animal housing and operating room facilities. Our animal facility and space problems can be effectively resolved only with the completion of a major construction project for a separate building originally scheduled for 1984 but currently scheduled for 1987.

A total of 28 requirements have been approved for the Department and 22 authorizations have been allocated which has improved our personnel problems somewhat. Our principal remaining difficulty in personnel is in identifying and obtaining qualified military personnel. Severe shortages in Med Lab Specialists (92B), Biological Research Assistants (01H), Animal care Specialists (91T) and Veterinarians have taken their toll in keeping many of our positions empty.
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Appendix C
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Appendix D
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DEPARTMENT OF THE ARMY
Brooke Army Medical Center
Fort Sam Houston, Texas 78234
DEPARTMENT OF CLINICAL INVESTIGATION
PUBLICATIONS
DEPARTMENT OF CLINICAL INVESTIGATION


DEPARTMENT OF MEDICINE


Thornsvard, C. Anemias. (textbook, in press)

Allergy-Immunology Service


Cardiology Service


Murge, J.P., Chi, G.S. Right and left heart ejection dynamics in pericardial tamponade. In "Pericardial Disease." Raven Press (in press). (C)


Korke, S.A. Pulmonic stenosis in atrioventricular and ventriculocardial discordance with an intact ventricular septum and anterior aorta. Proceedings of the 10th Annual Session of the Association of Army Cardiology. 1981. (C)

Dumore, S. Second heart sound dynamics in atrial septal defects (ASD). Proceedings of the 10th Annual Session of the Association of Army Cardiology. 1981. (C)

Brown, D.L. Exercise induced abnormalities of left ventricular relaxation in coronary artery disease. Proceedings of the 10th Annual Session of the Association of Army Cardiology. 1981. (C)

Bird, J.J. Left ventricular external work loss in valvular aortic stenosis: Correlation with severity. Proceedings of the 10th Annual Session of the Association of Army Cardiology. 1981. (C)

Satia, R.A. The effect of arterial pressure reflections on myocardial supply-demand dynamics. Proceedings of the 10th Annual Session of the Association of Army Cardiology. 1981. (C)

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Emergency Medicine

Wolcott, B. Reproducibility of clinical data and decisions in the management of upper respiratory illnesses: A comparison of physicians and non-physicians providers. Medical Care, 1981. (C)


Wolcott, B. On the relationships among headache symptoms. J. Chr. Dis. 1981. (C)

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Infectious Disease Service


Nephrology Service


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Shildt, R.A., Rubin, R.N., Schiffman, g., Gioma, P. Polyvalent pneumococcal immunization of patients with plasma cell dyscrasias. Cancer (in press) 1981. (C)


DEPARTMENT OF OBSTETRICS AND GYNECOLOGY


DEPARTMENT OF PEDIATRICS


DEPARTMENT OF PSYCHIATRY


DEPARTMENT OF RADIOLOGY


DEPARTMENT OF SURGERY

Anesthesiology and Operative Service

Roddel, S.L., Ritter, R.R. Serum levels following epidural administration of morphine and correlation with relief of post-surgical pain. Anesthesiology. 54:17 1981. (C)

Surgical Service


Neurological Surgery Service


Ophthalmology Service


Orthopaedic Service


Cardiothoracic Surgery Service


Urology Service


PHARMACY SERVICE


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Allen, R.C. Oxygen-dependent *Streptococcus faecalis* chemiluminescence: The importance of metabolism and medium composition. Amer. Soc. of Microbiologists, Dallas, TX, 1-4 Mar 81. (C)

Allen, R.C., Guest Lecturer, Rush Medical Center, Chicago, IL. (C)

Allen, R.C., Guest Lecturer, Department of Microbiology, University of Texas, Austin, TX., Sep 81. (C)

Allen, R.C. Direct Quantification of Phagocyte Oxygenation Activity in Whole Blood: A Chemilumigenic Probe Approach. XI International Congress of Clinical Chemistry, Vienna, Austria, 30 Aug-5 Sep 81. (C)

Allen, R.C., Guest Lecturer, European Society for Biochemistry, Auctenhausen, Germany, 8 Sep 81. (C)

Allen, R.C., Guest Lecturer, Brussels, Belgium, 12 Sep 81. (C)


Anderson, J.H. Glucose Induced Hyperinsulinism during Endotoxemia in Dogs - A Possible Mechanism. Annual Meeting of Southern Sugar Club, Kiawah Island, SC, 25 Feb-3 Mar 81. (C)

Anderson, J.H. Glucose Induced Hyperinsulinism during Endotoxemia in Dogs - A Possible Mechanism. American Diabetes Assoc., Endocrine Society, and Army of Military Endocrinologists, Cincinnati, OH, 13-19 Jun 81. (C)

Anderson, D.G. Separation of Guinea Pig Peritoneal Exudate Cells on Percol Gradients: Comparison of Morphology and Oxygenation Activity in Response to Various Stimuli. Federation of Societies for Experimental Biology, Atlanta, GA, 15 Apr 81. (C)

Hunter, J.J. Chemiluminescence Following Exposure of Anaerobic Broth Medium to Atmospheric Oxygen: The Role of Ozone in Oxidation Reactions. Amer. Soc. of Microbiologists, Dallas, TX, 1-6 Mar 81. (C)

Madonna, G.S. Immunoglobulin-Mediated Opsonification of Shigella sonnei. Phase II: Functional Study Based on Granulocyte Chemiluminescence. Amer. Soc. of Microbiologists, Dallas, TX, 5 Mar 81. (C)

Stevens, D.L. Effects of Phospholipase C and Theta Toxin from C. Perfringens upon Human Neutrophil Functions. Amer. Fed. for Clinical Research, 2-27 Apr 81. (C)

**DEPARTMENT OF MEDICINE**

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Bird, J.J. Subvalvular Gradient in Aortic Stenosis Without Subvalvular Obstruction. 53rd Scientific Session of the American Heart Association, Miami, FL, Nov 80. (C)

Craig, W.F. Evaluation of Involuntary Relaxation in Normal Man During Rest, Exercise, and Isopteronal Infusion. 53rd Scientific Session of the American Heart Association, Miami, FL, Nov 80. (C)

Margo, J.P. Relaxation Abnormalities in Hypertrophic Cardiomyopathies. 53rd Scientific Session of the American Heart Association, Miami, FL, Nov 80. (C)

Margo, J.P. Invited Speaker: Core Curriculum Symposium on Heart Sounds and Murmurs. 29th Annual Scientific Session of the American College of Cardiology, San Francisco, CA, Mar 81. (C)

Margo, J.P. Chairman, Clinical and Basic Muscle Physiology, Coronary Blood Flow and Echoangiography. Annual Session of the American Society of Clinical Investigation, San Francisco, CA, April 81. (C)

Margo, J.P. Clinical and Basic Muscle Physiology, Coronary Blood Flow, and Echocardiography. Annual Session of the American Society of Clinical Investigation, San Francisco, CA, Apr 81. (C)

Margo, J.P. Chairman, 10th Annual Session of the Association of Army Cardiology, Fort Sam Houston, TX, May 81. (C)

Margo, J.P. Chairman, 10th Annual Session of the Association of Army Cardiology, Fort Sam Houston, TX, May 81. (C)

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Margo, J.P. Chairman, 10th Annual Session of the Association of Army Cardiology, Fort Sam Houston, TX, May 81. (C)
Bird, J.J. Left Ventricular External Work Loss in Valvular Aortic Stenosis: Correlation with Severity. 10th Annual Session of the Association of Army Cardiology, Fort Sam Houston, TX, May 81. (C)

Schatz, R.A. The Effect of Arterial Pressure Reflections on Myocardial Supply-Demand Dynamics. 10th Annual Session of the Association of Army Cardiology, Fort Sam Houston, TX, May 81. (C)

Dermatology Service


Babcock, W.S. Case Presentation Zola Cooper Memorial CPC, Southern Medical Association Meeting, San Antonio, TX, 17 Nov 80.

Salsche, S.J. Malignant Melanoma - Diagnosis and Treatment. Texas Association of Physician Assistants, Austin, TX, 18 Nov 80.


Salsche, S.J. Morpheaform Basal Cell Carcinoma. 6th Annual Uniformed Services Dermatology Seminar, Bethesda, MD, 8 May 81.

Babcock, W.S. Moderator of Clinical Pathology Conference. 6th Annual Uniformed Services Dermatology Seminar, Bethesda, MD, 7 May 81.


Fulk, C.S. Under Agarose Chemotaxis by Psoriatic Leukocytes. Third International Symposium on Psoriasis, Stanford University Medical Center, Stanford, CA, 13-17 Jul 81. (C)

Nephrology Service


Oncology Service

McCracken, J.D. Oat Cell Carcinoma of the Lung. Oregon Society Clinical Oncology, Portland, OR, 29 Jan 81.

McCracken, J.D. Chemotherapy of Pancreatic Cancer. ACS Mid-Winter Symposium, Portland, OR, 30 Jan 81.

McCracken, J.D. Chemotherapy of Gastric Cancer. ACS Mid-Winter Symposium, Portland, OR, 30 Jan 81.

McCracken, J.D. Chemotherapy of the GI Malignancies. St. Vincent's Hospital Cancer Conference, Bridgeport, Conn., 7 Feb 81.


Madden, S.A. Treatment of Metastatic Colorectal Cancer to Liver with Intraperitoneal 5FU or 5FU or Mitomycin in Previously Untreated Patients. Current Concepts in Hem/Onc, USA, Washington DC, 4 Feb 81.


McCracken, J.D. Combination Chemotherapy, Radiotherapy and BCG Immunotherapy in Limited Small Cell Carcinoma of the Lung. X11th International Congress of Chemotherapy, Florence, Italy, 9 Jul 81.

S.M. Experience with Mitosantrone. XI1th International Congress of Chemotherapy, Florence, Italy, 21 Jul 81.


Pulmonary Disease Service

Petters, L.A. Surgery in Bullous Lung Disease. 33rd Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, Aurora, CO, 19 Jan 81.

Woodward, J.A. Upper Airway Obstruction Secondary to Enlarged Tonsils. 33rd Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, Aurora, CO, 19 Jan 81.

Matthews, J.H. Exercise Testing in the Evaluation of Pulmonary Sarcoidosis. 33rd Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, Aurora, CO, 20 Jan 81.

Narath, N.R. The Unilateral Hyperlucent Lung. 33rd Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, Aurora, CO, 20 Jan 81.

Sullivan, G.J.P. Squamous Cell Carcinoma. 33rd Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, Aurora, CO, 20 Jan 81.

Pil. Pulmonary Strongyloidiasis. 33rd Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, Aurora, CO, 20 Jan 81.

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY


DEPARTMENT OF PEDIATRICS

L.O. The Computerized Triage of Pediatric Patients. University Association of Emergency Medicine, San Antonio, TX, Apr 81. (C)

L.O. Computers in a Pediatric Acute Care Facility. 5th International Congress of Emergency Surgery, Brighton, England, Jun 81. (C)

DEPARTMENT OF PSYCHIATRY

L.S. DSM-III Organic Mental Disorders. AMEDD Psychiatry Conference, Ft. Rucker, TX, 80.
DEPARTMENT OF RADIOLOGY


Telepak, R.J. I-125 Fibrinogen Studies in Carotid Ulcer Disease. AMEDD Radiology Symposium, Walter Reed Army Medical Center, Washington DC, 27 May 81.

Telepak, R.J. Nuclear Cardiology in the Community Hospital. Harlingen Medical Society, Harlingen, TX, 29 Jun 81.

Telepak, R.J. Nuclear Cardiology in the Community Hospital. San Angelo Medical Society, San Angelo, TX, 15 Sep 81.

DEPARTMENT OF SURGERY

Anesthesiology and Operative Service

Weddel, S.I. Serum Levels Following Epidural Administration of Morphine and Correlation with Relief of Post Surgical Pain. American Society of Anesthesiology, St. Louis, MO, Oct 80.

Gooding, D.E. Light Wandel Intubations. Department of Anesthesia, Bay City Memorial Medical Center, Panama City, FL, 26 Jan 81.

General Surgery Service


Smith, K.L. Review of Colorectal Cancer in Patients Under 40. 33rd Annual Southwestern Surgical Clinic Congress, Monterey, CA, 4-7 May 81.


Baer, V.F. Arteriovenous Fistula: A Historical Review. Gary P. Wratten Surgical Symposium, San Antonio, TX, 29 Apr-1 May 81.

Spebar, M.J. Hiroshima Revisited. Gary P. Wratten Surgical Symposium, San Antonio, TX, 29 Apr-1 May 81.

Spebar, M.J. Changing Trends in causalgia. 33rd Southwestern Surgical Clinical Congress, Monterey, CA, 4-7 May 81.


Spebar, M.J. Medical Aspects of Nuclear Warfare. Distinguished Visiting Professor Series, Uniformed Services University of Health Sciences, Bethesda MD, 27 Aug 81.


Walters, M.J. Emergency Treatment of Burn Patients. U.S. Air Force Medical RED FLAGG, Germany, Sep 81.


Rosenthal, D. Management of Perforated Rectal Prolapse. Texas Colorectal Grand Rounds, South Texas School of Medicine, San Antonio, TX, 21 Aug 81.

Rosenthal, D. Rectal Prolapse and Procidentia. Guest Lecturer, Surgical Grandrounds, South Texas School of Medicine, San Antonio, TX, 21 Aug 81.


Harriss, R.D. in Vitro Assessment of Human Pituitary Tumor Neoplastic Activity. International SEM Symposium, University of Nijmegan, The Netherlands, 13-16 Sep 81.
Ophthalmology Service

Brennan, M.W. Traumatic Optic Neuropathy: Mechanisms and Management. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

Glover, A.T. Intraocular Lens Implantation in the Residency Program at Brooke. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81. (C)

Mein, C.E. Planned Extracapsular Cataract Extraction and Posterior Chamber Intraocular Lens Implantation. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81. (C)

Zervas, J. Pierre Robin Syndrome: A Case Presentation and Discussion. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

Gearhart, J. Over-Refraction Made Easy. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

Davitt, W.F. Ocular Complications in Craniofacial Fibrous Dysplasia. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

San Martin, A. Contact Lens Associated Giant Papillary Conjunctivitis. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

White, L.S. Graves Orbitopathy - Surgical and Nonsurgical Management. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

Renner, D.A. Foveal Macular Retinitis. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

Griffin, D.G. Management of "Lost" Lens Nucleus into Vitreous. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

Hudnun, W.M. Bietti's Tapetoretinal Degeneration without Marginal Corneal Dystrophy: Crystalline Retinopathy. Alamo City Ophthalmology Residents' Conference, University of Texas Health Science Center, San Antonio, TX, 10-11 Apr 81.

Orthopaedic Service

Hochreiter, G.C. A Case Report of Mesenchymal Chondrosarcoma of the Pelvis and Its Treatment with a Review of the Literature. Society of Military Orthopaedic Surgeons, Wilford Hall USAF Medical Center, San Antonio, TX, 2-6 Nov 80.
Thomas, S.R. GET Scan, A New Kind of CAT. Society of Military Orthopaedic Surgeons, Wilford Hall USAF Medical Center, San Antonio, TX, 2-6 Nov 80.

Thomas, S.K. Experience with the TARA Hip Resurfacing at Brooke Army Medical Center. Society of Military Orthopaedic Surgeons, Wilford Hall USAF Medical Center, San Antonio, TX, 2-6 Nov 80.

Spires, T.D. Congenital Scoliosis Due to a Single Hemivertebra. Society of Military Orthopaedic Surgeons, Wilford Hall USAF Medical Center, San Antonio, TX, 2-6 Nov 80.


Thomas, S.R. TARA Hip Resurfacing Experience at Brooke Army Medical Center. American College of Surgeons, Galveston, TX, 29-31 Jan 81.


Podiatry and Its Role in Management of Trauma to the Foot and Ankle. Army Physical Therapy Annual Seminar, San Antonio, TX, Mar 81.

Anatomy, Examination and Classification of Rotational Instabilities of the Knee. Texas Physical Therapy Association, University of Texas Health Science Center, San Antonio, TX, 28-29 Mar 81.

Reconstructive Surgery for Chronic Anterolateral and Posterolateral Instability of the Knee. Texas Physical Therapy Association, University of Texas Health Science Center, San Antonio, TX, 28-29 Mar 81.

Principles of a Functional Knee Rehab Program. Texas Physical Therapy Association, University of Texas Health Science Center, San Antonio, TX, 28-29 Mar 81.


Subtalar Subluxation - Its Diagnostic Criteria and Treatment. Bandera Podiatry Seminar, University of Texas Health Science Center, San Antonio, TX, Apr 81.


Prevention and Care of Football Injuries. Mothers' Club, Cole High School, San Antonio, TX, 14 Sep 81.

Knee Instability. U.S. Army Medical Department Activity, West Point, NY, 17-19 Sep 81.
Cardiathoracic Surgery Service

Collins, G.J. Renovascular Hypertension. Vascular Symposium, St. Catherine's Hospital, Garden City, KA, 2 Nov 81.

Collins, G.J. Cardiovascular Insufficiency. Vascular Symposium, St. Catherine's Hospital, Garden City, KA, 2 Nov 81.

Collins, G.J. Venous Disorders: Medical and Surgical Management. Vascular Symposium, St. Catherine's Hospital, Garden City, KA, 2 Nov 81.


Schuchmann, G.F. Coronary Artery Disease. William Beaumont Army Medical Center, El Paso, TX, 21 Nov 80.


Schuchmann, G.F. Moderator of the Clinical Session at the 10th Annual Session of the Association of Army Cardiology, Brooke Army Medical Center, Fort Sam Houston, TX, 20 May 81.

Hall, R.V. Combined Valve Replacement and Coronary Artery Bypass in the Elderly. 10th Annual Session of the Association of Army Cardiology, Brooke Army Medical Center, Fort Sam Houston, TX, 20 May 81.

Hall, R.V. Current Status of Prosthetic Cardiac Valve Replacement. TV Lecture, San Antonio, TX, 27 Jul 81.

Freake, J.A. Surgical Management of Empyema Lung Abscess and Bronchopleural Fistula. TV Lecture, San Antonio, TX, 21 Sep 81.

Urology Service


Spiegel, R.S. Familial Testicular Tumors. 28th Annual James C. Kimbrough Urological Seminar, San Diego, CA, 17-21 Nov 80.


Spence, C.R. Urological Diagnostic Studies. Gonzalez County Medical Society, Gonzalez, TX, 24 Jul 81.

Gangai, M.P. Case Presentation at the Texas Urological Society Meeting, Kerrville, TX, 9-11 Apr 81.

PHARMACY SERVICE


SOCIAL WORK SERVICE


Allen, J.D. Shadow at the Table: The Absentee Father. Biennial Symposium. Family Service Association of America, San Antonio, TX, 11 Sep 81.
**Detail Summary Sheet**

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**TITLE:**
Determination of Opsonizing Antibody in People Receiving Polyvalent Pneumococcal Vaccine

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**Principal Investigator:**
Robert L. Allen, M.D., Ph.D., Maj, MC

**Facility:**
Brooke Army Medical Center

**Dept/Sec:**
Department of Clinical Investigation

**Associate Investigators:**
Deborah J. Hunter, SP 5

**Key Words:**
Pneumococcal vaccine
Opsonification
Streptococcus species
Chemiluminescence

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**Objective:**
To Determine the serum opsonizing activity in selected patients in response to a polyvalent pneumococcal vaccine.

**Technical Approach:**
Pre- and postimmunization sera were obtained from patients undergoing immunization against *Streptococcus pneumoniae* using polyvalent pneumococcal vaccine (Pneumovax<sup>®</sup> MSD). These sera are being tested for opsonic activity directed against a number of serotypes of *Streptococcus pneumoniae* as well as other streptococcal species. A highly sensitive chemiluminescent assay has been developed for quantification of neutrophil (PMNL) leukocyte O<sub>2</sub>-redox metabolism, and this technique is being applied to the quantification of the rate of opsonification for these sera.

**Progress:**
Preliminary testing of selected pre- and postimmunization sera has been carried out. At present, the major difficulty is the preparation, stabilization, and quantification of the type-specific streptococcal antigen so as to insure uniformity of measurements.

In the course of investigation, important observations have been made with regard to interaction of streptococcal metabolic products, such as H<sub>2</sub>O<sub>2</sub> and lactic acid, with PMNL myeloperoxidase. These observations have led to a collaborative study with Drs. P. G. Quie and E. L. Mills of the Department of Pediatrics of the University of Minnesota. The results of this research have been published in the Journal of Infectious Disease 144: 344-348, 1981.
Assessment of Opsonic Capacity and Phagocyte Functionality in Microliter Quantities of Whole Blood

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

Technique Approach:
- The use of two novel, high quantum yield, oxidizable substrates for quantification of phagocyte O2-redox activity in whole blood has been achieved. Both luminol, 5-amino-2,3-dihydro-1,4-phthalazinedione, and indothricin, 10,10'-dihydro-9,9'-bisthiobenzimidazolide, have been employed in this manner. Other substrates are also under investigation. A technique for titration of serum opsonic capacity, based on the rate of activation of PMNL, has also been established using chemilumigenic probes.

### Key Words:
- Complement
- Immunoglobulin
- Chemilumigenic probes
- Redox metabolism
- Est Accumulative Cost: OMA Cost: $24,143
- Review Results: Continue

Chemilumigenic probing has been developed into an ultra-sensitive technique for continuous and non-destructive assessment of oxygenation activity of PMNL and monocytes. The results of differential probing, using probes with different physical characteristics and chemical reactivities, indicate that the oxygenation responses of PMNL and monocytes differ with regard to the type of stimulus employed. The technique allows measurement of PMNL and monocyte function in submicroliter quantities of whole blood.

With regard to the study of opsonification, important observations have been made on the roles of alternative and classical pathway complement, IgG and IgM in the mechanisms of bacterial opsonification. Furthermore, the chemilumigenic probe approach shows promise as a method for detection of circulating immune complexes.
The measurement of Cyclic Nucleotide Levels in Purified Populations of Lymphocytes incubated with Mitogens.

Start Date: 6 Feb 79
Est Comp Date: Jun 82

Objective: To purify guinea pig lymphocytes on density gradient into functional subpopulations and measure intracellular levels of cyclic AMP and cyclic GMP after incubation of the purified cells with the mitogens in vitro.

Technical Approach: Guinea pig lymph node cells are separated into seven locations using discontinuous gradients of 40-75% Percoll. The purified cells are exposed to various lectins and at different time periods the cells are treated with a precipitating reagent and the cyclic nucleotides extracted. The purified cells are then purified by HPLC and measured by radioimmunoassay. Cyclic AMP and cyclic GMP levels are then correlated with the mitogenicity of the lectin, time of incubation and the cell type. Cell populations are characterized by light's stain and observation under a microscope for morphology and by immunoglobulin technique for T and B cell identification.

Process: No significant progress was made on the project due to the lack of a high pressure liquid chromatograph. A high pressure liquid chromatograph has been obtained, and the development of a purification technique and analysis of samples can now proceed.
**Studies on the Opsonization and Phagocytosis of Invasive and Non-invasive Shigella Species by Polymorphonuclear Leukocytes (PMNL).**

**Objective:** To investigate the roles of nonspecific and specific immunoglobulin and complement in effecting opsonization and microbicidal action of PMNL against various enteric invasive bacteria.

**Technical Approach:** Bacterial cultures are grown in BHI broth and opsonized with serum from rabbits immunized with the given strain of bacteria. Serum is separated into IgG, IgM and IgA using either Sepharose 6B or DEAE Sephadex column chromatography. PMNL are separated from blood by either dextran sedimentation or Percoll. Stimulation of PMNL NADH-reductase metabolism as required for oxidative killing is measured by a chemiluminescent technique using luminol as a chemiluminescent probe. Measurement of this PMNL-CL is accomplished with a Packard 1900 scintillation counter. Killing of organisms is measured at the end of each CL run by plating samples with appropriate controls with neutral red, incubating the plates overnight at 37°C, counting bacterial colonies and calculating an antibacterial index for each group of samples.

**Results:** A method which simultaneously measures PMNL-CL and bacterial killing has been developed. This method will be used to analyze immunoglobulin and complement opsonic requirements necessary for stimulation of PMNL microbicidal activity and whether this activity results in decreased viability of the microbe. As such, *Shigella sonnel* phase I and phase II, *Shigella flexneri* 1 and 2 forms and perhaps various Salmonella strains will be studied. During the course of development of this method we have found that IgG to opsonize *S. sonnel* phase I in the absence of complement requires specific IgM requires the action of complement.
**Title:** The effect of Prostaglandin Synthesis Inhibitors on In vitro Suppressor cell Activity in lymphocytes from Patients with Common Variable Agammaglobulinemia.

**Status:** Ongoing

**Est Comp Date:** Oct 82

**Associate Investigators:**
- Michel N. Laham, M.D., MAJ, MC
- Charles M. Loyd, SFC

**Abstract:**

To test the in vitro activity of prostaglandin synthesis inhibitors, such as indomethacin, on T-cell suppressor activity found in lymphocytes from patients with common variable agammaglobulinemia. The reversal of suppressor activity on immunoglobulin cells by such inhibitors may indicate a possible for an effective therapeutic drug for this immunodeficiency.

**Approach:**

Human peripheral blood lymphocytes (HPBL) from normal patients, patients with common variable agammaglobulinemia, or HPBL subjected to a suppressor cell stimulant are incubated in the presence of pokeweed mitogen and selected cultures in the presence of immunomodulating drugs. After culture, the cells are harvested and plated on slides in agar. Immunoglobulin cells are detected using the reverse hemolytic plaque assay. Plaques are developed in HPBL with sheep red blood cells coated with protein A. Immunoglobulin coated slides containing the cells are incubated with anti-human immunoglobulin and complement to develop the plaques. The plaques are then visualized by a high power microscope. Increased numbers of plaques indicate lymphocyte suppressor activity. Plaque counts of normal patient cultures and normal patient cultures are compared to determine the presence of suppressed cell activity. Suppressed cultures incubated with immunomodulating drugs are evaluated for release from suppressor activity.

**Results:** Due to the shortage of agammaglobulinemic patients admitted to BAMC, the laboratory has focused on studying the effects of immunomodulating drugs on lymphocytes artificially suppressed cultures. Development of a method to isolate T-suppressor cells from these populations is also being developed. A preliminary report published as an abstract in Clinical Research indicated that several drugs that induce lupus symptoms were able to stimulate increased numbers of plaques after incubation with cells in culture. Further studies have also shown that steroids have a large capacity to stimulate plaque formation.
The Development of a *Pseudomonas aeruginosa* Vaccine for Laboratory Animals, Phase II.

Objective: To develop a safe and effective, multivalent, *Pseudomonas aeruginosa* vaccine and hyperimmune globulin for laboratory animals.

Technical Approach: Ribosomal vaccines are prepared as described previously. Ribosomes are dissociated from all available serotypes of *P. aeruginosa*. Rabbits are divided into two groups and each group is immunized with half the total number of vaccine preparations. After immunization, the rabbits are bled for the immune sera. Groups of mice are injected with the multivalent antisera and challenged with live cultures of randomly chosen clinical isolates of *P. aeruginosa*. Mice are scored for percentage of survivors for each challenge set. The percentage of clinical isolates of *Pseudomonas* against which statistically significant protection was achieved by the multivalent antisera was calculated.

Results: Ribosomes were dissociated into 30S and 50S ribosomal subunits by the addition of magnesium ions to buffer containing $10^{-3}$ M $Mg^{++}$ and the subunits separated by ultracentrifugation through a sucrose density gradient. These ribosomal subunits were shown to contain a protective antigen, since antisera raised against the isolated subunits were capable of passive transfer of protection. To determine if a relationship existed between the ribosomal vaccine and outer membrane protein (OMP), a preparation of OMP was made from *P. aeruginosa* and used to immunize rabbits. The following properties of the antisera to OMP were found: 1) antisera to OMP was capable of passive protection of mice against live *Pseudomonas*, 2) antisera to OMP showed serological reactivity with ribosomal subunits using a complement fixation assay, 3) antisera to OMP also precipitated with unfractionated ribosomal vaccine in order to hinder the above results suggest a relationship exists between a protective antigen associated with ribosomes and an outer membrane protein(s).
Chemiluminescence (CL) in Populations of Immunocompetent Cells.

Objective: To quantitate the oxidative metabolic response of stimulated populations of immunocompetent cells isolated from mouse or guinea pig peritoneal cavity, liver, and lymph nodes using chemilumogenic probes.

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

Methodology: Peritoneal cells from guinea pigs injected IP with 0.5% caseinate are harvested at 7 days. Macrophages (MΦ) and polymorphonuclear leukocytes (PMNL) are separated after the harvested cells are subjected to density gradient centrifugation on Percoll. The purified cells are treated with various chemical, lectin and phagocytic stimulants as well as catalytic inhibitors and scavenger enzymes. The resulting oxygenation activity is measured by chemilumogenic probe (CLP) technique. Luminol and DAS are used as CLP and the resulting chemiluminescence (CL) is measured in Beckman luminometer with counters modified to be single photon counters.
Therapeutic Manipulation of Metabolic Endocrine Controls During Infection

Start Date: 11 Mar 81

Principal Investigator: James H. Anderson, Jr., M.D., MAJ, MC

Facility: Brooke Army Medical Center

Dept/Sect: Department of Clinical Investigation

Associate Investigators: Gerald A. Merrill, CPT, MSc, Linda Hansen, DAC

Key Words: Metabolic Endocrine Controls Infection

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

Technical Approach: Animals with a variety of induced infections will be studied for glucose tolerance and insulin secretion, binding and effects as well as specific biochemical and physiological function of the islets of Langerhans and cellular insulin receptors on monocytes, hepatocytes and other cells.

Review Results: Continuation of this study at BAMC awaits completion of the laboratory animal facility.
**Investigation of the Involvement of Endogenous Opiates in the Development of the Metabolic Pathophysiology of Infection and Endotoxin Shock**

**Objective:** To determine the influence of stress-relased endogenous opiates on hormonal release by the endocrine pancreas (insulin, glucagon, pancreatic polypeptide and somatostatin) as a result of infection or endotoxin shock.

**Approach:**

A. A series of dogs were treated with glucose and/or insulin after being given an LD<sub>50</sub> dose of E. coli endotoxin. The animals were then studied with blood sampling during a six-hour post-endotoxin period.

Endogenous opiates will be utilized in *vitro* studies with islets of Langerhans isolated from rats to examine insulin synthesis and release.

B. The animal experiments have been completed and the major task of analysis of the samples is currently underway. Samples will be analyzed for insulin, glucose, glucagon, methionine enkephalin, and &endorphin.

C. Continuation of this part of the study awaits completion of a new animal facility.
Objective: To examine the hypothesis that Venezuelan equine encephalomyelitis (VEE) vaccine virus is diabetogenic in animals.

Technical Approach: Animals inoculated with VEE TC83 vaccine (live virus) are studied for glucose tolerance and insulin secretion as well as specific biochemical and physiological function of the islets of Langerhans.

Cost: OMA Cost: $1,360  Review Results: Continue

Continuation of this study at BAMC awaits completion of the animal facility.
Investigation of the Use of Sodium Fluoride for Prevention of Peptidase Degradation of Endogenous Opiates in Plasma

Objective: To provide a rapid and inexpensive method to prevent enzymatic degradation of endogenous opiates (Methionine, enkephalin, Leucine enkephalin, and \( \beta \) endorphin) to permit radioimmunoassay measurement of relevant levels in plasma.

Approach: Known quantities of \( {{^{125}}I} \) labeled endogenous opiates (Methionine, enkephalin, Leucine enkephalin, and \( \beta \) endorphin) were added to samples of whole blood made endogenous opiate poor by incubation at 37°C for 24 hrs. The blood was either treated with NaF (6mg/ml) or 1 N HCl with Leucine (100 \( \mu \)l/900 \( \mu \)l) + enkephalin extracted by MeOH via C-18 Seppak cartridges. Total activity recovered was assessed for each procedure and the effect of each procedure on the degradation enzymes was determined as a percent of the labeled enkephalins.

After submitting the protocol, refinements in the acid extraction procedure and MeOH elution from a C-18 Seppak column of the enkephalins were made to increase recovery of enkephalin from plasma. Therefore the \( {{^{125}}I} \) NaF was assessed in terms of the modified procedure.

It tended to increase the plasma fraction of blood recovered compared to MeOH therefore diluting the \( {{^{125}}I} \) activity/unit plasma. However, total activity recovered in the plasma phase by each procedure was not significantly different (75-78%). In excess of 90% of the activity was eluted by MeOH from the 18 Seppak. Slightly higher percentage of remaining activity was not attributed to the extracted samples by antibody as compared to the NaF, possibly because non-enkephalin entities were eliminated in the extraction...
process. In this lab no increase in recovery by using NaF could be demonstrated compared to the refined acid extraction procedure. Although ease of use of NaF is an advantage, the ability to concentrate the enkephalins by drying the MeOH and redissolving the opiates in the proper assay buffer is of greater advantage. The further investigation of the use of NaF to prevent enkephalin degradation is therefore not warranted.

No publications are anticipated from this project although results will be incorporated into publications from related protocols.
**Detail Summary Sheet**

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<td>The Use of Monoclonal Antibody to a Pseudomonas Ribosomal Protein Antigen for Passive Immunization Against <em>P. aeruginosa</em>.</td>
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<td><strong>Principal Investigator:</strong></td>
<td>Michael W. Lieberman, Ph.D., CPT, MSC</td>
<td><strong>Facility:</strong></td>
<td>Brooke Army Medical Center</td>
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<td><strong>Objective:</strong></td>
<td>To determine whether monoclonal antibody to a <em>P. aeruginosa</em> ribosomal protein antigen can protect mice by passive immunization against challenge with <em>P. aeruginosa</em>.</td>
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**Technical Approach:** Mice are immunized with the *Pseudomonas* ribosomal vaccine, cells are excised and spleen cell suspensions prepared. Spleen cells and lymphoma cells (obtained from another laboratory where they are maintained in culture) are mixed in the presence of polyethylene glycol, resulting in a fusion of the two cell types. The fused cells, called hybridomas, are then fluorescence labeled with conjugated antigen. Next, the hybridoma cells are screened by the fluorescence activated cell sorter and plated such that individual cells are deposited in separate wells of tissue culture plates and allowed in culture for several weeks. The hybridoma clones produced are then tested for antibody production to a particular antigen. Antibody positive colonies are subcultured and injected into the peritoneal cavity of mice. Peritoneal fluid is then collected from the mice and should contain reasonably large amounts of monoclonal antibody. All monoclonal antibody preparations will be tested for antibodies to both protein and LPS antigens and those preparations showing antibody activity to protein antigen only will be tested for passive mouse protection. Preparation of *Pseudomonas* ribosomal vaccines and passive mouse protection experiments will be performed as previously described (C-7-77).

**Progress:** This protocol has just been initiated.
Detail Summary Sheet

Title: The Simultaneous Determination of Instantaneous Aortic Flow, High Fidelity Intracardiac Pressures, Intracardiac Phonocardiography, Echocardiographic Dimensions and Derived Indices in Man.

Start Date: 6 Mar 73

Principal Investigator
Joseph F. Margo, M.D., COL. MC
Department of Medicine/Cardiology

Key Words:
Instantaneous aortic flow
Cardiac catheterization
Intracardiac phonocardiography

Objectives:
1. To develop new techniques in cardiac catheterization, especially in the area of multi-solid state sensor catheters including high fidelity pressure sensors and electromagnetic flow meters. To utilize high speed biplane angiography and external echocardiography in conjunction with such techniques.

2. To utilize these techniques to define sophisticated parameters of ventricular function in patients with various cardiac diseases.

3. To develop specialized computer-assisted analyses of the data derived from such studies.

4. To quantitate left ventricular hydraulic output work.

5. To measure aortic and pulmonary artery input impedance by Fourier analysis and determine the effect of changing physiological states upon the impedance.

Methodology: All adult patients for routine right and left heart catheterization are evaluated in the usual manner by a cardiac fellow prior to catheterization. The evaluation includes strip chart echocardiography to determine suitability for certain aspects of the protocol. During catheterization, specially custom-designed, right and left heart catheters are introduced into right and left heart such that instantaneous high fidelity pressures are recorded from the pulmonary artery, right ventricle, right atrium, left ventricle, and aorta. In addition, electromagnetically derived aortic and pulmonary pressures are recorded from the same sites that high fidelity pulmonary artery and aortic pressures are obtained. Patients are studied during rest or exercise, and depending upon the patient's disease during a variety of stresses or pharmacologic interventions. Some patients also undergo simultaneous external echocardiography during catheterization. The study is terminated after bi-plane ventricular angiography and coronary arteriography is indicated.

Results: Significant progress during FY 1981 resulted in publications including: aortic input impedance in normal man and left ventricular
(continued)

...ejection dynamics in patients with hypertrophic and congestive cardiomyopathies. Currently work is in progress to evaluate the fluid dynamic changes responsible for subvalvular gradients in patients with aortic stenosis. Concurrently data analysis continues in ten patients from whom pulmonary artery impedance spectra were obtained in a high-fidelity micromanometry. It is anticipated that software development for computer-assisted data analysis will commence in the near future and will be carried out under new protocols as they are approved.
Date: 1 Oct 81 Proj No: C-9-75 Status: Ongoing

TITLE: Clinical Outpatient Algorithm Validation - A Pilot Study.

Start Date: 30 Sep 74 Est Comp Date: Dec 81
Principal Investigator Barry W. Wolcott, M.D., COL, MC
Facility Brooke Army Medical Center
Dept/Sec: Associate Investigators:
Department of Medicine/Emergency Medicine Richard M. Tompkins, M.D.
Key Words: Algorithm Validation

Accumulative MEDCASE Est Accumulative Periodic
Cost: OMA Cost: Review Results: Continue

Objective: To determine if clinical outpatient algorithms originally used to treat civilian outpatient populations can be validated and improved in a military outpatient environment.

Technical Approach: Collecting standard data bases on selected, defined outpatient populations presenting for evaluation of acute symptoms and then doing studies of their outcomes. Data base items linked to good/poor outcomes identified by statistical analysis.

Progress: Project will be completed in December 1981. Following completion, we will write a report defining an algorithm-directed acute care system which could be used within or without the Army Medical Department.
**Detail Summary Sheet**

| Date: | 15 Jun 81                                                                 | Proj No: | C-23-76                  | Status: | Completed                      |

**TITLE:**
Demonstration of a Testosterone Binding Protein in Semen.

| Start Date: | 25 Feb 76                                                                 | Est Comp Date: | Sep 81 |

**Principal Investigator**
Albert M. Thompson, M.D., COL, MC

**Dept/Sec:**
Department of Medicine/Endocrinology

**Key Words:**
Testosterone binding protein
Electrophoresis

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<td>OMA Cost: $68</td>
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**Objective:** To demonstrate a testosterone binding protein in semen.

**Technical Approach:** Electrophoresis of testosterone-labeled semen on polyelectrolyte gel and isolation of the labeled band.

**Progress:** No specific testosterone binding substance could be isolated by the technique used.
Mechanism of Modulation of Lymphocyte Responses by Complement.

**Start Date:** 15 Sep 76  
**Est Comp Date:** Jul 82

**Principal Investigator:** Michel N. Laham, M.D., MAJ, MC  
**Dept/Sec:** Department of Medicine/Allergy-Immunology  
**Facility:** Brooke Army Medical Center  
**Associate Investigators:** David G. Burleson, Ph.D., MAJ, MSC  
Fatima Ebrahim, SSG

**Key Words:** Complement  
**Accumulative MEDCASE Cost:** $4,476

**Objectives:**
- To determine whether the cleavage of complement component C3 by activated C1 and C4 takes place in the fluid phase.
- To determine whether generation of breakdown products of C2 correlates with the modulatory effect on lymphocytes.
- To investigate the effect of intact vs cleaved C2 on the generation of suppressor T cells.

**Progress:** Purified human C1, C4 and C2 are sequentially added to a suspension of peripheral blood lymphocytes in complement fixation buffer in a ratio of 1:15. Aliquots of the supernatants are withdrawn at 10, 20, 40 and 60 minutes, and kept frozen at -70°C until they can be assayed for residual C2 activity. At each time interval stated, the lymphocytes are sedimented, washed free of complement fixation buffer and resuspended in RPMI 1640 to determine the proliferative responses to mitogens and the ability to suppress normal cells.

**Progress:** The main obstacle to the successful completion of this study has been our inability to obtain fresh EAC14 cells. As a result, we have not been able to measure residual C2 hemolytic activity. We are renewing our efforts to coordinate the shipment of cells so that we may obtain them within 24-48 hours of their shipment.
are given a prescribed dose of the drug to be used prior to long-wave ultraviolet light exposure. The cumulative dosage of the drug to the skin is gradually increased to promote pigmentation (tanning). The patient is protected by special ultraviolet glasses that block visible light. The light dosage is carefully regulated to avoid overexposure of the skin. All patients received therapy in the pathology evaluation room with drug therapy.

Since the beginning of the study, four new patients have entered the study and have not been reported. One patient had palmoplantar psoriasis, three patients had plaque type psoriasis, and one patient had parapsoriasis. The patient with palmoplantar psoriasis had greater than 95% improvement of his lesions. Two of the patients with plaque type psoriasis had no recurrence, while other patients with plaque type psoriasis had some recurrence after discontinuing treatment.
Objective: To establish whether in vivo tetracycline labeling can be used to aid the endoscopist in locating pathologic pulmonary tissues when viewed through a fiberoptic bronchoscope incorporating an ultraviolet light source.

Technical Approach: Antimicrobials of the tetracycline family are known to exhibit a characteristic fluorescence under ultraviolet light. It is also known that tetracycline will concentrate in abnormal tissues such as tumor. For this reason, it has been theorized and subsequently shown that patients given tetracycline can have an induction of a bright yellow fluorescence which can be seen under ultraviolet light in various tumor tissues. It is therefore proposed that patients who are suspected of having lung cancer who will undergo fiberoptic bronchoscopy be treated with tetracycline 250 mg q.i.d. for four days. At the time of fiberoptic bronchoscopy, if tumor tissue is seen, it would be biopsied, and no further procedures done. However, if no abnormal tissue is seen under routine fiberoptic bronchoscopy, then the patient would be examined with an ultraviolet light source. At that time, if an area of abnormal fluorescence is seen, a biopsy would be done in the routine fashion. Patients to be studied would include all patients who have consented to have the procedure performed, who would otherwise have an indication for fiberoptic bronchoscopy, i.e., patients with suspected lung tumors.

Progress: Due to personnel shortages and technical difficulties, no progress has been made on this protocol.
<table>
<thead>
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<th>Date: 6 Feb 79</th>
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**Title:** Evaluation of Antidiarrhea, Lomotil and Placebo in Acute Diarrheas

**Summary:**

- **Start Date:** 6 Feb 79
- **Est Comp Date:**
- **Principal Investigator:** Leonard Duran, M.D., CPT, MC
- **Dept/Sec:** Department of Medicine/Gastroenterology
- **Keywords:** Acute diarrhea, Antidiarrhea, Lomotil, Placebo
- **Accumulative MEDCASE:**
- **Est Accumulative Cost:**
- **Periodic OMA Cost:**
- **Review Results:**

**Objective:** To evaluate the effectiveness of Antidiarrhea, an over-the-counter drug, of Lomotil, a prescription drug approved as effective adjunctive therapy, and of a placebo in the treatment of acute diarrhea.

**Method of Approach:** Patients age 18-65 presenting to the Brooke Army Medical Center, Emergency Room and Acute Minor Illness Clinic with symptoms compatible with a diagnosis of acute diarrhea, will be considered for the study. The diarrhea must have begun less than 48 hours before enrollment in the study, and the patient must have experienced at least three watery, liquid bowel movements within the previous twenty-four hours. Eligible participants will be assigned to one of three groups. Group 1 will receive Antidiarrhea, Group 2 will receive Lomotil, and Group 3 will receive the Antidiarrhea placebo.

**Progress:** The study was terminated by the drug company. 80 cases were completed. The drug company had recommended we study 320 cases in order that we might have meaningful statistics.
Headache and Back Pain Clinical Algorithm Validation, Cost Analysis and AMOSIST Reliability.

Start Date: 22 Mar

Principal Investigator
Robert D. Slay, M.D., MAJ, MC

Dept/Sec:
Department of Medicine/Emergency Medicine

Key Words:
Algorithm
AMOSIST

Objectives: To determine if new clinical algorithms, used to evaluate and treat patients presenting with acute headache and back pain, utilized by physician extenders, can be validated as effective in an outpatient population.

To compare the process of outcome data obtained by AMOSISTS and Internists (utilizing the same standard data base) in the evaluation and treatment of adults with headache or back pain.

To utilize the process of outcome data generated by the AMOSISTS and Internists to generate new clinical algorithms of measurable cost and outcome.

Technical Approach: Data were collected by medical corpsmen in the walk-in clinic and emergency room using a common checklist. The items on the checklist were chosen, based on an extensive literature review, to detect serious or potentially serious conditions causing headaches and to discriminate between tension and migraine headaches.

Four weeks after each encounter, research assistants reviewed each patient's record and contacted the patient by telephone to determine the outcome of the illness. An internist who was not involved in the patient's care used the checklist, follow-up, and the other data in the medical record to assign a diagnosis.

Progress: Seven hundred twenty six patients presented with acute headaches which were diagnosed as tension (38%), migraine (25%), no diagnosis (30%) and other (6%). No patient had a life-threatening diagnosis. Although the internist making diagnoses had access to a great deal of information in addition to the initial clinical data for each patient, a simple rule based on 3-7 of the initial findings could duplicate his diagnostic decision with at least 80% accuracy.
Date: 8 Oct 81  Proj No: C-14-79  Status: Terminated

TITLE:
Immunoglobulin Regulation in Rheumatic Disease.

Start Date: Mar 79
Est Comp Date:

Principal Investigator
Gordon Kelley, M.D., MAJ, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Rheumatology

Associate Investigators:
I. Jon Russell, M.D.

Key Words:
Rheumatic disease
Immunoglobulin regulation

Objective:
To further characterize the physicochemical properties of a complement factor in patients with systemic lupus erythematosus, rheumatoid arthritis, dermatomyositis, progressive systemic sclerosis, Sjogren's syndrome, and sarcoidosis, and to study the cellular interactions responsible for its function.

Approach:
This is a collaborative study with Dr. I. Jon Russell, University of Texas Health Science Center at San Antonio.

Blood samples will be obtained from normal control volunteers and from patients with a variety of connective tissue diseases including systemic lupus erythematosus, rheumatoid arthritis, dermatomyositis, progressive systemic sclerosis, Sjogren's syndrome, and sarcoidosis for evaluation as outlined in the study protocol.

To date, no patients from BAMC have been entered on this study; therefore, the study is terminated.
Detail Summary Sheet

Date: 6 Oct 81  Proj No: C-34-79  Status: Completed

TITLE: Triple Corticoid Integrated System (TCIS) 0.015% Cream Compared to 0.5% Hydrocortisone Cream in Treating Lichen Planus.

Start Date: 9 Aug 79  Est Comp Date:

Principal Investigator
Charles W. Lewis, M.D., COL, MC

Dept/Sec:
Department of Medicine/Dermatology

Associate Investigators:
J.R. Cook, M.D., MAJ, MC

Key Words:
Lichen planus

Accumulative MEDCASE | Est Accumulative | Periodic
Cost: | OMA Cost: | Review Results:

Objectives: To determine the efficacy of TCIS cream (0.015%) in lichen planus without occlusion.

To compare the efficacy of TCIS cream (0.015%) against 0.5% hydrocortisone in the same vehicle in treating lichen planus.

Technical Approach: The two test agents were applied to opposite sides of the body in the same area, in patients with symmetrical lichen planus, e.g. both forearms, both thighs, etc. Responses were evaluated and graded at two and four weeks. The study was double-blinded.

Progress: A total of 13 patients was studied at BAMC. Nine responded better to TCIS cream; two responded better to 0.05% hydrocortisone; two responded equally. In cooperation with others, a total of 51 patients were studied nationally. Overall results were similar to ours, indicating significantly better response of lichen planus to TCIS cream.
Date: 22 Oct 81  Proj No: C-35-79  Status: Terminated

TITLE:
Maintenance of Patency of the Ductus Arteriosus in Neonates with Cyanotic Congenital Heart Disease

Start Date: Aug 79  Est Comp Date:  

Principal Investigator: Kenneth R. Bloom, M.D., LTC, MC  Facility: Brooke Army Medical Center

Dept/Sec: Department of Medicine/Cardiology

Associate Investigators: Joseph P. Murgo, M.D., COL, MC

Key Words: 
Patent ductus arteriosus
Cyanotic congenital heart disease

Accumulative MEDCASE Est Accumulative Periodic
Cost: OMA Cost: Review Results:

Objective: To maintain an adequately patent ductus arteriosus in neonates who have cardiac malformations such that their immediate survival is dependent on blood flow through this channel. This will be done by infusion of Prostaglandin E1 until diagnostic studies are completed and surgery carried out.

Technical Approach: Newborn infants presenting to the neonatal intensive care unit at BAMC and who have cyanotic congenital heart disease form this study group. Prostaglandin is infused through an umbilical artery catheter placed at the level of the ductus or, in some conditions, intravenously. Effects of the prostaglandin infusion are assessed by peripheral PO2 measurement and, when applicable, by blood pressure measurements in the leg.

Progress: The study is terminated due to the projected departure of the principal investigator.
Detail Summary Sheet

Date: 23 Sep 81 Proj No: C-37-79 Status: Ongoing

TITLE:
Ankle Trauma Study.

Start Date: Sep 79 Est Comp Date: Sep 82

Principal Investigator
N. Joe Thompson, M.D., LTC, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Emergency Medicine

Associate Investigators:
Barry W. Wolcott, M.D., LTC, MC
Robert Highley, M.D.
James Bushyhead, M.D.
Robert Wood, M.D.

Key Words:
Trauma
Algorithm

Accumulative MEDCASE Cost: Est Accumulative OMA Cost:
Periodic Review Results: Continue

Objective: To define predictors for the clinical diagnosis of ankle fracture, ligament rupture and strain; to develop cost efficient scheme for x-ray utilization in diagnosis of ankle trauma; to evaluate effects of different treatment modalities; to elucidate natural history of ankle trauma; to construct a family of algorithms with cost efficiency ratios; to determine best protocol for optimal care in ankle trauma.

Technical Approach: Each patient with indirect ankle trauma is offered the opportunity to enter the study. A PGY-2 in Emergency Medicine follows a precise format for obtaining a history and performing a physical exam which includes both plain and stress x-rays. The x-rays are then interpreted by the physician and assigned to a specific classification established by the study protocol. A previously established therapeutic modality is randomized. The patient is treated according to the established classification of the ankle injury and the randomized therapeutic modality. Follow-up at 48 hours and 90 days is done, depending upon the injury classification.

Progress: 666 patients have been entered on the study; however 900 are needed to complete the study. A final report will be submitted upon completion.
**Detail Summary Sheet**

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<td><strong>Start Date:</strong></td>
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<td><strong>Associate Investigators:</strong></td>
<td>Joseph P. Murgio, M.D., COL, MC</td>
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**Objective:** To determine the efficacy of Metoprolol (LopressorR) in reducing the incidence of overall and cardiac death in survivors of recent myocardial infarction.

**Technical Approach:** Patients satisfying multiple criteria are enrolled within two weeks of acute myocardial infarction and given either placebo or metoprolol (Lopressor) 200 mg/day and followed on medication for one year. Metoprolol or placebo are administered in a randomized, double-blind fashion prospectively.

**Progress:** A total of 19 patients has been enrolled. Three have dropped out because of noncompliance. One patient has expired. Since the study is double blind, no results are available.
Detail Summary Sheet

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<tr>
<td><strong>TITLE:</strong> Clotting Studies in Liver Disease</td>
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**Start Date:** 24 Jan 80  
**Est Comp Date:** Jan 82  
**Facility:** Brooke Army Medical Center  
**Associate Investigators:** John F. Schultheiss, M.D., LTC, MC, Thomas F. O'Meara, M.D., MAJ, MC, Barbara Reeb, DAC

**Dept/Sec:** Department of Medicine  
**Key Words:** Prothrombin time, Vitamin K

| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|---------------------------|---------------------------|-------------------------|

**Objective:** Attempt to predict whether patients with prolonged prothrombin times with liver disease will or will not respond to Vitamin K administration.

**Technical Approach:** Patients who are to get Vitamin K will be given 10 mg. intramuscularly every 12 hours for the first 2 days. Serial prothrombin times will be recorded at 12 hour intervals for the first three days. An Echis carinatus time will be performed as a companion to the prothrombin time determination. The data will be analyzed retrospectively to determine whether Echis carinatus adequately predicted those patients who would respond or did respond to Vitamin K administration.

**Progress:** To date insufficient patients have been entered on this study in order to perform any meaningful evaluation. If patient accrual is not accelerated during the next year, this study will be terminated.
Detail Summary Sheet

Date: 1 Oct 80  Proj No: C-7-80  Status: Ongoing

TITLE:
Evaluation of the Coagulation and Fibrinolytic Systems in Patients Undergoing Prostatectomy.

Start Date: 24 Jan 80  Est Comp Date: Sep 82

Principal Investigator
Glenn M. Mills, M.D., MAJ, MC

Dept/Sec:
Department of Medicine/Hematology

Key Words:
Prostatectomy  Coagulation system  Fibrinolytic system

Accumulative MEDCASE Cost:  Est Accumulative OMA Cost: $6,541

Periodic Review Results: Continue

Objectives: To conduct a detailed and prospective study of both the coagulation and fibrinolytic systems in patients undergoing either transurethral prostatectomy (TURP) or open prostatectomy.

To familiarize the hematology laboratory personnel with the use of chromogenic substrates for the measurement of components of both the coagulation and fibrinolytic systems.

Technical Approach: All tests reviewed in the original protocol have been standardized and are currently being performed by our laboratory. The Hematology Lab personnel have gained experience in the utilization of these assay methods and accurate data are being recorded on all tests.

Progress: Fifty patients have been registered on this study with 20 controls. Patient accrual has been completed and the only remaining part of this project is the completion of the laboratory analysis of the control patients with the statistical analysis of data. We plan to present this project in abstract form at the Tri-Service Urology Meeting.
The Value of Immunotherapy with Dermatophagoides Mite Extract in the Treatment of House Dust Allergy.

Objective: To assess the value of immunotherapy with Dermatophagoides mite extract in the treatment of house dust allergy.

Technical Approach: This study was to be a double-blind study using mite extract in immunotherapy from patients with clinical housedust sensitivity.

Progress: This study has been terminated. Our assumption for this study was that mites are an important allergen to housedust and that mites should therefore be present in housedust samples. It is now clear, however, that in San Antonio (and probably throughout the southwest), most homes do not contain dermatophagoides mites, most likely because the relative humidity is too low for their survival. No patients were enrolled into the study.
TITLE: Role of Digoxin in Preventing Myocardial Toxicity in Cancer Patients Receiving Adriamycin.

Start Date: 6 Jun 80  Est Comp Date: Jun 82

Objective: To determine whether digoxin, administered prior to and during Adriamycin-containing chemotherapy regimens, reduces the incidence and extent of myocardial toxicity in cancer patients.

Technical Approach: Cancer patients to be treated with Adriamycin will be alternately assigned to one of two groups: (a) digoxin-treated, or (b) control. In order to assure equitable distribution of patients by age, sex and tumor type, participating medical oncologists will be aware of and adjust patient assignments as necessary. Participating cardiologists will be unaware of which patients are receiving digoxin and, therefore, all echocardiographic results will be interpreted by "blind" observers.

Digitalization of the digoxin-treated group will consist of the administration of 1.5 gm digoxin PO in divided doses for two days. Serum digoxin levels will be obtained from digoxin-treated patients prior to starting Adriamycin and before each echocardiogram.

All patients will undergo routine echocardiographic evaluation by m-mode technique, a method commonly used to evaluate cardiac function in patients on Adriamycin.

Progress: Approximately 7-10 patients are still needed on the Digoxin treated arm to complete this study. Patient accession has been slow secondary to patient early removal from study for progressive disease and patients being treated at facilities (other than BAMC) without echocardiography capabilities.
An Evaluation of Local Anesthetic Skin Testing and Progressive Challenge in Patients with a History of an Adverse Reaction to Local Anesthetics

Start Date: 24 Jun 80

Est Comp Date: FY 82

Principal Investigator
Daniel A. Ramirez, M.D., MAJ, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Allergy-Immunology

Associate Investigators:

Key Words:
Local anesthetic skin testing
Challenge
Adverse reaction

Accumulative MEDCASE
Cost:
Est Accumulative OMA Cost:
Periodic
Review Results:
Continue

Objective: To confirm the safety and usefulness of this approach in a larger number of patients with histories of previous suspected adverse reactions to local anesthetics.

Technical Approach: Patients with history of adverse reactions to local anesthetics are being entered into this study, and evaluated with skin testing and progressive challenge. The challenge reaches 2 cc of S.C. 1% lidocaine.

Progress: Approximately 10 patients have been studied at BAMC. No adverse reactions have occurred with challenge. These patients are being entered into a larger multicenter study at Fitzsimons Army Medical Center.
Establishment of a Plasma Bank for Oncology Patients.

Objective: To collect and freeze plasma samples from patients with cancer.

Technical Approach: Collection of blood specimens has been proceeding smoothly in the Oncology Chemotherapy Clinic. Specimens are collected in this location and immediately centrifuged, and the plasma collected. It is temporarily frozen in the refrigerator in the Oncology Clinic and then transported the same day to the -70° freezers in the Department of Clinical Investigation.

Progress: Approximately 100 patients have been registered on this study with their specimens being collected and frozen.
Objective: To determine the safety and efficacy of sulconazole nitrate 1% solution in the once-a-day, three-week treatment of tinea cruris in adult men and women as compared to 1% clotrimazole solution.

Technical Approach: Sulconazole or Clotrimazole was applied once daily to skin lesions. KOH and fungus culture was done initially and at 2, 3 and 7 weeks. Medication was stopped at end of 3 weeks, and 4 weeks later the patient was re-evaluated for relapse.

Progress: Twenty-four patients entered the study and 22 patients completed. Twelve patients were treated with Sulconazole, and 10 patients were treated with Clotrimazole. All 22 patients cleared by the end of three weeks. There was no significant difference between the two medications.
**Detail Summary Sheet**

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<tr>
<td>Double-blind Parallel Comparison of Sulconazole Nitrate 1% Solution and Placebo Solution in the Treatment of Tinea Versicolor.</td>
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<td>Principal Investigator</td>
<td>Charles W. Lewis, M.D., COL, MC</td>
<td>Facility</td>
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**Accumulative MEDCASE** | **Est Accumulative** | **Periodic** | **Cost:** | **OMA Cost:** | **Review Results:** Continue |
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**Objective:** To determine the safety and efficacy of sulconazole nitrate 1% solution in the once-a-day, three-week treatment of tinea versicolor in adult men and women as compared to placebo solution.

**Technical Approach:** This was a double blind study of Sulconazole Nitrate solution versus placebo applied to tinea versicolor lesions once daily for three weeks. KOH and Wood's lamp examination at two weeks and three weeks. If KOH was negative at three weeks, treatment was stopped and patient re-evaluated four weeks later.

**Progress:** Twenty-three patients completed the study. Twelve patients treated with placebo showed no evidence of clearing. Fungus was demonstrated by KOH. Eleven patients treated with Sulconazole Nitrate cleared completely, and KOH was negative by three weeks. It was concluded that Sulconazole Nitrate was superior to placebo in treatment of tinea versicolor.

At the request of the drug company, an additional 36 patients will be studied on this protocol.
Assessment of Granulocyte Function and Serum Opsonic Capacity in Nephrology Patients Undergoing Dialysis.

Objectives: To assess granulocyte function in nephrology patients undergoing dialysis.
To assess serum opsonic capacity in these patients.
To investigate the relationship between dialysis associated activation of complement and the neutropenia observed during the initial phase of dialysis.
To assess peritoneal macrophage function in patients undergoing peritoneal dialysis.

Technical Approach: Blood samples are obtained from the arterial and venous tubings of patients undergoing routine hemodialysis. These samples are then taken to the laboratory where white cell counts and differentials are obtained and samples of the white cells are assessed for their opsonic capacity using several different molecular probes. Serum samples from each experiment are frozen and saved for batch analysis of complement components including molecular fragments.

Progress: Twelve patients have been studied in detail using a variety of different methodologies. From the basis of the data developed thus far, six patients will be restudied with analysis using a standard methodology which should permit tighter grouping of the mean data.
The Effect of Nutrition on the Humoral-Phagocytic Axis.

Objectives: To evaluate the microbicidal activity of the humoral-phagocytic axis of host immune defense using chemiluminescence techniques in malnourished patients.

To evaluate the effect that nutritional repletion has on serum opsonic capacity and on polymorphonuclear leukocyte function as measured by chemiluminescence.

Technical Approach: Fifteen to twenty patients judged to be malnourished as defined by the parameters listed in the protocol were to be studied. After hyperalimentation, the changes in chemiluminescence with changes in nutritional status were to be correlated.

Progress: The principal investigator decided not to initiate the study.
**Detail Summary Sheet**

**Date:** 22 Oct 81  
**Proj No:** C-42-80  
**Status:** Terminated

**TITLE:**  
Solumedrol for the Treatment of Acute Myocardial Infarction

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<td>Principal Investigator</td>
<td></td>
<td></td>
<td>Brooke Army Medical Center</td>
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<tr>
<td>Francis R. D'Silva, M.D., MAJ, MC</td>
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<td>Dept/Sec:</td>
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<td></td>
<td>Joseph P. Murgio, M.D., COL, MC</td>
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<tr>
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**Objective:** To evaluate the efficacy of two pharmacologic IV doses of Solumedrol in reducing the mortality and morbidity associated with acute myocardial infarction.

**Technical Approach:** Study terminated.

**Progress:** The study was terminated because of a conflict of interest since the principal investigator has taken over the study C-5-80, Lopressor Intervention Trial.
Detail Summary Sheet

Date: 14 Oct 81  Proj No: C-1-81  Status: Completed

**TITLE:**
Hemoserine Inhibition of Sickling as Viewed by Electron Microscopy

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<tr>
<td>Georges C. Benjamin, M.D., CPT, MC</td>
<td>Brooke Army Medical Center</td>
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<td>Dept/Sec:</td>
<td>Associate Investigators:</td>
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<tr>
<td>Department of Medicine/Internal Medicine</td>
<td>Lucia Olaade, DAC</td>
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<tr>
<td>Key Words:</td>
<td>Steven K. Koester, DAC</td>
</tr>
<tr>
<td>Hemoserine inhibition</td>
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<tr>
<td>Sickling</td>
<td></td>
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<tr>
<td>Electron microscopy</td>
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</tbody>
</table>

**Accumulative MEDCASE** | Est Accumulative Cost: $20 | Periodic Review Results: |

**Objective:** To evaluate the effect of hemoserine on polymerization of hemoglobin S in the intact erythrocyte.

**Technical Approach:** Whole blood was obtained by venipuncture in EDTA. After fixing with Karnovsky's fixative, smears of each sample was viewed by light microscopy.

**Progress:** One patient was available for study. At 0.1 M concentrations, hemoserine did not inhibit sickling in the two assays performed. EM of the sickled cells showed filament formation in the deoxygenated treated and untreated cells. The oxygenated controls were too hemolyzed to study.
Date: 14 Oct 81  Proj No:  C-2-81  Status:  Ongoing

TITLE: Evaluation of the Coagulation, Fibrinolytic, and Humoral Immune Abnormalities Induced by Crotalus Atrox (Western Diamond Back Rattlesnake) Snakebite

Start Date: 10 Oct 80  Est Comp Date:  Sep 82

Principal Investigator: John J. Posch, DAC
Facility: Brooke Army Medical Center

Dept/Sec: Department of Medicine/Hematology
Associate Investigators:
- Glenn M. Mills, M.D., MAJ, MC
- Robert C. Allen, M.D., Ph.D., MAJ, MC
- Thomas G. Glass, Jr., M.D.

Key Words: Snakebite  Envenomated  Rattlesnake

Accumulative MEDCASE  |  Est Accumulative Cost: $5,864  |  OMA Cost:  Periodic  Review Results:  Continue

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

Technical Approach: Coagulation tests as outlined in the protocol are being performed on snakebite patients. Serum and plasma specimens are stored at -70°C for further evaluation to include chemiluminescence technique for the evaluation of opsonic function and complement activity. Venoms collected from C. atrox specimens of different sizes were preliminarily tested for possible differences in coagulant vs fibrinolytic activity. Significant differences were noted and venoms were subsequently obtained from three different size ranges of snakes. Thrombin-like activities and fibrinolytic activities were evaluated on all individual venoms. Further characterization of the procoagulant and fibrinolytic processes involved is being performed using plasma and fibrinogen coagulation procedures.

Progress: Specimens from 24 snakebite victims have been collected and stored in frozen aliquots. Twelve of these patients were serially collected on subsequent days. Approximately one-half of the total amount of coagulation procedures to be performed on these are completed. Chemiluminescence procedures will be performed when all specimens are received. Although coagulation abnormalities and clinical bleeding problems have been observed in several of these patients, final conclusions are pending completion of tests and rest of patient group.
Study of Granulocyte Function in Leukemia Patients Receiving Granulocyte Transfusions

Start Date: 10 Oct 81
Est Comp Date: Sep 82
Principal Investigator: Glenn M. Mills, M.D., MAJ, MC
Facility: Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology
Associate Investigators:
  - Donald C. Townsend, M.D., MAJ, MC
  - Robert C. Allen, M.D., Ph.D., MAJ, MC
  - Terry E. Pick, M.D., LTC, MC
Key Words:
  - Granulocyte function
  - Leukemia
  - Granulocyte transfusion

Objectives:
- Prospective evaluation of neutrophil function and humoral immunity in patients with leukemia.
- Evaluation of changes induced in humoral immunity and neutrophil function by either radiation therapy or chemotherapy.
- Evaluation of kinetics of transfused neutrophils in leukemia patients.
- Correlation of improvement in neutrophil function and humoral immunity in recipients of granulocyte transfusions and clinical course.

Technical Approach:
Baseline evaluation of the patient's humoral opsonic capacity will be performed. Granulocyte redox function will also be studied. Additional studies will be performed with routine CBCs during the induction phase of chemotherapy. Once a patient has entered remission of his leukemia, a repeat study will be performed on a monthly basis. Serum opsonic capacity and granulocyte redox function will be assayed by the micro technique of probe amplified chemiluminescence.

Progress:
Only one patient to date has been studied. This is secondary to low patient accrual with no patients needing granulocyte transfusion in the last 10 months at Brooke. If sufficient patients cannot be accrued to this study over the next year, it will be terminated.
The Natural History of Patients with Large Local Reactions (LLR) Following a Hymenoptera Sting

Start Date: 3 Feb 81
Est Comp Date: Sep 83

Principal Investigator
Daniel A. Ramirez, M.D., LTC, MC

Department of Medicine/Allergy-Immunology
Associate Investigators:

Key Words:
Hymenoptera sting
Large local reactions (LLR)

Objective: To study the natural history of patients who have experienced LLR following an insect sting. Several aspects of this problem will be studied:

a. What is the risk of systemic anaphylaxis in this group of patients? and
b. Can patients with histories of LLR and at risk of anaphylaxis be identified prospectively.

Technical Approach: Patients who meet the above objectives will undergo the following:

a. Venom skin testing - up to 1 ug/ml of concentration.
b. Obtain specific venom IgE and IgG.
c. Stay challenged under controlled conditions to assess current reactivity.
d. Obtain specific venom IgE and IgG's following sting challenge.

Progress: Eight patients with positive skin tests to venom have been entered into the study. None of these patients have consented to in-hospital study. The plan for these patients is to follow-up on field stings when it occurs.
**Detail Summary Sheet**

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<th>Date: 9 Nov 81</th>
<th>Proj No: C-8-81</th>
<th>Status: Ongoing</th>
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</table>

**TITLE:** Comparative Evaluation of Methods of Surveillance for Nosocomial Infections

**Start Date:** 3 Feb 81  
**Est Comp Date:** Sep 82

**Principal Investigator:** C. Kenneth McAllister, M.D., LTC, MC  
**Facility:** Brooke Army Medical Center

**Dept./Sec.:** Department of Medicine/Infectious Disease  
**Associate Investigators:** John L. Carpenter, M.D., LTC, MC

**Key Words:** Nosocomial infection

| Objective: To study several different methods by which Infection Control personnel might search for nosocomial infections, as well as the method presently employed at Brooke Army Medical Center (BAMC), in order to define clearly a system which would most efficiently achieve the goals of surveillance for nosocomial infections. |
|---|---|---|

| Objective: To study several different methods by which Infection Control personnel might search for nosocomial infections, as well as the method presently employed at Brooke Army Medical Center (BAMC), in order to define clearly a system which would most efficiently achieve the goals of surveillance for nosocomial infections. |

**Technical Approach:** Data for this study will be collected on McBee Keysort cards. A card will be initiated for each patient whose chart is actually reviewed by a member of the Infection Control Surveillance Team. Charts will be selected for review on the basis of the presence of one or more of the nine screening clues (positive culture, fever, antibiotic therapy, a verbal report, presence on an ICU, isolation precautions, hospital stay of 31 days or more, and leukemia) disclosed during survey activities. During the chart review, the presence of additional factors associated with NI will be noted on the "Also Present" column. A determination as to whether or not a NI is present will be made. As appropriate, the site will be indicated. Follow-up on the patient will be noted simply by initiating a new card for each review of the chart with entries being confined to the small section devoted to follow-ups.

**Progress:** Initial review of the data is inconclusive. Further study is indicated.
Objective: To define the state of thyroid function in seriously ill oncology patients.

Technical Approach: Ten patients will be studied. Blood will be drawn and T<sub>3</sub>, T<sub>4</sub>, PTH, TSH, T<sub>3</sub>RIA, and RT<sub>3</sub> will be measured. Patients on thyroid hormone or with a family history of thyroid disease will be excluded.

Progress: Seven patients have been studied thus far and thyroid function results are pending.
Evaluation of the Complement System and Humoral Immunity in Patients Undergoing Fibrinolytic Therapy.

Start Date: 3 Feb 81  Est Comp Date: Jun 82
Principal Investigator: David Dooley, M.D., CPT, MC
Facility: Brooke Army Medical Center
Dept/Sec: Department of Medicine
Associate Investigators:
Key Words:
Complement system
Humoral immunity
Fibrinolytic therapy

Accumulative MEDCASE Est Accumulative Periodic
Cost: OMA Cost: Review Results: Continue

Objective: To conduct a prospective evaluation of the effects of fibrinolytic therapy on the complement and humoral immune systems.

Technical Approach: No deviation from the ascribed technical approach as listed in the protocol have been performed.

Progress: Three patients have been studied. Complete evaluation and analysis of data will be pending further patient accrual. It is anticipated this study will accrue adequate numbers of patients during the next fiscal year.
**Title:** Study of Granulocyte Function, Complement Activity and Coagulation in Patients with the Adult Respiratory Distress Syndrome (ARDS)

**Start Date:** 4 Feb 81  
**Est Comp Date:** Jun 82  
**Facility:** Brooke Army Medical Center

**Principal Investigator:** Nathan Erteschik, M.D., CPT, MC  
**Department:** Department of Medicine/Internal Medicine

**Associate Investigators:**
- Glenn M. Mills, M.D., MAJ, MC  
- Robert C. Allen, M.D., Ph.D., MAJ, MC  
- David Glendenning, M.D., LTC, MC

**Key Words:**
- ARDS  
- Complement  
- granulocyte-induced endothelial damage

**Accumulative MEDCASE Cost:**  
**Accumulative OMA Cost:**  
**Periodic Review Results:** Continue

**Objectives:**
- Evaluation of neutrophil metabolism by chemiluminescence in patients with ARDS.
- Measurement of complement activity via the classical and alternate pathways in patients with ARDS.
- Study of the coagulation and fibrinolytic systems in patients with ARDS.
- Correlation of steroid therapy with the above objectives in patients with ARDS.

**Technical Approach:** Arterial and mixed-venous blood samples are collected from patients with both arterial and Swan-Ganz catheter lines in place. Samples are collected for: WBC metabolism and complement activity using chemiluminescence; CBC; Pt, PTT; Fibrinogen, FSP, TT, Plasminogen and plasminogen activators, pre-kallikrein and kallikrein inhibitors, HMWK. These are performed on plasma prepared from anticoagulated whole blood with Na citrate, centrifuged and stored at -70°C.

**Progress:** Three categories of patients: 1) ARDS, with 2 patients; 2) cardiac catheterization group, with 7 patients; 3) other patients with both catheter lines in place but without ARDS, with 10 patients. Coagulation studies are still stored, and waiting to be completed on patients already in the study.
Effect of DMSO on Human Squamous Cell Cultures

Objective: Using in vitro human squamous carcinoma cell lines ("LO 16), we will determine whether DMSO induces their differentiation into more mature epithelial cells.

Technical Approach: Squamous cell cultures will be perpetuated in vitro by periodic transfer into fresh monolayers in RPMI 1640. Once an in vitro cell line is established, the effect of DMSO will be determined by adding serial dilutions of DMSO to individual monolayer cultures. After varying intervals from 10-60 minutes, the cells will be washed free of DMSO and incubated in fresh RPMI 1640 at 37°C and 5% CO₂. After 24-48 hours of incubation, the individual monolayers will be fixed and stained using H&E, and the degree of differentiation determined by light microscopy.

Progress: So far, considerable difficulty has been encountered in establishing the cells line due to bacterial killing.
**Detail Summary Sheet**

**Date:** 10 Jun 81  
**Proj No:** C-19-81  
**Status:** Transferred

**TITLE:** The Prevalence of Antibiotic Tolerant *Staphylococcus Aureus* in Nasal Cultures of Different Adult Population Groups

<table>
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<th>Start Date:</th>
<th>11 Mar 81</th>
<th>Est Comp Date:</th>
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</table>

**Principal Investigator**  
Frank J. Baker, M.D., MAJ, MC

**Dept/Sec:** Department of Medicine/Infectious Disease

**Key Words:**  
*Staphylococcus aureus*

**Objective:** To perform an epidemiological survey of *Staphylococcus aureus* tolerance from isolates not causing clinical infection and determine prevalence rates in different adult population groups.

**Technical Approach:** This study was not started.

**Progress:** The study was transferred to William Beaumont Army Medical Center.
Identification of Bacterial Receptors on the Intestinal Mucosa of Rabbits and Determination of Its Role in the Pathogenesis of Bacterial Diarrhea

Start Date: 1 Apr 81
Est Comp Date: Jun 82

Robert A. Berendson, M.D., MAJ, MC
Facility: Brooke Army Medical Center

Department of Medicine/Gastroenterology
Associate Investigators:
John F. Schulteiss, M.D., LTC, MC
C. P. Cheney, Ph.D., CPT, MSC

Bacterial receptors
Bacterial diarrhea

Accumulative MEDCASE: ____________
Est Accumulative Cost: ____________
OMA Cost: $632

Accumulative Periodic
Review Results: Continue

Objectives: Isolate segments of small intestine from adult rabbits, and compare the adherence ability of RDEC-1 and several control E. coli strains to these intestinal segments.

Indirectly examine the various segments of intestine to determine if there are any differences in the carbohydrate content between receptor positive and receptor negative intestinal segments.

Determine the role the host receptors for RDEC-1 located on the intestinal mucosa by orally challenging receptor positive and receptor negative rabbits.

Technical Approach: Four adult female New Zealand white rabbits will be mated with designated male rabbits, and their litters allowed to be maintained as naturally as possible by the mother. On days 18, 21, 24, 28, and 35, infant rabbits from each litter will be sacrificed and segments of rabbit small intestine will be frozen rapidly in isopentane. Frozen intestinal tissue will be sectioned in a cryostat and an attempt will be made to identify the specific sugar units which may constitute the receptor for RDEC-1 and E. coli which has specific adherence to rabbit small bowel. For this, the tissue will be exposed to different lectins, which are sugar specific proteins, in an attempt to block adherence of RDEC-1 over the sectioned tissue after exposure to the lectin. An indirect immunophorescent technique will be used to identify RDEC-1 adherence.

Process: The first group of female rabbits was mated in early July. The first two litters were born in mid-August. In the last six weeks, we have sacrificed the rabbits following the schedule outlined above. The frozen tissue is being kept in the Department of Clinical Investigation. At the present time, some of the lectins have not been received, and we are waiting for these so we can go into the second part of the experiment.
**Detail Summary Sheet**

<table>
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<th>Proj No:</th>
<th>C-25-81</th>
<th>Status:</th>
<th>Ongoing</th>
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**TITLE:**

Single-Dose Treatment of Urinary Tract Infections in Women

<table>
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<tr>
<th>Start Date:</th>
<th>1 Apr 81</th>
<th>Est Comp Date:</th>
<th>Sep 82</th>
</tr>
</thead>
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**Principal Investigator**

C. Kenneth McAllister, M.D., LTC, MC

**Dept/Sec:**

Department of Medicine/Infectious Disease

**Associate Investigators:**

AMOSIST personnel

**Key Words:**

Urinary Tract Infection

<table>
<thead>
<tr>
<th>Objective:</th>
<th>To investigate the efficacy and safety of treating women with uncomplicated UTI's of the lower urinary tract with a single dose antibiotic.</th>
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<tr>
<th>To demonstrate a cost savings to the US Army by utilizing a single dose of antibiotic therapy for UTI vs 10-14 days of conventional therapy.</th>
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<table>
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<tr>
<th>To provide a convenient means of treating UTI which optimizes patient compliance and follow-up.</th>
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</table>

**Technical Approach:**

Twenty-six women entered into the study. Study design such that only adult women ages 18-55 with symptoms/signs compatible with cystitis are given 3.0 grams amoxycillin single dose therapy (SDT). SDT patients receive urine culture plus gram stain prior to therapy; and at 3 to 9 days, then the final culture at 4 weeks post treatment.

<table>
<thead>
<tr>
<th>Progress:</th>
<th>Results thus far are 90% curative at initial follow-up. No conclusions have been drawn at this point other than efficacy and safety has been confirmed.</th>
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<tr>
<th>Accumulative MEDCASE</th>
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<th>Periodic</th>
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<tr>
<td>Cost</td>
<td>OMA Cost:</td>
<td>Review Results: Continue</td>
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72
**TITLE:**

The Effect of Sterile Gloves on the Incidence of Contamination and Infection of Intravenous Catheters

<table>
<thead>
<tr>
<th>Start Date: 1 Apr 81</th>
<th>Est Comp Date: Sep 82</th>
</tr>
</thead>
</table>

**Principal Investigator**

Charles E. Davis, Jr., M.D., CPT, MC

**Dept/Sec:**

Department of Medicine/Infectious Disease

**Key Words:**

Intravenous catheters
Infection
Contamination

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**Objective:** To study the effect of the use of sterile gloves during the insertion of intravenous catheters on the incidence of infection of indwelling intravenous catheters and sepsis secondary to intravenous catheter infection.

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**Technical Approach:** Participants will be divided into two groups. Group 1 will have the IV inserted by one of the investigators with the added precaution of wearing of sterile gloves. Group 2 will have the catheter inserted in a similar manner but without sterile gloves. Skin cultures will be taken before and after placement of the IV.

The following variables will be analyzed: Relation of technique of insertion to (1) incidence of pre and post-insertion positive skin cultures, (2) incidence of positive catheter culture and time to occurrence, (3) incidence of phlebitis and time to occurrence and (4) incidence of catheter being the source of bacteremia to occurrence.

**Progress:** Due to a change in principal investigators, no progress has been made.
Detail Summary Sheet

Date: 16 Oct 81  Proj No: C-27-81  Status: Ongoing

TITLE:

Start Date: 1 Apr 81  Est Comp Date: Unknown
Principal Investigator  Facility
Stuart J. Salasche, M.D., LTC, MC  Brooke Army Medical Center
Dept/Sec:  Associate Investigators:
Department of Medicine/Dermatology
Key Words:
Karyology
Basal Cell Epithelioma
Cell culture

Accumulative MEDCASE  Est Accumulative  Periodic
Cost:  OMA Cost: $123  Review Results: Continue

Objective: To investigate chromosomal abnormalities in basal cell epithelioma cells and to initiate a cell culture line for this and further studies.

Technical Approach: Part of the tissue specimen taken for biopsy for basal cell carcinoma is taken to the lab and pure BCC islands devoid of fibrous stroma are torn out, chopped up and placed in cell culture media and then incubated.

Progress: Progress has been virtually nil due to several problems, most notably the cell culture lines becoming infected and discarded within 48 hours. Antibiotics added to media so far has not helped.
In vitro Synthesis of Immunoglobulins and Suppressor Cell Activity in Patients with Solid Tumors and Lymphomas on and off Therapy

Start Date: 1 Apr 81
Est Comp Date: Jun 82

Objective: To evaluate the in vitro synthesis of immunoglobulins in patients with different types of tumors.

To determine whether suppressor T-cell activity is increased in patients with lymphoma as compared with solid tumor patients.

To assess the effect of chemotherapy on immunoglobulin synthesis and suppressor cell activity in both groups of patients.

Technical Approach: 20 cc of blood are obtained from each patient by venipuncture. Peripheral blood lymphocytes are isolated by sedimentation on Ficoll-Hypaque. The cells are assayed for their proliferative responses to mitogens and their ability to synthesize immunoglobulins by a reverse hemolytic plaque assay. Mixed lymphocyte cultures are also carried out to determine the cells ability to suppress proliferation and antibody synthesis by normal lymphocytes.

Progress: Forty-eight patients have been studied so far in nine separate experiments. Twelve of the patients were studied before and after chemotherapy. There were no significant differences in proliferative responses or antibody synthesis. However, there appears to be decreased suppression of normal cells after therapy.
Detail Summary Sheet

Date: 16 Oct 81  Proj No:  C-29-81  Status: Ongoing

TITLE: Treatment of Severe Erythema Multiforme with Systemic Steroids

Start Date: 3 Apr 81  Est Comp Date: Unknown
Principal Investigator Charles W. Lewis, M.D., COL, MC
Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology
Associate Investigators: Nancy D'Silva, M.D., CPT, MC
Key Words: Erythema multiforme  Eric W. Kraus, M.D., MAJ, MC
Steroids

Accumulative MEDCASE:  Est Accumulative Cost:  OMA Cost:  Periodic Review Results: Continue
Objective: To determine if Prednisone is effective in the treatment of severe erythema multiforme.

Technical Approach: A 3-4 mm punch biopsy or an excisional biopsy for H and E will be performed as confirmation of the clinical diagnosis. Direct immunofluorescence will be performed on the biopsy specimen in an effort to demonstrate immune deposit if present. Involved areas will be photographed upon entrance into the study. Follow-up photographs will be taken at 1, 3, 7, and 15 days after institution of prednisone of placebo therapy.

Progress: So far we have not received any appropriate patients for the study.
Detail Summary Sheet

Date: 16 Oct 81  Proj No: C-31-81  Status: Ongoing

TITLE: Profile of Aortic Impedance in Patients with Congestive Cardiomyopathy

Start Date: 11 May 81  Est Comp Date: May 82

Principal Investigator: Joseph P. Murgo, M.D., COL, MC

Dept/Sec: Department of Medicine/Cardiology

Key Words: Aortic impedance, Congestive cardiomyopathy, Cardiac catheterization

Accumulative MEDCASE Cost:  Est Accumulative OMA Cost: Periodic Review Results: Continue

Objective: To evaluate the role of afterload reduction and exercise on the aortic impedance profile of patients with congestive cardiomyopathy.

Technical Approach: Patients admitted to this study have undergone elective cardiac catheterization to evaluate the possibility of surgically correctable problems and to assess the hemodynamic response to afterload reduction by nitroprusside and exercise. Routine left and right heart catheterizations were performed. High-fidelity multisensor pressure velocity catheters were employed to obtain simultaneous aortic pressure and flow-velocity information. This data was stored on electromagnetic tape and submitted to a computer for Fourier analysis following the catheterization procedures. Standard hemodynamic parameters were evaluated and the aortic input impedance spectra plotted.

Progress: To date, data have been obtained from ten patients with congestive cardiomyopathy. Work continues in data analysis and a preliminary statistical analysis has been performed. Nitroprusside increased cardiac output and reduced left ventricular end-diastolic pressure. No significant change in heart rate was found. Exercise resulted in an increase in heart rate, slight change in cardiac output and significantly increased pulmonary capillary pressure.
Objective: To gather detailed information about renal function in patients with primary hyperparathyroidism at the time of diagnosis, and to follow these functions serially in patients not undergoing surgery. These data should permit a more precise estimate of the risk of "medical" therapy versus "surgical" therapy in patients with mild, asymptomatic, primary hyperparathyroidism.

Technical Approach: Patients entered into this study are being admitted to the hospital for 5-days of metabolic balance studies and renal function tests which include the ability to concentrate and dilute the urine. Response to ammonium chloride loading and bicarbonate administration, calcium excretion and assorted data on endocrine function including parathyroid hormone assays are also being obtained at the same time.

Progress: To date seven patients have been entered and completed the first phase of the study and are now being followed in the Renal Clinic. Three more patients have been identified who are suitable for entrance into the study and will be studied when facilities are available.
The Effect of Propranolol on Cardiac Ejection Fractions as Determined by Gated Scans in Thyrotoxic Patients

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

Technical Approach: MUGA studies are being done on Grave's patients at 0 and 3 hours pre- and post-institution of Propranolol therapy 60 mg. p.o. Six patients have had MUGA studies. The decrease in dv/dt and ejection fraction has been consistent except in one case where the second MUGA was done at 2 hours.

Progress: We do not have a severely ill patient to draw a conclusion. But, in normals, a mild decrease in ejection fraction occurs at 3 hours.
Detail Summary Sheet

Date: 16 Oct 81  Proj No: C-35-81  Status: Ongoing

TITLE:
Hepatic Artery Embolization in the Management of Primary or Metastatic Hepatic Neoplasm

Start Date: 15 Jun 81  Est Comp Date: Jun 83

Principal Investigator
Walter H. Harvey, M.D., CPT, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Oncology

Associate Investigators:
J. Dean McCracken, M.D., COL, MC

Key Words:
Hepatic artery embolization
Hepatic neoplasm

Accumulative MEDCASE  Est Accumulative Periodic
Cost: OMA Cost: Review Results: Continue

Objectives: To determine the response rate of hepatic embolization of primary or metastatic neoplasia in liver.

To evaluate the morbidity of hepatic embolization.

To evaluate the response rates of patients undergoing embolization with metastatic disease to liver to a historical control group.

Technical Approach: Hepatic artery embolization using Ivalon\textsuperscript{R} particles for peripheral embolization and steel coils for proximal embolization was utilized in the management of patients with hepatic neoplasm. Nine patients with regionally confined disease in the liver and who had failed either hepatic artery infusion or systemic chemotherapy were eligible. Embolization was carried out through a percutaneous femoral approach. Hepatic artery placement was verified by angiography.

Progress: Six patients with colon cancer and one patient each with hepatoma, squamous cell carcinoma and uterine leiomyosarcoma make up the study group. Seven patients are still alive with two patients deceased. No deaths were attributable to the embolization procedure. Median follow-up time is 3 months. The longest follow-up is eight months with the patient alive and with stable disease in the liver. Although this study is limited by the short follow-up period and few numbers of patients, hepatic artery embolization may be useful in the management of regionally confined hepatic neoplasm.
Title: Comparison of Gray-Scale Ultrasonography and Computed Tomography with Infusion Nephrotomogram in Early Diagnosis of Adult-type Polycystic Kidney Disease

Start Date: 15 Jun 81  Est Comp Date: Jun 83

Principal Investigator: Lucius F. Wright, M.D., MAJ, MC
Facility: Brooke Army Medical Center

Dept/Sec: Associate Investigators:
Department of Medicine/Nephrology
Harold Cable, M.D., CPT, MC

Key Words:
- Polycystic kidney disease
- Gray-scale ultrasonography
- Computed tomography
- Nephrotomogram

Objective: To compare Gray-scale ultrasonography and abdominal computed tomography to infusion nephrotomography in establishing the diagnosis of adult-type polycystic kidney disease in asymptomatic persons at risk.

Technical Approach: Children of patients known to have polycystic kidney disease who agree to be screened will have infusion nephrotomography, Gray-Scale ultrasonography and abdominal CT scan with and without contrast enhancement to assess them for the presence of polycystic kidney disease. The patients who are to be studied have a 50% risk of having inherited the disease from their infected parent. These studies will be reviewed all at one time after they are obtained by investigators who are blinded to the results of the other studies.

Progress: Thus far, four subjects have been entered into the study, and approximately fifteen others have been identified who are likely to qualify for admission.
**Detail Summary Sheet**

**Date:** 16 Oct 81  
**Proj No:** C-37-81  
**Status:** Ongoing

**TITLE:**  
Evaluation of Curettage and Electrodesiccation in Treatment of Human Basal Cell Epitheliomas

<table>
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<th>Start Date:</th>
<th>15 Jun 81</th>
<th>Est Comp Date:</th>
<th>Jun 82</th>
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<tbody>
<tr>
<td>Principal Investigator</td>
<td>Stuart J. Salasche, M.D., LTC, MC</td>
<td>Facility</td>
<td>Brooke Army Medical Center</td>
</tr>
<tr>
<td>Dept/Sec:</td>
<td>Department of Medicine/Dermatology</td>
<td>Associate Investigators:</td>
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| Key Words: | Basal cell epithelioma  
Curettage  
Electrodesiccation | |

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<th>Accumulative MEDCASE</th>
<th>Est Accumulative Cost:</th>
<th>Periodic Review Results:</th>
<th>Continue</th>
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</table>

**Objective:** To assess the adequacy of curettage and electrodesiccation as a method of treatment for basal cell epitheliomas of the skin in a prospective study.

**Technical Approach:** Patients with small, previously untreated basal cell carcinoma were treated in the standard fashion with electrodesiccation and curettage. After completion of the procedure a small surgical saucerized excision was taken 1 mm around and under the defect and subjected to frozen section inspection in order to determine if any tumor cells remained. If tumor cells were identified, further tissue was taken until a tumor free plane was attained.

**Progress:** Fifty study cases have been completed thus far with residual tumor islands found in 12 cases (24%). The majority of these positive cases were from lesions on the nose and in the nasolabial fold. Since the anticipated overall cure rate with this procedure is claimed to be 95% for these small, primary BCE, we feel our findings are very significant and plan to continue the study to statistically significant numbers.
Detail Summary Sheet

Date: 16 Oct 81  Proj No: C-38-81  Status: Ongoing

TITLE:
The Use of Mannitol and Lasix in Intractable Ascites

Start Date: 15 Jun 81  Est Comp Date: Jun 82

Principal Investigator
Willie R. Whitaker, M.D., CPT, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Internal Medicine

Associate Investigators:
Lucius F. Wright, M.D., MAJ, MC

Key Words:
Intractable ascites
Mannitol
Lasix

Objective: To compare Thiazide to a combination of Mannitol plus Lasix in maintaining urine output and mobilizing intractable ascites in patients with cirrhosis.

Technical Approach: Patients admitted to the Gastroenterology Service with ascites that fails to respond to bed rest and sodium restriction are eligible for diuretic therapy with either Thiazide or Mannitol and Lasix. The choice of treatment is determined randomly and after three days to assess response a crossover phase is provided.

Progress: This is a new study and thus far no patients have been entered.
**Detail Summary Sheet**

<table>
<thead>
<tr>
<th>Date:</th>
<th>16 Oct 81</th>
<th>Proj No:</th>
<th>C-39-81</th>
<th>Status:</th>
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<tr>
<td><strong>TITLE:</strong></td>
<td>Program on the Surgical Control of the Hyperlipidemias</td>
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<tr>
<td><strong>Start Date:</strong></td>
<td>15 Jun 81</td>
<td><strong>Est Comp Date:</strong></td>
<td>Jun 86</td>
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<tr>
<td><strong>Principal Investigator</strong></td>
<td>Ronald R. Blanck, COL, MC</td>
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<tr>
<td><strong>Dept/Sec:</strong></td>
<td>Department of Medicine</td>
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<tr>
<td><strong>Key Words:</strong></td>
<td>Hyperlipidemias, Myocardial infarction, Atherosclerosis</td>
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</table>

**Objective:** To follow atherosclerotic plaque progression in coronary arteries in patients following myocardial infarction who have been randomized into a control group and a group that has experienced marked cholesterol reduction by modified intestinal bypass. By extension, this is a test of the hypothesis that altering lipid levels significantly alters atherosclerosis.

**Technical Approach:** Data is being collected from clinical record cover sheets and patients contacted for possible inclusion in the study.

**Progress:** So far, none of the actual study has been carried out at Brooke Army Medical Center, though it is anticipated this will occur next fiscal year.
Objective: To study the quantitative role of the liver in the homeostasis response of a conscious dog to acute hyperkalemia.

Technical Approach: The approach used involves quantitatively time integrated response of serum potassium to infusion of potassium under a variety of metabolic circumstances. In an effort to develop data on the quantitative role in the liver and maintenance of internal homeostasis and protection against acute hyperkalemia, cannulas will be placed to permit sampling of the portal and hepatic vein. The technical approach has not varied from that described in the original clinical investigation protocol.

Progress: This project will be initiated once the clinical investigation animal facility is available.
**Objective:** To determine if $H_1$ and $H_2$ receptor blockade singly or in combination cause a reduction in serum concentrations of parathormone and ionized calcium in a patient with hypoparathyroidism.

**Technical Approach:** A patient with hypoparathyroidism was placed on a metabolic diet off all diuretics, calcium, and vitamin D supplements. Once serum calcium stabilized, the patient was started on thiazide diuretic and salt-restricted diet in an attempt to raise serum calcium levels (Porter et al NEJM 298:11577, 1978). Patient still required supplemental calcium and vitamin despite these measures. He was then challenged with cimetidine for three days which failed to produce any decline in serum.

**Progress:** Patient's serum calcium was 7.0-7.2 mg% at the initiation of the study. With the restriction of sodium intake and administration of thiazide diuretics, serum calcium declined even further to less than 6.0 mg%. Electrocardiogram showed Q-T prolongation and patient had positive Trousseau's sign at this point in his course. On hospital day nine, 1.25-dihydroxy Vitamin D was started along with calcium supplements. Serum calcium increased over a period of several days to about 8.0 mg% and remained stable at that despite subsequent challenge with cimetidine. Joint challenge with $H_1$ receptor blockers (hydroxyzine) and $H_2$ receptor blockers (cimetidine) were not performed due to fact patient had already spent three weeks in the hospital.
Effect of Aspirin (ASA) on Airway Responses

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

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

Progress: Currently awaiting necessary MEDCASE items to be purchased to begin this project.
DATE: 16 Oct 81     Proj No: C-54-81     Status: Ongoing

TITLE: Phosphate Homeostasis in the Normal and Renal Failure Dogs

Start Date: 6 Aug 81     Est Comp Date: Unknown

Principal Investigator
Lucius P. Wright, M.D., MAJ, MC

Dept/Sec: Department of Medicine/Nephrology

Facility
Brooke Army Medical Center

Associate Investigators:
Charles J. Foulks, M.D., MAJ, MC

Key Words:
Homeostasis
Renal failure

Accumulative MEDCASE: Estimate
Accumulative OMA Cost: Review
Periodic Cost: Continue

Objective: To define the kinetics of phosphate elimination in response to a number of maneuvers in normal dogs and in dogs with experimentally induced reductions in renal failure. These data will be used to examine the hypothesis that secondary hyperparathyroidism develops in early renal failure as a consequence of the need to amplify the renal excretory response to phosphate loading that occurs as an inevitable result of eating.

Technical Approach: This protocol is designed to test the feasibility of developing time integrated constants for serum phosphate and urine phosphate excretion in response to intravenous and oral phosphate loading in conscious dogs.

Progress: Implementation of this study awaits completion of the Clinical Investigation Laboratory Animal Facility.
Detail Summary Sheet

Date: 16 Oct 81  Proj No: C-56-81  Status: Ongoing

TITLE:
Evaluation of Indomethacin as a Protective Agent Against Radiation-Induced Esophagitis

Start Date: 17 Aug 81  Est Comp Date: Aug 82

Principal Investigator
Robert A. Berendson, M.D., MAJ, MC

Dept/Sec:
Department of Medicine/Gastroenterology

Associate Investigators:
John F. Schultheiss, M.D., LTC, MC
Gary West, M.D., COL, USAF, MC
John R. Sharp, M.D., LTC, USAF, MC

Key Words:
Esophagitis
Radiation therapy

Objective: To determine if the administration of Indomethacin to patients undergoing radiotherapy of the chest area will prevent the development of esophagitis.

Technical Approach: Patients receiving radiation therapy for different mediastinal tumors in a port that will include radiation to the esophagus will be randomized blindly into four groups - one group of controlled subjects and three groups which will receive three different dose levels of Indomethacin, an agent that has been demonstrated in animal studies to be protective for radiation-induced esophagitis. The patients will undergo, prior to radiation therapy, esophagoscopy with photographs, with biopsies and brushings being taken at this time. At the completion of radiotherapy, each patient will undergo a second endoscopy with biopsy, photography, and collection of serum specimens. The patients will be asked to report any difficulty with odynophagia or dysphagia at weekly intervals. The treatment group will be compared with the control group and with each other using Student's Test and a one-way fixed effect model analysis of variance.

Progress: This is a new study. The placebo tablets have been obtained and, in the course of the next few weeks, we intend to go ahead with the coding of the placebo and the Indomethacin tablets. We expect to start including patients in the study in the near future.
Detail Summary Sheet

Date: 16 Oct 81  Proj No: C-58-81  Status: Ongoing

TITLE:
The Specificity of the Priming on the Nasal Mucous Membranes by Allergens and the Effect of Pharmacological Intervention

Start Date: 20 Aug 81  Est Comp Date: Aug 83

Principal Investigator
Daniel A. Ramirez, M.D., LTC, MC

Dept/Sec:
Department of Medicine/Allergy-Immunology

Key Words:
Allergen
Nasal mucous membranes

Accumulative MEDCASE Cost: OM Cost:

Periodic Review Results:
Continue

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

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

Progress: The equipment necessary to perform nasal airway resistance measurements is not available. We are waiting for MEDCASE items to be purchased so this project can be started.
**Detail Summary Sheet**

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<th>Date:</th>
<th>16 Oct 81</th>
<th>Proj No:</th>
<th>C-59-81</th>
<th>Status:</th>
<th>Ongoing</th>
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</table>

**TITLE:** Utility of Urological Investigation of Females with Invasive Urinary Tract Infections

**Start Date:** 20 Aug 81  
**Eat Comp Date:** Aug 82

**Principal Investigator**  
John L. Carpenter, M.D., LTC, MC

**Facility**  
Brooke Army Medical Center

**Dept/Sec:** Department of Medicine/Infectious Disease

**Associate Investigators:**  
C. Kenneth McAllister, M.D., LTC, MC

**Key Words:**  
Urinary tract infection  
Cystoscopy  
Intravenous pyelogram

**Objective:** To investigate the sensitivity and specificity of intravenous pyelograms and cystoscopies in female patients who have failed single-dose treatment of urinary tract infections.

To determine the cost effectiveness of these urological investigations in this subset of patients with urinary tract infections.

**Technical Approach:** All patients who failed single dose amoxycillin therapy for urinary tract infections as per the protocol C-25-81 are entered onto the protocol. They undergo cystoscopy and intravenous pyelogram in order to determine the percent of such patients who have surgically correctible anatomic defects that contribute to urinary tract infections.

**Progress:** At the present time no patients have been entered onto this protocol.
**Detail Summary Sheet**

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<td><strong>TITLE:</strong></td>
<td>A Phase IV Surveillance Study of Sucralfate in the Treatment of Duodenal Ulcer Disease - An Open Label Study</td>
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<tr>
<td><strong>Start Date:</strong></td>
<td>1 Sep 81</td>
<td><strong>Est Comp Date:</strong></td>
<td>Jun 82</td>
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<tr>
<td><strong>Principal Investigator:</strong></td>
<td>John F. Schultheiss, M.D., LTC, MC</td>
<td><strong>Facility:</strong></td>
<td>Brooke Army Medical Center</td>
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<tr>
<td><strong>Dept/Sec:</strong></td>
<td>Department of Medicine/Gastroenterology</td>
<td><strong>Associate Investigators:</strong></td>
<td>Robert A. Berendson, M.D., MAJ, MC; Leonard Duran, M.D., CPT, MC; Joseph W. Jackson, M.D., MAJ, MC, USAF</td>
</tr>
<tr>
<td><strong>Key Words:</strong></td>
<td>Duodenal ulcer disease; Sucralfate</td>
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<th>Periodic Review Results:</th>
<th>Continue</th>
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<tbody>
<tr>
<td><strong>Objective:</strong></td>
<td>To observe the use of Sucralfate in a population of duodenal ulcer patients for effectiveness and to detect possible adverse reactions.</td>
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</table>

**Technical Approach:** Participants will be asked to take one Sucralfate tablet on an empty stomach one-half hour before meals three times a day and at bedtime. During the course of the study, participants will be asked to refrain from using aspirin, aspirin-containing drugs, and any analgesics they have been using to relieve ulcer symptoms. Treatment will terminate at the end of six weeks.

**Progress:** This is a new study.
Objective: To determine the safety and efficacy of sulconazole nitrate 1% solution in the treatment of acute symptomatic tinea pedis in adult men and women as compared to 1% clotrimazole solution.

Technical Approach: In this double-blind parallel comparison patients will be treated once a day for four weeks with 1% sulconazole or 1% clotrimazole solution. Patients will be examined on initiation of therapy, at two weeks, and on completion of four weeks of therapy. To determine relapse rate, patients who are KOH negative at four weeks will return for examination four weeks after the end of therapy.

Progress: This is a new study.
TITLE: Double-Blind Parallel Comparison of Sulconazole Nitrate 1% Cream and Miconazole Nitrate 2% Cream in the Treatment of Symptomatic Tinea Pedis

Start Date: 24 Sep 81

Principal Investigator
Charles W. Lewis, M.D., COL, MC

Facility
Brooke Army Medical Center

Associate Investigators:
Eric W. Kraus, M.D., MAJ, MC

Dept/Sec: Department of Medicine/Dermatology

Key Words:
Tinea Pedis

Accumulative MEDCASE Cost:
Est Accumulative OMA Cost:
Periodic Review Results: Continue

Objective: To compare the safety and efficacy of sulconazole nitrate 1% cream in the treatment of symptomatic tinea pedis in adult men and women as compared to that of miconazole nitrate 2% cream.

Technical Approach: Patients will be treated once a day for four weeks with either sulconazole or miconazole nitrate cream. The two drugs will be randomly assigned. Patients will be examined on initiation of therapy, at two weeks, and on completion of four weeks of therapy. Patients who are KOH negative after four weeks of therapy will be re-examined at eight weeks to determine the incidence of relapse.

Progress: This is a new study.
DATE: 9 Nov 81  Proj No: C-12-79  Status: Ongoing  

TITLE: Clinicopathologic Study of Uterine Vascular Changes with and without Hormonal Influence

Start Date: Mar 79  
Facility: Brooke Army Medical Center  

Principal Investigator  
Charles V. Wilson, M.D., CPT, MC  

Dept/Sec: Department of Obstetrics and Gynecology  
Associate Investigators: Milton H. Leman, M.D., COL, MC  

Key Words:  
Uterine vascular changes  
Oral contraceptives

Accumulative MEDCASE:  
Cost:  
OMA Cost:  
Periodic Review Results: Continue

Objective: To study the association of intimal thickening of uterine arteries with oral contraceptive use in women undergoing hysterectomy with and without cervical and uterine pathology.

Technical Approach: All patients undergoing hysterectomy by an abdominal or vaginal route are eligible for the study and will have their operation performed in the standard manner. The operative specimen will be taken directly by the pathologist for both electron microscopic and light microscopic fixation and preparation. Sections will be made of both uterine and myometrial vessels and examined for intimal thickening and other abnormal vascular changes. The patients will be divided into study groups for comparison as follows: Group I - no hormonal exposure; and Group II - hormonal exposure, 50-100 micrograms, for 1 year, 1-2 years, or 2 years or more.

Progress: This project was temporarily delayed due to inability to obtain pathological data. This situation has been rectified and patients are once again being enrolled on the study.
Objective: To determine whether Fluorouracil cream is a better therapeutic agent with less side effects and toxicity than Podophyllum.

Technical Approach: Participants in the study were divided into two groups. To insure the groups were scientifically comparable, they were stratified based on the size and number of lesions. Group I was treated with 5% Fluorouracil cream for 5 days each week x 4 weeks. Group II received application of podophyllum once each week x 4 weeks.

Progress: Sixteen patients were entered into the study. In Group II six patients were treated; three were stratified in the less than 1 cm group, and three were greater than 1 cm. In Group I three patients had lesions less than 1 cm and seven had lesions greater than 1 cm.

The overall average response was a response grade of 3.3 in 3 weeks for fluorouracil versus a response grade of 2.7 over 3.5 weeks for podophyllum. Though these numbers are still insufficient to be significant, the 5-FU appears to be more efficacious in the larger condyloma than podophyllum.
**Detail Summary Sheet**

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<th>Date:</th>
<th>20 Apr 81</th>
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**TITLE:**
Identification of T-cell Leukemias-Lymphomas with Heterologous Antisera

**Start Date:** Jan 80  
**Est Comp Date:**

<table>
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<th>Principal Investigator</th>
<th>Facility</th>
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<tbody>
<tr>
<td>Lizardo Corzo, M.D., LTC, MC</td>
<td>Brooke Army Medical Center</td>
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<thead>
<tr>
<th>Dept/Sec:</th>
<th>Department of Pathology</th>
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<tr>
<td>Associate Investigators: Isidoro Chapa, DAC</td>
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**Key Words:**
- T-cell lymphoid neoplasms
- Non-T leukemias-lymphomas

**Objective:** To use anti-human peripheral T-cell serum and anti-human brain serum (in addition to other currently established techniques) to distinguish T-cell lymphoid neoplasms from non-T leukemias-lymphomas in adult and pediatric patients. Pathologic diagnoses, initial extent of disease, age groups and remission rates will be compared between the two groups.

**Technical Approach:**

**Progress:** We have not been able to demonstrate the specificity of our rabbit sera for peripheral CLL B-cells or of our rabbit anti-human brain sera for T-cells.

In view of the fact that anti-T and anti-B antisera are now commercially available, the study is terminated.
Objective: To study multiple cytochemical parameters of epithelial neoplasms and thereby determine if cytochemical profiles may contribute to the accurate diagnosis of these tumors. The study would also evaluate the feasibility and reliability of cytochemistry of postmortem tissues.

Technical Approach: We will attempt to study 50 cases which will first be separated into diagnostic groups (based on light and electron microscopic interpretations). Within each group autopsy vs surgical specimens will be distinguished. In this fashion, within similar tumor groups, we will evaluate if major difference exists in staining reactions between biopsy and postmortem tissues and if certain reactions are characteristic for specific tumor types.

Progress: This study was terminated due to the release from active duty of the principal investigator.
DATE: 16 Oct 81  
PROJ No: C-21-80  
STATUS: Ongoing

TITLE: In Vitro Demyelination and Remyelination of Cultured Mammalian Central Nervous Tissue.

Start Date: 7 May 1980  
Est Comp Date: Jan 82

Principal Investigator: Roby P. Joyce, M.D., MAJ, MC

Facility: Brooke Army Medical Center

Dept/Sec: Department of Pathology

Associate Investigators:

Key Words: Demyelination, Remyelination, Central Nervous Tissue

Accumulative MEDCASE Cost:  
OMA Cost: $805

Periodic Review Results: Continue

Objective: To establish at Brooke Army Medical Center the capability to study demyelination and remyelination of mammalian central nervous tissue in a reliable cell culture laboratory model.

Technical Approach: Minced newborn mouse cerebellum is cultured in Eagle's basic medium enriched with fetal calf serum and glucose at 35.5°C in a 5% CO₂ incubator. Twice weekly the cultures are washed and fed. Using an inverted tissue culture microscope and 35mm camera attachment, the growth and eventual decline of the colonies is documented.

Progress: Continuing efforts to establish a reliable mammalian central nervous system tissue culture laboratory model for the study of demyelination and remyelination have been frustrated by the lack of consistency of our results. Originally, the cultures were of excellent quality but recent attempts to culture the tissue have been associated with bacterial contamination and failure to grow. Steps being taken to correct these problems include media changes, the use of different incubation techniques, and re-evaluation of our technique (especially regarding sterility).
Detail Summary Sheet

Date: 20 Oct 81
Proj No: C-64-81
Status: Ongoing

TITLE:
Detection of Rotavirus in Selected Pediatric Patients Utilizing Rotazyme, Rotavirus Diagnostic Kit

Start Date: 23 Sep 81
Est Comp Date: Aug 82

Principal Investigator
Thomas R. Perez, DAC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Pathology/Virology

Associate Investigators:
S. Vern Juchau, M.D., LTC, MC
James Higbee, Ph.D., MAJ, MSC
George J. Kasai, Ph.D.,
Paula Mosman, DAC

Key Words:
Rotavirus
Rotazyme, Rotavirus Diagnostic Kit

Accumulative MEDCASE Cost: OMA Cost: Periodic Review Results: Continue

Objectives:
To field test the Rotazyme Kit as a possible new diagnostic procedure for detection of active rotavirus infections in pediatric gastroenteritis patients.

To provide a definitive rotavirus diagnosis allowing physicians to make a proper diagnosis and alert him to potential complications.

To potentially reduce the use of antimicrobial agents

To provide better patient management.

To determine BAMC area seasonal period for rotavirus infections.

Technical Approach:
A stool sample will be submitted for rotavirus and bacterial culture. If a stool sample is impractical, a rectal swab may be submitted using a "Virocult" for rotavirus study and a bacterial "Culturette" for bacterial culture. The stool/rectal swab submitted will be processed by standard methods for detection of other possible viral agents. Specimens will also be analyzed using the Rotazyme, Rotavirus Diagnostic Kit.

Progress: This is a new study.
Assessment of Opsonic Capacity and Phagocytic Function in the Newborn
Using Microliter Quantities of Whole Blood

Objective: To employ recently devised chemiluminescent techniques to investigate the humoral-phagocyte axis of immune defense in neonates. In particular:

A. Opsonic activity of neonate and maternal serum to different bacterial antigens.

B. Assessment of classical complement activity and also alternative complement activity in neonates with comparison to maternal and control adult serum.

C. Assessment of neonate polymorphonuclear leukocyte microbicidal metabolic responsiveness to immune and non-immune stimuli.

Technical Approach: Maternal bloods were collected by venipuncture with the routine laboratory blood specimens at the time of presentation in labor. Infant blood was collected from the ligated umbilical cord at delivery. At three days of age, blood is routinely obtained from the infant for PKU determination. Any additional drops of blood will be collected at this time and used for PMNL testing and where possible for measurement of opsonic capacity. At two weeks of age a repeat PKU is drawn by heel stick. Any additional drops of blood will be collected and assayed as described above.

Progress: The results indicate that maternal specific activity is high-normal using the luminol-opsonified zymosan technique. This view is consistent with the observation that myeloperoxidase activity is higher in pregnant females. The specific activity of newborn cord blood phagocytes was, however, significantly depressed relative to maternal or control specimens. The specific oxygenation responses using DBA-PMA were
equivalent for control and maternal specimens; but once again, the newborn specimens were depressed as measured by this technique. The results support the conclusion that both myeloperoxidase and superoxide associated oxygenation by phagocytes in newborn whole blood are depressed at the time of birth.
Date: 1 Oct 81  Proj No: C-35-74  Status: Ongoing

**TITLE:**
Clinical Evaluation of Cisternography Utilizing \textsuperscript{111}Indium DTPA.

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<th>Start Date: 25 Jan 74</th>
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<tr>
<td>Principal Investigator</td>
<td>Facility</td>
</tr>
<tr>
<td>Robert J. Telepak, M.D., LTC, MC</td>
<td>Brooke Army Medical Center</td>
</tr>
<tr>
<td>Dept/Sec:</td>
<td>Associate Investigators:</td>
</tr>
<tr>
<td>Department of Radiology/Nuclear Medicine</td>
<td>Ronald K. McCauley, M.D., MAJ, MC</td>
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**Key Words:**
- Cisternography
- Hydrocephalus

<table>
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<tr>
<th>Accumulative MEDCASE</th>
<th>Est Accumulative</th>
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<td>Cost:</td>
<td>OMA Cost:</td>
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**Objective:** To evaluate the safety and efficacy of \textsuperscript{111}Indium DTPA for cisternography.

**Technical Approach:** The isotope is introduced intrathecally. The patient is imaged at 6 and 24 hours after injection. Progress of the isotope is followed. Cotton pledgets are placed in the nose and ears of patients suspected of CSF leaks. They are removed and counted at 6 and 24 hours.

**Progress:** Three patients have been scanned in the past year. The information provided by this procedure has been very valuable in documenting problems involving CSF.
Date: 1 Oct 81  Proj No: C-12-77  Status: Ongoing

TITLE: Intravenous Administration of ¹³¹I (NP 59) for Adrenal Evaluation of Imaging.

Start Date: 15 Nov 76  Est Comp Date: Not known

Facility
Brooke Army Medical Center

Associate Investigators:
Roswell N. Beck, Jr., M.D., MAJ, MC
Ronald K. McCauley, M.D., MAJ, MC

Key Words:
Adrenal scan, NP-59

Objective: 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: The patient is injected I.V. with 1-2 millicuries of I-¹³¹I labeled NP 59. Scanning over the adrenal glands is performed at 3 days and again at approximately 7 days after injection. Visual image interpretation as well as computer enhanced processing of the images is used to evaluate them. In selected patients, two repeat studies employing dexamethasone suppression may also be performed.

Progress: During the past year, there was no usage of this product. The protocol is being maintained in an active status should a diagnostic need arise.
Objective: To evaluate the clinical efficacy of Tc-99m-PG as a diagnostic hepatobiliary and gallbladder agent.

Technical Approach: The patient is injected with 15 millicuries of 99m technetium labeled pyridoxylideneglutamate (PYG) with images obtained every 5 minutes in the anterior projection. In normal persons, activity is promptly seen in the liver, and then concentrates in the biliary tree with visualization of the gallbladder usually by 30 minutes after injection and evidence of activity within the bowel shortly thereafter. The scan is most useful for evaluating acute cholecystitis in which the gallbladder is not visualized because of obstruction of the cystic duct. The scan is also useful for evaluating patency of the biliary tree into the bowel and also for evaluating surgical anastomoses and shunts involving the biliary tree.

Progress: During the past year four patients were scanned. Although the studies provided very useful diagnostic information, the protocol was terminated due to the availability of a new product (99mTc Diethyl-IDA) which provides information considerably more useful in diagnosing the integrity of the hepatobiliary system.
**Detail Summary Sheet**

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<th>Date:</th>
<th>16 Oct 81</th>
<th>Proj No:</th>
<th>C-22-80</th>
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**TITLE:**
Correlation of Epidurography with Anatomical Investigation of the Lumbar Spinal Canal.

<table>
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<tr>
<th>Start Date:</th>
<th>23 Jun 80</th>
<th>Est Comp Date:</th>
<th>Jun 81</th>
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**Principal Investigator**
Nadi S. Hibri, M.D.

**Dept/Sec:**
Department of Radiology

**Key Words:**
Epidurography
Herniated nucleus pulposus

**Objective:** To gain a better understanding of the relationship of a herniated nucleus pulposus to the epidural and subarachnoid spaces.

**Technical Approach:** The spines are prepared at the time of autopsy in the following manner: a mixture of Knox gelatin, Renografin M-60 and acrylic paint is heated to approximately 80°C and then cooled to room temperature while stirring. The mixture is subsequently injected as a liquid into the epidural space, the vertebral bodies of L4 and L5, and the subarachnoid space. The specimen is cooled after it is removed which allows the injected mixture to gel and harden. Then CT of the lumbar spine is performed. Finally, the specimen is frozen solid and ban-sawed in as nearly as possible the same plane as that used for the CT sections. The ban-sawed sections are then thawed and photographed in color.

**Progress:** Four cadavers were examined in which we demonstrated vividly the relationship of the epidural space to the rest of the spaces within the spinal cord. This new information helped us in appreciating abnormalities on epidurograms we performed on 35 patients with low back pain in whom the clinical findings or myelograms were equivocal.
Detail Summary Sheet

Date: 1 Oct 81  Proj No: C-20-81  Status: Ongoing

TITLE: Technetium-99m-Diethyl-IDA for Diagnosis of Hepatobiliary and Gallbladder Pathology

Start Date: 18 Mar 81  Est Comp Date:

Principal Investigator: Robert J. Telepak, M.D., LTC, MC

Dept/Sec: Department of Radiology/Nuclear Medicine

Associate Investigators: Roswell N. Beck, M.D., LTC, MC

Key Words: Hepatobiliary Scan

Objective: To evaluate the clinical efficacy of 99mTc-EHIDA as a hepatobiliary agent.

Technical Approach: Each patient is studied following a 4-6 hour period of fasting (when possible). Following IV injection of 7-15 mCi of Technetium 99m Diethyl-IDA, simultaneous computer acquisition is performed for further delay analysis. After nuclear images are stored, distribution curve data is derived. Initially, views will be obtained every 5 minutes post injection for the first 30-45 minutes. Additional views are obtained at one hour and 24 hours if obstruction is suspected. If the gallbladder does not visualize in 1-2 hours, acute, chronic cholecystitis or gallbladder dysfunction is suspected.

Progress: During the past year, 75 patients were scanned utilizing this procedure. The results have been remarkable and provided extensive diagnostic data. This procedure provides a safe, rapid, non-invasive evaluation of the hepatobiliary system. Information acquired on patients in many cases eliminates the need for more invasive studies.

107
**Detail Summary Sheet**

**Date:** 16 Oct 81  
**Proj No:** C-21-81  
**Status:** Ongoing

**TITLE:**  
Evaluation of Young Amateur Boxers by Computed Tomography

**Start Date:** 26 Mar 81  
**Eat Comp Date:**

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luis Canales, M.D., COL, MC</td>
<td>Brooke Army Medical Center</td>
</tr>
</tbody>
</table>

**Dept/Sec:** Department of Radiology  
**Associate Investigators:**

**Key Words:**  
Computed tomography

<table>
<thead>
<tr>
<th>Accumulative MEDCASE Cost:</th>
<th>Est Accumulative OMA Cost:</th>
<th>Periodic Review Results:</th>
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</thead>
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</table>

**Objective:** To assess the extent of intracranial abnormalities that may develop in young amateur boxers.

**Technical Approach:** CT scanning if done of amateur boxers (head) after a boxing bout.

**Progress:** Fifteen cases have been studied. No abnormalities were found. More are needed for meaningful conclusions.
Detail Summary Sheet

Date: 20 Oct 81  Proj No: C-65-81  Status: Ongoing

TITLE:
Odontodysplasia and the Trico-Dento-Osseous Syndrome, Type II

Start Date: 23 Sep 81  Est Comp Date: Sep 82

Principal Investigator
Frank Quattromani, M.D., LTC, MC

Dept/Sec:
Department of Radiology

Key Words:
Odontodysplasia
Trico-Dento-Osseous Syndrome

Accumulative MEDCASE
Cost:  Est Accumulative
OMA Cost: $1,290

Periodic Review Results: Continue

Objective: The principal investigator has found odontodysplasia, tightly
coiled hair and calvarial osteosclerosis and thickening in four generations
of a family of German ancestry. A study of the entire family is proposed
not only for genetic counseling purposes, but also to gain a better under-
standing of this disease so that it may be distinguished from other closely
allied syndromes.

Technical Approach: To search for and identify appropriate blood group
markers present in affected individuals as well as those not affected to
determine whether there is association or linkage. Kindred known to have
the TDO Type II association will be examined and a detailed genetic and
historical study of the kindred will be performed.

Blood will be drawn for genetic association and linkage studies as well
as total body roentgenographic examination to demonstrate osseous structures
involved.

Progress: This is a new study.
Clinical Study of Intraocular Lenses.

Objective: 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: Data required for the study is collected and reported to the intraocular lens companies in the individual format required by each company. The data consists of ocular preoperative, operative, and postoperative information with particular emphasis on resulting vision and complications accompanying implantation of the intraocular lenses. The lens manufacturers then compile the data for the nationwide study and supply the FDA with the results.

Progress: In the past year several lens manufacturers have been released from the most detailed (core) investigations and now require only adjunct reporting of data and any adverse reactions.

Patients treated at BAMC have continued to show improved vision postoperatively.
**Detail Summary Sheet**

<table>
<thead>
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<th>Date:</th>
<th>20 Oct 81</th>
<th>Proj No:</th>
<th>C-14-80</th>
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<tbody>
<tr>
<td>TITLE:</td>
<td>Abdominal Wound Closure</td>
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<tr>
<td>Start Date:</td>
<td>Mar 80</td>
<td></td>
<td></td>
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<td>Indefinite</td>
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<tr>
<td>Principal Investigator</td>
<td>Michael J. Spebar, M.D., MAJ, MC</td>
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<tr>
<td>Dept/Sec:</td>
<td>Department of Surgery/General Surgery</td>
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<tr>
<td>Key Words:</td>
<td>Running suture, Interrupted suture, Wound closure</td>
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<tr>
<td>Objective:</td>
<td>To determine if there is a difference in wound closures performed by interrupted or running suture techniques on the fascial layers.</td>
<td></td>
<td></td>
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<tr>
<td>Technical Approach:</td>
<td>Wound closure techniques are evaluated for: (a) time of closure at operation and (b) immediate and long-term postoperative wound complications.</td>
<td></td>
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<tr>
<td>Progress:</td>
<td>The project continues to evaluate wound closure techniques with special reference to the continuous, monofilament suture material and the interrupted wire suture technique.</td>
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<tr>
<td>Associate Investigators:</td>
<td>General Surgery Residents</td>
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<td></td>
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</table>
Date: 20 Oct 81  Proj No: C-20-80  Status: Terminated

TITLE:
Evaluation of St. Jude Prosthetic Heart Valve

Start Date: May 80
Principal Investigator
George F. Schuchmann, M.D., COL, MC
Dept/Sec: Department of Surgery/Cardiothoracic
Key Words:
Prosthetic Heart Valve

Est Comp Date:
Facility
Brooke Army Medical Center

Associate Investigators:

Accumulative MEDCASE Est Accumulative Periodic
Cost: OMA Cost: Review Results:

Objective: Clinical evaluation of the St. Jude Medical bi-leaflet, center opening cardiac valve prosthesis.

Technical Approach:

Progress: Unfortunately, after going to the work of getting this protocol approved, the Company withdrew permission for us to implant St. Jude valves. This withdrawal of permission for use of this prosthesis was requested by FDA.
**Detail Summary Sheet**

**Date:** 20 Oct 81  
**Proj No:** C-7-81  
**Status:** Ongoing

**TITLE:** Open-ended Cutaneous Vasostomy

<table>
<thead>
<tr>
<th>Start Date: 3 Feb 81</th>
<th>Est Comp Date: Sep 82</th>
</tr>
</thead>
</table>

**Principal Investigator**

Rafael V. Mora, M.D., CPT, MC

**Dept/Sec:** Department of Surgery/Urology

**Associate Investigators:**

Mauro P. Gangai, M.D.

**Key Words:**

Spermatic granuloma  
Open-ended cutaneous vasostomy

**Objective:** To avoid the major complications, such as spermatic granuloma of the vas, epididymal discomfort and pain due to intravasal pressure buildup and spontaneous recanalization which often occur in patients who have a vasectomy performed in the conventional manner for surgical sterility.

**Technical Approach:** Under local anesthesia and through separate scrotal incisions, each vas is isolated, ligated distally with Weck clips, the distal end returned to the scrotum, the proximal (testicular end of each vas) spatulated and anastomosed to the lower edge of the incision with 4-0 chromic catgut, as a stoma.

**Progress:** Seventy-eight patients that presented to the Urology Clinic for elective sterilization and followed for six months post vasectomy are the basis of this study. The patients were prospectively randomized into two groups: Group A - a total of 34 patients who underwent the open-ended cutaneous vasostomy and Group B - a total of 41 patients who underwent vasectomy by the conventional technique. The complications in each group were tabulated:

<table>
<thead>
<tr>
<th>Group A (Open-ended vasostomy)</th>
<th>Group B (Ligature vasectomy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistent vascutaneous fistula - 1</td>
<td>Symptomatic sperm granuloma - 3</td>
</tr>
<tr>
<td>Spermatocele at skin level - 1</td>
<td>Spermatocele - 1</td>
</tr>
<tr>
<td>Epididymitis - 3</td>
<td>Epididymitis - 2</td>
</tr>
<tr>
<td></td>
<td>Hematoxydrotele - 1</td>
</tr>
</tbody>
</table>
The purpose of this study was to decrease the sequelae from conventional vasectomy using the open-ended technique. In spite of having a higher percentage of epididymitis (9%) in Group "A", as opposed to 5% in Group "B", there were no patients with symptomatic sperm granuloma in Group "A" as opposed to 7.5% incidence of symptomatic sperm granuloma in Group "B".
**Detail Summary Sheet**

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<tr>
<td>TITLE:</td>
<td>Immunoglobulin A Levels in Blood and Nasal Secretions of Patients with Nasal Polyposis</td>
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<tr>
<td>Start Date:</td>
<td>11 Mar 81</td>
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<td>Facility</td>
<td>Brooke Army Medical Center</td>
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<tr>
<td>Principal Investigator</td>
<td>Warner L. Bruner, M.D., CPT, MC</td>
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<tr>
<td>Dept/Sec:</td>
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<tr>
<td>Key Words:</td>
<td>Accumulative Immunoglobulin A Nasal polyposis</td>
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<td>Accumulative MEDCASE Cost:</td>
<td>Est Accumulative OMA Cost:</td>
<td>Periodic Review Results:</td>
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</table>

**Objective:** A possible etiologic mechanism for nasal polyposis is sought by trying to identify a derangement in the immunologic status of patients with polyps.

**Technical Approach:**

**Progress:** Terminated due to technical difficulty with laboratory support and investigator's desire to approach problem from different aspect.
Objective: To determine if the use of prophylactic, broad-spectrum antibiotics will significantly decrease the incidence of wound sepsis following elective cholecystectomy for chronic cholecystitis and/or cholelithiasis.

Technical Approach: Patients undergoing elective cholecystectomy will be randomized into control and study groups. The control group will receive no antibiotics. The study group will receive intravenous Cefamandole immediately prior to surgery and 6 and 12 hours after surgery. Cultures of bile for aerobes and anaerobes will be obtained intraoperatively. Patients will be followed postoperatively for signs and symptoms of wound sepsis.

Progress: To date, 13 patients have been enrolled in the study group and 7 patients have been enrolled in the control group. Neither group has experienced a wound infection.
Objective: To determine if there is a difference in the therapeutic effectiveness of the Federal Standard 25% Normal Serum Albumin U.S.P. (which requires refrigeration with 10 year shelf life) and the commercially available 25% Normal Serum Albumin U.S.P. (which requires no refrigeration with 3 year shelf life).

Technical Approach: A clinical trial evaluating the clinical response of patients to the commercially available 25% normal serum albumin, non-refrigerated, to the Federal standard 25% normal serum albumin USP. The indications for use of the volume expanders was left up to the treating physicians. The clinical results of the commercially available albumin is compared with the response in patients during the past three years.

Progress: The study is just getting underway. Initial impressions are that there appears to be no difference in the two sources of albumin.
**Detail Summary Sheet**

Date: 21 Oct 81  Proj No: C-30-81  Status: Ongoing

**TITLE:**
Renal Sequelae of Vasectomy

<table>
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<th>Start Date:</th>
<th>10 Apr 81</th>
<th>Est Comp Date:</th>
<th>Apr 83</th>
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<tr>
<td>Principal Investigator</td>
<td>Ian M. Thompson, M.D., CPT, MC</td>
<td>Facility</td>
<td>Brooke Army Medical Center</td>
</tr>
</tbody>
</table>

**Dept/Sec:**
Department of Surgery/Urology

**Key Words:**
Vasectomy
Renal sequelae

**Objective:** To determine, in a retrospective manner, if any changes in renal function occur after vasectomy.

**Technical Approach:** As per the requested change recently submitted, the protocol has been changed to incorporate 30 men who are randomly chosen from the Urology Clinic population who have undergone vasectomy in the past. These men will be compared to 30 randomly selected, age-matched controls for assessment of blood pressure and renal function (24 hour clearance of protein and creatinine).

**Progress:** As the first protocol's patient selection process was found to be unworkable, no patients have been studied.
The Role of Continuous Peritoneal Lavage in the Treatment of Severe Acute Pancreatitis

Objective: To determine the efficacy of continuous peritoneal lavage in decreasing the morbidity and mortality of severe acute pancreatitis.

Technical Approach: Patients diagnosed as having severe acute pancreatitis will be randomized into control and study groups. The control group will receive standard care for pancreatitis with surgical intervention when appropriate. The study group will undergo continuous peritoneal lavage with Inpersol for not less than 48 hours and not more than 5 days.

Progress: To date, no patients have been identified as having severe acute pancreatitis.
**Detail Summary Sheet**

<table>
<thead>
<tr>
<th>Date:</th>
<th>21 Oct 81</th>
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<th>Status: Ongoing</th>
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**TITLE:**
Anterior Vitrectomy for Aphakic Cystoid Macular Edema - Collaborative Study

<table>
<thead>
<tr>
<th>Start Date:</th>
<th>15 Jun 81</th>
<th>Est Comp Date: Unknown</th>
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</table>

**Principal Investigator**
Donald G. Griffith, M.D., COL, MC

**Dept/Sec:**
Department of Surgery/Ophthalmology

**Key Words:**
Vitrectomy
Aphakic cystoid macular edema

**Accumulative MEDCASE Est Accumulative Periodic**
Cost: OMA Cost: Review Results:

**Objective:** To learn what effect, if any, anterior vitrectomy has on persistent cystoid macular edema occurring after cataract extraction.

**Technical Approach:** patients with aphakic cystoid macular edema and evidence of vitreous abnormality will be randomly selected for vitrectomy or for nonsurgical management.

**Progress:** No patients have yet been enrolled in the study at BAMC.
**Detail Summary Sheet**

**Date:** 21 Oct 81  
**Proj No:** C-41-81  
**Status:** Ongoing

**TITLE:**  
Hearing Levels in Otherwise Healthy Children Who Were Exposed to Ultrasound While Fetuses

**Start Date:** 15 Jun 81  
**Est Comp Date:** Mar 82

**Principal Investigator**  
Warner L. Bruner, M.D., CPT, MC

**Facility**  
Brooke Army Medical Center

**Dept/Sec:**  
Department of Surgery/Otolaryngology

**Associate Investigators:**  
Joseph M. Brock, CPT, MSC  
Mark Russell, CPT, MSC

**Key Words:**  
Ultrasound

**Accumulative MEDCASE Cost:**  
**Est Accumulative Cost:**  
**OMA Cost:**  
**Periodic Review Results:**

**Objective:**  
To measuring hearing levels of otherwise healthy children who underwent diagnostic ultrasound in utero.

**Technical Approach:**  
Puretone audiometry through very high frequencies is performed on children exposed to diagnostic ultrasound in utero.

**Progress:**  
Difficulty in locating subjects who were exposed at BAMC have been encountered. Five or six ears tested so far have shown mild high frequency hearing loss as compared to established norms.
**Detail Summary Sheet**

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<td><strong>TITLE:</strong></td>
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<tr>
<td></td>
<td>Cardiac Surgery Prospective Follow-up Project</td>
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<tr>
<td><strong>Start Date:</strong></td>
<td>20 Aug 81</td>
<td><strong>Est Comp Date:</strong> Aug 84</td>
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<tr>
<td><strong>Principal Investigator</strong></td>
<td>George F. Schuchmann, M.D., COL, MC</td>
<td><strong>Facility</strong></td>
<td>Brooke Army Medical Center</td>
</tr>
<tr>
<td><strong>Dept/Sec:</strong></td>
<td>Department of Surgery/Cardiothoracic</td>
<td><strong>Associate Investigators:</strong></td>
<td>James B. Peake, M.D., LTC, MC</td>
</tr>
<tr>
<td><strong>Key Words:</strong></td>
<td>Cardiac surgery</td>
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<td><strong>Est Accumulative OMA Cost:</strong></td>
<td>Periodic Review Results:</td>
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<tr>
<td><strong>Objectives:</strong></td>
<td>To follow-up patients who have had cardiac surgical procedures to assess: a. short-term outcome; b. long-term outcome; c. prognostic factors and relate above to work status and military service.</td>
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</tbody>
</table>

**Technical Approach:** Detailed preoperative, intraoperative, immediate post-operative and periodic long term data are being collected on every patient undergoing open heart surgery. This is being done in the form of questionnaires with data processed via computer.

**Progress:** Our patient population and postoperative follow-up time thus far is insufficient to establish any trends. Tabulation of data has been delayed pending installation of data processing equipment and training personnel to operate the machine.
Detail Summary Sheet

Date: 21 Oct 81  Proj No: C-60-81  Status: Ongoing

TITLE:
Post-Cholecystectomy Analgesia and Respiratory Function in Patients Treated with Epidurally Administered Morphine, Bupivicaine or Sterile Saline

Start Date: 1 Sep 81  Est Comp Date: Jan 82

Principal Investigator:
Chester E. Pruett, M.D., MAJ, MC

Facility:
Brooke Army Medical Center

Dept/Sec:
Department of Surgery/Anesthesiology

Associate Investigators:
Wallace H. Good, Jr., M.C., CPT, MC

Key Words:
Epidural morphine
Analgesia

Accumulative MEDCASE  Est Accumulative  Periodic
Cost: OMA Cost:  Review Results:

Objective: To document the postoperative respiratory function and analgesia obtained in patients undergoing right subcostal approach for cholecystectomy given epidurally applied morphine (the test drug) as compared to Bupivicaine (a previously reported modality) or sterile saline (a placebo control).

Technical Approach: Patients undergoing cholecystectomy will be randomly assigned to receive either epidural morphine, bupivicaine or sterile saline. The anesthesia applied will be a single epidural injection of 10 ml of sterile test solution - either 5 mg preservative free morphine, 25 mg Bupivicaine, or sterile saline, followed by an inhalational -- relaxant (non-narcotic) oral endotracheal general anesthetic, an accepted balanced anesthetic for cholecystectomy. Postoperatively, the patients will be observed in the surgical recovery room for 24 hours post-injection, during which time the patient will be given all routine post-cholecystectomy medications and pain medication upon request. Patients will be encouraged to deep breathe, use the incentive spirometry and ambulate.

The data obtained will be evaluated as follows: Student t-test for duration of hospital stay, subtotal and total medication dosage, time to first ambulation and first meal, and spirogram analysis and non-parametric testing for pain report; chest x-ray; and surgical and nursing staff impression analysis.

Progress: This is a new study.

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Detail Summary Sheet

Date: 21 Oct 81 Proj No: C-40-80 Status: Ongoing

TITLE:
Evaluation of PO₂ Changes Associated with Intravenous Sedation for Outpatient Oral Surgery

Start Date: 1 Nov 80 Est Comp Date: 1 Jan 82

Principal Investigator
Richard A. Kraut, D.D., LTC, DC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Dentistry/Oral Surgery

Associate Investigators:

Key Words:
PO₂ changes
Intravenous sedation
Oral Surgery

Objective: To determine the change from baseline PO₂ in patients undergoing outpatient oral surgery - (a) utilizing local anesthesia; (b) utilizing local anesthesia and intravenous Valium; and (c) utilizing local anesthesia and intravenous Valium and Sublimaze.

Technical Approach: Thirty patients will be selected for each of the three study groups. Patients will be selected from those patients who require removal of at least one maxillary and one mandibular impacted wisdom tooth. Patients will be assigned to study groups based on their request for sedation or local anesthesia. Patients requesting sedation will be alternately assigned to Group B and C.

The following monitors will be used on all patients included in this study:

1. ECG - a cardiac monitor utilizing a 2 channel oscilloscope with cardioverter/defibrillator connected in line.

2. A respiratory monitor with a digital rate display and a graphic display on the 2nd channel of the oscilloscope.

3. An automatic hands-off blood pressure monitor set for readings every 2 minutes.

4. A continuous cutaneous oxygen monitor.

Progress: 75% of data has been collected.
Detail Summary Sheet

Date: 21 Oct 81 Proj No: C-62-81 Status: Ongoing

TITLE:
Effect of Supplemental Nasal Oxygen on the PO₂ of Patients Undergoing Outpatient Oral Surgery

Start Date: 23 Sep 81 Est Comp Date: Jan 82

Principal Investigator
Richard A. Kraut, D.D., LTC, DC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Dentistry/Oral Surgery

Associate Investigators:

Key Words:
Nasal oxygen
PO₂

Accumulative MEDCASE Est Accumulative Periodic QMA Cost:
Cost: Review Results:

Objective: To determine the changes from baseline PO₂ in patients undergoing outpatient oral surgery with supplemental nasal oxygen utilizing local anesthesia or local anesthesia plus intravenous Valium and Sublimaze.

Technical Approach: Twenty patients will be included in each of the study groups. Patients will be assigned to a study group based on their request for sedation or local anesthesia. The patients will be divided into four study groups. Group A will receive local anesthesia and supplemental oxygen via nasal prongs; B local anesthesia and supplemental oxygen via a nasal mask; C intravenous sedation and supplemental oxygen with nasal prongs; and D will receive intravenous sedation and supplemental nasal oxygen via a nasal mask. Heart rate, blood pressure, and mean arterial blood pressure will be recorded every two minutes during the surgical procedure. A continuous graphic recording of the PO₂ will be generated via the transcutaneous oxygen monitor.

Progress: This is a new study.
TITLE: Evaluation of PO₂ Changes During Surgical Removal of Wisdom Teeth Utilizing General Anesthesia

Start Date: 23 Sep 81
Est Comp Date: Jan 82

Principal Investigator: Richard A. Kraut, D.D., LTC, DC

Facility: Brooke Army Medical Center

Dept/Sec: Associate Investigators: Department of Dentistry/Oral Surgery

Key Words: PO₂ changes
Wisdom teeth

Objective: To determine the changes in partial pressure of oxygen experienced by patients having wisdom teeth removed under general anesthesia.

Technical Approach: Twenty-five consecutive patients who request outpatient general anesthesia in association with the removal of their impacted wisdom teeth are to constitute the study group. The Roche Transcutaneous Oxygen Monitor to be utilized in this study will provide a written graphic record of the PO₂ of the patient. This is to serve as the data collection vehicle for collecting PO₂'s in this study.

Progress: This is a new study.
**Detail Summary Sheet**

<table>
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<tr>
<th>Date:</th>
<th>22 Oct 81</th>
<th>Proj No:</th>
<th>C-11-81</th>
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<tr>
<td>TITLE:</td>
<td>Teaching the Language and Learning Disabled Soldier</td>
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<tr>
<td>Start Date:</td>
<td>4 Feb 81</td>
<td>Est Comp Date:</td>
<td>Sep 82</td>
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<tr>
<td>Principal Investigator</td>
<td>Judith Riggan, MAJ, AMSC</td>
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<td>Dept/Sec: Physical Medicine and Rehabilitation Service/Occupational Therapy</td>
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**Accumulative MEDCASE**

| Est Accumulative OMA Cost: | Periodic Review Results: |

**Objective:** To determine if Academy of Health Science students who are documented as "Language and Learning Disabled Adults" (LLD), can be helped to succeed in their Advanced Individual Training program thus reducing attrition and/or failure rates at the Academy of Health Sciences.

**Technical Approach:** All soldiers beginning AIT in the 91E Dental Specialist Course are administered a questionnaire pertaining to past educational experiences during their initial orientation class. Those identified with potential learning disabilities are referred to Occupational Therapy, BAMC, for more definitive evaluation. Should the SM seem to be learning disabled, he/she is then given a battery of tests which evaluate sensory integrative dysfunction, performance/potential levels, and clinical observation of perceptual and psycholinguistic skills. Remediation in the Occupational Therapy Learning Abilities Clinic is then provided for these soldiers diagnosed as true Learning Disabled (LD).

**Progress:** Since initiation of this study, 56 soldiers have been individually screened by Occupational Therapy for possible learning disabilities. Fifteen of those revealed some academic weakness but could not be directly attributed to a learning disability, but rather limited learning potential and/or language barriers. Sixteen were evaluated and diagnosed as learning disabled. Eleven of those sixteen were formally treated in Occupational Therapy.

A "Past Education Questionnaire" has been developed as a screening tool and is used regularly during each 91E orientation class. A commercially available evaluation tool, which is statistically significant for documenting LD, has been purchased and is currently being implemented into the evaluation process.
The course materials for the 91E Dental Specialist Course have been modified for the LD soldier who has difficulty reading: the technical manual is available on audio cassette; note taking has been significantly reduced; tests are given orally by the instructors or from audio cassette; visual aids (slides viewgraphs, etc.) have been reviewed and modified to reduce clutter, etc.

Inservice programs are being presented to the instructional staff of the Academy of Health Sciences pertaining to symptoms and treatment of the LD soldier. This inservice will become a routine presentation for all newly assigned AHS faculty during the Faculty Development Unit.

Further study is required, beyond the 91E course, to determine the number of LD soldiers who filter into the Academy of Health Sciences for Advanced Individual Training. These statistics are needed to help determine the need for an occupational therapist with SID/LD credentials on the Academy of Health Sciences TDA.
Objective: To evaluate a treatment method, TENS, as a way to control post-operative knee pain.

Technical Approach: Eleven patients who had undergone reconstructive knee surgery were entered into the experimental group. These patients used TENS whenever needed for the first three days following surgery. Eight control patients did not use TENS. The amount of pain medication used by the two groups was then compared.

Progress: All patients in the TENS group reported that the use of TENS helped control their pain. Although this group used less pain medication, the decrease was not significant. The results may have been affected by problems in experimental procedure and/or design.
Detail Summary Sheet

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<th>6 Nov 81</th>
<th>Proj No: C-30-80</th>
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**TITLE:**
An Analysis of Factors Involved in Encouraging Research Among Physical Therapists

**Start Date:** Jun 80  
**Est Comp Date:**

**Principal Investigator**
Cary C. Bucko, 2LT AMSC  
**Facility:** Academy of Health Sciences  
**Dept/Sec:** Physical Therapy Section  
**Associate Investigators:**

**Key Words:**
Research  
Physical Therapists

**Objective:**
To provide a data-base for planning, administrative decision making, and/or policy formation.

**Technical Approach:**
Questionnaires were sent to 500 randomly selected members of the American Physical Therapy Association active membership list of 1980. Various motivational factors were analyzed in this study to determine the reasons why physical therapists were not doing research.

**Progress:**
The majority of respondents cited lack of time and lack of training in research methodology as their primary reasons for not conducting research. In addition, many therapists also indicated career advancement as a major motivating factor for doing research. Ideas and suggestions on how to rectify the situation were discussed.
# Measurable Support of Ankle Taping and Semi-rigid Support: A Comparative Study

**Objective:** To evaluate two methods of ankle support: a semi-rigid support system constructed of Surlyn and ankle taping.

**Technical Approach:** A comparison was made of the effectiveness of ankle taping utilizing the Gibney Basketweave and heel lock and a semi-rigid support constructed of Surlyn in restricting active inversion. Twenty-nine subjects had both methods applied concurrently such that one ankle was taped while the other was splinted. The first experimental group (14 subjects) was randomly selected to have the left ankle taped while the second experimental group (15 subjects) was randomly selected to have the left ankle splinted. Three measurements of maximum active inversion range of motion were taken on both ankles: (1) pre-support, (2) pre-exercise, and (3) post-exercise. The subject's active inversion range of motion was measured with the Leighton-Flexometer.

**Progress:** A comparison of measurements taken pre-exercise and post-exercise for both taping and splinting resulted in no significant difference in retention of support as measured in available degrees of active inversion range of motion. The findings of this study indicate that both methods of support are comparably effective in restricting inversion range of motion throughout a specific level and amount of exercise.
**Detail Summary Sheet**

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<td><strong>TITLE:</strong></td>
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<td>Bilateral Comparison of Isokinetic Force Measurements of the Knee Extensors</td>
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<td><strong>Start Date:</strong></td>
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<tr>
<td>Principal Investigator</td>
<td>Jill Bliss and Elise Dewit, 2LTs, AMSC</td>
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**Objectives:**
To determine whether a significant difference exists between the torque generated by the knee extensors of the dominant and non-dominant lower members.

If such a difference exists, to observe whether it is accentuated or minimized at increasing limb velocities.

**Technical Approach:**
Knee extension efforts were measured on the Cybex 2 Dynamometer at 30, 180, and 240°/sec for 32 young adult subjects. At each of the three speeds, the highest peak torque was recorded for the left and right lower members.

**Progress:**
Statistical application of a two-way analysis of variance with interaction showed no statistically significant difference in torque ($p < .01$) when comparing dominant versus non-dominant or left versus right lower members. In addition, the speed of limb movement did not have any effect upon the relationships studied.
Factors Precipitating Hamstring Strains in Track Athletes.

Objectives: To add to the existing knowledge of preventive sports medicine. To assist supervisory personnel in planning training programs to avoid hamstring strains. To predict the high risk individuals so that programs can be implemented to correct any deficiencies.

Technical Approach: A study of 95 high school track athletes was conducted to determine the most significant precipitators of hamstring injuries. The factors investigated included: bilateral hip joint flexibility, type of event, dominant leg, years of experience, age, sex, previous injury, and quadriceps:hamstring strength ratios as measured with a cable tensiometer.

Progress: Thirteen of the athletes sustained hamstring strains during the study. These 13 tended to be less flexible in the injured leg, were more experienced in track competition, and had a greater difference between quadriceps and hamstring strength in the injured leg. It was noted that 77% of all the injured athletes had sustained a previous injury to the injured leg. Certain events contributed to injury more than others, but age and sex showed no correlation to injury. Dominant leg correlated only in the hurdles.
Objective: To provide a data base for planning and setting goals for treatment and rehabilitation programs involving the dorsiflexors and plantar flexor musculature as well as the ankle itself for the dominant leg.

Technical Approach: This study was an attempt to define the normal limits of strength as related to age, sex, and body weight. Forty normal subjects, 20 male and 20 female, ages 23-60 were tested in plantar flexion and dorsiflexion on the Cybex Isokinetic Dynamometer (Cybex II®).

Progress: Statistically significant correlations (p < .05) were found between age and torque, sex and torque, and age, sex and body weight and torque (torque in both dorsiflexion and plantar flexion). Regression equations, predicting 63% of the variation in dorsiflexion and 75% of the variation in plantar flexion were constructed.
Detail Summary Sheet

Date: 6 Nov 81  Proj No: C-47-81  Status: Completed

TITLE:
Treatment of Low Back Pain Using Acupressure Touch and Massage

Start Date: 2 Jul 81  Est Comp Date:
Principal Investigator
Joseph 1. Hodges, 2IT, AMSC
Dept/Sec: Physical Therapy Section
Key Words: Acupressure

Accumulative MEDCASE  Est Accumulative  Periodic
Cost: OMA Cost: Review Results:

Objective: To evaluate the efficacy of basic Touch for Health techniques as a way to control the symptoms of acute low back pain.

Technical Approach: Kinesiological muscle balancing techniques were applied to patients with acute or subacute low back pain to determine if these techniques offered immediate symptomatic relief. Pain level, spinal flexion, and abdominal strength changes were measured in 13 patients who were treated with muscle balancing techniques taught in a basic Touch For Health course, and in 13 patients who received a placebo treatment.

Progress: Touch For Health balancing significantly decreased pain, increased ability to perform a sit-up, and increased range of spinal flexion. Acupressure touch and massage techniques as taught in a basic Touch For Health class were effective in reducing the symptoms of acute low back pain.
Ir

Detail Summary Sheet

Date: 6 Nov 81  Proj No: C-48-81  Status: Completed

TITLE:
Analysis of Splinting as a Treatment for Carpal Tunnel Syndrome

Start Date: 2 Jul 81  Est Comp Date:  
Principal Investigator  Facility
William J. Tatu, 2LT, AMSC  Academy of Health Sciences
Dept/Sec:  Associate Investigators:
Physical Therapy Section
Key Words:
Carpal tunnel syndrome

Accumulative MEDCASE  Est Accumulative  Periodic  Review Results:
Cost:  OMA Cost:  

Objective: To assess the results obtained by the Physical Medicine Service at
BAMC in treating carpal tunnel syndrome with splinting.

Technical Approach: The records of twenty-five patients treated with resting
hand splints for carpal tunnel syndrome were reviewed to assess the end result
of treatment. Sixteen patients had bilateral involvement which brought the
total to forty-one wrists. Distal sensory latencies, duration of symptoms
and subjective complaints of the patients were extracted for statistical analy-

sis.

Progress: Results indicated a statistically significant relationship between
successful treatment and duration of symptoms (p < .05). Fourteen wrists
failed to benefit from treatment, five of those patients underwent surgery.
No correlation was found between initial severity of symptoms and successful

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**Detail Summary Sheet**

**Date:** 6 Nov 81  
**Proj No:** C-49-81  
**Status:** Completed

**TITLE:**  
Effect of Ice Facilitation on Grip Strength in Normals

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<td>Principal Investigator</td>
<td>Alfred B. Woodhead, 2LT, AMSC</td>
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<td>Dept/Sec:</td>
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**Objective:** To evaluate the effect of quick ice facilitation on the grip strength of normal individuals.

**Technical Approach:** Twenty-seven normal men and women were randomly assigned applications of quick or placebo ice to the flexor and extensor surfaces of their dominant arm. Grip strength was measured on a tensiometer at three points in the experiment. Grip strength was measured before application of ice or placebo, immediately after, and three minutes later. Six days after the first application, the subjects were tested again. Each person received the procedure with which they had not been tested.

**Progress:** An independent t-test revealed that the average difference between the mean grip strength immediately after quick ice facilitation, versus the mean grip strength after placebo icing, was not statistically significant ($t = 1.55, p = ns$). Quick ice facilitation produced no significant change in grip strength of normal individuals, when applied simultaneously to the flexor and extensor surfaces of the forearm.
Detail Summary Sheet

Date: 6 Nov 81  Proj No: C-50-81  Status: Completed

TITLE:
Analysis of Methods of Measuring Pelvic Tilt

Start Date: 2 Jul 81  Est Comp Date:  
Principal Investigator
Matthew J. Taylor, 2LT, AMSC  
Facility
Academy of Health Sciences  
Dept/Sec:
Physical Therapy Section  
Assisicate Investigators:

Key Words:
Pelvic tilt  
Lumbar lordosis

Accumulative MEDCASE Est Accumulative Periodic Cost: OMA Cost: Review Results:  

Objective: To evaluate several clinical methods of measuring lumbar lordosis.

Technical Approach: There is no objective measure of lumbar lordosis practically available to the physical therapist. This study sought to statistically substantiate three suggested methods. The reliability of each method was determined in a pre-test, the least reliable being ± 1.85° (p < .05). Thirty adults (18 men and 12 women), 23 to 79 years of age, were measured by each method and these measurements were then correlated with a radiographically obtained lumbosacral angle.

Progress: The three methods were mutually independent of the lumbosacral angle. These methods are reasonably reliable, but were not shown to be related to a clinically significant factor.
**Detail Summary Sheet**

**Date:** 6 Nov 81  
**Proj No:** C-55-81  
**Status:** Completed

**TITLE:**  
Electrical Skin Resistance Patterns as an Indicator of Postoperative Pain

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<th>Start Date:</th>
<th>18 Aug 81</th>
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**Principal Investigator**  
Carol Echtenkamp, 2LT, AMSC

**Facility**  
Academy of Health Sciences

**Dept/Sec:**  
Physical Therapy Section

**Associate Investigators:**  
Sandra Webster, 2LT, AMSC

**Key Words:**  
Electrical skin resistance

**Accumulative MEDCASE**  
Est Accumulative Periodic

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<th>Review Results:</th>
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**Objective:**  
To evaluate electrical skin resistance patterns as an objective indicator of pain.

Technical Approach: Electrical skin resistance measurements were made on both knees of thirty normal and eight postsurgical, knee surgery patients.

Progress: The results show no statistically significant difference ($t = .6072$, $p = .ns$) between the mean electrical skin resistance values for points on the right versus the left knees of the normal subjects. There was a statistically significant difference ($t = 2.4763$, $p < .05$) between the mean electrical skin resistance values for points on the involved versus the uninvolved knees of the postsurgical patients. This study indicates that the measurement of electrical skin resistance variations may represent an objective method for measuring pain.
Detail Summary Sheet

Date: 29 Oct 81  Proj No: C-19-80  Status: Completed

TITLE:
Autotransfusion in Penetrating Trauma - The Feasibility of Processing Contaminated Blood.

Start Date:  Apr 80  Est Comp Date: 

Principal Investigator
John D. Rumisek, M.D., CPT, MC

Facility
Reynolds Army Hospital

Dept/Sec:
Department of Surgery/General Surgery

Associate Investigators:

Key Words:
Autotransfusion
Penetrating trauma

Accumulative MEDCASE  Est Accumulative Periodic
Cost:  OMA Cost:  Review Results:

Objective: To quantitate the capabilities and limits of the Haemonetics Cell SaverR blood processing system to remove bacterial contamination from blood for infusion.

To define the utility of the Haemonetics Cell SaverR system for autotransfusion under conditions of severe penetrating trauma including battle-field injury for potential military utilization.

Technical Approach: The Haemonetics Cell SaverR blood recovery system was employed to process a mixture made to simulate enteric contamination of intraperitoneal blood in severe penetrating abdominal trauma.

Progress: With the exception of terminal ileal or colonic spillage where bacterial counts can exceed 100 billion colonies per ml, intraperitoneal blood in penetrating abdominal trauma can be processed by the cell wash system for safe autotransfusion. Bacterial counts are less than 1000 colonies per ml to the level of the mid ileum and, along with bile, urine, fragments of bone and tissue, are effectively washed from the salvaged blood in logarithmic fashion. In these circumstances, use of autotransfusion of salvaged blood in penetrating trauma can be life saving, providing clean, fresh, and young autogenous red cells. However, until improvements in filtration and antibiotic augmentation can be demonstrated to eliminate the astronomical numbers of viable bacteria in even 0.1 ml of fresh stool, autotransfusion or processed fecal contaminated blood must be avoided, perhaps even in the most heroic of attempts.
Adjuvant Chemotherapy for Patients with Locally Advanced Adenocarcinoma of the Large Bowel.

Objectives: To determine the effectiveness of the combination of MeCCNU + 5-FU as adjuvant chemotherapy.

To judge whether oral BCG adds to effectiveness.

Technical Approach: Patients with histologically proven Duke-C adenocarcinoma of the large bowel with no proven residua or metastatic disease and no prior chemotherapy or radiotherapy are eligible for entry into this protocol.

Treatment will conform with the schema outlined in the study protocol.

Progress: This study was recently closed. In two patients receiving chemotherapy plus BCG new primaries occurred at 26 months and 36 months. Total patient accrual was 620. Following the amendment to include a control arm, the recurrence rates were 36.5% (15/41) for the control arm, 30.5% (11/36) for chemotherapy and 31.2% (10/32) for chemotherapy and immunotherapy. Preamendment, the recurrence rate was 36.9% (52/141) for chemotherapy alone and 35.1% (42/134) for CT & IT.
**Combination Chemotherapy with or without Immunotherapy in High Risk Melanoma Patients: An Adjuvant Study.**

**Objectives:**
To determine the efficacy of BHD in preventing recurrence of disease and prolonging survival of patients who have received definitive surgical treatment for their primary lesions.

To determine the efficacy of BHD + BCG in preventing metastases and prolonging the disease-free interval.

To determine the immunocompetence of these patients.

**Technical Approach:** All patients with histologically confirmed diagnosis of malignant melanoma previously untreated with chemotherapy or radiotherapy, who are within four weeks of surgical excision of active disease, are eligible.

Therapy will follow the schema outlined in the study protocol.

**Progress:**
Two hundred and forty-one patients were entered on the study. Patients receiving chemotherapy alone (BHD) have a longer disease-free interval ($p = .09$) and survival ($p = .01$) than patients receiving chemotherapy (BHD) plus BCG. Age continues to be the most significant prognostic factor, with patients less than 40 years of age and 60 years of age and older doing better with chemotherapy alone, as are patients with 2 or more extremity primaries and those with the greatest depth of invasion.

In conclusion, the BHD is superior to BHD + BCG.
**Detail Summary Sheet**

**Date:** 22 Oct 81  
**Proj No:** SWOG 7522  
**Status:** Completed

**TITLE:**  
Chemotherapy, Splenectomy with or without Immunotherapy in the Treatment of Chronic Myelogenous Leukemia

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<tr>
<td>Principal Investigator</td>
<td>J. Dean McCracken, M.D., COL, MC</td>
<td>Est Comp Date:</td>
<td>Associate Investigators:</td>
<td>Richard A. Shildt, M.D., LTC, MC</td>
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<td>Dept/Sec:</td>
<td>Department of Medicine/Oncology</td>
<td>Est Comp Date:</td>
<td>Associate Investigators:</td>
<td>John D. Cowan, M.D., MAJ, MC</td>
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<td>Key Words:</td>
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<td>Immunotherapy</td>
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<td>Objective:</td>
<td>To study the effects of chemotherapy, splenectomy and/or immunotherapy on leukemic cytogenetics, immune status, appearance of blastic transformation, and any influence in overall survival.</td>
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**Technical Approach:** All patients with confirmed diagnosis of benign phase CML not previously treated with any of the agents used in this study are eligible.

Treatment will conform with the schema outlined in the study protocol.

**Progress:** The study has been completed, and a manuscript is being prepared. However, final results of the study are not available for this report.
DATE: 22 Oct 81  Proj No: SWOG 7524  Status: Completed

TITLE: Chemotherapy in Stages III and IV Ovarian and Endometrial Cancer

Start Date: FY 76

Principal Investigator
J. Dean McCracken, M.D., COL, MC

Dept/Sec: Department of Medicine/Oncology

Key Words: Ovarian cancer, Endometrial cancer, Chemotherapy

Accumulative MEDCASE Cost: OMA Cost: Periodic Review Results:

Objectives: To compare the effectiveness of chemotherapy alone vs chemotherapmy for remission induction in Stages III and IV ovarian and endometrial carcinoma.

To test the effectiveness of chemotherapy plus immunotherapy vs chemotherapy in maintaining complete remissions.

To test effectiveness of continued chemotherapy plus immunotherapy vs chemotherapy in inducing complete remission or maintaining partial remissions in patients with occult disease at restaging or in patients achieving only partial remission during 12 month induction therapy.

Technical Approach: Patients with histologically confirmed ovarian carcinoma or endometrial carcinoma Stage III or IV with no prior chemotherapy or concurrent progestational agent therapy are eligible. Adenocarcinoma of cervix and germ cell of the ovary are eligible.

Therapy will be according to the schema outlined in the study protocol.

Progress: There has been statistical evidence that the ovarian cancer patients treated with AC + BCG had higher complete response-rates and longer median survival durations than those treated with AC alone.

For evaluation purposes, Stage III and Stage IV endometrial carcinoma patients were analyzed separately. Although the number of evaluable patients was small, no difference was seen between patients in CR or PR. Treatment was noted to be well tolerated and no difference was observed in the survival rates, response rates or response durations. It was concluded that BCG showed no evidence of adding any benefit when combined with Adriamycin and Cyclophosphamide.
SWOG 7524 (continued)

It was thought that the way each disease manifests itself could be a contributing factor as to why there was such a large difference in this regimen's effect on ovarian cancer (AC + BCG) as opposed to endometrial cancer.
**Detail Summary Sheet**

**Date:** 22 Oct 81  
**Proj No:** SWOG 7632  
**Status:** Completed

**TITLE:**  
Combined Modality for Recurrent Breast Cancer.

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<td>Facility</td>
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| Key Words: | Breast cancer  
Hormonal therapy  
Chemotherapy |

**Accumulative MEDCASE**  
**Est Accumulative Cost:**  
**OMA Cost:**  
**Periodic Review Results:**

**Objectives:** To establish the survival of breast cancer patients when treating the first recurrence with a coordinated hormonal-chemotherapeutic approach.

To determine the efficacy of a response to the antiestrogen Tamoxifen in predicting response to ablative surgery.

To correlate hormonal manipulations with estrogen and progesterone receptors where possible.

**Technical Approach:** Only patients who have been surgically and/or radiotherapeutically treated with the intent to cure their primary disease are eligible. In addition, patients with castration are eligible.

**Progress:** ER+ patients have an overall response rate of 50%. Postmenopausal patients have progressively longer durations of response the longer postmenopausal. It appears that response to tamoxifen may predicate response to oophorectomy, as 4/15 postmenopausal patients who achieved CR or PR on tamoxifen achieved CR or PR with oophorectomy; 5/22 premenopausal patients achieved CR or PR with oophorectomy after failing tamoxifen, but 0/10 patients with CR or PR on tamoxifen responded to oophorectomy. While none of 21 patients achieved CR or PR with oophorectomy after failing to respond to tamoxifen, approximately 50% of all patients had prior adjuvant chemotherapy.
**Detail Summary Sheet**

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**TITLE:** Radiation Therapy in Combination with BCNU, DTIC or Procarbazine in Patients with Malignant Gliomas of the Brain

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<td>J. Dean McCracken, M.D., COL, MC</td>
<td>Brooke Army Medical Center</td>
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**Dept/Sec:** Department of Medicine/Oncology

**Associate Investigators:**
- Richard A. Shildt, M.D., LTC, MC
- John D. Cowan, M.D., MAJ, MC

**Key Words:**
- Glioma
- Radiation therapy

**Objective:** To compare the effectiveness of radiation therapy plus BCNU, radiation therapy plus DTIC, and radiation therapy plus Procarbazine for remission induction, duration of remission, and survival in patients with malignant gliomas of the brain.

**Technical Approach:** Patients with histologically confirmed primary central nervous tumors of the following histologic types are eligible: Astrocytoma, grades 3 and 4 (glioblastoma multiforme).

Therapy will follow the schema outlined in the study protocol.

**Progress:** There have been 198 evaluable patients entered on this study. The CR + PR rates in the BCNU, Procarbazine and DTIC limbs are 37%, 17% and 40%, respectively. Patients 50 years or older have a lower CR rate (15%) than those patients under the age of 50 (27%). There are no statistically significant differences in duration of CR or CR + PR for the three treatment arms. The difference in response rates between BCNU and DTIC is nearly statistically significant (p = .064, uncorrected).
Chemoimmunotherapy in non-Hodgkin's Lymphoma.

Objectives:
To compare the effectiveness, in terms of rate of response of two chemoimmunotherapy regimens (CHOP + Levamisole vs CHOP + Levamisole + BCG) against CHOP for remission induction in previously untreated patients with non-Hodgkin's lymphoma.

For patients proven to be in complete remission after induction, to compare the duration of documented complete response obtained by continued maintenance immunotherapy with Levamisole vs no maintenance therapy.

For patients with impaired cardiac function (not eligible for treatment with Adriaycin), with mycosis fungoides, or with only a partial response to 11 courses of treatment with CHOP-Levamisole + BCG, to estimate the complete response rate obtained by continued chemoimmunotherapy with COP + Levamisole.

To estimate the CNS relapse rate in patients with diffuse lymphomas when CNS prophylaxis with intrathecal cytosine arabinoside is used.

To continue to evaluate the impact of systemic restaging of patients judged to be in complete remission and the value of expert hematopathology review of diagnostic material from all cases.

To establish baseline and serial data on immunologic status in both chemoinmunotherapy groups.

Technical Approach: The patient must have the diagnosis of non-Hodgkin's lymphoma established by biopsy.

Therapy will follow the schema outlined in the study protocol.

Progress: There are currently 729 patients registered on the Induction Phase SWOG 7713. Of these patients 208 have had a second registration onto SWOG 7714. The study will continue to accrue new patients for approximately six more months.
TITLE: Management of Patients with Metastatic Adenocarcinoma of Unknown Primary.

Start Date: FY 78

Principal Investigator: J. Dean McCracken, M.D., COL, MC

Department of Medicine/Oncology

Key Words: Unknown Primary, Metastatic Adenocarcinoma

Objectives: To determine the yield of various diagnostic procedures in finding the site of tumor origin in patients who present with metastatic adenocarcinoma with no obvious primary source.

To compare the efficacy of combination chemotherapy using 5-FU, Adriamycin, and Cytoxan vs 5-FU alone in palliative management of patients with metastatic adenocarcinoma of unknown origin.

To assess the hematologic toxicity of the chemotherapy regimen on treated patients.

Technical Approach: Patients with metastatic adenocarcinoma with no obvious primary source are eligible for diagnostic evaluation. In addition they should meet the following criteria:

1. Should have histopathologic confirmation of their disease.

2. Patients must have measurable disease and an expected survival of six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: On the combination therapy arm there were 3/16 responders vs 0/19 on the single agent arm. Final analysis of the data obtained from this study is not available.
Continuous 5-Drug Induction with Intermittent CMPF vs CMPF + Levamisole for Maintenance in Patients with Estrogen Receptor Breast Cancer

Objectives: To determine the respective effects of Levamisole on the duration of response and survival of patients with advanced breast cancer concurrently treated with maintenance chemotherapy after a successful remission induction trial of continuous Cooper regimen.

To accumulate data on immunologic variables under the conditions of chemotherapy alone and combined chemotherapy and immunotherapy with Levamisole of advanced breast cancer.

Technical Approach: Only patients prove to be ER negative are eligible. Patients with measurable lesions and no previous experience of chemotherapy other than adjuvant chemotherapy will be entered on the study.

Therapy will follow the schema outlined in the study protocol.

Progress: The median survival in this study was a little over one year. There seems to be no difference between the two arms in length of remission or survival. There appears to be no advantage to the addition of Levamisole.
Detail Summary Sheet

Date: 22 Oct 81  Proj No: SWOG 7727  Status: Ongoing

TITLE: Combination Chemoimmunotherapy Utilizing BCNU, Hydroxyurea and DTIC with Levamisole vs DTIC plus Actinomycin-D in the Treatment of Patients with Disseminated Malignant Melanoma.

Start Date: FY 78  Est Comp Date:
Principal Investigator
J. Dean McCracken, M.D., COL, MC  Facility
Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology  Associate Investigators:
Key Words: Chemoimmunotherapy  Richard A. Shildt, M.D., LTC, MC
Malignant melanoma  John D. Cowan, M.D., MAJ, MC

Objective: To determine remission induction rates, remission duration, survival and toxicity in patients with disseminated malignant melanoma treated with BCNU, Hydroxyurea, and DTIC (BHD), BHD plus Levamisole, and intermittent single high dose DTIC plus Actinomycin-D in a prospective randomized clinical study.

Technical Approach: Patients with histologically proven disseminated malignant melanoma who have not been treated previously with any of the protocol agents shall be eligible. Patients must have measurable disease and estimated survival of at least two months.

Therapy will follow the schema outlined in the study protocol.

Progress: There continues to be no major difference in the three limbs of the study. Median survival for the DTIC + Actinomycin-D patients is 33 weeks; 27 weeks for BHD patients and 19 weeks for Levamisole patients. DTIC + Actinomycin-D appears to be most effective in poor risk patients. Immunotherapy has proved not to be of benefit in this study.
**Detail Summary Sheet**

**Date:** 22 Oct 81  
**Proj No:** SWOG 7765  
**Status:** Ongoing

**TITLE:**  
Adriamycin and Single Dose DTIC in Soft Tissue Sarcomas, Phase I/II.

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<tr>
<td>J. Dean McCracken, M.D., COL, MC</td>
<td>Facility</td>
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<td>Assoc. Investigators:</td>
<td>Brooke Army Medical Center</td>
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**Dept/Sec:**  
Department of Medicine/Oncology

**Key Words:**  
Soft tissue sarcoma

**Objective:** To determine the effectiveness and tolerance of Adriamycin and single dose DTIC in patients with metastatic sarcomas who have failed on higher priority treatment protocols.

**Technical Approach:** Eligible patients are those who have a biopsy-proven diagnosis of soft tissue or bony sarcoma with measurable metastases. Patients must have a life expectancy of at least six weeks. All patients must have some lesions which are measurable and can be followed for tumor responses.

Therapy will follow the schema outlined in the study protocol.

**Progress:** One hundred eight patients have been accrued so far with a broad distribution of malignancies, leiomyosarcoma being the most common. Six CR's and 10 PR's have been reported. Median survival is 30 weeks, females having a longer median survival than males.

This study remains open for bony sarcoma and mesothelioma patients only.
TITLE: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma.

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

Technical Approach: Eligible patients must have localized lesions at least extending into the submucosa and involving any of the deeper layers with the maximum allowable penetration into but not through the serosa; localized lesions extending through serosa, with or without direct extension to contiguous structures; a lesion diffusely involving the wall of the stomach with or without metastases to immediately adjacent perigastric nodes or a localized lesion of any depth with metastases to perigastric nodes in the immediate vicinity; a localized or diffuse lesion with metastases to perigastric nodes distant from primary.

Therapy will follow the schema outlined in the study protocol.

Progress: To date there are 57 patients registered. At present there are no differences between treatment arms.
**Objective:** To determine the response rate and survival, with some degree of precision, utilizing cis-diamminodichloroplatinum II (CACP) in the treatment of patients with squamous cell carcinoma of the esophagus which is growing despite more standard therapy.

**Technical Approach:** Patients must have a biopsy-confirmed diagnosis of epidermoid carcinoma of the esophagus in order to be eligible for the study.

Therapy will follow the schema outlined in the study protocol.

**Progress:** The CR + PR response rate in fully + partially evaluable patients was 26%.
Detail Summary Sheet

Date: 22 OCT 81          Proj No: SWOG 7808          Status: Ongoing

TITLE:
Combination Modality Treatment for Stage III and IV Hodgkin's Disease
MOPP 6.

Start Date: FY 79          Est Comp Date:
Principal Investigator
J. Dean McCracken, M.D., COL, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Oncology

Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

Key Words:
Hodgkin's disease

Accumulative MEDCASE Est Accumulative Cost:
OMA Cost: Periodic Review Results:

Objectives: To attempt to increase the complete remission rate induced with MOP-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a partial response at the end of six cycles of MOP-BAP.

To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when complete response has been induced with six cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Eligible patients must have a histological diagnosis of Hodgkin's which must be classified by the Lukes and Butler system.

Therapy will follow the schema outlined in the study protocol.

Progress: Currently, there are 112 eligible patients. Seventy-one patients are fully or partially evaluable, and of these 55 patients are fully evaluable. Seventy percent of the fully and partially evaluable patients are Stage IV. The arm that randomized patients with no prior radiotherapy who achieved CR to levamisole alone has been closed.
Brain Metastases Protocol.

Objectives: To determine the effectiveness of combined radiation therapy and metronidazole (Flagyl) in the treatment of patients with brain metastases from primary malignancies outside the central nervous system, compared with radiation therapy alone, as determined by objective response (brain and/or CAT scan) and/or increase in functional neurologic level and duration of response.

To determine the toxicity of multiple dose administration of metronidazole and radiation therapy.

Technical Approach: To be eligible for this study, patients must have histologic proof of a primary malignancy. There must be clinical suspicion of brain metastases documented by isotope brain scan and/or CAT scan. Patients must either have measurable disease on brain/CAT scan and/or neurologic status level of 2-4. Patients must have an expected survival time of at least one month.

Therapy will follow the schema outlined in the study protocol.

Progress: One hundred fifty-two evaluable patients are needed on this study. There are 65 evaluable patients registered thus far. The overall response rates for treatment #1 (Decadron) and Treatment #2 (Decadron + Metronidazole) are 30% and 39%, respectively. Although accrual has been slow, the study remains open for new patient registration.


TITLE:
Ifosfamide in the Treatment of Resistant Disseminated Malignant Melanoma.

Objectives: To determine the response rate and survival of Ifosfamide in patients with disseminated malignant melanoma who are either ineligible for higher priority studies or who have become resistant to standard therapy of a higher priority program.

To determine the qualitative and quantitative toxicity of Ifosfamide in patients with disseminated melanoma.

Technical Approach: All patients with histologically confirmed diagnosis of disseminated malignant melanoma who are not eligible for higher priority protocols or who have failed on standard regimens or higher priority programs are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirty-three patients have been entered on this study of which 22 are evaluable. All patients have been heavily pre-treated. One CR and four PR's have been reported.
**Detail Summary Sheet**

**Date:** 22 Oct 81  **Proj No:** SWOG 7817  **Status:** Completed

**TITLE:** Treatment of Advanced Germ Cell Neoplasms of the Testis.

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<td>J. Dean McCracken, M.D., COL, MC</td>
<td>Brooke Army Medical Center</td>
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<td>Department of Medicine/Oncology</td>
<td>Associate Investigators:</td>
<td></td>
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<tr>
<td>Key Words:</td>
<td>Germ cell neoplasm of testis</td>
<td>Richard A. Shildt, M.D., LTC, MC</td>
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<td></td>
<td>John D. Cowan, M.D., MAJ, MC</td>
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</table>

**Objectives:**

- To determine in a randomized fashion the effectiveness of cis-diamminedichloroplatinum (DDP) given in the conventional low-dose schedule daily x 5 days versus high-dose intermittent treatment in remission induction of disseminated testicular cancer, when combined with vinblastine and bleomycin.
- To determine the survival of patients who achieve a partial remission and are rendered disease-free by surgical removal of residual disease and maintained on the same chemotherapy as patients who achieved complete remission status on chemotherapy alone.
- To determine the effectiveness of cyclophosphamide, actinomycin-D, Adriamycin and vinblastine in the maintenance of remission status.
- To document the nature and extent of the hematologic and nonhematologic side effects of the various drug combinations.

**Technical Approach:** All patients with metastatic testicular cancer of germinal cell origin regardless of prior radiation therapy are eligible.

**Progress:** One-hundred-six eligible patients were entered with 94 being evaluable. The complete remission rate for the high-dose cis-platinum was 61%, and 44% for the low-dose. Seventy-one percent of patients receiving high-dose cis-platinum had no evidence of disease after cytoreductive surgery compared to 53% for the low-dose patients. Also, 90% of the patients on the high-dose arm are disease-free at one year compared to 65% in the low-dose arm.
ROAP-AdOAP in Acute Leukemia

Objectives: To compare the efficacy of the 4-drug combination chemotherapy regimen, ROAP (Rubidazone, vincristine, arabinosyl cytosine, and prednisone) to AdOAP (the same combination using Adriamycin in place of Rubidazone) in adult acute leukemia, as determined by remission rate, remission duration and survival.

To determine the comparative toxicity of these regimens.

To determine whether late intensification therapy at 9 months after complete remission will improve long-term, disease-free survival.

To determine whether immunotherapy using levamisole for 6 months after 1 month of complete remission on chemotherapy improves disease-free survival.

To determine the effects of intrathecal Ara-C on the incidence of CNS leukemia.

To determine reproducibility of the FAB/histologic classification and correlation to response to therapy in 200 consecutive cases of acute leukemia.

To study the effects of intensive supportive care in the management of acute leukemia.

Technical Approach: All patients over 15 with a diagnosis of acute leukemia who have not received extensive therapy (defined as more than one course of any other chemotherapeutic agent or combination of agents) will be eligible for this study. The diagnosis of acute leukemia will be made on bone marrow smear, clot section and/or biopsy. An absolute infiltrate of 50% leukemic cells or greater is required.

Progress: At this time there appears to be no difference between rubidazone and adriamycin. In SWOG 7824, the number of patients is still too small to determine if CNS leukemia is being caused by multiple spinal taps. It is too early to draw any conclusions on either the SWOG 7825 or SWOG 7816 arms.
Date: 22 Oct 81 Proj No: SWOG 7827 Status: Ongoing

Title: Combined Modality Therapy for Breast Carcinoma, Phase III

Start Date: FY 80
Principal Investigator
J. Dean McCracken, M.D., COL, MC

Est Comp Date: Unknown
Facility
Brooke Army Medical Center

Dept./Sec:
Department of Medicine/Oncology

Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

Key Words:
Receptor positive (ER+)
Chemotherapy

Accumulative MEDCASE Est Accumulative OMA Cost: Periodic
Cost: Review Results: Continue

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

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

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

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

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

Technical Approach: All patients must have had a radical or modified radical mastectomy with histologically proven breast cancer and with one or more pathologically proven axillary nodes. Primary neoplasm and clinically apparent axillary disease must be completely removed. Pretherapy studies must reveal no evidence of metastatic disease or involvement of the other breast. Patients with postoperative radiation therapy are eligible but will be randomized and evaluated separately. Therapy will follow the schema outlined in the protocol.

Progress: To date there are 326 patients registered on the study, of which 185 are available for analysis. There have been 7 relapses, all in the ER- group, and 4 deaths, 3 of which occurred in the ER- group. It is too early to make any comparisons between treatment groups at this time.
Combined Modality Therapy for Extensive Small-Cell Carcinoma of the Lung.

Objectives: To improve the complete response rate and long-term, disease-free survival of patients with extensive small-cell carcinoma of the lung.

To define, quantitate and quantify the toxicity of each regimen employed.

Technical Approach: There must be a diagnosis by the institutional pathologist of small-cell, undifferentiated carcinoma of the lung. Extensive small-cell carcinoma includes the following: 1) Any patient with evidence of metastatic spread beyond the hemithorax and supraclavicular nodes on either side; 2) Any patient with a cytology-positive pleural effusion; and 3) Any patient with prior radiation therapy to the primary tumor who presents with evidence of recurrent disease.

Patients meeting the above eligibility criteria will receive one of three treatment programs. Treatment program A consists of two standard drugs—Vincristine and Methotrexate. Treatment program B consists of Vincristine plus Adriamycin and Cyclophosphamide. Treatment program C consists of Vincristine, Adriamycin and Cytoxan plus VP-16. Therapy will follow the schema outlined in the study protocol.

Progress: The CR and PR response-rates among the three treatment arms were statistically identical; however, patients with a performance status of 0-1 had higher responses than those with a 2-4 performance status. A p value of .82 was observed in the survival rates of all treatment arms with a median survival of 30-31 weeks. Most importantly, reinduction patients had longer survival and longer time on study than maintenance patients.
Carcinoembryonic Antigen as an Indicator for Second Look Surgery in Colorectal Cancer, a Randomized, Prospective Clinical Trial, Phase III.

Objectives:
- To determine whether serial carcinoembryonic antigen (CEA) assays, following curative surgery, for Duke's B and C colorectal cancer leads to earlier detection of recurrence than standard follow-up procedures.
- To determine whether recurrence detected through elevated CEA values, plus "standard clinical follow-up", leads to an improvement in the percentage of patients converted to no evidence of disease status following a second look surgery as opposed to recurrence detected by "standard" clinical means alone.
- To determine whether there is a difference in crude survival between the CEA follow-up group and the standard follow-up group.

Technical Approach:
- To be eligible, the patient must have a completely resected Duke's B or C adenocarcinoma of the colon or rectum. Careful attention should be given to the examination of the liver. Suspicious areas should be biopsied to rule out metastatic disease. CEA values at 30 days post-initial resection must be normal, i.e., nonsmokers < 2.5 ng/ml, smokers < 5.0 ng/ml. Patients may be entered on the basis of institutional CEA done 4-6 weeks post-op with normal defined above.

Eligible patients will be placed in one of two follow-up plans. Plan A - Patients placed on this regimen will be closely monitored for the development of recurrent disease by means other than CEA with physical examinations, blood chemistry tests, nuclear medicine scans and x-rays at intervals from every two months to one year. Plan B is the same as Plan A with the exception that a CEA blood test will be done every two months for two years.

Progress: The surgical protocol for CEA as an indicator for second-look surgery was closed because of inadequate patient registration. It appeared biased, as the value of CEA is already too well established to perform such a study.
Evaluation of Chlorozotocin in Lung Cancer.

Objectives: To determine whether chlorozotocin has significant activity as determined by response rate and median duration of response, against small cell, large cell, adenocarcinoma or squamous carcinoma of the lung.

To observe for toxicities of chlorozotocin not yet described and better define the known toxicities.

To determine factors predisposing to excessive toxicity to this agent.

Technical Approach: To be eligible, the patient must have histologically proven lung cancer and must have measurable lesions. Patient must be off all prior anticancer treatment for at least three weeks and recovered from all acute toxicities of prior treatment.

The anticipated accrual rate to this study is 8-10 eligible patients/month. At this rate it would be feasible to accrue the necessary 120 response-evaluable patients allowing for an overall inevaluability rate of 20-25%.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been completed. A manuscript has been prepared and will be submitted to Cancer Treatment Reports for publication.
Phase II-II Comparison of FAM vs FAM + Vincristine vs Chlorozotocin in the Treatment of Advanced Gastric Adenocarcinoma.

Objectives: To determine whether or not vincristine increases the effectiveness (as determined by response rate and survival) of 5-FU plus mitomycin-C plus Adriamycin (FAM) in the treatment of advanced, previously untreated gastric adenocarcinoma.

To determine the efficacy, as determined by response rate and survival of chlorozotocin in the treatment of previously untreated gastric adenocarcinoma.

To determine by crossover, after relapse or failure on FAM, V-FAM or chlorozotocin, the effectiveness as determined by response rate and survival, of the alternate treatment in advanced gastric adenocarcinoma with prior therapy.

To determine the toxicities of such treatments.

Technical Approach: Patients must have histologically proven adenocarcinoma, Stage IV in extent, to be eligible for this study. They must not have received prior chemotherapy nor should they have received radiotherapy within four weeks of entry. Patients must have a minimum life expectancy of 6 weeks and a performance status of 0-3 in order to be eligible.

The protocol has been amended and the current title and arms being used are V-FAM versus m-AMSA.

Progress: The study has shown that V-FAM offers no advantage over FAM, and only adds vincristine's toxicity. The protocol will be amended replacing m-AMSA with DHAD.
**Detail Summary Sheet**

**Date:** 27 Oct 81  
**Proj No:** SWOG 7860  
**Status:** Ongoing

**TITLE:** Evaluation of MGBG in Solid Tumors and Refractory Hematologic Malignancies

**Start Date:** 11 May 81  
**Est Comp Date:** Unknown

**Principal Investigator:** J. Dean McCracken, M.D., COL, MC  
**Facility:** Brooke Army Medical Center  
**Dept/Sec:** Department of Medicine/Oncology  
**Associate Investigators:** Richard A. Shildt, M.D., LTC, MC, John D. Cowan, M.D., MAJ, MC

**Key Words:** Solid tumor, MGBG, Hematologic malignancy

**Accumulative MEDCASE Cost:**  
**Est Accumulative OMA Cost:**  
**Periodic Review Results:** Continue

**Objectives:** To determine response rate and remission duration with primary weekly intravenous therapy using MGBG in patients with advanced esophageal, breast, pancreatic, colorectal, and head and neck carcinomas and lymphoma.

To define the qualitative and quantitative toxicity of this regimen.

**Technical Approach:** Patients must have pathologically verified histologic diagnosis of cancer. MGBG is intended as initial chemotherapy for patients with inoperable or disseminated renal, esophageal, and pancreatic carcinoma. It is intended for use in patients with other forms of advanced malignancy (breast, head and neck, colorectal, lymphoma and multiple myeloma) if their disease has become progressive after initial chemotherapy and who are not candidates for SWOG studies of higher priority.

Therapy will follow the schema outlined in the study protocol.

**Progress:** This study was only recently opened to groupwide participation. No data are available at this time.
Concurrent Chemotherapy-Radiation Therapy of Selected Head and Neck Cancer.

Start Date: FY 79
Est Comp Date: Unknown
Facility: Brooke Army Medical Center

Department of Medicine/Oncology

Key Words: Head and neck cancer, Radiation therapy, Chemotherapy

Accumulative MEDCASE Cost: OMA Cost: 
Est Accumulative Periodic Review Results: Continue

Objectives: To assess the local and systemic toxicity of the concurrent administration of the chemotherapeutic agents, bleomycin and hydroxyurea with super voltage radiotherapy in the treatment of locally advanced squamous cancer of the head and neck.

To determine the maximum tolerated dose of both chemotherapeutic and radiotherapy when given according to the proposed regimen.

Technical Approach: Patients with locally advanced squamous cell carcinoma of the head and neck who are candidates for definitive or palliative radiotherapy are eligible. Patients must have histologic confirmation of their disease and must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: The complete remission response rates vary with dose levels #1 (38%) and #4 (36%) having lower response rates than dose levels #2 (56%) and #3 (55%). The median response duration has been 29 weeks for all patients. The CR + PR rate was 83%.
TITLE: Combined Modality Therapy for Head and Neck Cancer.

Start Date: FY 80       Est Comp Date: Unknown

Principal Investigator  Facility
J. Dean McCracken, M.D., COL, MC  Brooke Army Medical Center

Dept/Sec:  Associate Investigators:
Department of Medicine/Oncology  Richard A. Shildt, M.D., LTC, MC

Key Words:
Head and neck cancer
Chemotherapy
Radiation therapy

Accumulative MEDCASE  Est Accumulative Cost:  OMA Cost:  Periodic Review Results: Continue
Objectives: To compare the survival of Stage III and IV squamous cell carcinoma of the tongue, oral cavity, tonsil, oropharynx, hypopharynx and larynx subjected to radiation therapy followed by surgical excision, if possible, vs survival of patients subjected to chemotherapy with Cis-platinum, Oncovin and Bleomycin (COB), followed by radiation therapy and surgical excision if possible.

To determine the incidence and extent of complications arising from chemotherapy and radiotherapy followed by head and neck surgery vs radiotherapy and head and neck surgery.

Technical Approach: Previously untreated patients with a histologically confirmed diagnosis of advanced inoperable squamous cell carcinoma of the head and neck, Stages III and IV, of the oral cavity, tongue, tonsil, oropharynx, hypopharynx and larynx are eligible. There must be an evaluable lesion(s). Patients must have a life expectancy of 6 weeks or greater.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been 34 patients registered thus far. Of the 23 eligible patients there are 7 FE+PE patients on both treatment arms. On treatment arm #2 there have been 3 remissions with one patient relapsing 8 weeks after response.
**Detail Summary Sheet**

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<td><strong>TITLE:</strong> Hexamethylmelamine vs FAC in Advanced Transitional Cell Bladder Carcinoma in Patients with Impaired Renal Function, Phase II-III</td>
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<td><strong>Start Date:</strong> FY 79</td>
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<td>J. Dean McCracken, M.D., COL, MC</td>
<td>Brooke Army Medical Center</td>
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<td><strong>Associate Investigators:</strong></td>
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<tr>
<td>Department of Medicine/Oncology</td>
<td>Richard A. Shildt, M.D., LTC, MC</td>
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<tr>
<td><strong>Key Words:</strong></td>
<td>John D. Cowan, M.D., MAJ, MC</td>
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<td>Transitional cell bladder carcinoma</td>
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<th>Periodic Review Results: Continue</th>
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<tr>
<td><strong>Objective:</strong> To compare the efficacy (response rate) of hexamethylmelamine vs FAC (5-Fluorouracil, Adriamycin and Cyclophosphamide) in locally recurrent or disseminated transitional cell bladder carcinoma, in patients with impaired renal function, with crossover upon treatment failure.</td>
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**Technical Approach:** Patients with histologically proven $T_4$ transitional cell bladder carcinoma, if there is a contraindication to radical surgery or radiotherapy, and recurrent or residual cases after surgery, radiotherapy or both; and $M_1$ cases with liver, osseous, pulmonary or other metastases are eligible.

Therapy will follow the schema outlined in the study protocol.

**Progress:** Twenty-two patients have been entered on this study to date, and the accrual rate is improving.
TITLE: Multidrug Adjuvant Chemotherapy in Non-Metastatic Osteosarcoma - Comparison of Conpadri I with Compadri V, Phase III.

Start Date: FY 80  |  Est Comp Date: Unknown
Principal Investigator: J. Dean McCracken, M.D., COL, MC
Facility: Brooke Army Medical Center

Dept/Sec: Department of Medicine/Oncology

Associate Investigators:
- Richard A. Shildt, M.D., LTC, MC
- John D. Cowan, M.D., MAJ, MC

Key Words: Osteosarcoma, nonmetastatic

Accumulative MEDCASE
Objectives: To compare disease-free survival in patients with nonmetastatic osteosarcoma treated with (a) Conpadri-I using cyclophosphamide, vincristine, phenylalanine mustard, and Adriamycin with (b) those treated by Compadri-V using high-dose methotrexate with citrovorum factor in addition to those drugs mentioned above.

To determine prognostic differences in the subtypes of osteogenic sarcoma.

For patients undergoing treatment on the Compadri-V arm, to evaluate the effect of preoperative high-dose methotrexate on the amputation specimen.

Technical Approach: All patients with histologically established diagnosis of osteosarcoma without metastases may be registered for the study. Patients must be registered before amputation.

Therapy will follow the schema outlined in the study protocol.

Progress: This study is ongoing as a Pediatric Oncology Group protocol.
Evaluation of Estrogen-Antagonist in the Management of Refractory Large Bowel Tumors, Phase II.

Objective: To help judge whether there is any therapeutic significance in humans to the laboratory observation that some colorectal tumors, in men and women, have estrogen receptors as determined by response rate to tamoxifen.

Technical Approach: Patients with biopsy confirmed diagnosis of adenocarcinoma of the large bowel are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Tamoxifen's toxicity is virtually nonexistent. Median survival for these patients is 27 weeks. Survival curves for patients who have received prior chemotherapy versus those who have not, show an advantage for previously untreated patients (20 weeks versus 25 weeks). Patients entering the study with a performance status 0-1 showed a survival advantage over those entering with a performance status of 2 (34 weeks versus 13 weeks, respectively). Patients who underwent biopsy for ER determination had a considerably shorter survival time than those who did not (8 weeks versus 31 weeks, respectively).
**Detail Summary Sheet**

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<th>Status: Completed</th>
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**TITLE:**
Gallium Nitrate in Patients with Malignant Lymphoma - Hodgkin's and Non-Hodgkin's, Phase II.

**Start Date:** FY 79
**Facility:** Brooke Army Medical Center

**Principal Investigator:** J. Dean McCracken, M.D., COL, MC
**Associate Investigators:**
- Richard A. Shildt, M.D., LTC, MC
- John D. Cowan, M.D., MAJ, MC

**Dept/Sec:** Department of Medicine/Oncology
**Key Words:**
- Hodgkin's lymphoma
- Non-Hodgkin's lymphoma
- Gallium nitrate

**Accumulative MEDCASE**
**Cost:**

**Accumulative OMA Cost:**

**Periodic Review Results:**

**Objectives:**
To determine the efficacy, as measured by response rate, of gallium nitrate in patients with malignant lymphoma, both Hodgkin's and non-Hodgkin's types, in patients who have received prior therapy and are not eligible for higher priority studies.

To determine the nature and degree of toxicity of this drug.

**Technical Approach:**
All patients with malignant lymphoma who are not eligible for higher priority protocols are eligible. Patients must have a life expectancy of at least 6 weeks and clearly measurable disease.

Therapy will follow the schema outlined in the study protocol.

**Progress:**
Of the 31 patients registered on this study, three patients have had partial remissions for 4, 5 and 13 months. Of the 31 patients registered, 5 patients were Hodgkin's, 20 patients non-Hodgkin's and 6 patients of unknown histology. Gallium Nitrate appears to have some anti-tumor activity in non-Hodgkin's patients. However, there were not enough Hodgkin's disease patients to evaluate the study's objectives for this group.
Date: 23 Oct 81  Proj No: SWOG 7915  Status: Completed

TITLE: Combination Chemotherapy in the Therapy of Advanced Carcinomas of the Salivary Glands.

Start Date: FY 80  Est Comp Date:

Principal Investigator  Facility
J. Dean McCracken, M.D., COL, MC

Dept/Sec: Associate Investigators:
Department of Medicine/Oncology  Richard A. Shildt, M.D., LTC, MC
Key Words: John D. Cowan, M.D., MAJ, MC
Chemotherapy
Salivary gland carcinoma

Objective: To determine, and to document, the efficacy, as determined by the response rate, of a combination of Adriamycin, Cytoxan, and 5-Fluorouracil in the chemotherapeutic management of advanced, rapidly growing, epithelial tumors of the salivary glands not amenable to surgery or radiotherapy.

Technical Approach: Patients with biopsy-confirmed diagnosis of carcinoma arising in one of the major or minor salivary glands are eligible. The tumor must be aggressively and actively growing and all rational surgical and radiotherapy alternatives must have been exhausted.

Therapy will follow the schema outlined in the study protocol.

Progress: Results were encouraging in the three patients treated. It is hoped that the study will be reopened at a later date.
**Detail Summary Sheet**

**Date:** 23 Oct 81  
**Proj No:** SWOG 7916  
**Status:** Ongoing

**TITLE:**
Phase II Evaluation of Gallium Nitrate in Metastatic Urological Malignancies: Testicular, Bladder, Prostate and Kidney

**Start Date:** FY 80  
**Est Comp Date:** Unknown

**Principai Investigator:** J. Dean McCracken, M.D., COL, MC

**Facility:** Brooke Army Medical Center

**Dept/Sec:** Department of Medicine/Oncology

**Associate Investigators:**
- Richard A. Shildt, M.D., LTC, MC
- John D. Cowan, M.D., MAJ, MC

**Key Words:** Metastatic urological malignancies  
Gallium nitrate

**Accumulative MEDCASE**  
**Est Accumulative Cost:**  
**OMA Cost:**  
**Periodic Review Results:** Continue

**Objective:** To determine the efficacy of Gallium Nitrate, as determined by response rate, duration of response and survival, in patients with metastatic urological malignancies which include: testicular, bladder, prostate and kidney; who have failed on higher priority treatment protocols.

**Technical Approach:** All patients no eligible for higher priority SWOG studies with histologically proven, incurable, advanced, metastatic urological malignancies are eligible. Patients should not have had more than two previous types of combination or single agent chemotherapy trials. Patients must have a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

**Progress:** Thirty-seven patients have been entered: 17 renal cell, 16 prostatic, and 4 bladder carcinomas. There have been no responses in either the kidney or prostate categories. It was recommended that this study be closed to testicular, prostate and kidney patients. There has been one complete response in 4 patients treated for bladder cancer. The study will remain open for bladder patients only.
# Detail Summary Sheet

**Date:** 23 Oct 81  
**Proj No:** SWOG 7917  
**Status:** Completed

**TITLE:**  
Gallium Nitrate in Previously Treated Patients with Metastatic Breast Cancer, Phase II.

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<th>FY 80</th>
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<td>J. Dean McCracken, M.D., COL, MC</td>
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<td>Metastatic breast cancer Gallium nitrate</td>
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**Objectives:** To determine the efficacy (as determined by response rate and median duration of response) of Gallium Nitrate in metastatic carcinoma of the breast who have failed standard therapy.

To determine if an initially positive Gallium scan predicts response.

**Technical Approach:** To be eligible, patients must have histologic proof of breast cancer currently stage IV in extent. There must be measurable disease. Patients must not be eligible for higher priority protocols and should have had a previous trial with appropriate standard therapies (Cooper's regimen and/or hormonal manipulation).

Therapy will follow the schema outlined in the study protocol.

**Progress:** Twenty-six patients have been entered on the study, and twenty-two are fully or partially evaluable. There were no responses or improvements in the 22 patients. The median number of doses of gallium nitrate was 3. Median performance status was 1.
Detail Summary Sheet

Date: 23 Oct 81  Proj No:  SWOG 7918  Status:  Completed

TITLE:
Evaluation of m-AMS in Lymphoma - Hodgkin's and Non-Hodgkin's.

Start Date:  FY 80  Est Comp Date:
Principal Investigator  Facility
J. Dean McCracken, M.D., COL, MC  Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Oncology

Key Words:
Hodgkin's lymphoma
Non-Hodgkin's lymphoma
m-AMS

Accumulative MEDCASE  Est Accumulative Cost:
EA Cost:

Objectives: To determine the antitumor activity as determined by response rate and duration of response of m-AMS used in a single dose schedule in patients with Hodgkin's and non-Hodgkin's lymphoma, who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of this drug.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven, advanced Hodgkin's or non-Hodgkin's lymphoma are eligible. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: The study confirms that m-AMS is an active agent with remission seen in 7 of the 38 evaluable cases. The duration of the CR's is 9 months and 12+ months. The partial remissions are less impressive at 1, 2, 3 and 4 months.
<table>
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<th>Project No: SWOG 7920</th>
<th>Status: Ongoing</th>
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**Title:**

m-AMSA in Hepatocellular Carcinoma, Gallbladder Carcinoma and Bile Duct Carcinomas, Phase II.

**Start Date:** FY 80

**Principal Investigator:**

J. Dean McCracken, M.D., COL, MC

**Dept/Sec:**

Department of Medicine/Oncology

**Facility:**

Brooke Army Medical Center

**Associate Investigators:**

Richard A. Shildt, M.D., LTC, MC

John D. Cowan, M.D., MAJ, MC

**Key Words:**

Hepatocellular carcinoma

Gallbladder carcinoma

Bile duct carcinoma

**m-AMSA**

**Accumulative MEDCASE**

**Estimated Accumulative Periodic Review Results:**

Continue

**Cost:**

OMA Cost:

Periodic

**Objective:**

To determine the efficacy of m-AMSA at a dose of 120 mg/M2 IV every three weeks in producing regressions or remissions in patients with hepatocellular, bile duct, and gallbladder carcinoma.

**Technical Approach:**

All patients who have histologically confirmed hepatocellular carcinoma, gallbladder carcinoma or bile duct carcinoma beyond hope of surgical cure are eligible. There must be histologic proof of residual, recurrent or metastatic carcinoma. Patients must have measurable disease and a life expectancy of at least 4 weeks.

Therapy will follow the schema outlined in the study protocol.

**Progress:**

To date there are 23 hepatoma, 10 gallbladder and 8 bile duct patients entered on study. This study remains open for gallbladder and bile duct only. Responses to date: hepatoma 2 PR' and 2 improvements; gallbladder - 1 PR and 1 improvement; and bile duct - 1 PR.
**Detail Summary Sheet**

**Date:** 23 Oct 81  
**Proj No:** SWOG 7921  
**Status:** Completed

**TITLE:**  
Methyl-Gloxyl BIS-Guanylhydrazone (MGBG) in Metastatic Carcinoma of the Breast.

**Start Date:** FY 80  
**Est Comp Date:**

**Principal Investigator**  
J. Dean McCracken, M.D., COL, MC

**Dept/Sec:**  
Department of Medicine/Oncology

**Associate Investigators:**  
Richard A. Shildt, M.D., LTC, MC  
John D. Cowan, M.D., MAJ, MC

**Key Words:**  
Breast carcinoma  
Methyl-Gloxyl BIS-Guanylhydrazone

**Objectives:**  
To determine response rate and remission duration with weekly intravenous therapy using MGBG in patients with carcinoma of the breast who have failed on higher priority treatment protocols.

To define the qualitative and quantitative toxicity of this regimen.

**Technical Approach:** All patients not eligible for higher priority SWOG studies with histologically proven, incurable, advanced, metastatic carcinoma of the breast are eligible. Patients must have clearly measurable disease and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

**Progress:** There were 54 patients evaluable for response, all had received prior extensive chemo- or hormonal therapy. There was 1 CR documented at autopsy; 1 improvement and 10 patients with stable disease lasting a median of 6 weeks.
TITLE: Combination of CTX, Adria and Cis-Platinum vs m-AMSA in Patients with Advanced Transitional Cell Cancer of the Urinary Bladder with Good Renal Function, Phase II-III.

OBJECTIVES: To determine the response rate to the combination chemotherapy of CAP vs m-AMSA in patients with advanced transitional cell carcinoma of the urinary bladder not amenable by surgical resection and/or radiotherapy, who have good renal function.

To determine the response rate to CAP vs m-AMSA after failure or progression on either arm upon crossover to the alternate treatment arm.

Technical Approach: Patients with histologic diagnosis of transitional cell carcinoma of the urinary bladder, Stage IV, or patients who have failed on previous surgery and/or radiotherapy are eligible. Patients must have measurable disease and a life expectancy of at least 8 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been 21 patients entered. The majority are too early to evaluate. Of the 9 evaluable patients, there have been 2/4 responses to m-AMSA and 3/5 to the combination treatment.
Detail Summary Sheet

Date: 21 Oct 81  Proj No: SWOG 7923  Status: Completed

TITLE:
Gallium Nitrate in Metastatic Squamous Cell Carcinoma and/or Local Recurrent Squamous Cell Carcinoma of the Head and Neck.

Start Date: FY 80  Est Comp Date: 

Principal Investigator:
J. Dean McCracken, M.D., COL, MC

Facility:
Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Oncology

Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

Key Words:
Gallium nitrate
Squamous cell carcinoma of head and neck

Accumulative MEDCASE Est Accumulative
Cost: OMA Cost: Review Results:

Objectives: To determine the efficacy as determined by response rate of Gallium Nitrate in patients with metastatic squamous cell carcinoma and/or local recurrent squamous cell carcinoma of the head and neck who have failed on higher priority treatment protocols.

To determine if Gallium scan results may be predictive of anti-tumor effect.

Technical Approach: All patients not eligible for higher priority SWOG protocols with histologically proven, incurable, advanced, metastatic squamous cell carcinoma or local recurrent squamous cell carcinoma of the head and neck are eligible. Patients must have clearly observable and/or measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Eighteen patients have been registered thus far, with 9 fully or partially evaluable patients, 7 too early to evaluate and 1 patient not evaluable. Thus far there have been no responses seen.
Multimodal Therapy for Limited Small Cell Carcinoma of the Lung, Phase III.

Objectives: To determine the efficacy of sequentially alternating mutually noncross-resistant, multidrug regimens in remission induction and intensification therapy in patients with limited small cell lung cancer. To determine the value of chest radiotherapy added to intensive systemic chemotherapy in reducing chest recurrences and in improvement of survival. To determine the relative efficacy and toxicity of low-dose, extensive chest radiation when used in close chronologic sequence with systemic multi-agent chemotherapeutic regimens. To determine whether radiotherapy ports should be set according to tumor size prior to or after induction chemotherapy. To determine the value of combined systemic chemotherapy and radiotherapy in the control of bulky chest disease.

Technical Approach: Patients with histologically or cytologically proven small cell carcinoma of the lung will be eligible for this study. All patients must have so-called "limited disease".

Therapy will follow the schema outlined in the study protocol.

Progress: In 94 evaluable patients treated with chemotherapy alone, 35% have achieved CR, 47% PR, with an overall response rate of 82%. Sex, performance status and tumor size seem to have no effect on remission durations. At this time the median survival is 53 weeks; however, it is still early.
Detail Summary Sheet

Date: 23 Oct 81          Proj No: SWOG 7925          Status: Ongoing

TITLE:
Chemoimmunotherapy in Stages III and IV Ovarian Carcinoma: A-C plus BCG, vs A-C plus Cis-Platinum, vs A-C plus Cis-Platinum plus BCG, Phase III.

Start Date: FY 80          Est Comp Date: Unknown

Principal Investigator
J. Dean McCracken, M.D., COL, MC

Facility
Brooke Army Medical Center

Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

Dept/Sec: Department of Medicine/Oncology

Key Words:
Ovarian carcinoma
Chemoimmunotherapy

Accumulative MEDCASE Cost: OMA Cost: Periodic Review Results: Continue

Objectives: To compare the effectiveness of A-C + BCG vs A-C + Cis-Platinum for remission and induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma.

To compare the effectiveness of A-C + Cis-Platinum vs A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival in patients with Stage III and IV ovarian carcinoma.

To compare the effectiveness of A-C + BCG vs A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma.

To compare the toxicities of the A-C + BCG, A-C + Cis-Platinum and A-C + Cis-Platinum + BCG regimens.

Technical Approach: Only patients with epithelial type neoplasms will be eligible for this study. The patient must have histologically confirmed diagnosis of ovarian carcinoma.

Therapy will follow the schema outlined in the study protocol.

Progress: It has been noted that patients who receive cis-platinum enter remission earlier than those who do not. The previous amendment utilizing intravenous Cytoxan instead of the oral form is proving successful.

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Detail Summary Sheet

Date: 23 Oct 81    Proj No: SWOG 7927/8    Status: Ongoing

**TITLE:**
Chemotherapy for Multiple Myeloma, Phase III.

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<td>Facility</td>
<td>Brooke Army Medical Center</td>
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<tr>
<td>Dept/Sec</td>
<td>Department of Medicine/Oncology</td>
<td>Associate Investigators:</td>
<td>Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC</td>
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<tr>
<td>Key Words</td>
<td>Multiple myeloma Chemotherapy</td>
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Accumulative MDCASE: Est Accumulative Cost: OMA Cost: Periodic Review Results: Continue

Objectives: To compare the effectiveness of four different drug combinations for remission induction in previously untreated patients with multiple myeloma.

For patients with a 75% tumor reduction, to evaluate the role of 12 months of chemotherapy maintenance with VCP or VCP plus levamisole, when compared with previous experiences.

Technical Approach: Only previously untreated patients with the diagnosis of multiple myeloma will be eligible for this study. Patients should have objective evidence of and be symptomatic from complications due to myeloma.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been good. As yet, no analysis has been prepared.
TITLE: Evaluation of Acridinylamino-Methanesulfon-M-Anisidine (AMSA) in Metastatic Squamous Carcinoma of the Head and Neck, Phase II.

Objectives: To determine the antitumor activity, response rate and duration of response in patients with metastatic squamous cell carcinoma of the head and neck who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of this drug.

Technical Approach: All patients not eligible for higher priority SWOG studies, with histologically proven, incurable, advanced squamous cell carcinoma of the head and neck are eligible. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-nine patients have been entered on the study, and sixteen have been evaluated for response. Of the 7 patients evaluated for response in the good-risk treatment arm, 1 patient had stable disease with 6 patients having increasing disease. In the poor-risk group, one patient showed a partial response, with 8 patients having increasing disease. Too many patients had received prior chemotherapy making them poor-risk and ineligible for the higher dose of m-AMSA.
**Detail Summary Sheet**

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<td>Chemotherapy of Functioning and Nonfunctioning Islet Cell Carcinoma with Chlorozotocin.</td>
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<td><strong>Start Date:</strong></td>
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<td>Brooke Army Medical Center</td>
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<td>Key Words:</td>
<td>Islet cell carcinoma Chlorozotocin</td>
<td>Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC</td>
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**Objectives:**
To study the response of functioning and non-functioning islet cell carcinomas to chlorozotocin.

To obtain pathology materials for review on all patients entered into this study.

**Technical Approach:** Eligible patients must have biopsy-proven islet cell carcinoma not amenable to further surgical therapy, and a minimum life expectancy greater than 6 weeks. All patients must have objectively measurable disease or a significant biochemical abnormality specific for their islet cell tumor.

Therapy will follow the schema outlined in the study protocol.

**Progress:** Two patients have shown improvement, and there have been no other responses.
**Detail Summary Sheet**

**Date:** 23 Oct 81  
**Proj No:** SWOG 7936  
**Status:** Ongoing

**TITLE:** Evaluation of Mitomycin-C + Vincristine + Bleomycin + Cis-Platinum vs Mitomycin-C + Cis-Platinum vs Cis-Platinum in the Treatment of Disseminated Carcinoma of the Uterine Cervix, Phase II.

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**Principal Investigator:** J. Dean McCracken, M.D., COL, MC  
**Facility:** Brooke Army Medical Center  
**Dept/Sec:** Department of Medicine/Oncology  
**Associate Investigators:** Richard A. Shildt, M.D., LTC, MC, John D. Cowan, M.D., MAJ, MC  
**Key Words:** Uterine cervix carcinoma

**Accumulative MEDCASE Cost:**  
**Est Accumulative Cost:**  
**OMA Cost:**  
**Periodic Review Results:** Continue

**Objectives:** To determine the response rate, duration of responses, and survival of (1) cis-platinum alone, (2) cis-platinum combined with mitomycin-C, and (3) cis-platinum with mitomycin-C, vincristine, and bleomycin, in patients with advanced squamous cell carcinoma of the cervix no longer amenable to surgery or radiation therapy.

To document the nature and extent of the hematologic and non-hematologic side effects of the above three drug regimens.

**Technical Approach:** All patients with incurable squamous cell carcinoma of the uterine cervix who are not candidates for surgery or radiotherapy and are not eligible for higher priority SWOG studies are eligible. Patients must have no uncontrolled active or potentially active site of infection, must have at least one measurable lesion and must have a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

**Progress:** There is a significant problem with patient accrual with only 21 patients registered thus far. Because there is already considerable Phase II data on cis-platinum in cervical cancer, it was decided that the cis-platinum alone arm could be dropped to aid in the study's progress.
Evaluation of m-AMSA in Metastatic Carcinoma of the Genitourinary Tract Except Renal Carcinoma, Phase II.

Title: Evaluation of m-AMSA in Metastatic Carcinoma of the Genitourinary Tract Except Renal Carcinoma, Phase II.

Start Date: FY 80

Principal Investigator
J. Dean McCracken, M.D., COL, MC

Dept/Sec:
Department of Medicine/Oncology

Key Words:
Metastatic genitourinary tract carcinoma m-AMSA

Objectives: To determine the antitumor activity of AMSA, as determined by response rate, duration of response, and survival, in patients with metastatic carcinoma of the genitourinary tract who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of this drug.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven, incurable, advanced, metastatic carcinoma will be eligible. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol

Progress: Only five patients have been entered; all are too early to evaluate.
Date: 26 Oct 81  Proj No: SWOG 7940/1/3 Status: Ongoing

TITLE:
Evaluation of 5-FU vs a Phase II Drug in Metastatic Adenocarcinoma of
the Large Bowel, Phase II-III.

Start Date: FY 80  Est Comp Date: Unknown

Principal Investigator:
J. Dean McCracken, M.D., COL, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Oncology

Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

Key Words:
Metastatic adenocarcinoma of large bowel
MGBG
Gallium Nitrate
DHAD

Accumulative MEDCASE  Est Accumulative  Periodic
Cost: OMA Cost: Review Results: Continue

Objectives: To determine the relative activity of a phase II drug (MGBG
SWOG 7941, Gallium Nitrate SWOG 7943, DHAD SWOG 7944) in previously untreated
patients with disseminated colon and rectal cancer.

To compare the survival of patients with disseminated colon cancer
receiving a Phase II agent (MGBG/Gallium Nitrate/DHAD) as first therapy to the
survival of patients receiving fluorinated pyrimidine 5-Fluorouracil (5-FU)
therapy first.

To determine the effect of a previously administered Phase II drug on
the response rate seen with 5-FU in patients with disseminated colon and
rectal cancer.

Technical Approach: Eligible patients must have biopsy proven adenocarcinoma
arising from the colon or rectum. Patients must have clinically measurable
recurrent or disseminated disease to qualify for the study. Obstructive
lesions in the colon and rectum must have been bypassed or adequately main-
tained by decompression measures. Patients must have a life expectancy of
at least 10 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been no responses to date on the 5-FU arm. There is
no significant difference between 5-FU and MGBG between good and poor risk,
male and female. In both arms there was a significant difference between
performance status groups 0-1 versus 2, with a median survival of 25 versus
18 weeks respectively. Twenty-five patients have been placed on the DHAD
arm, 4 have crossed-over to 5-FU; toxicity has been minimal.
**Detail Summary Sheet**

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<td>Appendix VI SWOG 7940, Evaluation of Indicine-N-Oxide in Metastatic Adenocarcinoma of the Large Bowel, Phase II</td>
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<td>J. Dean McCracken, M.D., COL, MC</td>
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<td></td>
<td>Richard A. Shildt, M.D., LTC, MC</td>
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<td>John D. Cowan, M.D., MAJ, MC</td>
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<td>Indicine-N-Oxide</td>
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<td>Large bowel</td>
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**Objectives:**
- To determine the efficacy of indicine-N-oxide administered in a single dose schedule in patients with advanced adenocarcinoma of the colon and rectum by evaluation of response rates.
- To determine more completely the nature and degree of toxicities of indicine-N-oxide in an expanded Phase II study.

**Technical Approach:**
Eligibility is as outlined in SWOG 7940.

Therapy will follow the schema outlined in the study protocol.

**Progress:**
- This is a new study.
**Detail Summary Sheet**

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<th>Date: 27 Oct 81</th>
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**TITLE:** Appendix VI SWOG 7940, Evaluation of DHAD in Metastatic Adenocarcinoma of the Large Bowel, Phase II

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**Principal Investigator:** J. Dean McCracken

**Associate Investigators:** Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

**Key Words:** DHAD, Metastatic adenocarcinoma, Large bowel

**Accumulative MEDCASE Cost:** OMA Cost: Periodic Review Results: Continue

**Objectives:**
To determine the response-rate and remission duration in patients with colorectal carcinoma treated with dihydroxyanthracenedione in a single-dose, every 3-week schedule.

To define the qualitative and quantitative toxicities of dihydroxyanthracenedione.

**Technical Approach:** Patient eligibility is as outlined in SWOG 7940.

Therapy will follow the schema outlined in the study protocol.

**Progress:** Twenty-five patients have been placed on the DHAD arm, 4 have crossed-over to 5-FU; toxicity has been minimal.
**Detail Summary Sheet**

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**TITLE:**
Appendix VI SWOG 7940, Evaluation of AZQ in Metastatic Adenocarcinoma of the Large Bowel, Phase II Portion

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**Principal Investigator**
J. Dean McCracken, M.D., COL, MC

**Dept/Sec:**
Department of Medicine/Oncology

**Key Words:**
Adenocarcinoma large bowel

**Facility**
Brooke Army Medical Center

**Associate Investigators:**
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

**Accumulative MEDCASE Cost:**

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<th>Est Accumulative Cost:</th>
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<th>Periodic Review Results:</th>
<th>Continue</th>
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**Objectives:**
To determine the antitumor activity of AZQ in colorectal carcinoma by determination of response-rate and remission duration.

To further determine the nature and extent of AZQ toxicity in a Phase II study.

**Technical Approach:**
Patient eligibility is as outlined in SWOG 7940.

Therapy will follow the schema outlined in the study protocol.

**Progress:**
This is a new study.
**TITLE:**

Study of Postinfarction Nephrectomy and Medroxyprogesterone Acetate (Depo-Provera) in Metastatic Renal Cell Carcinoma.

**Start Date:** FY 80  
**Est Comp Date:** Unknown

**Principal Investigator**
J. Dean McCracken, M.D., COL, MC

**Dept/Sec:**
Department of Medicine/Oncology

**Key Words:**
Metastatic renal cell carcinoma  
Postinfarction nephrectomy  
Depo-Provera

**Objectives:**
To determine the response rate and survival patterns in patients with disseminated renal cell carcinoma treated with postinfarction nephrectomy.

To determine the response rate and survival patterns of patients with disseminated renal cell carcinoma who relapse or do not respond to postinfarction nephrectomy when treated with Depo-Provera.

**Technical Approach:** Patients with measurable disseminated renal cell carcinoma who have not had removal of the primary cancer and in whom metastatic disease is not resectable at the time of nephrectomy are eligible. Patients must have an expected survival of at least 3 months.

**Therapy will follow the schema outlined in the study protocol.**

**Progress:** More than 20 patients have been entered on study with 14 being evaluable. The 14 evaluable patients are categorized as follows: 1 PR, 4 stable disease, 8 no response, and 1 postoperative mortality. Nine patients received Depo-Provera resulting in 1 PR, 1 stable disease, and 7 no responses.
Evaluation of m-AMSA in Metastatic or Recurrent Epithelial Carcinomas of the Female Genital Tract.

Start Date: FY 80
Principal Investigator: J. Dean McCracken, M.D., COL, MC
Department of Medicine/Oncology
Key Words: Epithelial carcinoma of female genital tract
m-AMSA

Objectives: To determine the antitumor activity of AMSA in patients with metastatic or recurrent epithelial carcinomas of the ovary, endometrium, cervix, vagina or vulva who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of AMSA in patients treated by the split-course three-day schedule.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven incurable, advanced, metastatic or recurrent epithelial carcinoma of the ovary, endometrium, cervix, vagina or vulva are eligible. Patients must have clearly measurable disease and a life expectancy of 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: As a whole, AMSA does not seem to be effective in epithelial Gyn carcinomas. However, the agent did seem to be well tolerated on the daily x 3 schedule. Of the 15 patients who were evaluated, no complete or partial responses occurred. The study was closed to ovarian patients.
Evaluation of Methyl-Gloxyl Bis-Guanylhydrazone (MGBG) in Metastatic Renal Carcinoma.

Start Date: FY 80

Principal Investigator: J. Dean McCracken, M.D., COL, MC

Dept/Sec: Department of Medicine/Oncology

Key Words: Metastatic renal carcinoma

Methyl-Gloxyl Bis-Guanylhydrazone (MGBG)

Objectives: To determine the response rate and remission duration with weekly intravenous therapy using MGBG in patients with metastatic renal carcinoma.

To define the qualitative and quantitative toxicity of this regimen.

Technical Approach: Eligible patients are those with a histologically proven diagnosis of incurable, advanced, metastatic renal cell carcinoma. All patients must have measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Of the 58 evaluable patients, 3 showed a partial response (5% response rate). This Phase II study does not confirm the earlier, more encouraging Phase I trial results.
**Detail Summary Sheet**

**Date:** 26 Oct 81  
**Proj No:** SWOG 7960  
**Status:** Completed

**TITLE:**  
Colchicine in Refractory Hodgkin's Disease, CLL, Lung and Breast Cancer.

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<tr>
<th>Start Date:</th>
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<tbody>
<tr>
<td>Principal Investigator</td>
<td>J. Dean McCracken, M.D., COL, MC</td>
<td>Facility</td>
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<tr>
<td>Dept/Sec:</td>
<td>Department of Medicine/Oncology</td>
<td>Brooke Army Medical Center</td>
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<tr>
<td>Associate Investigators:</td>
<td>Richard A. Shildt, M.D., LTC, MC, John D. Cowan, M.D., MAJ, MC</td>
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<tr>
<td>Key Words:</td>
<td>Refractory Hodgkin's, CLL, Lung and Breast Cancer, Cochicine</td>
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**Objectives:**

- To determine the maximum dose of colchicine which may be safely administered on a once weekly basis.
- To determine the response rate (standard error ± 10%) to weekly, intravenous colchicine in each of the tumor types tested.
- To determine quantitative and qualitative toxicity of the drug on this schedule.

**Technical Approach:** Patients with chronic lymphocytic leukemia, Hodgkin's disease, breast and lung cancer (both small and non-small cell) are potential candidates for this study after they have developed progressive disease on SWOG protocols of higher priority. They must have a life expectancy of at least 6 weeks and a Performance Status of 0-3. Measurable disease is desirable but not required.

It is estimated that 30 patients in each category will need to be entered in order to have 25 patients which are response-evaluable.

Therapy will follow the schema outlined in the study protocol.

**Progress:** A good response to colchicine has been noted in small cell lung cancer.
**TITLE:**
m-AMSA in Melanoma, Myeloma, Lymphoma, Oat Cell Lung and Breast Carcinomas

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**Principal Investigator:**
J. Dean McCracken, M.D., COL, MC

**Facility:**
Brooke Army Medical Center

**Associate Investigators:**
- Richard A. Shildt, M.D., LTC, MC
- John D. Cowan, M.D., MAJ, MC

**Key Words:**
m-AMSA

**Objectives:**
- To determine the efficacy of m-AMSA at a dose of 120 mg/M² IV every 3 weeks in producing regressions or remission in metastatic melanoma, lymphoma, myeloma, metastatic oat cell lung carcinoma, and metastatic breast cancer, which are resistant to standard chemotherapies.

To determine the effect of m-AMSA on survival of patients with metastatic melanoma, lymphoma, myeloma, metastatic oat cell carcinoma of the lung, and metastatic breast cancer, which are resistant to standard chemotherapies.

To correlate in vitro m-AMSA sensitivities in the tumor stem cell colony drug system and in vivo m-AMSA activity in patients with metastatic melanoma, lymphoma, myeloma, metastatic oat cell carcinoma of the lung and metastatic breast cancer, all of which are resistant to standard chemotherapies.

**Technical Approach:**
Patients must have histologically confirmed melanoma, myeloma, breast carcinoma, lymphoma or oat cell carcinoma of the lung, refractory to standard therapies. Patients must have measurable disease and a life expectancy of six weeks.

Therapy will follow the scheme outlined in the study protocol.

**Progress:**
There were 69 breast patients entered in this broad Phase I pilot; of these, 30 are presently response evaluable resulting in 3 PR's and 5 disease improvements.

Minimal response has been seen in oat cell carcinoma with 12 patients having progression of disease and 2 with an improvement in disease status.

Thirteen evaluable melanoma patients have been entered on this study, all having been pre-treated. One PR has been reported, and 1 patient had less than a partial response, giving this agent a 5-10% response rate. Of these pre-treated patients, 10% are sensitive in vitro to m-AMSA, while a 26% sensitivity rate has been reported in patients who have not received prior chemotherapy.
SWOG 7963 (continued)

To date there are 7 evaluable patients. More data will be required before any conclusions can be made.

The study has been closed to lymphoma and breast cancer patients.
TITLE: Treatment of Early Squamous Cell Carcinoma of the Head and Neck with Initial Surgery and/or Radiotherapy Followed by Chemotherapy vs No Further Treatment, Phase III.

Start Date: FY 80
Est Comp Date: Unknown

Principal Investigator
J. Dean McCracken

Facility
Brooke Army Medical Center

Dept/Sec: Department of Medicine/Oncology
Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

Key Words:
Squamous cell carcinoma of head and neck
Radiotherapy
Chemotherapy

Objective: To determine if the disease-free interval and survival of patients in high risk categories of squamous head and neck cancer can be improved by adjuvant methotrexate after initial surgery, radiotherapy or both have resulted in no clinically evident disease.

Technical Approach: Patients with histologically proven squamous cell carcinoma of the head and neck who have been rendered clinically disease free by surgery or radiotherapy are eligible. Patients must be entered within three months of completion of radiotherapy or surgery.

Therapy will follow the scheme outlined in the study protocol.

Progress: Thus far there are 8 evaluable patients on the "no treatment" arm and 2 evaluable patients on the MTX arm. No data are available at this time.
Detail Summary Sheet

Date: 26 Oct 81  Proj No: SWOG 7969  Status: Ongoing

TITLE:
Hepatic Infusion and Systemic Combination Chemotherapy in the Treatment of Unresectable Hepatoma, Phase II.

Start Date: FY 80  Est Comp Date: Unknown

Principal Investigator
J. Dean McCracken, M.D., COL, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Oncology

Associate Investigators:
Richard A. Shildt, M.D., LTC, MC

Key Words:
John D. Cowan, M.D., MAJ, MC
Hepatoma, unresectable
Chemotherapy

Accumulative MEDCASE  Est Accumulative Periodic
Cost:  OMA Cost:

Objective: To determine the remission rate seen with induction chemotherapy consisting of intra-arterially infused 5-FUDR, Adriamycin and Streptozotocin in patients with hepatocellular carcinoma.

Technical Approach: Patients with a histologically confirmed diagnosis of unresectable hepatocellular carcinoma which is localized to the liver are eligible. Patients with local extension of tumor into contiguous organs are eligible. Patients must not have received prior chemotherapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual is very slow. Since there has been no untoward toxicity in the patients treated thus far, the study was opened for Group participation.
Study of Cis-Platinum for Recurrent Gliomas.

Objectives: To determine the efficacy of the chemotherapeutic agent cis-diammine dichloroplatinum (DDP) in the treatment of gliomas recurrent after prior therapy with irradiation (plus or minus chemotherapy).

To determine the duration of response and survival of patients receiving this therapy.

Strategic Approach: All patients with gliomas (grade I-IV) who have recurred following cranial irradiation will be eligible. It is essential that patients have evaluable lesions on either CT or radionuclide brain scan.

Therapy will follow the scheme outlined in the study protocol.

Progress: Thirteen patients have been entered on this study, with 12 patients still too early to evaluate.
Chlorozotocin in the Treatment of Advanced Sarcomas.

Objective: To determine whether chlorozotocin in a dose of 120 mg/m² has significant activity in sarcomas by determination of response rate and duration.

To describe toxicities of chlorozotocin not yet defined.

Technical Approach: Eligible patients must have biopsy proven advanced bony or soft tissue sarcoma. Patients must have measurable disease and an expected survival of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Forty-one patients have been entered on this study. There have been no significant responses.
Detail Summary Sheet

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<td>TITLE: Radiation Therapy in Combination with CCNU in Patients with Incompletely Resected Gliomas of the Brain, Grade I and II.</td>
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<td>Facility: Brooke Army Medical Center</td>
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<tr>
<td>Associate Investigators: Richard A. Shildt, M.D., LTC, MC, John D. Cowan, M.D., MAJ, MC</td>
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<td>Accumulative MEDCASE Est Accumulative Periodic Cost: OMA Cost:</td>
<td>Review Results: Continue</td>
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Objectives: To compare the survival of patients with incompletely resected Grade I and II gliomas treated with radiation alone versus radiation and CCNU.

To compare the effectiveness of radiation therapy versus radiation therapy plus CCNU for remission induction and duration of remission.

Technical Approach: Patients with histologically confirmed primary brain tumors of the following histologic types are eligible: Astrocytoma, Grade I and II with incomplete tumor resection. Patients who have had surgery with histologic diagnosis within the previous six weeks are eligible.

Therapy will follow the scheme outlined in the study protocol.

Progress: Eighteen patients have been entered on this study with 15 still too early to evaluate.
Detail Summary Sheet

Date: 27 Oct 81  Proj No: SWOG 7984  Status: Ongoing
TITLE:
Treatment of Chronic Stage CML with Pulse, Intermittent Busulfan Therapy with or without Oral Vitamin-A, Phase III
Start Date: Nov 80  Est Comp Date: Unknown
Principal Investigator
J. Dean McCracken, M.D., COL, MC
Facility
Brooke Army Medical Center
Dept/Sec: Associate Investigators:
Department of Medicine/Oncology
Key Words:
Leukemia
Busulfan
Vitamin A

Accumulative MEDCASE  Est Accumulative Periodic Cost: OMA Cost: Review Results: Continue
Objective: To determine the efficacy of standard pulse, intermittent busulfan therapy plus oral vitamin A in prolonging the chronic phase of CML, and hence in prolonging survival.

Technical Approach: All patients with newly diagnosed chronic stage CML will be eligible for entry onto protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.
Date: 26 Oct 81

TITLE:
Combined Modality Treatment for ER- Breast Cancer, Phase III.

Start Date: FY 80

Est Comp Date: Unknown

Facility
Brooke Army Medical Center

Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D.

Department of Medicine/Oncology

Key Words:
Breast cancer
Estrogen receptor negative (ER-)

Accumulative MEDCASE Est Accumulative
Cost:  OMA Cost:  Periodic

Objectives: To compare disease-free interval and survival among control
group Stage I (and Stage II node negative) breast cancer patients whose tumors are determined to be ER- at the time of mastectomy, versus Stage I (and Stage II node negative) ER- patients treated with adjuvant CMFV for 6 months.

To document recurrence patterns among untreated patients with Stage I breast cancer whose tumors are determined to be ER- at the time of mastectomy.

Technical Approach: All female patients having had a radical, modified radical, or total mastectomy, or segmental mastectomy with axillary node dissection for potentially curable, histologically proven breast carcinoma, whose axillary nodes are negative for tumor, and whose estrogen receptor assay on the primary tumor is less than 10 femtomoles/mg cytosol protein are eligible for this study. Patients must be registered within 28 days of mastectomy. Patients with previous oophorectomy are eligible provided the oophorectomy was not performed for tumor.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was modified to an intermittent drug regimen to be given for six months - Cytoxan, 5-FU, Methotrexate, Vinクリステェ vs no further treatment until relapse. Patient accrual has been slow, and no data are available for analysis at this time.
Testicular Cancer Intergroup Study.

Objectives: To compare the disease-free survival and overall survival for surgery alone (with chemotherapy for relapsers) vs surgery plus early adjuvant chemotherapy in patients with resectable Stage II testicular cancer.

To register and follow patients with non-seminoma, non-choriocarcinoma stage I testicular cancer, to define prognostic variables which may predict recurrence in this stage group.

To define the difference in disease-free rates and patterns of recurrence based upon histologic subtypes and extent of disease on initial presentation.

To evaluate the role of marker substances such as human chorionic gonadotropin, alpha-fetoprotein and lactic dehydrogenase in the early detection and management of recurrences in patients with stage I and stage II testicular carcinoma.

To evaluate the accuracy of lymphangiogram, CAT scans and ultrasound studies for staging of retroperitoneal nodal involvement.

Technical Approach: Patients with histologically confirmed carcinoma of the testis, stage I or stage II, are eligible. Patients should enter the study between two and four weeks after lymphadenectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: The Southwest Oncology Group has entered 8 patients in this intergroup study. Insufficient data have been collected for reporting purposes.
**Detail Summary Sheet**

**Date:** 26 Oct 81  
**Proj No:** SWOG 8001  
**Status:** Ongoing

**TITLE:**  
Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III.

<table>
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<th>Start Date:</th>
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**Principal Investigator**  
J. Dean McCracken, M.D., COL, MC

**Dept/Sec:**  
Department of Medicine/Oncology

**Key Words:**  
Acute lymphoblastic leukemia

**Accumulative MEDCASE**  
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**Cost:**  
**OMA Cost:**  
**Periodic**  
**Review Results:**  
Continue

**Objective:** To evaluate the effectiveness as determined by the complete remission rate of the L10 protocol using Vincristine, Prednisone and Adriamycin for induction, followed by intensive consolidation in the treatment of acute ALL.

To compare the effect on remission duration and survival of two maintenance regimens: the L10 "eradication" regimen vs cyclic therapy with POMP-CPAP-OPAL.

To determine the reproducibility of the FAB histologic classification and correlation to response to therapy of ALL in adults.

**Technical Approach:** Patients are eligible with the diagnosis of acute lymphoblastic leukemia who satisfy the following criteria:  
A) Absolute infiltration of the marrow with >50% blasts;  
b) Absolute infiltration is defined as the total blast cell percentage (%) multiplied by the bone marrow cellularity percentage divided by 100;  
c) If the absolute infiltrate is 30-49%, evidence of progressive disease prior to entering the study will be required.

**Therapy** will follow the schema outlined in the study protocol.

**Progress:** Twelve patients have been entered, and it is too early for a comprehensive analysis. However, on patients with adequate data, there have been 8/9 complete responses. Because of poor patient accrual, it was decided to stop the randomization on the maintenance phase. Therefore Arm 1, the POMP-CPAP-OPAL therapy will be closed and all patients will now receive the L10 cyclic therapy.
**Detail Summary Sheet**

**Date:** 26 Oct 81  **Proj No:** SWOG 8003  **Status:** Completed

**TITLE:**
Evaluation of MGBG in Non-Oat Cell Cancer of the Lung, Phase II.

**Start Date:** FY 80  **Est Comp Date:** Unknown

**Principal Investigator**
J. Dean McCracken, M.D., COL, MC

**Dept/Sec:**
Department of Medicine/Oncology

**Objectives:** To determine the response rate and remission duration with weekly intravenous therapy using MGBG in patients with non-oat cell carcinoma of the lung who have failed on higher priority treatment protocols.

To define the qualitative and quantitative toxicity of this regimen.

**Technical Approach:** All patients not eligible for higher priority SWOG studies with histologically proven, incurable, advanced metastatic non-oat cell carcinoma of the lung are eligible. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

**Progress:** The median overall survival for all evaluable patients is 16 weeks. The comparison among three cell types does not show any significant differences.
Detail Summary Sheet

Date: 26 Oct 81 Proj No: SWOG 8004 Status: Ongoing

TITLE:
Evaluation of DHAD in Soft Tissue and Bone Sarcomas, Phase II.

Start Date: FY 80 Est Comp Date: Unknown
Principal Investigator
J. Dean McCracken, M.D., COL, MC
Facility
Brooke Army Medical Center
Dept/Sec:
Department of Medicine/Oncology
Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC
Key Words:
Sarcoma, soft tissue and bone
DHAD

Accumulative MEDCASE Est Accumulative Periodic Cost: OMA Cost: Review Results: Continue
Objectives: To determine the efficacy, by response rate, of Dihydroxyantranilic acid (DHAD) in patients with soft tissue and bone sarcomas, who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of this drug used in a single dose every three-week schedule.

Technical Approach: All patients must have histologically proven, incurable soft tissue or bone sarcomas, not eligible for higher priority SWOG studies, in order to be eligible for study. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty seven patients have been accrued so far; however, most of them are too early to be evaluated.
Detail Summary Sheet

Date: 27 Oct 81  Proj No: SWOG 8005  Status: Ongoing

TITLE:
Evaluation of DHAD in Refractory Malignant Lymphomas, Phase II - Pilot

Start Date: 11 May 81  Est Comp Date: Unknown

Principal Investigator
J. Dean McCracken, M.D., COL, MC

Dept/Sec:
Department of Medicine/Ongoing

Facility
Brooke Army Medical Center

Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

Key Words:
DHAD
Malignant melanoma

Objectives: To determine response-rate and response duration of patients with refractory malignant lymphomas, both Hodgkin's disease and non-Hodgkin's lymphoma treated with anthrancenedione used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of anthrancenedione in a Phase II study.

Technical Approach: All patients with malignant lymphoma who are not eligible for higher priority SWOG protocols are eligible. There are no age restrictions and patients must have a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: The Phase I data indicates a potentially very active agent in refractory malignant lymphoma patients. Thus far there has been one partial response in the two evaluable cases on study.
**Detail Summary Sheet**

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**TITLE:** Postoperative Reductive Chemotherapy for Stage III or IV Operable Epidermoid Carcinoma of the Oral Cavity, Oropharynx, Hypopharynx, or Larynx, Phase III

**Start Date:** Nov 80

**Principal Investigator**
J. Dean McCracken, M.D., COL, MC

**Dept/Sec:** Department of Medicine/Oncology

**Key Words:**
Epidermoid carcinoma

**Est Comp Date:** Ongoing

**Facility**
Brooke Army Medical Center

**Associate Investigators:**
- Richard A. Shildt, M.D., LTC, MC
- John D. Cowan, M.D., MAJ, MC

**Accumulative MEDCASE Est Accumulative Periodic Cost:**
| OMA Cost: | Review Results: Continue |

**Objective:** To determine the length of remission, recurrence-rates, survival-rates, and pattern of recurrence for patients receiving therapy utilizing surgery and postoperative radiation vs. combined therapy utilizing preoperative chemotherapy, surgery and postoperative radiation therapy in operable Stage III or IV epidermoid carcinoma of the head and neck.

**Technical Approach:** Patients with operable lesions will be randomized between two therapeutic programs: Arm I - combined therapy including surgery and postoperative radiation therapy; or Arm 2 - combination chemotherapy followed by surgery and radiation therapy. Patients randomized to the chemotherapy limb will receive 3 courses of chemotherapy consisting of cis-platinum, methotrexate, vincristine and bleomycin.

**Progress:** This is a new study.
Detail Summary Sheet

DATE: 226 Oct 81  Proj No: SWOG 8008   Status: Ongoing

TITLE: Evaluation of Dihydroxyantracenedione (DHAD) in Refractory Breast Cancer, Phase II.

Start Date: FY 80  Est Comp Date: Unknown

Principal Investigator
J. Dean McCracken, M.D., COL, MC

Dept/Sec:
Department of Medicine/Oncology

Key Words:
Breast cancer
Dehydroxyantracenedione (DHAD)

Accumulative MEDCASE  Est Accumulative Periodic
Cost: OMA Cost: Review Results: Continue

Objectives: To determine the response rate and remission duration of refractory breast cancer in patients treated with antracenedione used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: Eligible patients must have pathologically verified histologic diagnosis of breast cancer. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Ninety-seven patients have been entered to date. However, there is no response data available at this time.
Detail Summary Sheet

**TITLE:**
Evaluation of DHAD in Patients with Refractory Small Cell Lung Cancer, Phase II.

**Start Date:** FY 80
**Facility:** Brooke Army Medical Center

**Principal Investigator:** J. Dean McCracken, M.D., COL, MC
**Associate Investigators:** Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

**Key Words:** Small cell lung cancer, DHAD

**Objectives:** To determine the response rate and remission duration of refractory small cell lung cancer in patients treated with DHAD used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

**Technical Approach:** Eligible patients must have pathologically verified histologic diagnosis of small cell lung cancer. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

**Progress:** No responses have been seen in the 12 evaluable patients to date. This agent seemed to be well tolerated with minimal activity. It was felt that it would be worthwhile to investigate this agent in patients with no prior Adriamycin.
Evaluation of DHAD in Advanced Prostate Cancer, Phase II.

Objectives: To determine the response rate and remission duration in patients with prostate cancer treated with DHAD used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: Eligible patients must have pathologically verified histologic diagnosis of prostate cancer. All patients must have measurable or evaluable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Eight patients have been entered to date; it is too early for analysis at this time.
### Detail Summary Sheet

**Date:** 26 Oct 81  
**Proj No:** SWOG 8011  
**Status:** Ongoing

**TITLE:**
Evaluation of DHAD in Patients with Advanced Renal Cell Carcinoma, Phase II.

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**Principal Investigator**
J. Dean McCracken, M.D., COL, MC

**Dept/Sec:**
Department of Medicine/Oncology

**Key Words:**
Renal cell carcinoma  
DHAD

**Objectives:**
To determine the response rate and duration of response in patients with advanced renal cell carcinoma treated with DHAD used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

**Technical Approach:** All patients with advanced renal cell carcinoma not eligible for higher priority protocols are eligible. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

**Progress:** Thirty-eight patients have been entered, all of which are too early to evaluate.
# Treatment for Advanced Adenocarcinoma and Large Cell Carcinoma of the Lung: FOMi vs CAP vs FOMi/CAP, Phase III

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## Principal Investigator
J. Dean McCracken, M.D. COL, MC

## Dept/Sec:
Department of Medicine/Oncology

## Associate Investigators:
- Richard A. Shildt, M.D., LTC, MC
- John D. Cowan, M.D., MAJ, MC

## Key Words:
- Lung
- Adenocarcinoma
- Large cell carcinoma

## Objectives:
- To evaluate by pairwise comparison the response-rate, duration of response and survival of 3 regimens FOMi, CAP and FOMi/CAP in patients with advanced (TNM Stage III M1) adenocarcinoma and large cell undifferentiated carcinoma of the lung.
- To evaluate the degree of non-cross resistance of FOMi in CAP failures and of CAP on FOMi failures.
- To compare the toxicities and side effects of FOMi and CAP.

## Technical Approach:
Patients are eligible who have a histologically confirmed diagnosis of adenocarcinoma of the lung or large cell undifferentiated carcinoma of the lung. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

## Progress:
Patients who fail FOMi or CAP are crossed over to the third arm - FOMi/CAP and are analyzed separately. No unusual problems or toxicities have been reported.
Colchicine in Refractory Chronic Lymphocytic Leukemia, Phase I-II.

Objectives: To determine the maximum dose of colchicine that may safely be administered on a once weekly basis.

To determine the response rate standard error (+/- 10%) in patients with chronic lymphocytic leukemia.

To determine quantitative and qualitative toxicity of the drug colchicine administered on a once weekly basis.

Technical Approach: Patients with chronic lymphocytic leukemia who have demonstrated progressive disease on studies of higher priority are eligible. Patients must have recovered from toxicities resulting from prior treatment before the initiation of treatment with colchicine.

Therapy will follow the schema outlined in the study protocol.

Progress: Eleven patients have been entered. Seven are evaluable and showed no response.
Date: 28 Oct 81  Proj No: SWOG 8015  Status: Ongoing

TITLE: Evaluation of Two Combination Chemotherapy Programs, Adriamycin and Cis-Platinum (AP) vs Adriamycin, Cis-platinum plus VP-16 (VAP), in the Treatment of Extensive Squamous Cell Carcinoma of the Lung, Phase III

Start Date: Jan 81  Est Comp Date: Unknown

Principal Investigator
J. Dean McCracken, M.D., COL, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Oncology

Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

Key Words:
Lung
Squamous cell carcinoma

Accumulative MEDCASE  Est Accumulative  Periodic Cost:  OMA Cost:  Review Results:  Continue

Objectives: To determine the activity, in terms of response-rate, remission duration, and survival in patients with extensive squamous cell (epidermoid) carcinoma of the lung, for two combination chemotherapy programs: Adriamycin and Cis-platinum vs VP-16, Adriamycin and Cis-platinum.

To evaluate the relative toxicities of these respective regimens.

To assess the feasibility and reliance of applying "measurable versus evaluable" criteria of tumor regression in determining therapeutical response.

To correlate tumor grade with response and survival.

Technical Approach: Eligible patients are those with "extensive" squamous cell (epidermoid) lung carcinoma defined as "spread beyond the hemithorax and ipsilateral scalene, supraclavicular and mediastinal lymph nodes", equivalent with TNM system Stage III class M1 with any T or N other than mediastinal, supraclavicular scalene nodes involved. Relapsing or recurrent TNM Stage I or II patients, failing after radiation therapy alone to the primary site of involvement are also eligible for study.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, and it is too early to give an evaluation at this time.
Detail Summary Sheet

<table>
<thead>
<tr>
<th>Date: 28 Oct 81</th>
<th>Proj No: SWOG 8017</th>
<th>Status: Ongoing</th>
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<tbody>
<tr>
<td>TITLE: 5-FU, Adriamycin, Streptozotocin and Cyclophosphamide (FAC-S) in the Treatment of Metastatic Carcinoid Tumors, Phase II</td>
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<tr>
<td>Start Date: Nov 80</td>
<td>Est Comp Date: Unknown</td>
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<tr>
<td>Principal Investigator: J. Dean McCracken, M.D., COL, MC</td>
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<tr>
<td>Dept/Sec: Department of Medicine/Oncology</td>
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<tr>
<td>Associate Investigators: Richard A. Shildt, M.D., LTC, MC, John D. Cowan, M.D., MAJ, MC</td>
<td></td>
<td></td>
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<tr>
<td>Key Words: Carcinoid</td>
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<tr>
<td>Accumulative MEDCASE Cost:</td>
<td>Est Accumulative OMA Cost:</td>
<td>Periodic Review Results: Continue</td>
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</table>

**Objectives:** To determine whether combination chemotherapy employing 5-FU, Cyclophosphamide, Adriamycin and Streptozotocin is effective in the management of metastatic carcinoid.

To study the duration of survival of patients with metastatic carcinoid tumor treated with combination chemotherapy regimens.

To provide further information concerning the response and/or survival of patients with metastatic carcinoid originating in different sites and having different metastatic patterns.

**Medical Approach:** All patients must have biopsy-proven carcinoid tumor not amenable to further surgical therapy with no prior chemotherapy. A minimum life expectancy of 6 weeks and a performance status of 3 or better per Southwest Oncology Group criteria is necessary. All patients must have objectively measurable disease either as a measurable lesion or significant biochemical abnormality specific for their tumor.

Therapy will follow the schema outlined in the study protocol.

**Progress:** This is a new study.
Adriamycin + VP-16 vs Adriamycin Alone in Advanced Adenocarcinoma of the Breast, Phase II

Start Date: Jan 81
Est Comp Date: Unknown

J. Dean McCracken, M.D., COL, MC
Facility: Brooke Army Medical Center

Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

Key Words:
Adenocarcinoma
Breast

Objectives: To determine the efficacy of the Adriamycin and VP-16 combination in the treatment of previously treated patients with disseminated breast cancer, as determined by response-rate compared with Adriamycin alone.

To determine the length of the remission on VP-16 maintenance after an Adriamycin/VP-16 regimen.

Technical Approach: Patients must have histological proof of breast cancer currently Stage IV with measurable lesions. ER+, ER-, and ER unknown patients are eligible. Patient must have adequate cardiac function and no clinical evidence of congestive heart failure.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has only 4 patients entered to date and they are too early for analysis.
## Combined Modality Therapy for Disseminated Soft Tissue Sarcomas, Phase III

<table>
<thead>
<tr>
<th>Date: 28 Oct 81</th>
<th>Proj No: SWOG 8024</th>
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### TITLE: Combined Modality Therapy for Disseminated Soft Tissue Sarcomas, Phase III

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<tbody>
<tr>
<td>J. Dean McCracken, M.D., COL, MC</td>
<td>Brooke Army Medical Center</td>
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<tbody>
<tr>
<td>Department of Medicine/Oncology</td>
<td>Richard A. Shildt, M.D., LTC, MC</td>
</tr>
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<table>
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<tr>
<th>Accumulative MEDCASE Cost:</th>
<th>Est Accumulative MEDCASE Cost:</th>
<th>Periodic Review Results: Continue</th>
</tr>
</thead>
</table>

**Objectives:** To compare the effectiveness of bolus administration of Adriamycin and DTIC, to continuous infusion administration of Adriamycin and DTIC, in remission induction of patients with disseminated soft tissue sarcomas.

- To compare the toxicities of these two drug schedules.
- To determine the feasibility on a group-wide basis of surgical excision of accessible lesions in partially responding patients.
- To compare the histology of the diagnostic lesion with the histology of tumor removed from the partial responder.

**Clinical Approach:** Patients with a biopsy confirmed diagnosis of a soft tissue sarcoma with convincing clinical or biopsy-documented evidence of metastatic disease are eligible for this study. Patients must not have received any prior chemotherapy with the agents used in this study. Patients must have a life expectancy of 10 weeks, and all patients must have lesion(s) which is measurable and can be followed for tumor response.

**Therapy will follow the schema outlined in the study protocol.**

**Progress:** This is a new study.
### Title
Combination Chemotherapy for Chronic Lymphocytic Leukemia

### Objectives
To determine the response-rate and duration of remission in patients with **CLL** treated with combination chemotherapy consisting of Prednisone, Vincristine, Cytosine Arabinoside, Cytoxan, and Adriamycin.

To correlate parameters obtained in the clinical, pathological, and immunological staging with response to treatment.

To determine the effect of stopping chemotherapy after patients have achieved a complete remission plus two consolidation courses, in order to define a cured or stabilized fraction of patients.

### Technical Approach
All patients who fulfill the criteria for diagnosis of chronic lymphocytic leukemia according to the Rai Classification will be eligible for registration.

Therapy will follow the schema outlined in the study protocol.

### Progress
Twenty-six patients have been registered, most of whom are too early to evaluate. Evidence so far suggests that this regimen is equal to the CAP regimen. Combination chemotherapy appears to be more effective than single-agent therapy.
Cis-Platinum in the Treatment of Refractory Epidermoid Carcinoma of the Penis, Phase II

<table>
<thead>
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<th>Date:</th>
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<th>SWOG 8026</th>
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<td>Cis-Platinum in the Treatment of Refractory Epidermoid Carcinoma of the Penis, Phase II</td>
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<tr>
<td>Start Date:</td>
<td>Jan 81</td>
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<td>Department of Medicine/Oncology</td>
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<tr>
<td>Associate Investigators:</td>
<td>Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC</td>
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<td>Key Words:</td>
<td>Epidermoid carcinoma</td>
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Accumulative MEDCASE: | Est Accumulative MEDCASE: | Periodic Review Results: | Continue |
Accumulative Cost:   | OMA Cost:               |                          |          |
Objective: To determine response-rate and survival in patients with advanced epidermoid carcinoma of the penis treated with Cis-platinum.

Technical Approach: Patients must have epidermoid carcinoma of the penis confirmed by biopsy, Stage III or IV, refractory to surgery and radiotherapy. Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been entered, both of which showed a partial response.
Date: 28 Oct 81 Proj No: SWOG 8027 Status: Ongoing

TITLE:
The Natural History of Pathological Stage $T_{1-2} \text{ N}_0 \text{ M}_0$ ER+ Breast Cancer, Phase III

Start Date: 11 May 81 Est Comp Date: Unknown

Principal Investigator
J. Dean McCracken, M.D., COL, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Oncology

Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

Key Words: Breast cancer

Accumulative MEDCASE Est Accumulative Periodic Cost: OMA Cost: Review Results: Continue

Objective: To document recurrence-rates, patterns of recurrence, and survival among patients with Stage I or Stage II node negative ($T_{1-2} \text{ N}_0 \text{ M}_0$) breast cancer whose tumors are determined to be estrogen receptor positive at the time of surgery.

Technical Approach: All female patients having had a radical, modified radical, or adequate local excision, with axillary node dissection for histologically proven breast carcinoma, whose axillary nodes are negative for tumor, and whose estrogen receptor assay on the primary tumor is positive are eligible for this study.

Progress: This is a new study; no reportable data are available at this time.
Evaluation of DHAD in Gynecologic Cancers, Stage II

Objectives: To determine the response-rate and remission duration in patients with gynecologic tumors treated with DHAD used in a single dose every-three-week schedule.

To define the qualitative and quantitative toxicities of DHAD as administered in this Phase II Study.

Technical Approach: To be eligible for this study, patients must have a pathologically verified histologic diagnosis of ovarian (epithelial type), endometrial, or cervical (squamous cell type) carcinoma. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.
**Detail Summary Sheet**

<table>
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<th>Date:</th>
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<th>Proj No: SWOG 8030</th>
<th>Status: Ongoing</th>
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<td><strong>TITLE:</strong></td>
<td>Evaluation of DHAD in Advanced Squamous Cell Carcinoma of the Head and Neck, Phase II</td>
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<td><strong>Start Date:</strong></td>
<td>11 May 81</td>
<td><strong>Est Comp Date:</strong> Unknown</td>
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<td><strong>Principal Investigator:</strong></td>
<td>J. Dean McCracken</td>
<td><strong>Facility:</strong> Brooke Army Medical Center</td>
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<td><strong>Dept/Sec:</strong></td>
<td>Department of Medicine/Oncology</td>
<td><strong>Associate Investigators:</strong> Richard A. Shildt, M.D., LTC, MC, John D. Cowan, M.D., MAJ, MC</td>
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<td><strong>Key Words:</strong></td>
<td>Squamous cell carcinoma</td>
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| **Accumulative MEDCASE** | **Est Accumulative Cost:** OMA Cost: | **Periodic Review Results:** Continue |

**Objectives:** To determine the response-rate and remission duration in patients with advanced squamous cell carcinoma of the head and neck treated with DHAD used in a single dose every-three-week schedule.

To define further the qualitative and quantitative toxicities of DHAD.

**Technical Approach:** To be eligible for this study, patients must have a verified histologic diagnosis of squamous cell carcinoma of the head and neck region. All patients must have a life expectancy of at least three months.

Therapy will follow the schema outlined in the study protocol.

**Progress:** This is a new study.
Evaluation of DHAD in Refractory Multiple Myeloma, Phase II

Objectives: To determine the response-rate and response duration of patients with refractory multiple myeloma treated with dihydroxyanthracenedione (DHAD) used in a single dose every-three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: All patients with multiple myeloma who are not eligible for higher priority Southwest Oncology Group protocols are eligible. Patients must have clearly measurable myeloma protein levels and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was recently activated. Only four patients have been accrued to date. However, preliminary information shows evidence of in vitro activity with this agent in myeloma in the myeloma stem cell assay.
**Detail Summary Sheet**

**Date:** 29 Oct 81  
**Proj No:** SWOG 8032  
**Status:** Ongoing

**TITLE:**
Evaluation of DHAD in Acute Leukemia, Phase II

**Start Date:** 11 May 81  
**Est Comp Date:** Unknown

**Principal Investigator:** J. Dean McCracken, M.D., COL, MC  
**Facility:** Brooke Army Medical Center

**Dept/Sec:** Department of Medicine/Oncology  
**Associate Investigators:** Richard A. Shildt, M.D., LTC, MC  
John D. Cowan, M.D., MAJ, MC

**Key Words:** Acute leukemia

**Accumulative MEDCASE Est Accumulative Periodic**  
**Cost:** OMA Cost: Review Results: Continue

Objectives: To determine the efficacy of dihydroxyanthracenedione (DHAD) in patients with adult acute leukemia, who have failed on higher priority treatment protocols, as determined by response-rate and remission duration.

To determine the nature and degree of toxicity of this drug used in a single-dose, every-three-week schedule.

**Technical Approach:** Eligible patients must have a bone marrow diagnosis of acute leukemia.

Therapy will follow the schema outlined in the study protocol.

**Progress:** Thirteen patients have been registered, but are too early to evaluate.
Detail Summary Sheet

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<th>Date:</th>
<th>29 Oct 81</th>
<th>Proj No: SWOG 8033</th>
<th>Status: Ongoing</th>
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**TITLE:**
Trial of m-AMSA in Sarcomas of the Bone and Cartilage, Phase II

<table>
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<tr>
<th>Start Date:</th>
<th>11 May 81</th>
<th>Est Comp Date: Unknown</th>
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</table>

**Principal Investigator:**
J. Dean McCracken, M.D., COL, MC

**Facility:**
Brooke Army Medical Center

**Dept/Sec:**
Department of Medicine/Oncology

**Associate Investigators:**
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

**Key Words:**
Bone sarcoma
Cartilage sarcoma

**Objective:**
To determine the efficacy of m-AMSA in producing regression or remission in refractory sarcomas arising within the bone or cartilage.

**Technical Approach:**
All patients having histologically proven disease with bony and cartilagenous sarcomas who failed accepted standard intervention with surgery, chemotherapy, and/or radiotherapy are eligible. Patients must have measurable disease and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

**Progress:**
This study has just recently been activated. It is too early for analysis.
Combined Therapies for Squamous Cell Carcinoma of the Esophagus, Phase II

Objectives: To determine the feasibility and toxicity of combined radiotherapy and chemotherapy with 5-fluorouracil and cis-platinum followed by surgery in patients with epidermoid carcinoma of the middle or distal esophagus.

To determine the time to local or distant progression in patients treated by these three combined modalities.

To determine the survival of patients treated by these three combined modalities.

To determine the response-rate by clinical and pathological staging at the time of surgery.

Technical Approach: Previously untreated patients with biopsy-proven squamous cell carcinoma of the middle or distal esophagus are eligible. Patients must be judged medically to be a surgical candidate for laparotomy and thoracotomy. Patients must have a life expectancy of 6 weeks or greater.

Therapy will follow the schema outlined in the study protocol.

Progress: Nine patients have completed the study. Five had no cancer in resected specimens. One patient, not really eligible for the study, was treated according to protocol with an increase in radiation dose to 5,000 rads. This patient has a normal barium swallow nine months after treatment.
**Detail Summary Sheet**

**Date:** 29 Oct 81  
**Proj No:** SWOG 8038  
**Status:** Ongoing

**TITLE:**  
Vinblastine in Advanced Ovarian Cancer, Phase II

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<tr>
<th>Start Date:</th>
<th>11 May 81</th>
<th>Est Comp Date: Unknown</th>
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**Principal Investigator**  
J. Dean McCracken, M.D., COL, MC

**Dept/Sec:**  
Department of Medicine/Oncology

**Key Words:**  
Ovarian cancer

**Facility:**  
Brooke Army Medical Center

**Associate Investigators:**  
Richard A. Shildt, M.D., LTC, MC  
John D. Cowan, M.D., MAJ, MC

**Accumulative MEDCASE Cost:**  
Est Accumulative OMA Cost:  
Periodic Review Results: Continue

**Objectives:**  
To determine the response-rate and remission duration with intravenous therapy using Velban as a continuous infusion in patients with advanced ovarian cancer.

To define further the qualitative and quantitative toxicity of the continuous infusion of Velban.

**Technical Approach:**  
To be eligible, patients must have histologically confirmed, advanced, incurable ovarian cancer who are refractory to or ineligible for treatment on Southwest Oncology Group protocols of higher priority. Patients must have measurable disease and a life expectancy of six weeks or more.

Therapy will follow the schema outlined in the study protocol.

**Progress:**  
This is a new study. It is too early for any evaluation at this time.
Detail Summary Sheet

Date: 29 Oct 81  Proj No: SWOG 8040  Status: Ongoing

TITLE:
Evaluation of Combination Chemotherapy (FAM-S) vs a Phase II Drug in Pancreatic Adenocarcinoma,
Phase II

Start Date: 22 May 81  Est Comp Date: Unknown

Principal Investigator
J. Dean McCracken, M.D., COL, MC

Depr/Sec:
Department of Medicine/Oncology

Key Words:
Pancreatic adenocarcinoma

Facility
Brooke Army Medical Center

Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

Accumulative MEDCASE  Est Accumulative  Periodic
Cost:  OMA Cost:  Review Results:  Continue

Objectives: To determine the response-rate and survival in patients with advanced pancreatic adenocarcinoma treated with 5-FU, Adriamycin, Mitomycin-C and Streptozotocin (FAM-S).

To determine further the toxicity of the FAM-S regimen.

To determine the activity of a Phase II drug in previously untreated patients with advanced adenocarcinoma of the pancreas by determination of response-rate and duration of response and survival.

To determine further the toxicity of each Phase II agent.

Technical Approach: Patients with histologic confirmation of adenocarcinoma of the exocrine pancreas with distant metastases and/or those with localized disease not amenable to curative surgery or radiotherapy are eligible. All patients must have objectively measurable disease and a life expectancy of at least 10 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. It is too early for analysis.
Title: Evaluation of MGBG in Pancreatic Adenocarcinoma, Phase II

Start Date: 22 May 81

Principal Investigator: J. Dean McCracken, M.D., COL, MC

Facility: Brooke Army Medical Center

Dept/Sac: Department of Medicine/Oncology

Associate Investigators: Richard A. Shildt, M.D., LTC, MC
John A. Cowen, M.D., MAJ, MC

Key Words: Pancreatic adenocarcinoma

Objectives: To determine the response-rate and its duration in patients with advanced adenocarcinoma of the pancreas treated with MGBG.

To determine the qualitative and quantitative toxicities of MGBG when given or this schedule.

Technical Approach: Patient eligibility is as stated in SWOG 8040.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.
Detail Summary Sheet

Date: 29 Oct 81  Proj No: SWOG 8043  Status: Ongoing

TITLE: Evaluation of DHAD in Pancreatic Adenocarcinoma

Start Date: 22 May 81  Est Comp Date: Unknown

Principal Investigator
J. Dean McCracken, M.D., COL, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Oncology

Associate Investigators:
Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

Key Words:
Pancreatic adenocarcinoma

Accumulative MEDCASE Cost: OMA Cost: Periodic Review Results: Continue

Objectives: To determine the antitumor activity of DHAD, as determined by response-rate and duration of response, used in a single dose schedule every three weeks in patients with advanced adenocarcinoma of the pancreas.

To determine additional information concerning the nature and degree of toxicity of this drug.

Technical Approach: Patient eligibility is as outlined in SWOG 8040. In those patients treated initially on the FAM-S arm, patients must have received no mitomycin-C for 6 weeks; no Adriamycin, 5-FU or streptozotocin for 3 weeks; and must show evidence of hematologic recovery prior to beginning treatment with DHAD.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.
Date: 29 Oct 81  Proj No: SWOG 8051  Status: Ongoing

TITLE: Evaluation of L-Alanosine in Acute Leukemia, Phase II

Start Date: 25 Sep 81  Est Comp Date: Unknown

Principal Investigator
J. Dean McCracken, M.D., COL, MC

Facility
Brooke Army Medical Center

Dept /Sec: Associate Investigators:
Department of Medicine/Oncology
Richard A. Shildt, M.D., LTC, MC

Key Words:
John D. Cowan, M.D., MAJ, MC
Acute leukemia
L-Alanosine

Accumulative MEDCASE Cost: OMA Cost: Periodic
Est Accumulative Cost: Review Results: Continue

Objectives: To determine the antitumor activity of L-alanosine as determined by response-rate and duration of response in patients with acute leukemia who are not eligible for higher priority studies.

To determine the nature and degree of toxicity of this drug.

Technical Approach: Patients with acute leukemia, either lymphocytic or non-lymphocytic, not eligible for higher priority Southwest Oncology Group studies are eligible. Patients must have at least a 30% cellular marrow and 30% leukemic cells.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.
### Details Summary Sheet

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<td>SWOG 8066</td>
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**TITLE:** Adjuvant Intrahepatic Chemotherapy with Mitomycin-C and 5-FU Combined with Hepatic Radiation in High Risk Patients with Carcinoma of the Colon, Phase II-Pilot

**Start Date:** Jan 81  
**Est Comp Date:** Unknown

**Principal Investigator:**  
J. Dean McCracken, M.D., COL, MC

**Dept/Sec:**  
Department of Medicine/Oncology

**Key Words:**  
Carcinoma of colon

**Facility:**  
Brooke Army Medical Center

**Associate Investigators:**  
Richard A. Shildt, M.D., LTC, MC  
John D. Cowan, M.D., MAJ, MC

<table>
<thead>
<tr>
<th>Objective:</th>
<th>To determine the toxicities of combined intra-arterial chemotherapy with hepatic radiotherapy in patients after total clinical resection of cancer of the colon who have a high risk of recurrence, for potential use in an adjuvant Group-wide protocol.</th>
</tr>
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<tbody>
<tr>
<td>Technical Approach:</td>
<td>To be eligible, the patient must have adenocarcinoma of the large bowel with involvement of the adjacent regional lymph nodes. There must be no evidence of any residual tumor.</td>
</tr>
<tr>
<td>Therapy will follow the schema outlined in the study protocol.</td>
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**Progress:** To date two patients have completed the treatment outlined in the protocol and are disease-free; they did not suffer any acute toxicities from the treatment.
Detail Summary Sheet

Date: 29 Oct 81  Project No: SWOC 8090  Status: Terminated

TITLE:
A Descriptive Study of Chemotherapy Drug Extravasation and Treatments Commonly Instituted Among the Southwest Oncology Group, Ancillary Study

Start Date: 1 Apr 81  Est Comp Date:  
Principal Investigator
Rosemary Madden, CPT ANC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Medicine/Oncology
Associate Investigators:

Key Words:
Ancillary Study

Accumulative MEDCASE  Est Accumulative  Periodic
Cost: OMA Cost: Review Results:

Objectives: To provide descriptive information about extravasation of commonly used chemotherapeutic agents in humans, including correlation between local tissue damage and dose of medication, concentration of medication, and factors affecting treatments commonly used in the Southwest Oncology Group for drug extravasation.

Technical Approach: Any male or female adult patient who is receiving intravenous chemotherapy and has evidence of an extravasation is eligible for the study.

Progress: This study was not started due to transfer of principal investigator.
Use of Human Tumor Cloning System to Select Chemotherapy for Patients with Ovarian Cancer Refractory to Primary Therapy, Ancillary Study

Objectives: To utilize the human tumor cloning assay to select single agent chemotherapy for patients with epithelial-type ovarian cancer, refractory to standard therapy.

To determine if the human tumor cloning system can be utilized to select individual patient's therapy in a cooperative group setting.

Technical Approach: Eligible patients must have a pathological diagnosis of epithelial-type ovarian cancer in pleural or peritoneal fluid. Patients should have measurable disease and a life expectancy of at least three months.

Progress: This is a new study.
Radiation therapy with and without Chemotherapy for Malignant Mesothelioma localized to One Hemithorax, Phase III

Start Date: 22 May 81

Est Comp Date: Unknown

Principal Investigator: J. Dean McCracken, M.D., COL, MC

Facility: Brooke Army Medical Center

Dept/Sec: Department of Medicine/Oncology

Associate Investigators: Richard A. Shildt, M.D., LTC, MC
John D. Cowan, M.D., MAJ, MC

Key Words: Mesothelioma

Objectives: To evaluate in a randomized prospective manner, the efficacy of Adriamycin in improving the disease-free interval in patients who will receive hemithoracic radiotherapy for Stage I pleural mesothelioma.

To further define prospectively the efficacy of radiotherapy to the involved hemithorax in patients with pleural mesothelioma.

Technical Approach: Eligible patients will have histologically confirmed malignant mesothelioma of the pleural cavity. Patients with measurable disease or evaluable disease as well as those in whom all gross disease has been resected will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.
APPENDIX B

GYNECOLOGY ONCOLOGY GROUP
**Detail Summary Sheet**

**Date:** 26 Oct 81  
**Proj No:** GOG 20  
**Status:** Ongoing

**TITLE:** A Randomized Comparison of Adriamycin vs No Further Therapy in Patients with Uterine Sarcomas, Stage I and II, Phase III

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<th>FY 81</th>
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<tr>
<td><strong>Principal Investigator</strong></td>
<td>Milton H. Leman, M.D., COL, MC</td>
<td><strong>Facility</strong></td>
<td>Brooke Army Medical Center</td>
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<td><strong>Dept/Sec:</strong></td>
<td>Department of Obstetrics and Gynecology</td>
<td><strong>Associate Investigators:</strong></td>
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</table>
| **Key Words:** | Uterine Sarcoma  
Adriamycin |

**Accumulative MEDCASE** | **Est Accumulative Periodic Cost:** | **OMA Cost:** | **Review Results:** | Continue

**Objective:** To determine if adjuvant chemotherapy will improve the cure rate in uterine sarcomas, Stage I and II.

**Technical Approach:** Patients with histologically proven sarcomas of the uterine corpus will be considered if they have Stage I or Stage II disease clinically, and if they have no known gross residual disease following surgery. Preoperative or postoperative pelvic radiotherapy may be given at the discretion of the principal investigator, but a decision about this mode of therapy must be made prior to the chemotherapy randomization. Therapy will follow the schema outlined in the study protocol.

**Progress:** There is no significant difference in survival and progression-free interval between the two programs. Moreover, Mantel-Haentzel techniques adjusting for such parameters as stage, histology, prior radiotherapy and various combinations of these three have been employed, revealing no treatment difference.
**Objective:** To assess the therapeutic effectiveness of immunotherapy (intravenous C-parvum) used concomitantly with radiation in patients with advanced carcinoma of the uterine cervix.

**Technical approach:** Patients with histologically confirmed, previously untreated carcinoma of the uterine cervix (adenocarcinoma or squamous carcinoma) are eligible.

Therapy will be in accordance with the schema outlined in the study protocol.

**Progress:** Preliminary analysis suggests that C-parvum does not add any therapeutic effect as an adjuvant to radiotherapy in this patient population.
TITLE: A Randomized Comparison of Melphalan Therapy Alone vs Melphalan plus Immunotherapy (C. Parvum) in the Treatment of Women with Stage III (Optimal) Epithelial Carcinoma of the Ovary (Phase II).

Objective: To determine the efficacy of adjuvant nonspecific immunotherapy to standard alkylating agent therapy in patients with Stage III optimal carcinoma of the ovary.

Technical Approach: Patients in "optimal" category (≤ cm or less greatest diameter of residual tumor(s) with proven primary Stage III epithelial cancer of the ovary) who have undergone tumor-reductive surgery will be included in the study.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no significant difference when the duration of progression-free interval and survival are compared by therapy. When progression-free interval and survival are compared by size of residual tumor at surgery, both are highly statistically significant. However, it is too early to draw any conclusions.
**Detail Summary Sheet**

**Date:** 26 Oct 81  
**Proj No:** GOG-26  
**Status:** Ongoing

**TITLE:**  

**Start Date:** FY 78  
**Est Comp Date:** Unknown

**Principal Investigator**  
Milton H. Leman, M.D., COL, MC

**Facility**  
Brooke Army Medical Center

**Dept/Sec:**  
Department of Obstetrics and Gynecology

**Associate Investigators:**

**Key Words:**  
Pelvic malignancies  
Chemotherapy

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**Objective:** This protocol constitutes a Phase II design outlining the procedures that will be performed to screen for activity of new agents or drug combinations in patients with advanced recurrent pelvic malignancies. Its intent is to determine the efficacy of chemotherapeutic agents in patients whose advanced malignancies have been resistant to high priority methods of treatment.

**Technical Approach:** This is a study of multiple chemotherapeutic agents. Therapy will follow the schema outlined in the study protocol. Agents to be used in this study include: Piperazinedione, Cis-platinum, VP-16, Galacticol, Baker's Antifol, ICRF-159, Maytansine, m-AMSA and Yoshi 864.

**Progress:** Cis-platinum has marked activity as first line chemotherapy of squamous cell carcinoma of the cervix and is active as second line therapy of advanced ovarian carcinoma at the dose and schedule tested. The drugs appear to be inactive against endometrial carcinoma but may have limited activity in the therapy of sarcomas and cervical adenocarcinomas.

Because of the demonstrated activity of Cis-platinum in squamous cell carcinoma of the cervix, a phase III study comparing three different regimens of Cis-platinum in advanced squamous cell carcinoma of the cervix was activated as GOG 43.
Because of the demonstrated activity of Cis-platinum in epithelial ovarian carcinoma, protocol COG 47 was activated comparing Adriamycin plus Cyclophosphamide plus Cis-platinum with Adriamycin plus Cyclophosphamide.

VP-16 - VP-16 appears to have minimal activity against ovarian adenocarcinoma and insignificant activity against squamous cell carcinoma of the cervix at the dose and schedule tested.

Galacticol - Complete and partial remissions in carcinoma of the cervix have been 19% which is encouraging enough for future studies, possibly in combination with other drugs. One complete remission continues at 33+ months.

Complete and partial remissions in carcinoma of the ovary were 15%. Almost all of these patients had received prior chemotherapy. One complete remission continues at 24+ months; the other relapsed 15 months after entry.

Baker's Antifol - Although limited activity is noted, this drug is not as useful as more conventional drugs and probably will not add to current therapeutic regimens.

IRCF - IRCF appears to have moderate activity in squamous cell carcinoma of the cervix at the dose and schedule tested despite induction of significant myelosuppression. Results of this study will be used to determine the future role, if any, of IRCF-159 in the treatment of gynecologic cancer either alone or in combination with other drugs.

AMSA and YOSHI - It is too early to evaluate the results. When these are obtained, they will be used to determine the future role, if any of AMSA and YOSHI in the treatment of gynecologic cancer either alone or in combination with other drugs.
Date: 27 Oct 81  Proj No: GOG 31  Status: Ongoing

**TITLE:**
A Randomized Comparison of Local Excision vs Cryosurgery in Patients with Limited Grade 1, 2, or 3 Cervical Intraepithelial Neoplasia.

Start Date: FY 79  Est Comp Date: Unknown

**Principal Investigator**
Milton H. Leman, M.D., COL, MC

**Facility**
Brooke Army Medical Center

**Dept/Sec:**
Department of Obstetrics and Gynecology

**Associate Investigators:**

**Key Words:**
Cervical neoplasia
Cryosurgery

**Objective:** To evaluate and compare the immediate and long-term effectiveness of outpatient cryosurgery and outpatient local excision in the treatment of limited cervical intraepithelial neoplasia grade 1, 2 or 3, in a randomized prospective study.

Technical Approach: All eligible patients must have a tissue diagnosis of cervical intraepithelial neoplasia within six weeks prior to randomization in the study. All patients must have a lesion which can be completely delineated through the colposcope. Only patients with the following histologic diagnosis will be eligible: mild dysplasia, moderate dysplasia, severe dysplasia, and carcinoma in situ.

Therapy and randomization will follow the schema outlined in the study protocol.

**Progress:** Median follow-up for the evaluable patients on this study is only 13.5 months; consequently, it is still too early to perform a meaningful analysis.
**Detail Summary Sheet**

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<tr>
<td>TITLE:</td>
<td>A Randomized Comparison of Surgical Conization vs Cryosurgery in Patients with Extensive Grade 3 Cervical Intraepithelial Neoplasia.</td>
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<td>Principal Investigator</td>
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<td>Facility</td>
<td>Brooke Army Medical Center</td>
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<td>OMA Cost:</td>
<td>Review Results:</td>
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**Objective:** To evaluate and compare the immediate and long-term effectiveness of outpatient cryosurgery to the standard cold-knife conization in the treatment of extensive cervical intraepithelial neoplasia Grade 3 in a randomized prospective study.

**Technical Approach:** All eligible patients must have a diagnosis of cervical intraepithelial neoplasia within six weeks prior to randomization in the study. All patients must have a lesion which can be completely delineated through the colposcope. The lesion should involve at least two quadrants of the portio. Only patients with the following histologic diagnosis will be eligible: severe dysplasia and carcinoma in situ.

Therapy and randomization will follow the schema outlined in the study protocol.

**Progress:** It is too early to draw conclusions. The protocol has been modified to allow more time (12 weeks) from tissue diagnosis to entry into protocol.
# Detail Summary Sheet

**Date:** 27 Oct 81  
**Proj No:** GOG 33  
**Status:** Completed

**TITLE:** A Clinical-Pathologic Study of Stage I and II Carcinoma of the Endometrium.

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<td>Facility</td>
<td>Brooke Army Medical Center</td>
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<td>Key Words:</td>
<td>Endometrial carcinoma</td>
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**Objective:** To determine the incidence of pelvic and aortic lymph node metastases and the relationship of these node metastases to other important prognostic factors.

**Technical Approach:** All patients with histologically proven endometrial carcinoma clinical FIGO Stage I and II who are medically suitable for hysterectomy and lymphadenectomy are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

**Progress:** Preliminary evaluation would tend to indicate that this larger study verifies the findings of the pilot study. It would appear that this study could define the surgical procedure required for optimal evaluation of endometrial cancer.
Detail Summary Sheet

Date: 27 Oct 81                      Proj No: COG 34                      Status: Ongoing
TITLE: A Randomized Study of Adriamycin as an Adjuvant After Surgery and Radiation Therapy in Patients with High Risk Endometrial Carcinoma, Stage I, and Occult Stage II.
Start Date: FY 78                              Est Comp Date: Unknown
Principal Investigator
Milton H. Leian, M.D., COL, MC
Dept/Sec: Department of Obstetrics and Gynecology
Associate Investigators: Brooke Army Medical Center
Key Words: Endometrial carcinoma                Radiation therapy
           Adriamycin
Accumulative MEDCASE          Est Accumulative Periodic
Cost:                              OMA Cost:                        Review Results: Continue
Objective: To study differences in morbidity and patient survival as functions of various tumor growth patterns as well as treatments.

Technical Approach: All patients with primary, previously untreated, histologically confirmed invasive carcinoma of the endometrium Stage I, and Stage II occult, all grades, with one or more of the following high risk criteria are eligible: (1) all lesions with equal to or greater than one-half myometrial involvement; (2) positive pelvic and/or para-aortic nodes; (3) microscopic evidence of cervical involvement but no gross clinical involvement of the cervix. The following types of histologically confirmed uterine carcinoma are eligible: adenocarcinoma, adenosarcoma, adenosquamous carcinoma.

Therapy will follow the scheme outlined in the study protocol.

Trend: It is too early to draw any meaningful conclusions from the data available.
**Surgical-Pathologic Study of Women with Squamous Cell Carcinoma of the Vulva.**

**Start Date:** FY 78  
**Est Comp Date:** Unknown

**Principal Investigator**  
Milton H. Leman, M.D., COL, MC

**Dept/Sec:**  
Department of Obstetrics and Gynecology

**Key Words:**  
Squamous cell carcinoma of vulva

**Objectives:**  
To determine the validity of current FIGO staging to the histopathologic prognostic factors of size of lesion, location of lesion, depth of invasion of tumor in millimeters, histologic grade, and site and number of positive lymph nodes in Stage I-IV carcinoma of the vulva.

To rapidly accumulate prospectively significant surgical pathologic data for development of further protocols for subsets of disease identified.

To determine morbidity of primary radical surgical therapy.

**Technical Approach:**  
All patients with primary, previously untreated, histologically confirmed, invasive squamous cell carcinoma of the vulva clinically determined to be Stage I through IV are eligible.

Therapy will follow the schema outlined in the study protocol.

**Progress:**  
It is too early to evaluate the data obtained from this study.
Detail Summary Sheet

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<td>TITLE:</td>
<td>Randomized Study of Radiation Therapy vs Pelvic Node Resection for Patients with Invasive Squamous Cell Carcinoma of the Vulva Having Positive Groin Nodes.</td>
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<td>Facility</td>
<td>Brooke Army Medical Center</td>
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<td>Department of Obstetrics and Gynecology</td>
<td>Associate Investigators:</td>
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Accumulative MEDCASE:  
Est Accumulative OMA Cost:  
Periodic Review Results: Continue

Objective: To determine the benefit and morbidity of adding adjunctive radiation therapy to pelvis and groin for patients with positive groin nodes at radical vulvectomy and bilateral groin dissection.

Technical Approach: All patients with primary, previously untreated, histologically confirmed squamous cell carcinoma of the vulva such that radical vulvectomy suffices to remove all of the local lesion and whose surgery revealed that there were nodes in the groin on one or both sides containing metastatic carcinoma are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.
Detail Summary Sheet

Date: 27 Oct 81  Proj No: GOC 40  Status: Ongoing

TITLE:
A Clinical-Pathologic Study of Stage I and II Uterine Sarcomas.

Start Date: FY 79  Est Comp Date: Unknown
Principal Investigator: Milton H. Leman, M.D., COL, MC
Facility: Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology
Associate Investigators:
Key Words:
Uterine sarcoma

Objective: To determine the incidence of pelvic and aortic lymph node metastases associated with Stage I and II uterine sarcomas, the relationship of these node metastases to other important prognostic factors such as mitotic index of the tumor, and the complication rate of the procedures.

Technical Approach: All patients with histologically proven uterine sarcoma clinical Stage I and II who are medically suitable for hysterectomy and lymphadenectomy are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: It is too early for meaningful analysis of data.
Detail Summary Sheet

Date: 27 Oct 81       Proj No: COG 41       Status: Ongoing

TITLE:
Surgical Staging of Ovarian Carcinoma.

Start Date: FY 79       Est Comp Date: Unknown
Principal Investigator
Milton H. Leman, M.D., COL, MC
Facility
Brooke Army Medical Center
Dept/Sec:
Department of Obstetrics and Gynecology
Associate Investigators:

Key Words:
Ovarian carcinoma

Accumulative MEDCASE       Est Accumulative       Periodic
Cost:                      OMA Cost:               Review Results: Continue

Objectives: To determine the spread of ovarian carcinoma in intraperitoneal structures and retroperitoneal lymph nodes by direct examination, cytologic sampling, and biopsy.

To establish a surgical protocol for patients entered into COG ovarian cancer treatment protocols.

To determine the complication rate of the procedures.

Technical Approach: Patients with all histologic types of primary ovarian cancer are eligible, including epithelial tumors, germ cell tumors, stromal tumors, and all others. Patients must be entered within two weeks of the therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: There are presently insufficient data to permit a detailed analysis. Initial results indicate a good correlation between reported stage and surgical stage for stage I, II and III patients.
## Detail Summary Sheet

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**Title:**
Treatment of Recurrent or Advanced Uterine Sarcoma. A Randomized Comparison of Adriamycin vs Adriamycin and Cyclophosphamide, Phase III.

**Start Date:** FY 79  
**Est Comp Date:** Unknown

**Principal Investigator**  
Milton H. Leman, M.D., COL, MC

**Facility**  
Brooke Army Medical Center

**Dept/Sec:**  
Department of Obstetrics and Gynecology

**Associate Investigators:**

**Key Words:**  
Uterine sarcoma

**Objectives:** To determine if Adriamycin alone is more effective than Adriamycin and Cyclophosphamide in producing responses in advanced or recurrent uterine sarcoma.

To determine the duration of response for each different treatment arm.

**Technical Approach:** Patients with primary Stage III, primary Stage IV or recurrent uterine sarcoma are eligible. Both patients with measurable and non-measurable disease are eligible, but they will be analyzed separately. Patients with all cell types of uterine sarcoma are eligible.

Randomization and therapy will follow the schema outlined in the study protocol.

**Progress:** Thirty-three patients have measurable disease. To date, there has been 1 complete response, 5 partial responses, 9 progressions and 18 with stable disease. The regimens are well tolerated.
TITLE: A Randomized Comparison of Cis-platinum 50mg/m² IV Every 3 weeks vs Cis-platinum 100mg/m² IV Every 3 weeks vs Cis-platinum 20mg/m² IV Daily x 5 Days in Treatment of Patients with Advanced Carcinoma of the Cervix, Phase III.

Start Date: FY 79

Principal Investigator
Milton H. Leman, M.D., COL, MC

Department of Obstetrics and Gynecology

Carcinoma of cervix

Accumulative MEDCASE Cost: OMA Cost: Periodic Review Results: Continue

Objectives: To confirm the effectiveness of cis-diamminedichloroplatinum (DDP) in advanced and recurrent squamous cell carcinoma of the cervix no longer responding to radiation therapy or surgery.

To compare the frequency and duration of response and adverse effects of DDP therapy using three different doses and treatment schedules.

To evaluate the roles of serial determination of serum carcinoembryonic antigen (CEA) levels in determining extent of disease, response to treatment, and in predicting treatment failure.

Technical Approach: Eligible patients must have histologically confirmed, locally advanced, recurrent, persistent, or metastatic squamous cell carcinoma of the cervix which is resistant to curative treatment with surgery or radiotherapy. All patients must have lesions which are measurable or evaluable by physical examination. Patients will have recovered from effects of recent surgery or radiotherapy, and will be free of clinically significant infection.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: There is no significant difference in response when the three regimens are compared. Median time to response for regimens A, B and C is 2.5, 1.9 and 2.4 months, respectively. Survival by response category shows a significant difference at the .001 level.
TITLE: Evaluation of Adjuvant Vincristine, Dactinomycin, and Cyclophosphamide Therapy in Malignant Germ Cell Tumors of the Ovary After Resection of All Gross Tumor, Phase III.

Start Date: FY 79

Accumulative MEDCASE
Objectives: To evaluate the effect of combined prophylactic vincristine, dactinomycin, and cyclophosphamide chemotherapy in patients with endodermal sinus tumor, embryonal carcinoma, immature teratoma (Grades 2 and 3), choriocarcinoma, and malignant mixed germ cell tumors of the ovary, Stages I and II after total removal of all gross tumor. To evaluate the role of serum markers, especially alpha-fetoprotein (AFP) and human chorionic gonadotropin (beta HCG), when these are present, in predicting response and relapse. To determine the role of restaging laparotomy in determining response, predicting relapse and planning further therapy.

Technical Approach: Patients with histologically confirmed malignant germ cell tumors of the ovary, Stages I or II, if previously untreated and completely resected, excluding patients with pure dysgerminoma unless classified as anaplastic, are eligible. Patients with grade 2 or 3 immature teratoma are also eligible. Patients with early Stage III disease will be accepted if all gross tumor is resected.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: Twenty-two patients have had second-look operations performed; 16 were negative, four were positive, and two had mature teratoma. Of the five positive second-looks, two had endodermal sinus tumors, one had embryonal carcinoma, and one had a mixture of rare ovarian components. In addition to these four, there are four other failure, three of whom had had negative second-look operations. All patients are alive.
**Evaluation of Vinblastine, Bleomycin, and Cis-platinum in Stage III and IV and Recurrent Malignant Germ Cell Tumors of the Ovary, Phase III.**

**Start Date:** FY 79

**Principal Investigator**
Milton H. Leman, M.D., COL, MC

**Department of Obstetrics and Gynecology**

**Key Words:**
Malignant germ cell tumor of ovary

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**Objectives:**

- To evaluate the effect of four cycles of combined Vinblastine, Bleomycin and Cis-platinum (VBP) chemotherapy in the management of patients with endometrial stromal tumor, embryonal carcinoma, immature teratoma (all grades), choriocarcinoma, and malignant germ cell tumors of the ovary with advanced or recurrent disease, incompletely resected.

- To evaluate the role of serum markers, especially alpha-fetoprotein (AFP) and human chorionic gonadotropin (beta hCG), when these are present, in predicting response and relapse.

- To determine the role of restaging laparotomy in patients in clinical remission, in assessing completeness of response, and in planning further therapy.

- To evaluate and compare the effect of Vinblastine, Dactinomycin and Cytarabine (VAC) chemotherapy in patients found to have persistent disease at the time of restaging laparotomy.

- To determine the need for maintenance Vinblastine therapy in patients with recurrence of disease at restaging laparotomy.

**Technical Approach:**

Patients with histologically confirmed malignant germ cell tumors of the ovary with advanced (Stage III-IV) or recurrent disease, incompletely resected, excluding patients with pure dysgerminoma (mature or seminolplastic) are eligible. Patients with incompletely resected Stage II disease and patients previously treated with Vinblastine, Dactinomycin and Cytarabine are also eligible.

**Therapy** will follow the schema outlined in the study protocol.

**Progress:** There continues to be considerable toxicity, however, early results are encouraging.
Title: A Randomized Comparison of Melphalan vs Intraperitoneal Chromic Phosphate in the Treatment of Women with Stage I (exclusive of Stage IA(i) GI and IB(i) GI) Epithelial Carcinoma of the Ovary, Phase III.

Objective: To evaluate the relative effectiveness of Melphalan vs intraperitoneal Chromic Phosphate as adjuvant therapy in Stage I exclusive of Stage IA(i) GI and Stage IB(i) GI epithelial cancers of the ovary in a randomized prospective study.

Technical Approach: Patients with surgical Stage IA(i) Gs, G3; IA(ii); IB(i) G2, G3; IB(ii), and IC epithelial cancer of the ovary who have undergone optimal staging described in GOG 41 are eligible.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: It is too early to draw any conclusions.
TITLE: A Randomized Study of Adriamycin + Cyclophosphamide vs Adriamycin + Cyclophosphamide + Cis-platinum in Patients with Advanced Ovarian Adenocarcinoma - Suboptimal Stage II, Stage IV and Recurrent, Phase III.

Start Date: FY 80
Est Comp Date: Unknown

Principal Investigator: Milton H. Leman, M.D., COL, MC
Facility: Brooke Army Medical Center

Dept/Sec: Department of Obstetrics and Gynecology
Associate Investigators:

Key Words: Ovarian adenocarcinoma

Objectives: To determine if the addition of Cis-platinum to Adriamycin plus Cyclophosphamide improves remission rate, remission duration or survival in Stage IV, suboptimal Stage III and recurrent ovarian adenocarcinoma.

To determine the frequency and duration of true complete remission using these regimens as judged at second-look laparotomy.

Technical Approach: Patients who have been diagnosed as Stage IV and suboptimal Stage III primary cases together with all recurrent cases are eligible. Both patients with measurable disease and patients without measurable disease, as a separate category, will be evaluated.

Therapy will follow the schema outlined in the study protocol.

Progress: To date, there is no survival difference. The addition of Cis-platinum appears to significantly influence response and progression-free interval but at this relatively early date there are still many censored observations.
Title: A Study of Progestin Therapy and A Randomized Comparison of Adriamycin vs Adriamycin + Cyclophosphamide in Patients with Advanced Endometrial Carcinoma After Hormonal Failure, Phase III.

Start Date: FY 80  Est Comp Date: Unknown
Principal Investigator: Milton H. Leman, M.D., COL, MC  Facility: Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology  Associate Investigators:
Key Words: Endometrial Carcinoma

Objectives:
- To evaluate the response of advanced or recurrent endometrial carcinoma to oral progestins in patients who have received no prior hormone therapy.
- To compare a combination of adriamycin and cyclophosphamide to adriamycin alone as therapy for advanced or recurrent endometrial carcinoma which no longer responds to or has failed to respond to progestins in patients who have received no prior cytotoxic drugs.

Technical Approach: To be eligible for entry on this study, all patients must have documented primary Stage III, primary Stage IV, recurrent or residual endometrial adenocarcinoma, adenoacanthoma or adenosquamous carcinoma. Those patients with positive cytology as evidence of spread are eligible as non-measurable disease cases.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.
A Surgical-Pathologic Study of Women with Invasive Carcinoma of the Cervix Stage IB and Randomly Assigned Radiation Therapy versus no Further Therapy in Selected Patients.

Title:  A Surgical-Pathologic Study of Women with Invasive Carcinoma of the Cervix Stage IB and Randomly Assigned Radiation Therapy versus no Further Therapy in Selected Patients.

Date:  27 Oct 81
Proj No:  GOG 49
Status:  Ongoing

Principal Investigator:
Milton H. Leman, M.D., Col., MC

Facility:
Brooke Army Medical Center

Dept/Sec:
Department of Obstetrics and Gynecology

Key Words:
Invasive carcinoma
Cervix

Objectives:
To determine by observations of the 5-year survival and disease-free interval, the validity of current FIGO staging to the histopathologic prognostic factors of size of lesion, location of lesion, depth of invasion of tumor, in millimeters, histology and grade, growth pattern, and site and number of positive lymph nodes in Stage IB carcinoma of the cervix.

To rapidly accumulate prospectively significant surgical pathologic data which will expedite development of further protocols.

To determine morbidity of primary radical surgical therapy.

To determine if radiation therapy will improve survival in selected patients with positive nodes.

Enrollment Approach:  All patients with primary, previously untreated, histologically confirmed, invasive carcinoma of the cervix (squamous cell, adenocarcinoma or adenoma) are eligible. Patients must have had a pelvic and para-aortic lymphadenectomy.

Therapy will follow the schema outlined in the study protocol.

Progress:  This is a new study. No reportable data are available.
Detail Summary Sheet

<table>
<thead>
<tr>
<th>Date: 27 Oct 81</th>
<th>Proj No: GOG 50</th>
<th>Status: Ongoing</th>
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</table>

**TITLE:**

A Study of Adriamycin as Postoperative Therapy for Ovarian Sarcoma, Primary or Recurrent, with No Prior Chemotherapy, Phase III.

<table>
<thead>
<tr>
<th>Start Date: FY 81</th>
<th>Est Comp Date: Unknown</th>
</tr>
</thead>
</table>

**Principal Investigator**

Milton H. Leman, M.D., COL, MC

**Facility**

Brooke Army Medical Center

**Department:**

Department of Obstetrics and Gynecology

**Associate Investigators:**

**Key Words:**

Ovarian sarcoma
Adriamycin

**Accumulative MEDCASE Est Accumulative Periodic Cost:**

OMA Cost: Review Results: Continue

**Objectives:**

To evaluate the efficacy of Adriamycin in the treatment of ovarian sarcomas, primary or recurrent, through historic controls.

To accumulate additional surgical-pathological data relative to ovarian sarcomas.

**Technical approach:**

All patients must have histologically confirmed primary Stage I-IV or recurrent ovarian sarcoma. Optimal reductive surgery is required for cases with advanced disease, whether primary or recurrent. Patients may have measurable disease, non-measurable disease or no residual disease postoperatively. The endometrium must be examined to exclude an endometrial origin of tumor.

Patients with primary Stage I-IV disease must be entered and protocol therapy begun within six weeks of surgery. Patients with recurrent disease must be entered and protocol therapy begun within six weeks of documented recurrence.

**Progress:**

This is a new study. No reportable data are available.

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**Detail Summary Sheet**

<table>
<thead>
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<th>Proj No: GOG 51</th>
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<tr>
<td>TITLE:</td>
<td>A Randomized Comparison of Droperidol versus THC in the Treatment of Nausea and Vomiting Produced by Cis-platinum Chemotherapy for Gynecologic Malignancies.</td>
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<tr>
<td>Start Date:</td>
<td>FY 81</td>
<td>Est Comp Date:</td>
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<td>Milton H. Leman, M.D., COL, MC</td>
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<tr>
<td>Dept/Sec:</td>
<td>Department of Obstetrics and Gynecology</td>
<td></td>
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<td>Key Words:</td>
<td>THC (Delta-9-Tetrahydrocannabinol)</td>
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<td></td>
<td>Droperidol (Dehydrobenzperidol)</td>
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<td></td>
<td>Cis-platinum</td>
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<tr>
<td>Objective:</td>
<td>To evaluate the effectiveness of Droperidol and THC as anti-emetic agents in chemotherapy of gynecologic malignancies treated with Cis-platinum.</td>
<td></td>
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</table>

**Technical Approach:** Patients with gynecologic malignancies who receive Cis-platinum as a single agent are eligible. Patients will be randomized to one of two treatment groups. Group 1 will receive THC by mouth during two courses of chemotherapy, and then take droperidol by injection for two chemotherapy courses. Group 2 will receive droperidol by injection for two chemotherapy courses and then THC by mouth during two courses of chemotherapy.

- This is a new study. No data are available.
Date: 27 Oct 81 Proj No: 7601 Status: Ongoing

**TITLE:**
Ovarian Cancer Study Group Protocol for Selected Stage IA1 - IB1 Ovarian Cancer (Well and Moderately Differentiated).

**Start Date:** FY 79  **Est Comp Date:** Unknown

**Principal Investigator:** Milton H. Leeman, M.D., COL, MC

**Facility:** Brooke Army Medical Center

**Dept/Sec:** Department of Obstetrics and Gynecology

**Associate Investigators:**

**Key Words:**
ovarian cancer

**Accumulative MEDCASE**

**Est Accumulative**

**Periodic**

**Cost:** OMA Cost:

**Review Results:** Continue

**Objectives:**
To define the natural history (relapse rate, relapse site, relapse free survival) of patients treated by surgery alone.

To determine whether prophylactic, adjuvant chemotherapy with melphalan alters the natural history.

To study the effect of various potential prognostic factors (stratification factors) on the natural history of patients treated by each form of therapy.

To determine the patterns of relapse for each form of therapy.

To establish the value of various staging parameters on the stage of disease and its natural history.

**Technical Approach:** All eligible patients must have a histopathologic diagnosis of common epithelial ovarian cancer of one of the following types: serous, mucinous, and those listed in Appendix I of the protocol. After definitive staging procedure, if the patient is a selective Stage IA1, or IB1, and the histologic grade is well or moderately differentiated, the patient is eligible.

**Therapy will follow the schema outlined in the study protocol.**

**Progress:** No reportable data are available.
DATE: 27 Oct 81   PRI# No: 7602   Status: Ongoing

TITLE: Ovarian Cancer Study Group Protocol for All Stage IC and II (A, B, C) and Selected Stage IAII and IBII Ovarian Cancer

Start Date: FY 79   Est Comp Date: Unknown

Principal Investigator: Milton H. Leman, M.D., COL, MC  Facility: Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology  Associate Investigators:
Key Words:
Ovarian cancer

Objectives: To define the natural history (relapse rate, relapse sites, disease-free survival, regression rate, duration of regression) of patients treated to surgery plus either chemotherapy or chemotherapy plus radiation therapy.

To study the effect of various potential prognostic factors (stratification variables) in the natural history of patients treated by each form of therapy.

To determine the patterns of relapse for each type of therapy.

To establish the value of prospective randomization in the study of the natural history.

Eligibility: All stage IA patients must have a histopathologic diagnosis of epithelial ovarian cancer and be one of the following: (1) stage IA, (2) stage IB, (3) stage IA II and IB II, or (4) stage IC. In the patient in Stage IB II, III, or IV, the histologic type must be epithelial, with a tumor histologic grade of one. Patients who have had no previous treatment are eligible.

Description: The protocol will follow the schema outlined in the study.
APPENDIX C

POLYCYTHEMIA VERA STUDY GROUP
Objective: To determine whether phlebotomy in conjunction with antiaggregating agents can decrease the frequency of thrombotic complications in patients with PV to the level in patients treated with 32P.

Technological Approach: Only those patients who have well-documented, active polycythemia vera, as demonstrated by rigorous diagnostic studies designed to eliminate spurious (stress) polycythemia, anoxic erythrocytosis, or erythrocytosis secondary to increased erythropoietin, or erythrocytosis without additional evidence of myeloproliferative disease either past or present, will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

In Tress: At the Group meeting, March 1981, it was reported that there were 2 thrombotic events in the aspirin/Persantine arm as compared to 2 thrombotic events in the 32-P arm. The one year major thrombotic complication rate on the phlebotomy arm of the study was 8% in comparison to 8.4% on the aspirin/Persantine arm. At the end of two years the major thrombotic incidence rate was equal, being approximately 12%. However, there had been a major increase in the incidence of hemorrhagic events in the aspirin/Persantine arm (6 vs 0). Accordingly, it was recommended that this protocol be closed to patient accrual and that those patients on the aspirin/Persantine arm be treated with phlebotomy alone at the discretion of the individual investigator.
Objective: To evaluate the efficacy of HU in patients of all ages with polycythemia vera who have active disease and to assess the influence of HU upon the symptoms and signs of active disease and upon the abnormal hematological and biochemical manifestations of the panmyelosis that characterize this condition.

Technical Approach: Only those patients who have well-documented, active polycythemia vera, as demonstrated by rigorous diagnostic studies designed to eliminate spurious (stress) polycythemia, anoxic erythrocytosis, or erythrocytosis secondary to increased erythropoietin, or erythrocytosis without additional evidence of myeloproliferative disease either past or present, will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: Initial response was evaluated in 88 patients entered in the group-wide study. Two patients who were previously untreated and four patients who were treated had no response to this drug. Of 40 previously untreated patients who had an initial response, response occurred from 5 days to 105 days after therapy was started with a median of 17 days. For the 42 previously treated patients who had initial response, response occurred from 6 days to 130 days with a median of 14.5 days.

The study was closed to patient entry; however, all patients now on hydroxyurea will continue to be followed.
Hydroxyurea in Thrombosis.

Objective: To evaluate the efficacy of hydroxyurea in preventing and controlling the symptoms of thrombosis and bleeding with 1) the clinical entity primary thrombocytopenia, 2) those patients with myelofibrosis-myeloid metaplasia with elevated platelet counts, and 3) those patients with unclassified myeloproliferative disease with elevated platelet counts.

Technical Approach: In order to be eligible for entry on this study, the patient must meet the following criteria: 1) Absence of Philadelphia chromosome, 2) Absence of an increased red cell mass, 3) bone marrow which shows marked megakaryocytic hyperplasia and abundant platelet clumps, 4) Thrombosis secondary to some identifiable cause, i.e., infection, cancer etc., and Patient must not have had a pre-existing cancer, other than skin cancer.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, there are 41 evaluable patients and 35 of these have achieved a platelet count of <600,000, 27 of whom sustained this for a year.
**Detail Summary Sheet**

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<td><strong>TITLE:</strong></td>
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<tr>
<td>Study of the Clinical Features and Natural History of Asymptomatic Patients with Myeloproliferative Disorders.</td>
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<td><strong>Start Date:</strong></td>
<td>FY 79</td>
<td><strong>Est Comp Date:</strong></td>
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<tr>
<td>Principal Investigator</td>
<td>Ray O. Lundy, M.D., LTC, MC</td>
<td>Facility</td>
<td>Brooke Army Medical Center</td>
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<tr>
<td>Dept/Sec:</td>
<td></td>
<td>Associate Investigators:</td>
<td>Glenn N. Mills, M.D., MAJ, MC</td>
</tr>
<tr>
<td>Department of Medicine/Hematology</td>
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<td>Myeloproliferative disorder</td>
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<th>Periodic OMA Cost</th>
<th>Review Results</th>
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**Objectives:**

To obtain a clinical and laboratory data base on patients with myeloproliferative disorders prior to the time they require treatment under other MPD protocols.

To define the natural course of the disease as to the development of:

1. splenomegaly,
2. progressive fibrosis,
3. leukemic conversion,
4. thromboembolic complications,
5. other neoplasms.

To demonstrate the development of cytogenetic and pathologic abnormalities in bone marrow and peripheral blood.

To establish predictors of a more symptomatic stage of the disease.

**Technical Approach:**

All newly diagnosed (less than one year), previously untreated patients (including patients transfused for a period of less than three months) considered to have one of the myeloproliferative disorders outlined in the protocol are eligible.

**Progress:**

Data on all patients entered into the myeloproliferative studies have been transferred to Duke University for evaluation.
TITLE: Efficacy Trial Using Cyproheptadine and Cimetidine for Pruritus in Polycythemia Vera

Start Date: 10 Oct 81

Principal Investigator
Ray O. Lundy, M.D., LTC, MC

Dept/Sec: Department of Medicine/Hematology

Key Words:
Pruritus
Polycythemia Vera

Accumulative MEDCASE Est Accumulative Periodic
Cost: OMA Cost: Review Results:

Objective: To determine whether $H_1$ and $H_2$ blocking agents used concomitantly are efficacious in alleviating the pruritus of polycythemia vera.

Technical Approach: Any patient with polycythemia vera in remission, i.e., Hct. of 40-45%, following treatment who suffers from persistent pruritus which worsens with bathing or showering and which does not antedate the onset of symptoms of polycythemia vera is eligible for this protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual in this study has been slow. However, of those patients entered on the study, the drug combination has been shown to be efficacious in treating pruritus but the number is still too small for a definitive statement.
APPENDIX D

PEDIATRIC ONCOLOGY GROUP
Evaluation of Natural History of Histiocytosis X in Childhood

Objective: To obtain information about the natural history of all forms of histiocytosis X and histiocytic medullary reticulosis.

Technical Approach: All new patients with a biopsy-proven diagnosis of histiocytosis X should be registered for the study.

This study involves reporting on the results of examinations, tests, and treatment during the course of the disease. The examinations and tests are as outlined in the study protocol.

Progress: For patients who developed progressive disease off therapy, the time to appearance of the last new lesion ranged from 2 months to 8 years with a median time of 1 year 8 months and a mean time of 2 years 4 months.

While detailed statistical analyses are not possible at this time, the following has been noted: males dominate the nonprogressive group.
Detail Summary Sheet

Date: 2 Nov 81  Proj No: POG 7607B  Status: Completed

TITLE:
AD-CON-FU/Lithium in Children with Metastatic Solid Tumors

Start Date: 25 Sep 81  Est Comp Date:
Principal Investigator
Terry E. Pick, M.D., LTC, MC
Dept/Sec:
Department of Pediatrics
Key Words:
Solid tumors

Accumulative MEDCASE  Est Accumulative  Periodic
Cost:  OMA Cost:  Review Results:

Objective: To determine the response rates of the combination of AD-CON-FU/
Lithium in the treatment of solid tumors in previously treated or untreated
children.

Technical Approach: Patients with objectively measurable tumors with epithelial
tumors or previously treated sarcomas who are not eligible for other
intergroup studies are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been completed prior to approval by the BAMC committees.
TITLE: MOPP + Bleo vs A-COPP with IF RT in Stage III Hodgkin's Disease in Children

Date: 2 Nov 81  Proj No: POC 7612  Status: Ongoing

Start Date: 25 Sep 81  Est Comp Date: Unknown

Principal Investigator
Terry E. Pick, M.D., LTC, MC

Facility
Brooke Army Medical Center

Dept/Sec: Department of Pediatrics

Associate Investigators:

Key Words:
Hodgkin's disease

Objective: To compare the effectiveness of IF radiotherapy plus MOPP + Bleo with IF radiotherapy plus A-COPP chemotherapy in treating Stage III Hodgkin's disease in children.

To determine the patient tolerance of the two chemotherapy regimens in terms of immediate toxicity including the incidence of infection.

Technical Approach: All children, 18 years or younger, with Stage III Hodgkin's disease including extranodal presentations + constitutional symptoms, regardless of specific with no prior therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No significant difference (p = .46) exists between the two treatment programs when compared by disease-free survival.
<table>
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<td><strong>Date:</strong> 2 Nov 81</td>
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<tr>
<td><strong>TITLE:</strong> Combination Chemotherapy with Vinblastine Sulfate and Bleomycin Infusion in Children with Metastatic Solid Tumors</td>
</tr>
<tr>
<td><strong>Start Date:</strong> 25 Sep 81</td>
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<td><strong>Principal Investigator</strong></td>
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<tr>
<td>Terry E. Pick, M.D., LTC, MC</td>
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<tr>
<td><strong>Dept/Sec:</strong></td>
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<td><strong>Key Words:</strong></td>
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| **Objectives:** To determine the response rate of vinblastine sulfate-bleomycin combination in children with advanced metastatic solid tumors. |
| To determine the toxicity of this combination in children. |

Technical Approach: All children under 18 years of age, previously treated, with recurrent or metastatic solid tumors and Hodgkin's and non-Hodgkin's lymphomas are eligible.

Progress: This study had been completed by the Pediatric Oncology Group prior to BAMC approval. No reportable data are available.
**Detail Summary Sheet**

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<th>Date: 2 Nov 81</th>
<th>Proj No: POG 7621</th>
<th>Status: Ongoing</th>
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**TITLE:**

MOPP vs OPP in the Treatment of Children with Recurrent Brain Tumors

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<th>Start Date: Feb 81</th>
<th>Est Comp Date: Unknown</th>
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**Principal Investigator**

Terry E. Pick, M.D., LTC, MC

**Facility**

Brooke Army Medical Center

**Dept/Sec:**

Department of Pediatrics

**Associate Investigators:**


**Key Words:**

Brain tumor

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**Objective:** To determine and compare response to MOPP or OPP in children with recurrent brain tumors.

Technical Approach: All patients who have been diagnosed to have a central nervous system tumor, and who have previously received maximally allowable dose of radiotherapy will be eligible for randomization which will require no prior therapy with either nitrogen mustard or BCNU. Patients must be 18 years of age or under at the time of diagnosis.

Therapy will follow the schema outlined in the study protocol.

**Progress:** No reportable data are available at this time.
Date: 2 Nov 81  Proj No:  POG 7623  Status:  Completed

TITLE:
Evaluation of Systemic Regimens in the Treatment of Leukemia of Childhood
ALinC #12

Start Date:  Nov 80  Est Comp Date:

Principal Investigator:
Terry E. Pick, M.D., LTC, MC

Dept/Sec:
Department of Pediatrics

Key Words:
Leukemia

Accumulative MEDCASE  Est Accumulative
Cost:  OMA Cost:  Periodic

Objective: To evaluate the desirability of prospective separation of various
prognostic groups among newly diagnosed cases of pediatric lymphatic leukemia.
Within each group variations of treatment regimens are compared with respect to
the length of initial remission produced by each.

Technical Approach: Eligible patients must be under 21 years of age and have
the diagnosis of ALL, ASL, or AUL.

Therapy will follow the schema outlined in the study protocol.

Progress: No significant differences between the treatments were observed.
In terms of complete response rates, the p-values are .30 (treatment com-
parison within good prognosis group) and .52 (treatment comparison within
poor prognosis group). There was no significant difference in disease-free
survival between ALinC 11 and ALinC 12.
### Detail Summary Sheet

**Date:** 2 Nov 81  
**Proj No:** POG 7703  
**Status:** Terminated

**TITLE:**  
Radiation Therapy with BCNU, DTIC, or Procarbazine in Malignant Brain Gliomas, Phase III

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<td>Terry E. Pick, M.D., LTC, MC</td>
<td>Brooke Army Medical Center</td>
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**Dept/Sec:** Department of Pediatrics  
**Associate Investigators:**

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<th>OMA Cost:</th>
<th>Review Results:</th>
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**Objective:** Not applicable.

**Technical Approach:** Not applicable.

**Progress:** This study had been completed by the Pediatric Oncology Group prior to approval at BAMC.
Detail Summary Sheet

Date: 2 Nov 81       Proj No: POG 7712       Status: Ongoing

TITLE:
Comparison of Treatment Regimens for the First CNS Relapse in Children with Acute Lymphocytic Leukemia - CNS #6

Start Date: 25 Sep 81       Est Comp Date: Unknown

Principal Investigator
Terry E. Pick, M.D., LTC, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Pediatrics

Associate Investigators:

Key Words:
Acute lymphocytic leukemia

Objective: To compare two therapies for CNS leukemia with respect to length of CNS remission and CNS toxicity.

Technical Approach: Patients less than 21 years of age at time of initial diagnosis with first CNS relapse who have not had more than one marrow relapse are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.
**Title:** Evaluation of Induction, Remission Maintenance with and without Periodic Reinforcement, and CNS Prophylaxis in Acute Non-Lymphocytic Leukemia

**Objectives:**
Evaluation of a remission-induction program in previously untreated acute non-lymphocytic leukemia (ANLL).

- A chemotherapeutic regimen maintenance will be evaluated and the effects of periodic reinforcement with this regimen will also be evaluated.
- The effects on development of CNS leukemia and the effects on prolongation of remission maintenance by the addition of CNS prophylaxis will be investigated.
- Outcome by histologic subgroups will be evaluated in response to therapy.

**Technical Approach:** Patients under 21 years of age with a diagnosis of acute myelocytic leukemia, acute myelomonocytic leukemia, chronic granulocytic leukemia in blastic crises, erythroleukemia or other rare forms of myelocytic leukemia are eligible.

- Therapy will follow the schema outlined in the study protocol.

**Progress:** Duration of remission and survival by treatment group is as follows:
VAP, Tr 1 - median duration 47 and 61 weeks, respectively; VAP Tr 2 - 54 and 58 weeks, respectively; TG & Ara-C - 15 and 40 weeks, respectively.
Detail Summary Sheet

Date: 2 Nov 81  Proj No: POC 7799  Status: Ongoing

TITLE:
Rare Tumor Registry for Childhood Solid Tumor Malignancies

Start Date: 25 Sep 81  Est Comp Date: Unknown
Principal Investigator
Terry E. Pick, M.D., LTC, MC
Dept/Sec:
Department of Pediatrics
Key Words:
Solid tumor

Accumulative MEDCASE  Est Accumulative Cost:  OMA Cost:  Periodic Review Results:

Objectives: To collect natural history data on malignancies which occur so rarely that large series of patients cannot be accumulated at any single institution.

To evaluate therapies in those groups of rare tumors in which fair numbers of cases can be accrued.

Technical Approach: Any child under the age of 18 years at diagnosis with a rare solid tumor is eligible for the study.

Progress: This is a new study.
Detail Summary Sheet

Date: 2 Nov 81  Proj No: POC 7812  Status: Ongoing

TITLE:
Anguidine in Central Nervous System Tumors

Start Date: 25 Sep 81  Est Comp Date: Unknown
Principal Investigator: Terry E. Pick, M.D., LTC, MC
Facility: Brooke Army Medical Center
Dept/Sec: Department of Pediatrics
Associate Investigators:
Key Words:
Central nervous system tumors

Objective: To determine the anti-tumor activity of anguidine in the treatment of malignant brain tumors in children and adolescents relative to clinical response and survival.

Technical Approach: Patients with histologically confirmed primary CNS tumors as follows are eligible: astrocytoma, Grades III and IV; ependymoma, oligodendroglioma; medulloblastoma and patients under 21 years of age with clinical diagnosis of recurrent brain stem glioma following radiation therapy are eligible. Patients must not be eligible for protocols of higher priority or treatment of proven or likely higher efficacy.

Progress: This is a new study.
Detail Summary Sheet

Date: 3 Nov 81  Proj No: POG 7818  Status: Ongoing

TITLE: Rubidazole in Children with ALL and AML in Relapse

Start Date: 25 Sep 81  Est Comp Date: Unknown

Principal Investigator: Terry E. Pick, M.D., LTC, MC
Facility: Brooke Army Medical Center

Dept/Sec: Department of Pediatrics
Associate Investigators:

Key Words:
Acute lymphocytic leukemia

Accumulative MEDCASE  Est Accumulative Cost: OMA Cost:

Objective: To determine the clinical efficacy and toxicity of rubidazole when used for the induction of remission in children with acute leukemia.

Technical Approach: Patients 21 years of age or under with acute leukemia in relapse, not eligible for protocols of higher priority, are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.
Detail Summary Sheet

Date: 3 Nov 81  Proj No: POG 7829  Status: Ongoing

TITLE:
Comparison of Two Dose Regimens of Intrathecal Methotrexate for CNS Leukemia, Phase II

Start Date: 25 Sep 81  Est Comp Date: Unknown
Principal Investigator
Terry E. Pick, M.D., LTC, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Pediatrics

Associate Investigators:

Key Words:
CNS leukemia

Accumulative MEDCASE  Est Accumulative  Periodic
Cost:  OMA Cost:  Review Results:

Objective: To compare the toxicity, response rates and duration of response obtained by using a two dose regimen of intrathecal methotrexate.

Technical Approach: Patients under the age of 21 with CNS leukemia in relapse who are not known to be resistant to intrathecal methotrexate are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.
Date: 3 Nov 81
Proj No: POG 7834
Status: Ongoing

TITLE:
Second Induction Maintenance in Acute Lymphocytic Leukemia, Phase III

Start Date: 25 Sep 81
Est Comp Date: Unknown

Principal Investigator
Terry E. Pick, M.D., LTC, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Pediatrics

Associate Investigators:

Key Words:
Acute lymphocytic leukemia

Accumulative MEDCASE Cost: OMA Cost: Periodic Review Results:

Objective: To determine in children in the first relapse of ALL in remission duration which can be achieved following an intensive and aggressive induction regimen and maintenance.

Technical Approach: Patients under the age of 21 years in their first CNS and/or extramedullary and/or bone marrow relapse with acute lymphocytic leukemia are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.
TITLE:
Evaluation of Systemic Therapy for Children with T Cell Acute Lymphatic Leukemia, Phase III

Start Date: 25 Sep 81

Principal Investigator
Terry E. Pick, M.D., LTC, MC

Dept/Sec:
Department of Pediatrics

Key Words:
Acute lymphatic leukemia
T-cell

Accumulative MEDCASE: Est Accumulative Cost:
Periodic OMA Cost:

Objective: To evaluate the effectiveness of a program of sequential systemic chemotherapy plus CNS treatment for children with untreated T-cell leukemia.

Technical Approach: Patients under the age of 21 with a diagnosis of T-cell leukemia as defined by SOWG 7865 including all patients who have 20% or greater E-rosetting leukemia cells are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.
Detail Summary Sheet

Date: 3 Nov 81  Proj No: POG 7843  Status: Ongoing

TITLE:
Evaluation of Rubidazone in the Treatment of Children with Solid Tumors, Phase II

Start Date: 25 Sep 81  Est Comp Date: Unknown
Principal Investigator
Terry E. Pick, M.D., LTC, MC

Facility
Brooke Army Medical Center

Dept/Sec:
Department of Pediatrics

Associate Investigators:

Key Words:
Solid tumor

Accumulative MEDCASE  Est Accumulative  Periodic Cost:  OMA Cost:  Review Results:

Objective: To determine the clinical efficacy of rubidazone in the treatment of malignant tumors in children with and without previous anthracycline therapy and to determine the toxicity of this drug in children with solid tumors.

Technical Approach: All patients under the age of 21 with a measurable tumor lesion, resistant to conventional chemotherapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.
**TITLE:**
Pilot ALinC 13C Acute Lymphoblastic Leukemia - Classification Portion

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<th>Date: 2 Nov 81</th>
<th>Proj No: POG 7865</th>
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<td><strong>Start Date:</strong> Nov 80</td>
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<td><strong>Principal Investigator:</strong> Terry E. Pick, M.D., LTC, MC</td>
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<th>OMA Cost:</th>
<th>Review Results:</th>
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**Objectives:** Subgroup classification of A.L.L. at time of diagnosis using a variety of laboratory methods. The present study is designed to:

1) familiarize each institution with the special subclassification laboratory procedures which will be required in ALinC 13 for patient registration;

2) collect data concerning laboratory subclassification results to determine in a preliminary fashion the degree of prognostic correlation of these results with already accepted clinical and laboratory prognostic factors (such as age, WBC, T-cell markers, etc.).

**Technical Approach:** Patients under 21 years of age with a diagnosis of acute lymphoblastic leukemia, acute undifferentiated leukemia, or acute stem cell leukemia are eligible.

**Progress:** No patients from BAMC were entered on this study. However, the study was completed by the Pediatric Oncology Group.
Objective: To determine the effectiveness of high dose intermittent chemotherapy to prevent local recurrence and/or metastases with surgical resection and a uniform radiation therapy regimen to control local disease.

Technical Approach: Patients with biopsy-proven localized Ewing's sarcoma with no prior chemotherapy and/or radiation therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.
Detail Summary Sheet

Date: 3 Nov 81 Proj No: POG 7906 Status: Terminated
TITLE:
Multidrug Adjuvant Chemotherapy in Non-Metastatic Osteosarcoma: Comparison of CONPADRI I with COMPADRI V
Start Date: Est Comp Date:
Principal Investigator Facility
Terry E. Pick, M.D., LTC, MC Brooke Army Medical Center
Dept/Sec: Associate Investigators:
Department of Pediatrics
Key Words:
Osteosarcoma

Accumulative MEDCASE Est Accumulative Periodic
Cost: OMA Cost: Review Results:
Objective: Not applicable.

Technical Approach: Not applicable.

Progress: This study was completed by the Pediatric Oncology Group prior to the final approval at BAMC.
Detail Summary Sheet

Date: 2 Nov 81  Proj No: POG 7909  Status: Ongoing

TITLE: Evaluation of MOPP Adjuvant Chemotherapy in the Treatment of Localized Medulloblastoma and Ependymoma

Start Date: May 81  Est Comp Date: Unknown

Principal Investigator: Terry E. Pick, M.D., LTC, MC

Facility: Brooke Army Medical Center

Dept/Sec: Department of Pediatrics

Associate Investigators: 

Key Words: Medulloblastoma  Ependymoma

Accumulative MEDCASE  Est Accumulative Cost: OMA Cost: Periodic

Review Results: Continue

Objective: To evaluate the efficacy and toxicity of the MOPP adjuvant chemotherapy in the prevention of local recurrence of distant metastasis in children with localized medulloblastoma and ependymoma.

Technical Approach: Patients between 1 and 21 years (inclusive) with histologically proven medulloblastoma and ependymoma are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been slow. The results of this study are too early to evaluate.
TITLE:
Evaluation of m-AMSA in Children with Acute Leukemia and Non-Hodgkins in Relapse

Start Date: Nov 80
Prinicipal Investigator
Terry E. Pick, M.D., LTC, MC
Dept/Sec:
Department of Pediatrics
Key Words:
Acute Leukemia
Non-Hodgkin's lymphoma

Accumulative MEDCASE: Est Accumulative Cost: OMA Cost: Periodic Review Results: Continue

Objectives: To determine the clinical efficacy of m-AMSA, as indicated by the induction of partial or complete remission in pediatric patients with acute leukemia or non-Hodgkin's lymphoma in relapse.

To further assess the toxicity of m-AMSA in children.

Technical Approach: All patients with acute leukemia (lymphocytic and non-lymphocytic) or non-Hodgkin's lymphoma in relapse who are 18 years of age or under at the time of diagnosis, who are not eligible for protocols of higher priority and who are resistant to standard forms of therapy, will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: The results of this study are too early to evaluate.
TITLE: National Wilms' Tumor Study, III

Start Date: 25 Sep 81
Est Comp Date: Unknown

Principal Investigator
Terry E. Pick, M.D., LTC, MC

Facility
Brooke Army Medical Center

Dept/Sec: Department of Pediatrics

Associate Investigators:

Key Words: Wilms' tumor

Objectives: To gain better understanding of Wilms' tumor by gathering detailed information regarding gross and histologic morphology.

To refine methods of treatment according to staging.

To test treatment hypotheses by randomized, prospective clinical trials according to stage and histologic grade of disease.

To gather information about family cancer in an attempt to identify children and families at high risk.

To study the late consequences of successful treatment given for Wilms' tumor.

Technical Approach: Patients under the age of 15 with Wilms' tumor are eligible.

Progress: This is a new study.
### Detail Summary Sheet

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<td><strong>TITLE:</strong></td>
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<td>Combination Chemotherapy with Adriamycin, Cis-Platinum, Vincristine, and Cytoxan in Children with Metastatic Neuroblastoma (Stage IV)</td>
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<td>Key Words:</td>
<td>Neuroblastoma, metastatic</td>
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<td><strong>OMA Cost:</strong></td>
<td><strong>Periodic Review Results:</strong></td>
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<tr>
<td>Objectives:</td>
<td>To delineate the toxicity of the combination of cytoxan, vincristine, adriamycin and cis-platinum in children with metastatic neuroblastoma.</td>
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<td>To do a preliminary analysis of the therapeutic efficacy prior to consideration of this four-drug combination as front-line therapy for children with Stage IV neuroblastoma.</td>
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<td>Technical Approach:</td>
<td>Children from 1 to 21 years of age with biopsy-proven metastatic neuroblastoma (Stage IV) who have not had prior exposure to cis-platinum are eligible.</td>
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<td></td>
<td>Therapy will follow the schema outlined in the study protocol.</td>
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**Progress:** This is a new study.
**Detail Summary Sheet**

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<th>Status: Ongoing</th>
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**TITLE:**
Circulating Immune Complexes in Pediatric Malignancies

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<th>Start Date: 25 Sep 81</th>
<th>Est Comp Date: Unknown</th>
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**Principal Investigator**
Terry E. Pick, M.D., LTC, MC

**Facility**
Brooke Army Medical Center

**Dept/Sec:**
Department of Pediatrics

**Associate Investigators:**

**Key Words:**
Immune complex

| Accumulative MEDCASE | Est Accumulative Cost: OMA Cost: Periodic Review Results: |
|----------------------|-----------------|-----------------|-----------------|-----------------|

**Objectives:**
To determine the incidence of elevated levels of circulating immune complexes at diagnosis in children with neuroblastoma, osteogenic sarcoma, ALL and AML.

To corelate serial levels of circulating immune complexes with disease activity should significant quantities be initially detected.

**Technical Approach:**
Newly diagnosed and staged patients under 21 years of age with neuroblastoma, osteogenic sarcoma, acute lymphocytic leukemia or acute myelogenous leukemia are eligible. Patients should not have had excisional surgery, chemotherapy or radiotherapy prior to initial serum sample.

**Progress:**
This is a new study.
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ACKNOWLEDGEMENT

We regretted the departure of former BAMC Commander Brigadier General Andre J. Ognibene and wish him every success in his new endeavors. We are enthusiastic about the future with Brigadier General Tracy E. Strevey, Jr., the new Commanding General of BAMC.

In every organization there are those who never receive the recognition they deserve. Mrs. Bodie Bratten, the Editorial Assistant, and SFC Chuck Lovi, the NCOIC, have continually given that extra effort that has assured the success of the Department of Clinical Investigation for which I am most appreciative.

JAMES H. ANDERSON, JR., M.D.
Major, MC
Chief, Department of Clinical Investigation
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