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BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON TEX
ANNUAL RESEARCH PROGRESS REPORT, FISCAL YEAR 1977, (U)
OCT 77 R ANSBACHER, R G PARRISH

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CLINICAL INVESTIGATION SERVICE

Annual Research Progress Report

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FISCAL YEAR 77-77

**Brooke Army Medical Center
Fort Sam Houston, Texas 78234**

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ERRATA

- a. Page III - "Contractural" should be "Contractual"
- b. Page VI - First entry should be "44"
- c. Page IX - Fifth entry should be "Eosinophilia"
- d. Page X - Sixth entry should be "Compromised"
- e. Page XI - First entry should be "Algoritihms"
- f. Page XIII - Second entry should be "Adult Acute Leukemia"
- g. Page 23 - Seventh entry should be "Patients"

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FOREWORD

The research reflected in this report is a credit to the entire staff of Brooke Army Medical Center. The quality of the work as well as the enormous number of publications and presentations (240) is indicative of a staff interested not only in delivering quality health care but also committed to improve that care by participating in clinical investigations. Since its inception in 1971, the Clinical Investigation Service has been dedicated to supporting and stimulating clinical inquiries. With the completion of administrative offices and laboratory facilities during FY 77, we are now more capable than ever to support clinical research activities and the resident training program at BAMC.

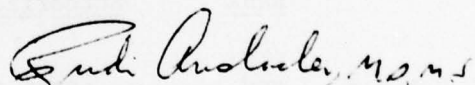
We are grateful to this facility's Commander, BG Floyd W. Baker, for his continued support and recognition of the instrumental role clinical investigations play in the delivery of quality health care and in maintenance of an effective teaching program. Likewise the support of the Clinical Investigation Consultant, Health Services Command, COL Norman W. Ream, is appreciated. The quality and sophistication of the equipment in the new laboratory facility is a direct result of COL Ream's active support of the BAMC Clinical Investigation Service.

This report and the efficient management of the multitude of administrative tasks in the Clinical Investigation Service would not be possible without the devoted and unselfish support of Mrs. Dodie Bratten to whom we express our most sincere appreciation.



ROB G. PARRISH, Ph.D.

Captain, MSC
Chief, Clinical Investigation
Service



RUDI ANSBACHER, M.D., M.S.

Colonel, MC
Chairman, Directorate for
Clinical Investigation Service

REPORT OF TOTAL ACTIVITIES OF CLINICAL INVESTIGATION SERVICE

FY 7T-77

A. Objectives

The Clinical Investigation Service was established at Brooke Army Medical Center 9 August 1971 to coordinate clinical investigation activities throughout the hospital complex. It is an independent service directly under the Chief, Professional Services and operated under the guidance of the Directorate for Clinical Investigation Service, composed of three members from the Department of Medicine and one each from Obstetrics-Gynecology, Pediatrics and Surgery; the Clinical Investigation Committee, composed of the chiefs of the various professional departments; and the Human Use Committee composed of lay personnel.

The Clinical Investigation Service was established to promote, stimulate, coordinate, and provide support for clinical investigation and development activities within Brooke Army Medical Center, including design of experiments, typing and editorial services, and technical liaison with outside facilities.

B. Technical Approach

<u>Name</u>	<u>Rank</u>	<u>Manpower</u> <u>Authorized</u>	<u>Title</u>
	LTC		Chief
Parrish, Rob G.*	CPT	68C00 8Z	Laboratory Dir/Biochemist
Giolma, John P.	CPT	68A00 8Z	Physiologist
Lieberman, Michael	CPT	68J00 8Z	Microbiologist
Greene, Joseph C.	SSG	92B3R	Sr Med Lab Sp, NCOIC
Sinegal, John H.	SSG	92B3R	Med Lab Sp
Plitt, James J.	SSG	01H2R	Biological Sci Asst
Wright, Gwendolyn	SP4	01H2R	Biological Sci Asst
McKissick, Donna C.	SP4	92B1R	Med Lab Sp
	SP4	92B1R	Med Lab Sp
	GS9	00334	Computer Sp
	GS7	00404	Biological Lab Tech
Chapa, Isidoro A.	GS7	00645	Med Lab Tech
Bratten, Dodie	GS6	01087	Editorial Asst

*Served as Chief during the period covered.

Directorate for Clinical Investigation Service

FY 7T-77

<u>Name</u>	<u>Rank</u>	<u>Organization</u>	<u>Title</u>
Ansbacher, Rudi	COL	Department of Obstetrics and Gynecology	Chairman
Parrish, Rob G.	CPT	Clinical Investigation Service	Recorder
Zeigler, Michael G.	COL	Department of Surgery	Member
Murgo, Joseph P.	LTC	Department of Medicine	Member
Bowman, Robert P.	LTC	Department of Medicine	Member
McNitt, Theodore R.	LTC	Department of Medicine	Member
Steele, Russell W.	LTC	Department of Pediatrics	Member

FY 78

McNitt, Theodore R.	LTC	Department of Medicine	Chairman
Parrish, Rob G.	CPT	Clinical Investigation Service	Recorder
Zeigler, Michael G.	COL	Department of Surgery	Member
Murgo, Joseph F.	LTC	Department of Medicine	Member
Steele, Russell W.	LTC	Department of Pediatrics	Member
Head, David R.	LTC	Department of Pathology and Area Lab Svcs	Member
Kennedy, Peter S.	MAJ	Department of Medicine	Member

Funding FY 7T-77

MEDCASE	\$ 66,262.00	3 Protocols
	\$ 52,986.00	Laboratory
	\$119,248.00	
Capital Equipment	\$ 2,462.00	4 Protocols
	\$ 6,098.00	Laboratory
	\$ 8,560.00	
Consumable Supplies	\$ 30,635.00	24 Protocols
	\$ 27,659.00	Laboratory
	\$ 4,342.00	Contractural Services
	\$ 62,961.00	
TOTAL	\$190,769.00	

C. Progress

Protocol Disposition FY 7T-77

	<u>Completed</u>	<u>Terminated</u>	<u>Ongoing to FY 78</u>
FY 72	1	0	2
FY 73	0	1	1
FY 74	3	1	6
FY 75	8	0	7
FY 76	10	8	14
FY 77	<u>9</u>	<u>2</u>	<u>37</u>
	31	12	67

During FY 7T-77, 110 manuscripts were accepted for publication in national and international journals; 59 of these emanated from Clinical Investigation Service sponsored projects. At the present time, there are 51 manuscripts pending acceptance for publication. Fifty-six manuscripts were reviewed by members of the Directorate for fulfillment of residency requirement. One hundred and thirty presentations were made at national and international meetings, and most of the material came from protocols registered in the Clinical Investigation Service.

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CODE:

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* - Clinical
⁺ - Chronological Order of Registration
⁻ - Fiscal Year in Which Registered

C - Completed
T - Terminated
O - Ongoing

P - Published
SP - Submitted for Publication
PR - Presentation

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

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

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Merrill, R.H. Potassium Homeostasis in Renal Failure. Nephrology Seminar entitled "Current Topics in Nephrology", 13 April 1977.

Whitman, W.H. The Hemolytic Uremic Syndrome/Thrombotic Thrombocytopenic Purpura Complex. Nephrology Seminar entitled "Current Topics in Nephrology", 12 April 1977.

Whitman, W.H. Calcium Disturbances in Chronic Renal Failure. Regional Dialysis Nurses and Technicians Meeting, May 1977.

Myers, W.D. The "Burnt" Kidney. Regional Dialysis Nurses and Technicians Meeting, May 1977.

Myers, W.D. Renal Function in the Thermally Injured Patient. 30th US Army Institute of Surgical Research Anniversary, 24 June 1977.

Myers, W.D. Renal Failure. Nursing Continuing Education Seminar. September 1977.

Neurology

Gunderson, C.H. A Problem Oriented Approach to Neurologic Diagnosis. University of Texas Health Science Center at San Antonio Postgraduate Course, 11 February 1977.

Oncology

McCracken, J.D. Tumors of Unknown Origin. University of Texas as San Antonio, Department of Medicine Oncology Conference, 10 August 1976.

Kennedy, P.S. Electronic Size Measurement of Platelet Aggregates. Hematology Section, City of Hope, Duarte, Calif., 2 June 1977.

Kennedy, P.S. Factors Affecting Size Distribution of Platelet Aggregates in Blood. New Methodological Techniques. Hematology-Oncology Grand Rounds, University of Texas, Galveston, Tex., 19 August 1977.
Hematology Section, Baylor College of Medicine, Houston, Tex., 9 September 1977

Rheumatology

Felt, J.C. Immune Complex Disease. Columbia Medical School of Wisconsin, Milwaukee, Wis., 16 September 1977.

Department of Obstetrics and Gynecology

Ansbacher, R. Is It Necessary to Order a Sperm Antibody Test in the Work-up of an Infertile Couple? Great Debates in Gynecological Endocrinology and Infertility, Baylor College of Medicine, Houston, Tex., 16 September 1976.

Ansbacher, R. Immunology of Infertility. Reproductive Endocrinology Postgraduate Course, 15th Annual Meeting of the Armed Forces District of the American College of Obstetricians and Gynecologists, Las Vegas, Nev., 20 September 1976.

Ansbacher, R. Critique of Paper "Cervical Implantation of an Ectopic Pregnancy: Two Case Reports". 15th Annual Meeting of the Armed Forces District of the American College of Obstetricians and Gynecologists, Las Vegas, Nev., 22 September 1976.

Ansbacher, R. Moderator, Scientific Session for Five Presentations and Discussions. 15th Annual Meeting of the Armed Forces District of the American College of Obstetricians and Gynecologists, Las Vegas, Nev., 23 September 1976.

Goode, J.A. Ileal Bypass in Pregnancy: Report of Cases and a Review. 15th Annual Meeting of the Armed Forces District of the American College of Obstetricians and Gynecologists, Las Vegas, Nev., 23 September 1976.

Wilson, M.E., Strauss, J.H., Caldwell, et al. Laminaria in Second Trimester F₂α-Urea, and Intravenous Oxytocin Abortions. 15th Annual Meeting of the Armed Forces District of the American College of Obstetricians and Gynecologists, Las Vegas, Nev., 22 September 1976.

Ansbacher, R. The Cervical Factor. Postgraduate Course "Improved Office Techniques in Treating Infertility Problems". 70 Annual Scientific Assembly of the Southern Medical Association, New Orleans, La., 7 November 1976.

Ansbacher, R. The Male Factor. Postgraduate Course "Improved Office Techniques in Treating Infertility Problems". 70th Annual Scientific Assembly of the Southern Medical Association, New Orleans, La., 7 November 1976.

Ansbacher, R. A.I.H. and A.I.D. Postgraduate Course "Improved Office Techniques in Treating Infertility Problems". 70th Annual Scientific Assembly of the Southern Medical Association, New Orleans, La., 7 November 1976.

Ansbacher, R. Evaluation of the Male in Infertile Couples. Visiting Professor, the Mayo Clinic, Rochester, Minn., 24 February 1977.

Ansbacher, R. Endometriosis: Surgical Treatment. Postgraduate Course in Reproductive Endocrinology on Hormone Therapy, Wilford Hall USAF Medical Center, Lackland Air Force Base, Tex., 19 March 1977.

Ansbacher, R. Evaluation of the Infertile Couple. Consultant for the Department of Ob-Gyn, William Beaumont Army Medical Center, El Paso, Tex., 24 March 1977.

Ansbacher, R. Endometriosis - Treatment. Consultant for the Department of Ob-Gyn, William Beaumont Army Medical Center, El Paso, Tex., 24 March 1977.

Ansbacher, R. Contraception: Past, Present, Future. Consultant for the Department of Ob-Gyn, William Beaumont Army Medical Center, El Paso, Tex., 24 March 1977.

Ansbacher, R. Immunology of Infertility. Consultant for the Department of Ob-Gyn, William Beaumont Army Medical Center, El Paso, Tex., 25 March 1977.

Ansbacher, R. Bleeding in Pregnancy. Consultant for the Department of Ob-Gyn, William Beaumont Army Medical Center, El Paso, Tex., 25 March 1977.

Ansbacher, R. Interpretation of the Semen Analysis (Male Factor). Postgraduate Course "Improved Office Techniques in Treating Infertility" 9th World Congress of Fertility and Sterility and 33rd Annual Meeting of the American Fertility Society, Miami Beach, Fla., 12 April 1977.

Ansbacher, R. Role of Immunology in the Infertile Couple. Postgraduate Course "Improved Office Techniques in Treating Infertility", 9th World Congress of Fertility and Sterility and the 33rd Annual Meeting of the American Fertility Society, Miami Beach, Fla., 12 April 1977.

Ansbacher, R. Evaluation of Tubal and Uterine Factors. Postgraduate Course "Improved Office Techniques in Treating Infertility", 9th World Congress of Fertility and Sterility and the 33rd Annual Meeting of the American Fertility Society, Miami Beach, Fla., 12 April 1977.

Ansbacher, R. Immunologic Aspects of Infertility. Luncheon Round Table Conference, 9th World Congress of Fertility and Sterility and the 33rd Annual Meeting of the American Fertility Society, Miami Beach, Fla., 13 April 1977.

Ansbacher R. Artificial Insemination with Husband and Donor. Luncheon Round Table Conference, 9th World Congress of Fertility and Sterility and the 33rd Annual Meeting of the American Fertility Society, Miami Beach, Fla., 15 April 1977.

Ansbacher, E. Immunologic Aspects of Male Infertility. General Session, 9th World Congress of Fertility and Sterility and the 33rd Annual Meeting of the American Fertility Society, Miami Beach, Fla., 14 April 1977.

Ansbacher, R. Donor Insemination: Indications, Technique, Results. General Session, 9th World Congress of Fertility and Sterility and the 33rd Annual Meeting of the American Fertility Society, Miami Beach, Fla., 15 April 1977.

Ansbacher, R. Mederator for Session on Urology. 9th World Congress of Fertility and Sterility and the 33rd Annual Meeting of the American Fertility Society, Miami Beach, Fla., 14 April 1977.

Ansbacher, R. Workup of the Male - Semen Analysis. Postgraduate Course "The Management of Infertility", 25th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists, Chicago, Ill., 7 May 1977.

Ansbacher, R. Treatment of the Male, A.I.H. and A.I.D. Postgraduate Course "The Management of Infertility", 25th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists, Chicago, Ill., 8 May 1977.

Ansbacher, R. Immunologic Aspects of Infertility. Breakfast Conference, 25th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists, Chicago, Ill., 9 May 1977.

Scientific Exhibit "Television as a Media for Patient and Physician Education". 15th Annual Meeting of the Armed Forces District of the American College of Obstetricians and Gynecologists, Las Vegas, Nev., 18-24 September 1976.

Department of Pathology and Area Laboratory Services

Head, D.R. Panel Member - Workshop "Hemoglobinopathies in the Military". Aerospace and Military Medicine Program, National Medical Association, 81st Annual Convention, 9 August 1976.

Head, D.R. Factor VIII for the Laboratories. Current Concepts in Pathology, Letterman Army Medical Center, San Francisco, Calif., 19-21 April 1977.

Koester, S.K., Shildt, R.A., Luedke, D.W., Laham, M.N., Kasai, G.J. Immunologic Response of Oncology Patients to Influenza Immunization. Texas Branch of the Society of American Microbiologists, San Antonio, Texas, 11 March 1977.

Oberhofer, T.R., Rowen, J.W., Cunningham, G.F. and Higbee, J.W. Evaluation of the Oxi/FermTM Tube System with Selected Gram Negative Bacteria. American Society for Microbiology, New Orleans, La., 8-13 May 1977.

Department of Pediatrics

Wood, D.A. International Aspect of Child Abuse in the Military and the Army's New Role as Child Advocate. Symposium on Child Abuse, Denver, Colo., October 1976.

Gold, L.F. and Steele, R.W. Acute Necrotizing Fasciitis and Myositis in a Neonate. Uniformed Services Pediatric Seminar, El Paso, Tex., 20-25 March 1977.

Steele, R.W., Marrero, G. and Canales, L. Plasma Infusion Correction of Opsonization for Pneumococcal Meningitis. Pediatric Society, San Francisco, Calif., 25-30 April 1977.

Steele, R.W. Neonatal Host Defenses Against K-1 and Non K-1 E. coli. Pediatric Society, San Francisco, Calif., 25-30 April 1977.

Department of Surgery

Office of the Chief

Duffy, M.M. Erection of the Upper Lateral Cartilages for Middle Third Nasal Defects. Symposium of Military Plastic Surgery, Walter Reed Army Medical Center, Washington, D.C., 17-19 January 1977.

Duffy, M.M. Better Breasts for Better Living Through Surgery. South Texas Chapter of the American College of Surgeons, Austin, Tex., 27-29 January 1977.

Anesthesiology

Rayburn, R.L. and Watson, R.L. CPRAM-Controlled Partial Rebreathing Anesthesia Method. Presented at the University of Florida, Gainesville;
All Children's Hospital, University of Southern Florida, Tampa;
Variety Childrens Hospital, University of Miami, Miami, Fla.; and
University of Tennessee, Knoxville, Tenn., September 1977.

Winnie, A., Watson, R.L., et al. Anticholinergic Differences - A Matter of Safety. Scientific Exhibit American Medical Association, Dallas, Tex., June 1976.

General Surgery

Jarstfer, B.S. Aorto-Prosthetic False Aneurysms. Walter Reed Army Medical Center, Washington, D.C., 9 December 1976.

Jarstfer, B.S. The Reflected Wave in Aorto-Iliac Evaluation. Walter Reed Army Medical Center, Washington, D.C., 10 December 1976.

Spebar, M.J. and Jarstfer, B.S. Coccidiomycosis in Surgical Practice. Southwestern Surgical Congress, Acapulco, Mex., 26 April 1977.

Plucinski, T.R. and Newman, H.K. Unsuspected Non-Medullary Carcinoma of the Thyroid in Patients with Hyperparathyroidism. Southwestern Surgical Congress, Acapulco, Mex., 27 April 1977.

Fanning, R.K. and Jarstfer, B.S. Late Aorto-Prosthetic Suture Line Disruption. Display, Southwestern Surgical Congress, Acapulco, Mex., 25-28 April 1977.

Ophthalmology

Van Gemert, J.V. Insertion and Postoperative Evaluation of Intraocular Lens. South Texas Chapter of the American College of Surgeons, Austin, Tex., 27-29 January 1977.

Orthopaedics

Harman, L.E., III. Epiphyseal Fractures of the Distal Femur. South Texas Chapter of the American College of Surgeons, Austin, Tex., 27-29 January 1977.

Plastic Surgery

Burton, F.C. The Neglect of Basal Cell Carcinoma. Texas Society of Plastic Surgeons, Dallas, Tex., 6-9 May 1976.

Gum, R.A. Plastic Surgery in the Military Service. Tenth Symposium Walter Reed Army Medical Center, Washington, D.C., 17-19 January 1977.

Cardiothoracic Surgery

Treasure, R.L. Historical Highlights of Thoracic Surgery in the Army. Association of Military Surgeons of the United States, San Antonio, Tex., 2 November 1976.

Walker, O.M. Bronchogenic Cysts. Southern Thoracic Surgical Association, Acapulco, Mex., 5 November 1976.

Treasure, R.L. Surgical Management of Aneurysms of the Ascending Aorta. Current Trends in Cardiovascular Disease Symposium, William Beaumont Army Medical Center, El Paso, Tex., 19 May 1977.

Walker, O.M. A Five-Year Experience with the Intra-aortic Balloon Pump at Brooke Army Medical Center. Current Trends in Cardiovascular Disease Symposium, William Beaumont Army Medical Center, El Paso, Tex., 19 May 1977.

Will, R.J. Sodium Nitroprusside and Propranolol Therapy for Management of Post Coarctectomy Hypertension. Current Trends in Cardiovascular Disease Symposium, William Beaumont Army Medical Center, El Paso, Tex.

Urology

Lubensky, J.D. Peyronie's Disease. Kimbrough Urological Seminar, San Diego, Calif., October 1976.

Gangai, M.P. Diagnostic Steps in the Evaluation of Patients with Intersex. Kimbrough Urological Seminar, San Diego, Calif., October 1976.

Spence, C.R. Chylous Ascites - A Rare Complication of Retroperitoneal Lymphadenectomy for Testis Tumor. South Central Section, American Urology Association, San Antonio, Tex., September 1976.
Kimbrough Urological Seminar, San Diego, Calif., October 1976.

Gangai, M.P. Clinical Aspects of Hematuria. Professional Staff Conference, Moncrief Army Hospital, Fort Jackson, So. Car., January 1977.

Gangai, M.P. Congenital Urologic Abnormalities. American College of Physicians - Current Topics in Nephrology, San Antonio, Tex. April 1977.

Gangai, M.P. The Management of Males with Urethral Stricture Disease. Air Force Clinical Surgeons Meeting, San Antonio, Tex., April 1977.

Gangai, M.P., Agee, R.E. and Spence C.R. The Use of Full Thickness Free Skin Grafts in the Treatment of Urethral Strictures in the Male. South Central Section, American Urology Association, San Antonio, Tex., September 1976.

James C. Kimbrough Urological Seminar, San Diego, Calif., November 1976.
Western Section, American Urology Association, San Francisco, Calif., March 1977 (Won First Prize for Clinical Investigation Exhibit).

Social Work Service

Schlie, J.A., Management and Supervisory Issues of Military Child Abuse Programs. National Conference on Child Abuse and Neglect. Houston, Tex., 19 April 1977.

Schnall, S.M. Characteristics and Management of Child Abuse and Neglect Among Military Families. Family Studies Branch, Naval Health Research Center, Military Family Research Conference, San Diego, Calif., 1-3 September 1977.

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MANUSCRIPTS SUBMITTED FOR PUBLICATION

Department of Medicine

Cardiology

Murgo, J.P., Alter, B.R., Dorethy, J.D., McGranahan, G.M. The ejection dynamics of hypertrophic cardiomyopathy during the presence and absence of intraventricular gradients. *Journal of Clinical Investigation*.

Murgo, J.P., Giolma, J.P., Westerhof, N. The contribution of systemic input impedance measurements to an analysis of wave reflections in normal man. *Circulation Research*.

Murgo, J.P., Giolma, J.P., Altobelli, S.A., Westerhof, N. Systemic input impedance in normal man during rest and dynamic exercise. *Circulation Research*.

Westerhof, N., Murgo, J.P., Giolma, J.P. Systemic input impedance - theory, experimental results, and human measurements. Chapter 14 in "Engineering Principles in Cardiovascular Research". Editor H.C. Hwang, University Park Press, to be published in 1978.

Murgo, J.P. Multisensor catheterization - five years experience. *Catheterization and Cardiovascular Diagnosis*.

Murgo, J.P., Dorethy, J.D., Alter, B.R. Normal right and left ventricular ejection dynamics in man during rest and exercise. *Circulation*.

Logsdon, J.R., Murgo, J.P., McGranahan, G.M. Right and left heart ejection dynamics during the Valsalva maneuver. *Circulation*.

Alter, B.R., Treasure, R.L., Martin, H.A., Humphrey, S.H., Murgon, J.P., McGranahan, G.M. Echocardiographic detection of a subannular aortic aneurysm. *American Journal of Cardiology*.

Uhl, G.S. Pericardial tamponade in systemic sclerosis (scleroderma). *Annals of Internal Medicine*

Dermatology

Rietschel, R.L. A method to evaluate skin moisturizers in vivo. Journal of Investigative Dermatology.

Rietschel, R.L., Wilmore, D.W. Heat loss in anhidrotic ectodermal dysplasia. Archives of Dermatology.

Kraus, E.W., Perianal basal cell carcinoma. Archives of Dermatology.

Madorsky, D.D. Arsenic in dermatology. Archives of Dermatology.

Rietschel, R.L., Carr, J.F., Lewis, C.W. Symmetrical lividity of the palms and soles. Archives of Dermatology.

Rietschel, R.L., Madorsky, D.D. Male pattern alopecia regrowth following topical fluorouracil therapy. Letter to the editor Archives of Dermatology.

Endocrinology

Thomason, A.M. Why should beta-blockade ameliorate the signs of hyperthyroidism? Annals of Internal Medicine.

Thomason, A.M. Hypothesis on pathogenesis of thyroid storm: thyroid storm results from a lack of normal triiodothyronine decrease in severe systemic illness. Lancet.

Gastroenterology

Hiatt, G.A. The role of esophagoscopy vs. radiography in diagnosing benign peptic esophageal strictures. Gastroenterology.

General Medicine

Rockey, P.H., Wolcott, B.W. The usefulness of x-ray examinations in the evaluation of patients with back pain. Annals of Internal Medicine.

Hematology

Bowman, R.P., Schmidt, G.J., Bunn, H.F. Broad clinical spectrum of hemoglobin SC disease. Hematology.

Marmer, D.J., Bowman, R.P. Utilizing a cell harvester and preserved labelled platelets to simplify the [³H] serotonin release assay for the detection of platelet isoantibodies. Blood, The Journal of Hematology.

Infectious Disease

Stevens, D.L., Everett, E.D. Sequential computerized axial tomography in tuberculous meningitis. Journal of the American Medical Association.

McNitt, T.R., Everett, E.D., Duplantis, A.J. Pulmonary function abnormalities in adult patients with rubeola. American Review of Respiratory Disease.

Stevens, D.L., Everett, E.D., Spebar, M.J., Traugott, R.C. Coccidioidal pericarditis: report of a case and a review of the literature. Journal of Thoracic and Cardiovascular Surgery.

Nephrology

Cosgriff, T.M., Olin, D.B., Nash, D.A. Hyporenemic hypoaldosteronism. Case report and observation of dissociated renin and erythropoietin activity. Journal of Chronic Diseases.

Oncology

Kennedy, P.S., Solis, R.T. Factors affecting the size of platelet aggregates in blood. American Journal of Physiology.

Deas, B.W., Kennedy, P.S. COMF-radiotherapy treatment of small cell carcinoma of the lung. Journal of Pediatric Medicine and Oncology.

Kennedy, P.S., Smith, B., McCracken, J.D. False-positive Sternberg-Reed cells present in pericardial effusion: A case report.

Department of Nursing

Molter, N.C. Needs of relatives of critically ill ~~patients~~ ^{patients} a descriptive study. Heart and Lung

Department of Obstetrics and Gynecology

Webster, J.C., Juden, A.G. Vaginitis complicating gold therapy for rheumatoid arthritis. American Journal of Obstetrics and Gynecology.

Wallace, R.L., Caldwell, R.A., Otterson, W.N. Inhibition of premature labor by terbutaline, a preliminary report. American Journal of Obstetrics and Gynecology.

Department of Radiology

Davv, E.G., Lull, R.J. ^{99m}Tc pertechnetate cerebral flow abnormality in superior sagittal sinus thrombosis. Radiology.

Goldberger, L.E., Neely, H.R., Stammer, J.L. Larbe mucosal ridges: an unusual roentgenographic manifestation of ulcerative colitis. Radiology.

Nadalo, L.A., Goldberger, LE. The Mallory-Weiss syndrome identified by esophagogram. Radiology..

Lull, R.J., Papp, S.D. Gallium scan findings in Korean hemorrhagic fever. *Journal of Nuclear Medicine*.

Department of Surgery

Anesthesiology

Rayburn, R.L., Graves, S.A. A new concept in controlled ventilation of children with the Bain anesthetic circuitry. *Anesthesiology*.

Watson, D.W., Rayburn, R.L. Horner's syndrome: a complication of lumbar epidural anesthesia. *Anesthesiology*.

General Surgery

Fanning, R.K., Steckler, R.M., Bailey, T., Zeigler, M.G. Massive pelvic crush injury treated successfully by hemicolectomy. *Journal of Trauma*.

Evans, M.R., Dorethy, J.F., Jarstfer, B.S. Acute aortic dissection resulting from retrograde left brachial cardiac catheterization. *Journal of Thoracic and Cardiovascular surgery*.

Butler, J.E. Epithelioid sarcoma: a report of an unusually aggressive case. *Journal of Surgical Oncology*.

Fanning, R.K., Jarstfer, B.S. Late aorto-prosthetic suture line disruption. *American Journal of Surgery*.

Spebar, M., Jarstfer, B.S. Coccidiomycosis in surgical practice. *American Journal of Surgery*.

Jarstfer, B.S. Smoking, lipids, and atherosclerosis. *Journal of the American Medical Association*.

Ophthalmology

Pramhus, C., Runyan, T.E., Lindberg, R.B. Ocular flora in the severely burned patient. *Annals of Ophthalmology*.

Runyan, T.E., Pramhus, C. The use of the hydrophilic lens in severely burned patients. *American Journal of Ophthalmology*.

Otolaryngology

Louviere, E.M. Radiation therapy of laryngeal carcinoma. *Annals of Otolaryngology, Rhinology and Laryngology*.

Cardiothoracic Surgery

Walker, O.M., Zumbro, G.L., Treasure, R.L. Bronchogenic cysts: problems in diagnosis and management. *Annals of Thoracic Surgery*.

Will, R.J., Walker, O.M., Traugott, R.C., Treasure, R.L. Sodium nitroprusside and propranolol therapy for management of post coarctectomy hypertension. *Journal of Thoracic and Cardiovascular Surgery*.

Urology

Spence, C.R. Chylous ascites - a rare complication of retroperitoneal lymphadenectomy for testis tumor. *Journal of Urology*.

Physical Therapy Service

Reid, B.C. Ambulation aid for a bent knee spica. *Journal of the American Physical Therapy Association*.

Stratton, S.A., Carpenter, M.M. Forced vital capacity following application of transcutaneous nerve stimulation. *Journal of the American Physical Therapy Association*.

Social Work Service

Schnall, S.M. Characteristics and management of child abuse and neglect among military families. *Proceedings of Military Family Research Conference*.

DEPARTMENT OF THE ARMY
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CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Effect of Some Common Dietary Constituents on the Solubility of Cholesterol in Lipid Bilayer Membranes.

WORK UNIT NO.: C-24-76

PRINCIPAL INVESTIGATOR: Rob G. Parrish, Ph.D., CPT, MSC

ASSOCIATE INVESTIGATORS: John H. Sinegal, SSG

OBJECTIVES

To determine if xanthine oxidase, polyunsaturated fatty acids, or other lipophilic or lipo-active dietary constituents might affect cholesterol solubility in lipid bilayer membranes and thus play a role in the etiology of atherosclerosis.

TECHNICAL APPROACH

The original plan, as outlined in the protocol itself, calls for construction of a heating block suitable for mounting on a microscope stage and intended to contain a glass microscope slide and coverslip. A phase contrast microscope would then be used to view phase changes in a phospholipid cholesterol mixture held between slide and coverslip. This plan encountered difficulties in that accurately measuring temperatures between a glass microscope slide and coverslip is extremely difficult, if not impossible, and secondly, space limitations between available phase contrast microscope objectives and stages is limiting in construction of a suitable heating block.

An ESR spectrophotometer is sensitive to free radicals; molecules containing an unpaired electron. Some nitroxides are stable free radicals and nitroxide analogs of biochemical compounds are commercially available. The nitroxide analog of cholestane (4',4'-Dimethylspiro[5 α cholestane-3',3' oxazolidin]-3-yloxy) resembles cholesterol in structure. The revised technical approach of this protocol is to use the spin labelled cholestane to observe formation of cholesterol or cholesterol analog clusters in the plane of a lipid bilayer membrane. Using the spin label technique, aggregates of two or more molecules can be detected. Thus, with ESR spectroscopy, temperature dependent phase changes can be detected in phospholipid bilayer membranes with accurate temperature determinations.

Personnel: 1 SP4 (3 months)
1 SSG (13 months)

PROGRESS

Lipids required for this protocol have been extracted, sealed in ampules, and are stored in the -70°C freezers in the Clinical Investigation Service Laboratory. Preliminary experiments using the cholestane spin label in phosphatidyl serine lipid bilayer membranes have shown that cholestane indeed does form clusters with cholesterol in this phospholipid membrane system. At concentrations between 1 and 10 mole% cholestane in a mixture of phosphatidyl serine and cholesterol (90 mole% PS - the balance cholestane and cholesterol), the spin label detected a phase transition in the phosphatidyl serine cholesterol system occurring at about 30°C . This is $20-25^{\circ}\text{C}$ higher than the corresponding phase transition in the absence of cholesterol. In principal, it should now be possible to observe changes in the formation of these sterol clusters, i.e. clusters of cholestane and cholesterol, in the presence of the dietary constituents mentioned in the objectives section.

Status: Ongoing.

"A Biophysical Study of ACTH-Receptor Interactions in Y-1 Adrenal Tumor Cells" with C.F. Allen-Rowlands and J.R. Rowlands of the Southwest Foundation for Research and Education. Presented at The Endocrine Society

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INVESTIGATION PROJECT RESUME

TITLE: Investigation of the Effect of CNS Active Drugs on Membrane Bound Cations

WORK UNIT NO.: C-28-76

PRINCIPAL INVESTIGATOR: Rob G. Parrish, Ph.D., CPT, MSC

ASSOCIATE INVESTIGATORS: Robert L. Watson, Jr., M.D., LTC, MC; James J. Plitt, M.S., SSG

OBJECTIVES

To better understand the effect of CNS depressants and narcotic antagonists on sodium and calcium bound to nerve membranes, and to develop a safe and efficient in vitro method of evaluating the potency of narcotics and narcotic antagonists.

TECHNICAL APPROACH

Calcium and sodium are both known to bind to phosphatidyl serine, a major constituent of neural tissue. Cephalin fraction, which contains PS, has been extracted from bovine brain and several grams of pure phosphatidyl serine have been separated from the cephalin fraction. The second phase of the research is to measure the binding of sodium and calcium to lipid bilayer membranes. Sodium-22 and calcium-44 have been purchased in order to observe their binding to phospholipid bilayer membranes.

Personnel: 1 SSG (10 months)

Funding: Consumable
Supplies

FY 77	\$ 808.78
FY 78	\$ 195.00
FY 76	

PROGRESS

Experiments have been used to refine techniques of handling small amounts of lipids and sodium 22 which is a gamma emitter. Experiments have shown that 1 to 4 sodiums per phosphate bind to phosphatidyl

C-28-76 (Continued)

serine lipid bilayer membranes. There appears to be a temperature dependence of the binding, but details of the temperature dependence will not be known until additional experiments are carried out. After details of sodium and calcium binding to phospholipid bilayer membranes are known, anesthetics and other neural active drugs can be added, and their effect on the binding of these physiologically important cations can be determined.

Status: Ongoing.

"Phospholipid Head Group Conformational Changes" presented at VIIth International Conference on Magnetic Resonance in Biological Systems, St. Jovite, Canada, September 1976.

Phospholipid Head Group Conformational Changes. Published Abstract. VIIth International Conference on Magnetic Resonance in Biological Systems.

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INVESTIGATION PROJECT RESUME

TITLE: Correlation of the Molecular Conformation of Erythromycin
2'Esters and Bioactivity.

WORK UNIT NO.: C-34-76

PRINCIPAL INVESTIGATORS: Dennis L. Stevens, M.D., MAJ, MC;
Rob G. Parrish, Ph.D., CPT, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To study the nuclear magnetic resonance of various erythromycin 2'esters in order to predict the feasibility of developing better drugs for clinical use.

TECHNICAL APPROACH

Erythromycin is administered as the ester of a variety of fatty acids covalently bound to the 2' position. The biological activity and toxicity of these esters has been established; however, the subtlety of the substitutions does not suggest the wide range of response obtained from administering the different esters.

Nuclear magnetic resonance techniques will be used to determine the conformation of several esters of erythromycin as a function of pH. Specifically, we will measure the Spin Lattice relaxation times (T_1 's) of different functional groups in the molecule. We will correlate the conformational changes with intestinal absorption, antibiotic potency, and hepatic toxicity reported in the literature. Ideally, the in vitro data we collect, coupled with the physiological data found in the literature will enable us to choose an ester which will yield an intermediate conformational change and will retain the qualities necessary for effective clinical use.

Personnel: None

Funding: None

C-34-76 (Continued)

PROGRESS

No progress has been made on this protocol due to the unavailability of an nmr spectrometer. However, arrangements are being made with the Southwest Foundation for Research and Education in San Antonio, Texas for the use of their nmr spectrometer.

Status: Ongoing.

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CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Physiological Origins and Clinical Applications of Cardiac
Related Electrical Impedance Waveforms.

WORK UNIT NO.: C-4-77

PRINCIPAL INVESTIGATOR: John Paul Giolma, Ph.D., CPT, MSC

ASSOCIATE INVESTIGATORS: Joseph P. Murgo, M.D., LTC, MC

OBJECTIVES

To better understand the origins of cardiac related thoracic impedance waveforms in man and to develop a basis of clinical applications of impedance techniques.

TECHNICAL APPROACH

Part I - Noninvasive Studies. Electrical impedance measurements are taken on the thorax of 20 normals and of patients with a variety of disease classifications along with systolic time interval information. Measurements are taken in the noninvasive laboratory of the Cardiology Service, BAMC, and include electrocardiogram, carotid pulse tracing, the electrical impedance baseline, electrical impedance changes, and the derivative of electrical impedance signal. Additionally, in some patients ultrasound echocardiograms are obtained simultaneously with the impedance measurement. The intent is to look for variations of timing and features of impedance signals between normals and the various patient groups.

Part II - Invasive Studies. Thoracic electrical impedance measurements are taken during the catheterization procedure on adult normals using physiologic maneuvers and injections of saline and contrast material to provide information concerning the contributions of the pulmonary and systemic circulation to the cardiac related impedance signal.

Personnel: None.

Funding: Consumable
Supplies

FY 77 \$ 73.50
FY 7T \$ 150.00

C-4-77 (Continued)

PROGRESS

Part I - Noninvasive Studies. The noninvasive data have been gathered on approximately 10 normals and 10 patients with a wide variety of valvular diseases. Disease classifications include: aortic stenosis, aortic insufficiency, mitral stenosis, mitral insufficiency, and combinations of the four. New data have been obtained on patients at a rate of about two per month. Preliminary results suggest that timing and amplitude features of the impedance derivative signal are affected as much by anatomical variations among subjects as they are by pathology. In the next year, approximately 20-30 additional patients and 10 additional normal subjects will be entered into this portion of the study,

Part II - Invasive Studies. One patient has been studied in the catheterization laboratory. Prior to use in this study, the available intensions required for sensitive patient areas. Technical difficulties with electrical interactions between the impedance instrument and the flow meters prevented obtaining usable data. New flow meters with reduced sensitivity have just arrived and must be tested in vitro along with the impedance instrument before proceeding further. During the catheterization procedure, the impedance signals along with all physiological signals used for research and clinical purposes will be stored on magnetic tape for later playback and analysis using the Cardiology Service Hewlett-Packard programmable calculators and digitizer.

Status: Ongoing.

Giolma, J.P. Co-chaired session on Bio-impedance at AAMI meeting, San Francisco, Calif., 13-17 March 1977.
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DEPARTMENT OF THE ARMY
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Fort Sam Houston, Texas 78234
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: The Development of a Gram-Negative Bacterial Vaccine for
Laboratory Animals.

WORK UNIT NO.: C-7-77

PRINCIPAL INVESTIGATOR: Michael M. Lieberman, Ph.D., CPT, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To develop a safe and effective, broad-spectrum, gram-negative bacterial vaccine for laboratory animals.

TECHNICAL APPROACH

The initial phase of the project encompasses the development of a ribosomal vaccine for several serotypes of Pseudomonas aeruginosa. The bacteria are grown in broth culture, harvested and washed by centrifugation, and subjected to ultrasonic disruption for preparation of crude extracts. The ribosomes are isolated from the extracts by ammonium sulfate fractionation and ultracentrifugation. The isolated ribosomes are chemically analyzed for protein and RNA content and tested for immunogenicity in mice. Mice are given two vaccinations seven days apart and directly challenged by inoculation of live virulent organisms ten days after the second vaccination. Control (non-vaccinated) mice are also challenged. The percentage of mice that survive 48 hours post challenge are scored to determine the extent of protection afforded by the vaccine.

Personnel: 1 SP5 (6 months)
1 SP4 (10 months)

Funding: Consumable
Supplies

FY 77 \$ 2,177.90

PROGRESS

To date ribosomal vaccines from six (out of 13) different serotypes of Ps. aeruginosa have been prepared and tested for immunogenicity in mice. The results obtained are summarized in the table below. The data show

Serotype number	Protein (mg/ml)	RNA (mg/ml)	Virulence of challenge inoculum ^a LD ₅₀ 's/challenge (inoculum)	Minimum dose of vaccine tested giving 60% or greater protection ^b
1	1.67	0.85	8	40 µg
2	1.15	1.11	40	1.6 µg
6	1.42	1.10	50	8.0 µg
8	2.46	1.62	50	8.0 µg
9	1.77	1.64	8	no protection up to 200 µg
13	2.00	1.02	8	1.6 µg

^aThe challenge culture is titrated for mouse lethality to determine the LD₅₀ dose (50% lethal dose = dose at which 50% of nonvaccinated mice die). From this value the number of LD₅₀'s in the challenge inoculum is calculated and is shown to vary from 8 to 50.

^bMice are vaccinated with varying doses of vaccine, from 1.6 to 200 µg (of RNA). The minimum dose of vaccine used which resulted in 60% or greater survival of mice challenged with the stated number of LD₅₀'s is shown.

that the ribosomal vaccines afforded protection against challenge with live, virulent organisms in five out of six of the serotypes tested. Challenge organisms were of homologous serotype to that from which the vaccine was prepared. Additional experiments will be conducted with vaccines from other serotypes as well as experiments in which vaccines are combined in order to produce a multivalent Pseudomonas vaccine. As additional chemical characterization of the ribosomal vaccine, an experiment was carried out in which the presence of sugars specific to lipopolysaccharide, glucose and rhamnose was demonstrated (in very low amounts) in the vaccine. The detection of these sugars was accomplished

C-7-77 (Continued)

by radiological means after paper chromatography of the neutral fraction of acid-hydrolyzed vaccine.

Status: Ongoing.

Lieberman, Michael M. Direct Evidence for the Presence of Lipopolysaccharide Components in a Pseudomonas Ribosomal Vaccine. Infection and Immunity (In Press).

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

INVESTIGATION PROJECT RESUME

TITLE: Oral Transplants of Freeze-Dried Allografts.

WORK UNIT NO.: C-12-75

PRINCIPAL INVESTIGATOR: Donald H. Newell, D.D., COL, DC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine whether freeze-dried bone allografts can be used in one, two, and combined one and two wall oral bony defects with predictable results.

TECHNICAL APPROACH

The surgical site is exposed via a buccal and lingual full or partial thickness mucoperiosteal flap. Intraosseous defects are recontoured and one wall or two wall bony defects are prepared by removing the cortical plate within the defect. The freeze-dried allograft material is mixed with sterile saline to a paste-like consistency and packed in and around the existing bony defect. The patients will be recalled one year post-grafting to re-open the operative site for evaluation and additional surgical intervention as indicated.

Personnel: None.

Funding: None.

PROGRESS

Due to a change in principal investigators, little or no progress has been made during this fiscal year.

Status: Ongoing.

DEPARTMENT OF THE ARMY
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CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of Enflurane (Ethrane) as an Amnesic Analgesic for
Outpatient Oral Surgery.

WORK UNIT NO.: C-20-76

PRINCIPAL INVESTIGATORS: Richard A. Kraut, D.D.S., MAJ, MC;
John E. Buhler, Jr., D.D.S., MAJ, MC

ASSOCIATE INVESTIGATORS: David W. Shelton, D.M.D., COL, DC; Robert L.
Watson, M.D., LTC, MC

OBJECTIVES

- a. To determine the feasibility of using Enflurane to create a state of cooperative amnesia for outpatient oral surgery.
- b. To determine the concentration of Enflurane required to create a state of cooperative analgesia and the level of amnesia associated with that state.
- c. To assess the length of recovery time needed after the administration of Enflurane as an amnesic agent, before patients can be sent home in the care of a responsible adult.

TECHNICAL APPROACH

A technique utilizing Enflurane in oxygen delivered by a nasal mask was developed and administered to 31 patients undergoing oral surgery in an outpatient setting. Expiratory gas analysis utilizing an infrared absorption technique was employed.

Personnel: None.

Funding: MEDCASE

FY 77	-
FY 7T	-
FY 76	\$10,200.00

PROGRESS

There were no anesthetic complications among the 31 patients who underwent oral surgery with 1.5% Enflurane in oxygen. Respiratory rate and

C-20-76 (Continued)

depth remained relatively constant through the surgical procedure as did heart rate. Blood pressure variation was negligible and never required therapeutic intervention.

One patient who underwent the anesthetic and surgical procedure without complication incorrectly answered 2 of the 5 discriminator questions and therefore was not included in the analysis of amnesic effect of the Enflurane.

The data from the 30 patients who correctly answered the discriminator questions were analyzed. Five questions were selected as being the most significant questions utilized to determine if the patients were amnesic while under the effect of 1.5% Enflurane. These questions were: 1. Was a mallet and chisel used during the removal of your upper tooth? 2. Was a dental drill used in removing your lower tooth? 3. Was your upper tooth removed before your lower tooth? 4. Was a dental drill used in removing your upper tooth? 5. Were you aware of any pressure at the surgical area during the procedure?. Twenty-three of the thirty patients were amnesic regarding all five of the above questions. ($p = .01$ sign test) Six of the patients were able to recall one of the above events and one patient recalled three of the above events. Of 150 possible responses, there were 141 responses indicative of amnesia, and 9 responses indicative of factual recall. The amnesic effect of 1.5% Enflurane with 8 liters/minute of oxygen delivered via nasal mask is 94%.

All of the patients were sufficiently recovered from their anesthetic to perform the psychomotor function test faster 30 minutes after their surgical procedure than their preoperative base level. The patients all showed marked decrease in the time required at 30 minutes after surgery compared to the time required 10 minutes after surgery. All patients were able to leave the oral surgery clinic within 15 minutes of completing the 30 minute postoperative test.

Conclusions: The favorable result utilizing nasal Enflurane in producing a state of COOPERATIVE AMNESIA in this small series of patients deserves further study as it appears to be a valuable and controllable technique, especially suited for outpatient oral surgical procedures.

Status: Ongoing.

Kraut, R.A.: An evaluation of enflurane as an amnesic agent for outpatient oral surgery. Presented at Scientific Session, American Society of Oral Surgeons Meeting, 23-28 September 1977, San Francisco, Calif.

Kraut, R.A.: An Evaluation of Enflurane as an Amnesic Agent for Outpatient Oral Surgery. Submitted for publication in Oral Surgery, Oral Medicine and Oral Pathology.

DEPARTMENT OF THE ARMY
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Fort Sam Houston, Texas 78234
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: A Study of the Effects of Taper, Preparation Height, and Axial Grooves upon Resistance Form of Full Crown Preparation.

WORK UNIT NO.: C-31-76

PRINCIPAL INVESTIGATOR: Gerald D. Woolsey, D.D., MAJ, DC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the relative resistance to oblique or transverse dislodging forces of several different cast gold crowns fabricated to fit stainless steel dies of 5, 10 and 15 degree of taper and 4, 6, 8, and 10 millimeters in length. Twelve of the test dies are to have parallel axial grooves and twelve are to be without grooves.

TECHNICAL APPROACH

Fifteen stainless steel dies were machined to tapers of 5, 10, and 15 degrees and preparation lengths of 3, 4, 6, 8, and 10 mm. Fifteen crowns were cast of type III gold for the dies. The crowns were fabricated so that the occlusal surface consisted of one continuous slope of 45° to provide an effective slope similar to the mandibular movement. Each occlusal surface was fabricated from a single stone mold with the only difference between castings being the axial walls (length and taper) which were waxed to the individual dies. The axial walls of the castings were fabricated with a minimum thickness of 1 mm. at the margin to prevent distortion of the metal margin during testing.

The stainless steel dies and their corresponding castings were inserted into a machined holding carriage in the load module of an Instron testing device. The load module measured the vertical force in pounds which was exerted on the sloped surface of the casting.

A load pin mounted on the moving vertical carriage of the Instron was designed to engage the gold casting on the upper part of the occlusal slope at a point which was in line with the axial wall of the stainless steel die. A maximum of 350 lb. was placed on each casting.

The first phase of the test was to determine which of the castings could be dislodged from their stainless steel dies. The second phase of the

C-31-76 (Continued)

test was to prepare parallel axial grooves in the stainless steel dies whose castings had been dislodged. Grooves 1 mm. wide and 1 mm. short of the finish line were prepared by hand. Two grooves were prepared for each die, one corresponding to each interproximal surface.

A second set of castings was prepared for the dies with grooves. The second phase castings and dies were tested in a manner as described for the first phase of the experiment.

Visual observation by two dentists and graphic analysis by the Instron testing device were used to determine failure or movement of casting.

Personnel: None.

Fundings: Consumable
Supplies

FY 77	-
FY 7T	-
FY 76	\$ 430.80

PROGRESS

Four groups of castings fabricated without grooves were dislodged by the Instron testing machine. No movements of the castings with grooves placed interproximally were detected either visually or by the Instron, graphically. In order to add credence to the interproximal placement of grooves, a third phase was conducted on the same four dies as in phase two. In this last experiment the castings were fabricated in order to orient the grooves on the buccal and lingual surface. In each case the castings moved slightly with the initial load of the Instron, then no movement was detected. There are two possible reasons for this small movement with no subsequent detectable motion. One reason could be a forcible seating of the rib of the casting into the base of the groove of the die; the second possible answer could be a decreased buccal-lingual diameter of the die and the relative parallelism of the grooves yielding a better resistance form.

Due to the movement of the castings with grooves placed buccally and lingually, it is felt that even though this movement was minute, it would have been enough to cause eventual clinical failure.

Conclusions: This study has attempted to demonstrate the importance of axial grooves on the resistance form of cast gold restorations, and the relative value of placing these grooves interproximally to resist the horizontal component of the masticatory chewing cycle, rather than placement on the buccal and lingual surfaces where resistance to buccal or lingual dislodgment is not as great.

C-31-76 (Continued)

The study has shown that teeth with long preparations and large taper have more resistance than short preparations with the same large taper.

Status: Completed.

DEPARTMENT OF THE ARMY
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CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Tissue Response to Metal Versus Acrylic Denture Base Materials.

WORK UNIT NO.: C-36-76

PRINCIPAL INVESTIGATOR: John W. Cressler, D.D., MAJ, DC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To clinically evaluate the response of supporting tissue in contact with metal as compared to acrylic based dentures in the same oral environment.

TECHNICAL APPROACH

1. Fifteen patients requiring maxillary complete dentures were selected on a random basis.
2. Metal inserts were incorporated on a quadrant basis in the palatal portion of the denture base.
3. After six months, the patients were recalled and the maxillary arch photographed.
4. Eighteen clinicians were selected from the staff to judge the response of the supporting tissues to the combination metal/acrylic resin based dentures as demonstrated in the photographs.

Personnel: None.

Funding: None.

PROGRESS

No statistical difference was noted in the response of the tissues to metal versus acrylic resin denture base materials.

Status: Completed.

DEPARTMENT OF THE ARMY
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Fort Sam Houston, Texas 78234
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Collagen Synthesis in vitro by Human Gingival Tissues.

WORK UNIT NO.: C-2-77

PRINCIPAL INVESTIGATOR: Stephen H. Jensen, D.D., CPT, DC

ASSOCIATE INVESTIGATORS: Roy C. Page, D.D.

OBJECTIVES

To learn how much and what types of collagen are synthesized by cells present in normal and diseased gingival tissues of humans.

TECHNICAL APPROACH

Twenty-five young adult individuals who are healthy and who do not have manifestations of inflammatory gingival and periodontal disease will be selected. Each individual will be given a thorough prophylaxis and instructions in oral hygiene.

On days 7, 14, and 21, following prophylaxis, the teeth will be examined for the presence of microbial deposits. At this time, approximately 0.5 ml. of lidocaine local anesthetic will be infiltrated on the buccal and lingual or palatal aspect of the upper or lower, right or left pre-molar region and a biopsy taken of the interdental papillae. Specimens will be sent to Dr. Roy C. Page, Professor of Pathology and Periodontics, University of Washington, Seattle, for evaluation.

Personnel: None.

Funding: None.

PROGRESS

Samples were obtained and sent to Dr. Roy C. Page, Professor of Pathology and Periodontics, University of Washington, Seattle. Infection developed in the samples while being transported and the study was, therefore, discontinued.

Status: Terminated.

DEPARTMENT OF THE ARMY
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CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: The Application of the Fluorescent Antibody Technique to the Investigation of Various Dermatoses.

WORK UNIT NO.: C-44-72

PRINCIPAL INVESTIGATOR: Richard L. DeVillez, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Eric W. Kraus, M.D., CPT, MC

OBJECTIVES

To demonstrate the presence or absence of skin autoantibodies or antibodies in the epithelium of sera of patients with a variety of bullous and nonbullous dermatoses.

TECHNICAL APPROACH

During this fiscal year, 39 renal tissue specimens, 3 lung tissue specimens, and 165 skin tissue specimens from hospitals throughout the world have been processed for immunofluorescence.

Personnel: None.

<u>Funding:</u>	MEDCASE	Consumable Supplies
FY 77		\$ 842.50
FY 7T	-	-
FY 76	\$ 1,734.00	-
FY 75	-	-
FY 74	-	\$ 277.90
FY 73	-	\$ 200.00

PROGRESS

We have received 165 skin specimens from around the world. These specimens were placed in a fixative that is very easy to use. We compared the immunofluorescent results from these fixed specimens to results

C-44-72 (Continued)

obtained by sending the specimens frozen. There is no significant loss of immunofluorescent staining with the fixed tissue technique making it the method of choice for sending specimens.

Recent advances in dermatology have shown new findings for immunofluorescence in various dermatological diseases. A significant new change is the development of an indirect immunofluorescent technique for detecting double stranded native DNA antibodies so important in the evaluation of patients with systemic lupus erythematosus.

Status: Ongoing

Presented at Texas Dermatologic Society Meeting, Houston, Texas, 14 May 1977.

DEPARTMENT OF THE ARMY
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CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

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

WORK UNIT NO.: C-28-73

PRINCIPAL INVESTIGATOR: Joseph P. Murgu, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: John Paul Giolma, Ph.D., CPT, MSC; Barry Alter, M.D., MAJ, MC; James F. Dorethy, M.D., MAJ, MC; Harold Felter, M.D., MAJ, MC; John Logsdon, M.D., MAJ, MC; Gregory Uhl, M.D., MAJ, MC; John Kirk, M.D., MAJ, MC; George M. McGranahan, Jr., M.D., COL, MC.

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 power.
5. To measure aortic and pulmonary artery input impedance by Fourier analysis and to determine the effect of changing physiologic states upon the impedance.
6. Detailed description of multiple specific objectives are to be found in the original protocol.

TECHNICAL APPROACH

All adult patients for routine right and left heart catheterization are evaluated in the usual manner by a cardiac fellow prior to catheterization. This evaluation includes strip chart echocardiography to determine the patient's suitability for certain aspects of the protocol.

C-28-73 (Continued)

During catheterization, special, custom-designed, right and left heart catheters are introduced into the right and left heart such that simultaneous high fidelity pressures are measured from the pulmonary artery, right ventricle, right atrium, left ventricle, and aorta. In addition, electromagnetically derived aortic and pulmonary flow velocities are recorded from the same sites that high fidelity pulmonary artery and aortic pressures are obtained. Patients are studied during both rest, supine exercise, and depending upon the patient's disease during a variety of other 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 if indicated.

Patients undergoing catheterization with the flow catheters also have aortic root and/or pulmonary angiography for purposes of determining the diameters of these great vessels. These parameters are necessary to calculate flow velocity from volumetric flow itself.

The Honeywell 316 computer, described in previous reports, has been expanded in order to provide terminals both in the old catheterization laboratory and in the new catheterization laboratory which was completed in July 1976. The capabilities of this computer have been previously described but significant advances and improvements in the research programs have been implemented during the past year. The lesser demands now placed on the old catheterization laboratory have greatly facilitated data analysis and reduction from tape recorded data during normal duty hours.

Angiocardiograms and echocardiograms are analyzed using the Hewlett Packard programmable calculator, digitizer, XY plotter and rapid impact printer. This latter system has also been expanded in the past year due to the enormous demands for its use. An additional 9830-A programmable calculator and digitizer has been added to the system with both the older and the newer systems sharing the mass memory 2.5 million word disc system.

Personnel: 1 CPT (12 months)
1 SP3 (1 month)
1 SP5 (1 month)

<u>Funding:</u>	MEDCASE	CONSUMABLE SUPPLY FUNDS		
		Consumable Supplies	Contractural Services	Reprints
FY 77	\$53,813.00	\$ 115.00		
FY 78		\$ 85.00		
FY 76	\$48,902.82			\$ 245.00
FY 75	\$33,653.44	\$ 129.76		
FY 74	\$29,354.25		\$43,573.00	
FY 73	\$43,000.00			

PROGRESS

The lack of technician assistance during this past fiscal year greatly hampered progress in the numerous complex and long-term projects that come under this protocol. Despite this, some progress was made in various areas as described below.

Flow velocity measurements in the aorta and pulmonary artery have now been underway for 2-3 years in this laboratory so that a meaningful data base has been derived from that small percentage of patients who come to catheterization and are found to have no organic heart disease. These patients form the basis for several papers involving complex and new hemodynamic measurements in normal man during rest, dynamic exercise, and the Valsalva maneuver.

A most important study on the ejection dynamics of hypertrophic cardiomyopathy during the presence and absence of intraventricular gradients has been completed and will shortly be submitted for publication.

Three extremely important studies involving the determination of systemic input impedance in man by computerized Fourier analysis have also been recently completed and the final reports from these studies are being prepared for publication. They include first: the analysis of systemic input impedance in man during rest with particular attention on the effects of wave reflections on the arterial pressure and flow wave forms, second: systemic input impedance for the first time has been analyzed in approximately 15 normal subjects during rest and dynamic exercise, third: several original and important results have been derived from a study of input impedance during the various phases of the Valsalva maneuver in man. Work is also underway to analyze the effects of respiration on pulmonic input impedance in the normal subject.

Another study has analyzed the effects of respiration on the simultaneous right and left heart stroke volumes and the relationships of these parameters to the splitting of the second heart sound.

Two patients with pericardial tamponade and hemodynamic embarrassment were also studied using the sophisticated techniques described above, and preliminary results from these studies appear to yield significant information to settle the controversy of the origin of the paradoxical pulse during tamponade.

Another effort has included a very significant analysis of five years of data collection on patients with pure aortic stenosis, pure aortic insufficiency, and mixed aortic stenosis and insufficiency. A similar study involving hemodynamics of mitral regurgitation is now under way.

The completion of the new cardiac catheterization laboratory in July 1976 and expansion of the Honeywell 316 computer system to allow simultaneous digital processing in both the old and new cardiac catheterization laboratories has made a significant contribution to the

C-28-73 (Continued)

progress of our work. Expansion also of the Hewlett Packard programmable calculator system will greatly relieve the time delays previously encountered in program development, data processing, and statistical analysis. Efforts are currently under way to recruit a technician to help the investigators involved in these projects in the coming year.

Status: Ongoing.

Murgo, J.P., Giolma, J.P., Altobelli, S.A. Physiologic signal acquisition and processing for human hemodynamic research in a clinical cardiac catheterization laboratory. Proceedings of the Institute of Electrical and Electronic Engineers, Vol. 65, No. 5, May 1977.

Alter, B.R. et al. Traumatic right coronary artery - right ventricular fistula with retained intramyocardial bullet. Amer J Cardiol (In Press).

Murgo, J.P., Alter, B.R., Dorethy, J.D., McGranahan, G.M. The ejection dynamics of hypertrophic cardiomyopathy during the presence and absence of intraventricular gradients. Submitted to Journal of Clinical Investigation.

Murgo, J.P., Giolma, J.P., Westerhof, N. The contribution of systemic input impedance measurements to an analysis of wave reflections in normal man. Submitted to Circulation Research.

Murgo, J.P., Giolma, J.P., Altobelli, S.A., Westerhoff, N.: Systemic input impedance in normal man during rest and dynamic exercise. Submitted to Circulation Research.

Westerhof, N., Murgo, J.P., Giolma, J.P. Systemic input impedance - theory, experimental results, and human measurements. Chapter 14 in "Engineering Principles in Cardiovascular Research". Editor H.C. Hwang, University Park Press, to be published in 1978.

Murgo, J.P. Multisensor catheterization - five years experience. Submitted to Catheterization and Cardiovascular Diagnosis.

Murgo, J.P., Dorethy, J.D., Alter, B.R. Normal right and left ventricular ejection dynamics in man during rest and exercise. Submitted to Circulation.

Logsdon, J.R., Murgo, J.P., McGranahan, G.M.: Right and left heart ejection dynamics during the Valsalva maneuver. Submitted to Circulation.

Logsdon, J.R., Altobelli, S.A., McGranahan, G.M., Murgo, J.P. Right and left heart ejection dynamics during the Valsalva maneuver in normal man. Circulation, Supplement #2, October 1976.

C-28-73 (Continued)

Murgo, J.P., Giolma, J.P., Altobelli, S.A. An automated system of processing hemodynamic signals for research in a clinical setting. Digest of the 11th International Conference on Medical and Biological Engineering. Ottawa, Can., October 1976.

Murgo, J.P., Alter, B.R., Dorethy, J.F., McGranahan, G.M. The dynamics of left ventricular ejection in obstructive and non-obstructive hypertrophic cardiomyopathy. Current Trends in Cardiovascular Disease. Wm. Beaumont Army Medical Center, May 1977.

Kirk, J.W., Dorethy, J.D., Murgo, J.P. Left ventricular performance in isolated aortic valve disease with and without coronary artery disease. Current Trends in Cardiovascular Disease. Wm. Beaumont Army Medical Center, May 1977.

Uhl, G.S., Felter, H.G., Logsdon, J.R., Murgo, J.P., McGranahan, G.M. Simultaneous right and left heart hemodynamics of pericardial tamponade. Current Trends in Cardiovascular Disease. Wm. Beaumont Army Medical Center, May 1977.

Felter, H.G., Murgo, J.P., Giolma, J.P., McGranahan, G.M. The effects of respiration on simultaneous right and left heart ejection dynamics - correlates to splitting of the second heart sound. Current Trends in Cardiovascular Disease. Wm. Beaumont Army Medical Center, May 1977.

Giolma, J.P., Murgo, J.P., Altobelli, S.A. An automated system of processing hemodynamic signals for research in a clinical setting. 11th International Conference on Medical and Biological Engineering, Ottawa, Canada, October 1976.

Logsdon, J.D., Altobelli, S.A., McGranahan, G.M., Murgo, J.P. Right and left heart ejection dynamics during the Valsalva maneuver in man. 49th Scientific Sessions of the American Heart Association, Miami Beach, Fla., November 1976.

Murgo, J.P. Ejection dynamics in hypertrophic cardiopathy, part of panel on Aseptic Hypertrophy, 26th Annual Scientific Sessions of the American College of Cardiology, Las Vegas, Nev., March 1977.

Murgo, J.P. The ejection dynamics in hypertrophic cardiomyopathy during the presence and absence of intraventricular gradients. Research Seminar, University of Washington, Seattle, Wash., Apr 1977. Cardiovascular Seminar, Cardiology Division, Harbor General Hospital, UCLA, Los Angeles, Calif., Apr 1977. Cardiovascular Seminar, University of California at San Diego, San Diego, Calif., Apr 1977. Research Seminar, Cardiology Division, Stanford University, Palo Alto, Calif., Apr 1977. Cardiovascular Research Seminar, University of Texas Health Science Center, San Antonio, Tex., May 1977.

C-28-73 (Continued)

Murgo, J.P. The dynamics of left ventricular ejection in obstructive and non-obstructive hypertrophic cardiomyopathy. 6th Annual Association of Army Cardiology Meeting, William Beaumont Army Medical Center, May 1977.

Kirk, J.W. Left ventricular performance in isolated aortic valve disease with and without coronary artery disease. 6th Annual Association of Army Cardiology Meeting, William Beaumont Army Medical Center, May 1977.

Uhl, G.S. Simultaneous right and left heart hemodynamics of pericardial tamponade. 6th Annual Association of Army Cardiology Meeting, William Beaumont Army Medical Center, May 1977.

Felter, H.F. The effects of respiration on simultaneous right and left heart ejection dynamics correlates to splitting of the second heart sound. 6th Annual Association of Army Cardiology Meeting, William Beaumont Army Medical Center, May 1977.

Murgo, J.P. Engineering principles applied to human hemodynamic research in a clinical cardiac catheterization laboratory. Southwest Research Institute, August 1977.

Murgo, J.P. Ejection dynamics of hypertrophic cardiomyopathy during the presence and absence of intraventricular gradients. Free University of Amsterdam, Amsterdam, Netherlands, September 1977.

Murgo, J.P. Aortic input impedance in man during rest, exercise, and the Valsalva maneuver. NATO Conference on "Engineering Principles in Cardiovascular Research", Urbino, Italy, September 1977.

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

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of Calcium Metabolism During Acute Renal Insufficiency.

WORK UNIT NO.: C-40-73

PRINCIPAL INVESTIGATOR: Richard H. Merrill, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the mechanism of hypercalcemia seen in some cases of acute renal insufficiency.

TECHNICAL APPROACH

All patients with acute renal failure will be surveyed. They will be divided into two groups in an alternate manner. The usual dietary and chemotherapeutic modalities for treating acute renal failure will be employed. Hemodialysis and peritoneal dialysis will be reserved for those patients who are uremic or in whom fluid and potassium balance cannot be controlled by conservative means. Serum phosphorus will be maintained below 6 mg. in one group, and the second group will go untreated. For those able to eat, 1000 mg. calcium and 1500 mg. phosphorus will be offered. Percutaneous renal biopsies will be examined by light microscopy, electron microscopy, and immunofluorescent microscopy. Patients with acute renal insufficiency will have three 6-hour dialyses a week. Serial determinations will be done to detect any manifestations of hypercalcemia. In addition, serum parathyroid hormone will be measured and an attempt will be made to correlate the hypercalcemia that is frequently seen following acute renal insufficiency with increased parathormone secretion.

In those patients developing hypercalcemia in the diuretic phase, efforts will be made to suppress parathormone secretion by calcium infusion or phosphorus depletion. When possible weekly eye examination will be performed to document early metastatic calcification. Skin biopsies will be analyzed for calcium.

Personnel: None.

Funding: None.

C-40-73 (Continued)

PROGRESS

To date no patient has been entered into this protocol. Since it is apparent that sufficient material will not be available to support this project in any reasonable time frame, this project is hereby terminated with no patients entered and no data collected.

Status: Terminated.

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

INVESTIGATION PROJECT RESUME

TITLE: Physiologic Evaluation of Pulmonary Status in Patients Undergoing Renal Dialysis.

WORK UNIT NO.: C-4-74

PRINCIPAL INVESTIGATOR: William W. Burgin, Jr., M.D., COL, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate the pulmonary function in renal dialysis patients both pre- and postdialysis and to better ascertain the physiologic changes which take place in the lung.

TECHNICAL APPROACH

It was initially anticipated that patients undergoing renal dialysis would be studied with sophisticated pulmonary function studies to ascertain the significance of fluid changes associated in patients on chronic dialysis with respect to interstitial lung water and basic pulmonary functions.

Personnel: None

Funding: None

PROGRESS

Necessary equipment to accomplish this study was delayed in its procurement and installation resulting in several other centers completing the study before Brooke Army Medical Center was able to initiate it.

Status: Terminated.

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

INVESTIGATION PROJECT RESUME

TITLE: Phase II Study of Aminoglycoside Antibiotic BB-K8.

WORK UNIT NO.: C-8-74

PRINCIPAL INVESTIGATOR: Theodore R. McNitt, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

1. To evaluate therapeutic effectiveness of BB-K8 in the treatment of hospitalized patients with infections caused by susceptible pathogens.
2. To establish an optimal therapeutic dosage schedule for BB-K8 which is safe and effective.
3. To establish a side effect profile for the drug.
4. To obtain information on the clinical pharmacology of the drug in diseased patients.

TECHNICAL APPROACH

BB-K8 is given by deep intramuscular injection at the appropriate site at a dose not to exceed 7.5 mg/kg q 12 hrs. Each patient and his clinical record will be evaluated twice a day throughout the course of drug therapy. Patients will be followed with daily urinalysis with microscopic examination. BUN and creatinine determinations will be performed every 48 hours. Audiograms will be performed on the 3rd, 6th and 10th days of therapy.

Personnel: None.

<u>Funding:</u>	<u>Consumable Supplies</u>
FY 77	\$ 315.00
FY 7T	-
FY 76	-
FY 75	\$ 85.74
FY 74	\$ 51.30

C-8-74 (Continued)

PROGRESS

Two patients have been treated with good bacteriological and clinical response. There has been no evidence of renal or auditory toxicity.

Since BB-K8 is now available commercially, this study is completed.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Platelet Transfusion - Efficiency and Methods to Improve Current Results in Thrombocytopenia Patients.

WORK UNIT NO. C-16-74

PRINCIPAL INVESTIGATOR: Robert P. Bowman, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Daniel Marmer, M.S., M.T. (ASCP)

OBJECTIVES

To improve the quality of platelet transfusions in thrombocytopenic patients and platelet transfusion complications.

TECHNICAL APPROACH

Patients with multiple platelet transfusions are evaluated for the presence of antibodies. Multiple antibody procedures such as complement fixation, serotonin release assay and platelet aggregation assay are employed. The platelets identified as having iso-antibodies are further studied to see if sensitivity is selective to isolated random donor platelets. A method of freezing platelets for the serotonin release assay to give a standard assay approach utilizing a multiple donor pool has been established.

Personnel: 1 SP5 (3 months)

<u>Funding:</u>	<u>Consumable Supplies</u>
FY 77	\$ 532.00
FY 7T	\$ 159.15
FY 76	\$ 301.10
FY 75	\$ 345.15

PROGRESS

The assays for platelet antibody identification have been established and are being utilized. A method of establishing a frozen platelet pool has been established, and it has been seen that the pool is functional

C-16-74 (Continued)

for at least a nine month period. Several patients have been studied to identify the efficacy of a single donor versus multiple donor platelet accumulation for transfusion.

Status: Ongoing

Marmer, Daniel: Platelet Transfusion - Efficiency and Methods to Improve Current Results in Thrombocytopenia Patients. Presented and Accepted Master's Thesis. Incarnate Word College, San Antonio, Texas.

Marmer, D.J. and Bowman, R.P. Utilizing a Cell Harvester and Preserved Labelled Platelets to Simplify the [³H] Serotonin Release Assay for the Detection of Platelet Isoantibodies. Submitted for Publication in Blood, The Journal of Hematology.

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

INVESTIGATION PROJECT RESUME

TITLE: Platelet Function in the Presence of Varied Platelet Antibodies.

WORK UNIT NO.: C-23-74

PRINCIPAL INVESTIGATOR: Robert P. Bowman, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: David R. Head, M.D., LTC, MC;
Richard E. Goyette, M.D., MAJ, MC

OBJECTIVES

To determine the capability of platelet function when stressed by a variety of platelet antibodies.

TECHNICAL APPROACH

To establish the function of an individual platelet after platelet antibodies are identified. Platelet antibody studies have been established and are functional. A new technique has been developed for looking at low platelet function. To date this has been a significant problem in that many patients with platelet antibodies have very low platelet counts and the actual function is difficult to determine.

Personnel: 1 SP5 (3 months)

Funding: Consumable
Supplies

FY 77	-
FY 77	-
FY 76	-
FY 75	-
FY 74	\$ 196.00

PROGRESS

A method of looking at platelet function with low platelet counts has been established by using a collagen stimulation and counting platelet

C-23-74 (Continued)

aggregates both before and after stimulation with collagen. Pilot study has been done which shows this procedure to be very efficacious and has shown no hindrance to platelet function in the present of platelet antibodies.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of Platelet Factor Four to Evaluate Hypercoagulable States.

WORK UNIT NO.: C-24-74

PRINCIPAL INVESTIGATOR: Robert P. Bowman, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To look at the plasma of patients who have a possible setting of hypercoagulability and to evaluate their plasma for platelet factor four activity.

TECHNICAL APPROACH

Patients with evidence of increased coagulation systemically have been evaluated by measuring platelet factor four levels.

Personnel: 1 SP5 (3 months)

Funding: None.

PROGRESS

A number of patients with thrombophlebitis and pulmonary emboli have been studied. The level of platelet factor four, however, has not been significantly changed in instances where a definite hypercoagulation is known to be occurring. Due to the inability of the assay to be discriminatory, a negative hypothesis was formed, and the procedure is no longer being performed.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of Antigens in Fire Ant Venom.

WORK UNIT NO.: C-41-74

PRINCIPAL INVESTIGATOR: Frank K. James, Jr., M.D., COL, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To study fire ant venom and/or its component parts and its effect on selective human volunteers known to be sensitive to it.

TECHNICAL APPROACH

Twenty-five fire ant sensitive patients who had a history of a systemic (anaphylactic) reaction were included in the study. Hypersensitivity in this group of patients was documented by a clearcut history of systemic reaction, previous positive skin testing, the patient's recollection of the sting and progression of reactions, and the progression of skin responses following the sting. In addition to the standard skin testing technique, 18 of the most highly sensitive patients were also evaluated utilizing the RAST technique.

Personnel: None.

Funding: Consumable
Supplies

FY 77	-
FY 77	-
FY 76	-
FY 75	\$ 75.96
FY 74	\$ 115.00

PROGRESS

The results of the skin testing technique utilizing whole body extract venom, alkaloids, and the RAST technique indicate that there are definitive and accurate methods for defining fire-ant-sensitive patients.

C-41-74 (Continued)

Our findings raise further intriguing questions since fire ant venom is hypoproteinaceous and has not been identified as having active enzymatic components such as hyaluronidase and phospholipase. Because the inoculum of the fire ant sting is approximately 1/100th to 1/1000th of the average honey bee sting, it implies not only that the venom is potent, but represents a complete departure from any other known animal venom affecting man.

Status: Completed.

James, F.K., Jr. Fire ant sensitivity. J of Asthma Research, 13, No. 4, 179-183, July 1976.

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

INVESTIGATION PROJECT RESUME

TITLE: Rejection of Verrucae Vulgaris - A Clinical Therapeutic Trial.
(Parts I and II. (Collaborative study with Letterman)

WORK UNIT NO.: C-6-75

PRINCIPAL INVESTIGATOR: Joseph H. Greenberg, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Charles W. Lewis, M.D., LTC, MC

OBJECTIVES

To determine if induction of a delayed hypersensitivity reaction over a verruca vulgaris will cause destruction of the verruca and possibly cause regression of other verrucae vulgaris not treated.

TECHNICAL APPROACH

Patients with multiple verrucae were divided into two treatment groups. The first group, if positive for a history of Rhus dermatitis, had one to three of their warts treated by an occlusive patch test with Rhus oleoresin. The second group, with a negative Rhus history, were screened intradermally for delayed hypersensitivity with common antigens. The antigen giving the strongest clinical reaction was injected intradermally into one or more verrucae.

Personnel: None.

Funding: None.

PROGRESS

The Rhus treatment group consisted of 17 patients treated, with 6 patients having resolution of treated and untreated warts. Three patients were technique failures. Thus a cure rate of approximately 50% was achieved with this antigen.

The intradermal antigen groups involved 34 patients who completed the study. Results were:

C-6-75 (Continued)

<u>ANTI</u> GEN	<u>#</u> PATIENTS	<u>SUCCESS</u>	<u>FAILURE</u>
Trichophyton	14	5	8
SK-SD	10	3	6
Candida	6	1	5
Mumps	5	1	1
PPD	1	0	1

These results were not significantly better than the known cure rates from using a variety of placebos in the treatment of warts.

Status: Completed.

Presented at the Texas Medical Association Meeting (Dermatology Section) 2 May 1975 and at the Dermatologic Therapeutic Seminar, Letterman Army Medical Center, Presidio of San Francisco, April 1976.

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

INVESTIGATION PROJECT RESUME

TITLE: Clinical Outpatient Algorithm Validation - A Pilot Study.

WORK UNIT NO.: C-9-75

PRINCIPAL INVESTIGATOR: Barry W. Wolcott, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if clinical outpatient algorithms originally used to treat civilian outpatient populations can be validated and improved in a military outpatient environment - a phase I study.

TECHNICAL APPROACH

Using the standardized data base collections of algorithm-directed AMOSIST's coupled with a standardized outcome analysis at a fixed point following the index visit, data on large numbers of patients presenting to the BAMC Emergency Room/AMIC with a variety of common chief complaints are examined. In some instances randomly selected patients are reevaluated by staff physicians using this same data base in order to be able to compare the process of care of algorithm-directed AMOSIST's and traditionally directed physicians. Investigations to this point have concentrated on patients presenting with upper respiratory illness, back pain, headache, and extremity trauma.

Personnel: None

Funding: Consumable
Supplies

FY 77	-
FY 77	-
FY 76	-
FY 75	\$3,125.00

PROGRESS

1. A second generation URI algorithm based on over 4,000 patient encounters with outcome analysis has been developed which decreased the

C-9-75 (Continued)

cost for patient evaluation by the AMOSIST's for patients with this complaint by over \$8.00. This new algorithm is being revalidated at BAMC, and has been distributed to other AMOSIST projects throughout the Army for their use.

2. The back pain algorithm is in the process of revision based on over 400 patient encounters. This revision is designed to decrease the utilization of back x-rays in clinical settings where they will not be of any benefit to the patient or the physician.

3. Based on over 500 patient encounters, an extremity trauma algorithm for use by AMOSIST's has been validated as medically effective.

4. Data has been collected on over 500 patients with headache, but analysis of this data has not yet begun.

Status: Ongoing.

Wolcott, B.W. Physician Extenders in the Delivery of Nonappointed Ambulatory Medical Care in the Military. Military Medicine 1976.

Wolcott, B.W. Algorithm-directed Triage in an Emergency Department. Journal of the American College of Emergency Physicians, 1976.

Wolcott, B.W. and Stieneker, R.E.: The Use of In-Barracks Screeners to Improve Military Sick Call. Accepted for Publication - Military Medicine.

Thompkins, R.K., Wood, R.W., Wolcott, B.W. and Walsh, B.T. Evaluating Physician's Assistants' Medical Care. Annals of Internal Medicine.

Rockey, P.H., and Wolcott, B.W. The Usefulness of X-ray Examinations in the Evaluation of Patients with Back Pain. Submitted to Annals of Internal Medicine for publication.

Clinical validation of upper respiratory illness algorithm. Abstract in Clinical Investigation, 1976.

Evaluating physician extenders' medical care: algorithm-assisted management of ambulatory patients with acute respiratory illnesses. Abstract in Clinical Investigation, 1976.

Observational study of algorithm-assisted upper respiratory illness management. Abstract in Clinical Investigation, 1976.

The usefulness of back x-rays in the evaluation of low back pain. Abstract in Clinical Investigation, 1977.

The reliability of clinical data. Abstract in Clinical Investigation, 1977.

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

INVESTIGATION PROJECT RESUME

TITLE: Platelet Function in Patients Undergoing Therapy with Velban and Bleomycin.

WORK UNIT NO.: C-17-75

PRINCIPAL INVESTIGATOR: Robert P. Bowman, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate patients undergoing intensive chemotherapy with Velban and Bleomycin for determination of platelet function abnormalities induced by these agents.

TECHNICAL APPROACH

Standard platelet function studies, such as bleeding time and platelet aggregation, are performed to evaluate the effect of these drugs.

Personnel: None.

Funding: None.

PROGRESS

A small number of patients have been evaluated and found to have normal platelet function in face of therapy with these medications. Patients are now very rarely on these medications alone and are receiving either other chemotherapeutic agents or other agents to combat disease which therefore make the platelet function indeterminable. No further studies will be done.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Platelet Function in Patients Undergoing Vincristine Therapy.

WORK UNIT NO.: C-18-75

PRINCIPAL INVESTIGATOR: Robert P. Bowman, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine any abnormalities of platelet function occurring in patients who are treated with Vincristine therapy.

TECHNICAL APPROACH

Patients receiving Vincristine as therapy as a single agent were evaluated for the establishment of platelet function. Vincristine is known to stimulate platelet production; however, the function of these platelets has not been delineated.

Personnel: None.

Funding: None.

PROGRESS

The majority of patients receiving Vincristine are receiving other agents. Therefore, it has been impossible to determine if abnormalities of the platelets are due to Vincristine or to another agent.

Status: Completed.

DEPARTMENT OF THE ARMY
Brooke Army Medical Center
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: In Vitro Lymphocyte Stimulation and Leukocyte Inhibitory Factor Assay in Patients Who Have Been Immunized Against Rabies.

WORK UNIT NO.: C-27-75

PRINCIPAL INVESTIGATOR: Adolf E. Rahm, Jr., M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Hartley A. Selfridge, SSG

OBJECTIVES

To study in vitro lymphocyte stimulation and leukocyte migration inhibition in patients who have been immunized against rabies.

TECHNICAL APPROACH

Human lymphocytes are separated from blood specimens by hypaque ficoll gradient. Following several washes they are incubated with rabies vaccine, treated with thymidine, and the rate of lymphocyte stimulation is estimated by the amount of radioactive thymidine taken up. In addition, lymphocytes and leukocytes are cultured in agarose wells with vaccine present to determine the amount of leukocyte migration inhibition.

Personnel: 1 SSG (2 months)

Funding: None.

PROGRESS

Because of difficulty in finding human volunteers, a cooperative effort was undertaken with Dr. George Baer, CDC, Atlanta, Ga., using vaccinated mice. The results of these studies are listed in Table 1 and were inconclusive. No definitive statement could be made regarding the vaccine status of these animals.

Status: Completed.

TABLE I

	Vaccine		Blank		Control	
	1:500	1:100	1:500	1:100	Vaccine/blank	
9 Dec 75 R. ear clip	523/3.6	173/1.3	54/1.3	65/1.6	144/41	
R. ear clip	560/4.2	383/2.9	531/5.2	299/2.9	132/102	
19 Jan 77 R. ear clip	10750/29.2	8184/22.2	16315/50.9	25384/79.3	368/320	
19 Jan 76 L. ear punch	12177/5.5	45765/20.7	10203/3.5	32824/11.2	2201/2911	
L. ear punch	9954/6.3	8366/5.3	5949/4.37	5111/3.7	1560/1360	
L. ear punch	5257/18.7	40037/14.2	24135/9.8	30820/12.2	2801/2510	

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

INVESTIGATION PROJECT RESUME

TITLE: Measurement of Transepidermal Water Loss in Anhidrotic Ectodermal Dysplasia and Erythroderma.

WORK UNIT NO.: C-29-75

PRINCIPAL INVESTIGATOR: Robert L. Rietschel, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

1. To measure total body evaporative water loss in skin conditions of excessive and insufficient transepidermal water loss and compare these values with measurements of water loss from small areas of skin.
2. To study the effect of various topical compounds in common dermatologic use on transepidermal water loss in individuals with excess or insufficient water loss.

TECHNICAL APPROACH

A stream of dry nitrogen gas is blown across the skin surface and then into an electrolytic moisture analyzer. The amount of moisture present is detected and expressed in mg/cm²/hr.

Personnel: None.

<u>Funding:</u>	Consumable Supplies	MEDCASE	Rental
FY 77	-	-	\$21.00
FY 7T	-	-	\$ 5.25
FY 76	-	-	\$21.00
FY 75	\$ 255.95	\$ 1,250.00	

PROGRESS

No patients with anhidrotic ectodermal dysplasia or erythroderma were available for study. The effects of various compounds used to treat dry skin were evaluated in one normal individual. A method for objective measurement of moisturization by dry skin treatments was developed.

Status: Ongoing.

C-29-75 (Continued)

Rietschel, R.L. A method to evaluate skin moisturizers in vivo. Submitted to Journal of Investigative Dermatology.

A Method to Evaluate Skin Moisturizers in Vivo. Presented at the Southern Regional Meeting of the Society of Investigative Dermatology, 6 November 1976

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

INVESTIGATION PROJECT RESUME

TITLE: Bone Scanning as a Method for Detecting Early Renal Osteodystrophy.

WORK UNIT NO.: C-2-76

PRINCIPAL INVESTIGATORS: Harvey Gersh, M.D., MAJ, MC;
Robert J. Lull, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Richard Merrill, M.D., LTC, MC

OBJECTIVES

1. To evaluate the ability of phosphate scans to diagnose early osteodystrophy.
2. To evaluate the extent and distribution of metastatic calcifications in patients with renal osteodystrophy.
3. To attempt to develop a tool for the evaluation of bone metabolism.

TECHNICAL APPROACH

Polyphosphate bone scans were utilized to evaluate renal osteodystrophy. Two approaches were used. First, the bone scan was utilized to make general observations such as metastatic calcifications. The scans were successful with this approach, but we felt more objective measurement data were necessary and we evolved approach #2. A computerized scintillation camera was utilized to compare soft tissue uptake to femur uptake of the isotope. Upon comparing the ratios of soft tissue counts to femur counts at four hours, the assumption was made that increased bone activity represented increased clastic metabolism of the bone. These data were then compared to histologic information obtained from an anterior iliac crest biopsy.

Personnel: None.

<u>Funding</u>	<u>Consumable Supplies</u>
FY 77	-
FY 7T	-
FY 76	\$ 632.00

C-2-76 (Continued)

PROGRESS

The initial analysis of these data suggests that long term patients on hemodialysis have statistically different uptake ratios than do new dialysis patients. This suggests that we can quantitate osteoclastic activity using the polyphosphate bone scan. Although our histologic correlation has not been completed, it appears that there are also comparable changes in bone histology. This information helps us quantitate clastic activity and therefore gives us dynamic information concerning renal osteodystrophy. Utilizing other methods such as densitometric changes, we now can determine net changes in bone and therefore can mathematically derive clastic activity from the other two parameters. This information not only helps us make an early diagnosis of osteodystrophy but also gives us some insight into the dynamic metabolism of bone and gives us more definitive information so that in the future we can analyze treatment choices with increased precision.

Status: Completed.

Diagnostic Maneuvers in Renal Osteodystrophy. Presented at the Nephrology Seminar, Academy of Health Sciences, January 1976.

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**BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON TEX
ANNUAL RESEARCH PROGRESS REPORT, FISCAL YEAR 1977, (U)
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DEPARTMENT OF THE ARMY
Brooke Army Medical Center
Fort Sam Houston, Texas 78234
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Measurement of Lower Esophageal Sphincter Pressure: An Assessment of Perfusion Rate and the Honeywell Model 31 Probe.

WORK UNIT NO.: C-4-76

PRINCIPAL INVESTIGATOR: James E. Gray, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

1. To determine whether perfusion of the esophageal motility catheter at varying perfusion rates affects the recorded lower esophageal sphincter pressure.
2. To compare lower esophageal sphincter pressures obtained with traditional perfused catheters and with the Honeywell Model 31 probe.

TECHNICAL APPROACH

See Progress.

PROGRESS

Due to persistent malfunction of the Honeywell motility equipment, this project has been terminated.

Status: Terminated.

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

INVESTIGATION PROJECT RESUME

TITLE: Adequacy of Dialysis with Sorbent-based Dialysate Regeneration System (REDY).

WORK UNIT NO.: C-7-76

PRINCIPAL INVESTIGATOR: Daniel A. Nash, Jr., M.D., MAJ, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate the sorbent based dialysate regeneration system for adequacy of dialysis relative to existing single pass systems.

TECHNICAL APPROACH

Long term hemodialysis with the RDY was compared to the standard recirculating single pass dialysate system (RSP) using immunological studies. These included lymphocyte populations; lymphocyte blastogenesis with Pha, PWM, Con A, tetanus and monilia; NBT tests; and quantitative IgG, M and A. Four chronic patients were dialysed exclusively with the REDY for four months. Changes in the immunological studies were compared to changes in control RSP patients.

Personnel: None.

<u>Funding</u>	<u>Consumable Supplies</u>	<u>MEDCASE</u>
FY 77	-	-
FY 78	-	-
FY 76	\$ 475.00	\$3,980.00

PROGRESS

Significant differences included an NBT test that was decreased by a mean of 9.6% on the REDY (P<.02). The REDY patients also demonstrated a 29.6 BI unit mean decrease of lymphocyte response to Con A(P<.02). Further, there was a significant reduction in IgA and IgM not seen with RSP dialysis.

C-7-76 (Continued)

While the NBT test results may reflect a less stressful dialysis procedure, the possibility of depressed leukocyte function with the REDY could not be excluded. Also a relative decrease in T-lymphocyte function with REDY dialysis is suspected from the Con A results. These findings in addition to the decreased IgA and IgM with REDY dialysis suggest a less effective normalization of uremic immunological deficiencies than with the RSP dialysis system. Further consideration should be given to adequacy of long term dialysis with the REDY system.

Status: Completed

Nash, D.A., Jr. Evaluation of long term hemodialysis with the sorbent based dialysate regeneration system (REDY)^R. Abstract in Proceedings of American Society of Nephrology, November 1976.

Evaluation of long term hemodialysis with the sorbent based dialysate regeneration system (REDY)^R. Presented at the 9th Annual Meeting of the American Society of Nephrology, 23 November 1976, Washington, D.C.

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

INVESTIGATION PROJECT RESUME

TITLE: Quantitative Studies of Phagocytosis - the Use of Acridine Orange (AO) as an Indicator of Phagocytic Ingestion and Bactericidal Effects.

WORK UNIT NO.: C-9-76

PRINCIPAL INVESTIGATOR: Dennis L. Stevens, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

1. To study the phagocytosis of polymorphonuclear leukocytes of acridine orange stained bacteria.
2. To develop a simple reliable assay of this process which will be amenable to clinical laboratory utilization.

TECHNICAL APPROACH

Acridine orange stained E. coli were fed to human granulocyte suspensions and the fluorescence spectra recorded at different incubation times. A new Aminco-Bowman R136 photomultiplier tube was utilized.

Personnel: None

Funding: Consumable
Supplies

FY 77	-
FY 7T	-
FY 76	\$ 549.46

PROGRESS

Although visual fluorescence differences in killed virus live bacteria may be apparent by fluorescence microscopy, no fluorescence spectral changes have been found utilizing the Aminco-Bowman fluorometer. The reason is not apparent at this point, but is probably related to the large amount of dye taken up by the granulocyte nucleus. As a final attempt to utilize this technique, PMN's will be lysed at various times, and the spectral scans will be performed on bacteria alone.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Antimicrobial Sensitivities of Methicillin Resistant Staphylococci.

WORK UNIT NO.: C-10-76

PRINCIPAL INVESTIGATOR: Adolph E. Rahm, Jr., M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Elwood D. Everett, M.D., LTC, MC; Hugh D. Peterson, M.D., COL, MC; Theodore R. McNitt, M.D., LTC, MC

OBJECTIVES

1. To determine the mean inhibitory concentrations of microtiter technique of 20 strains of methicillin resistant staphylococci to Gentamicin, Tobramycin, Amikacin, Vancomycin and Clindamycin.
2. To determine synergy by killing curves on 5 strains of methicillin resistant staphylococci with combinations of Vancomycin with Gentamicin, Tobramycin, Amikacin (BB-K8) and Clindamycin.

TECHNICAL APPROACH

Methicillin resistant staphylococcus strains obtained at the Institute of Surgical Research are incubated in wells containing various solutions of antibiotics to determine the concentration at which growth is inhibited. Following determination of inhibitory concentrations, organisms will be incubated with various combinations of antibiotics at subinhibitory concentrations to determine if there is synergism. Synergism will be determined by performing colony counts on the culture at increasing intervals of time.

Personnel: None.

Funding: Consumable
Supplies

FY 77	-
FY 77	-
FY 76	\$ 29.45

PROGRESS

The microtiter technique did not lend itself to this study. After several attempts at standardizing the technique, the study was terminated.

Status: Terminated

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

INVESTIGATION PROJECT RESUME

TITLE: Treatment of Hepatic Failure with an Elemental Diet.

WORK UNIT NO.: C-11-76

PRINCIPAL INVESTIGATOR: Hugh P. McElwee, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if an orally administered elemental diet will speed recovery and/or improve survival from hepatic failure.

TECHNICAL APPROACH

Patients with advanced liver disease and associated encephalopathy were treated in a double blind fashion with either placebo or a special elemental diet. Laboratory results were monitored, and we attempted to separate meaningful differences in patient response.

Personnel: None.

Funding: None.

PROGRESS

Two patients have been evaluated. We have decided to discontinue this study for the following reasons:

1. Patient variability at the time of presentation precludes meaningful evaluation of changing biochemical data based solely on diet.
2. One patient being treated with diet via naso-gastric tube developed esophagitis and associated variceal bleeding that necessitated discontinuing the trial.

Status: Terminated

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

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of Glycerol Lysis Time as a Rapid Screening Measure
for Red Cell Membrane Effects.

WORK UNIT NO.: C-15-76

PRINCIPAL INVESTIGATOR: Robert P. Bowman, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: John Posch, DAC

OBJECTIVES

1. To determine normal values of glycerol lysis time.
2. To determine if red cell membrane defects such as thalassemia and spherocytic anemias can be detected out of the range of normal.
3. To statistically evaluate the lysis curve and delineate the best and simplest points for correlating hemolysis to cellular defect.
4. To determine whether this test can be used as a rapid screening measure in a busy hematology clinic.

TECHNICAL APPROACH

Glycerol lysis time is being performed on a large number of patients to establish a number range of abnormalities.

Personnel: None.

Funding: Consumable
Supplies

FY 77	-
FY 7T	-
FY 76	\$ 213.15

PROGRESS

It has been suggested that this test be utilized as a rapid and inexpensive screening tool to differentiate patients with abnormal hemoglobins and thalassemsias from normals and those with iron deficiencies. A sizeable number of patients with these disorders have

C-15-76 (Continued)

been identified in the clinic and glycerol lysis time curves have been determined on them as well as on a large series of normal controls. Our present results, although at variance with a previous report on similar patients using 50% glycerol lysis times, does indicate that certain hemoglobinopathies including beta-thalassemia demonstrate unusually high glycerol lysis times. Patients with alpha-thalassemia and iron deficiency, however, demonstrate variable lysis times. We are evaluating slopes and other times (i.e., GLT 25%, 75%, 90% etc.) to determine if these parameters may be more helpful in differentiating spherocytic anemias. Glycerol lysis curves of patients with the more rare hemoglobin disorders, such as alpha-thalassemia, are being added to the study as these rare abnormalities are detected in the clinic.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: The Value of Antacid Therapy in Treatment of Duodenal Ulcers.

WORK UNIT NO.: C-19-76

PRINCIPAL INVESTIGATOR: Hugh P. McElwee, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: James E. Gray, M.D., MAJ, MC; Melvin L. Butler,
M.D., LTC, MC, LAMC; Staff, LAMC; Staff, WBAMC;
Staff, WRAMC

OBJECTIVES

To determine the efficacy of antacid therapy in duodenal ulcer disease.

TECHNICAL APPROACH

An attempt will be made to determine the effectiveness of antacids on the healing rate of duodenal ulcers. This is a double blind study comparing antacids vs. placebo. All patients will be diagnosed and followed by oral endoscopy to monitor response.

Personnel: None.

Funding: None.

PROGRESS

A similar study has now been completed at another institution; therefore, the study is terminated.

Status: Terminated.

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

INVESTIGATION PROJECT RESUME

TITLE: Therapeutic And Diagnostic Role of Air Calories.

WORK UNIT NO.: C-22-76

PRINCIPAL INVESTIGATOR: Michael Polsky, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Carl H. Gunderson, M.D., COL, MC

OBJECTIVES

To develop a device for the determination of the possible therapeutic and diagnostic role of air calories.

TECHNICAL APPROACH

The device in question would be a modified portable hot air blower. Air would flow through a tube connected to an ear-plug of the sort used in transistor radios. Since the surface to be contacted is the tympanic membrane, the flow of air need not be rapid, and conceivably the system will not require a fan. The system should incorporate a thermostat rendering possible adjustments between 37° and 44° C.

Personnel: None.

Funding: None.

PROGRESS

All attempts to assemble an appropriate device have met with failure. Therefore, the study is terminated.

Status: Terminated.

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

INVESTIGATION PROJECT RESUME

TITLE: Demonstration of a Testosterone Binding Protein in Semen.

WORK UNIT NO.: C-23-76

PRINCIPAL INVESTIGATOR: Albert Thomason, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To demonstrate a testosterone binding protein in semen.

TECHNICAL APPROACH

Attempts are being made to demonstrate a specific binding protein by using polyacrylamide gel electrophoresis and radioactive testosterone. Two approaches have been used so far: 1. To add the radioactive testosterone to the semen before the electrophoresis and then to count consecutive sections of the gel to see if any of the sections contained high counts; and 2. To place the testosterone directly into the gel and subsequent to the electrophoresis to section the gel into consecutive equal segments.

Personnel: None.

Funding: None.

PROGRESS

To date, no specific testosterone binding protein has been demonstrated by either of the techniques used. It is planned to verify that the technique is valid by using it to demonstrate sex hormone binding globulin in serum.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: The Use of Teichoic Acid Antibodies in Diagnosing Serious Staphylococcal Disease in Burn Patients.

WORK UNIT NO.: C-25-76

PRINCIPAL INVESTIGATOR: Theodore R. McNitt, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: E. Dale Everett, M.D., LTC, MC; Dennis L. Stevens, M.D., MAJ, MC

OBJECTIVES

1. To determine if teichoic acid antibody titers change in a diagnostic fashion in burn patients with staphylococcal infections.
2. To compare teichoic acid antibody titers in patients with methicillin sensitive and methicillin resistant staphylococcal infections.
3. To correlate teichoic acid antibody titers in burn patients with the degree of staphylococcal disease.

TECHNICAL APPROACH

Serial blood samples from thermally injured patients will be obtained and teichoic acid antibody titers will be measured by immunodiffusion assay after the method of Crowder and White.

Personnel: 1 SP5 (3 months)

Funding: Consumable
Supplies

FY 77	-
FY 7T	\$ 270.00
FY 76	\$ 360.00

PROGRESS

Sixty patients were entered into the study. There were ten episodes of severe Staphylococcus aureus infection but none had teichoic acid antibodies.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Effect of Vagal Stimulation on Canine Plasma Histamine Levels and Mast Cell Degranulation.

WORK UNIT NO.: C-26-76

PRINCIPAL INVESTIGATOR: Charles B. Brearley, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: William W. Burgin, Jr., M.D., COL, MC; Sammy C. Campbell, M.D.

OBJECTIVES

1. To determine if elevations of arterial blood histamine occur in anesthetized dogs following unilateral and bilateral vagal stimulation.
2. To determine the extent of mast cell degranulation in the lungs of anesthetized dogs following bilateral vagal stimulation.

TECHNICAL APPROACH

Dogs weighing approximately 15 kg were anesthetized with pentobarbital, intubated and ventilated with Bird Mark VII ventilator to keep arterial pH and PCO_2 in the physiologic range and to keep arterial CO_2 approximately 200 mm Hg. The right femoral artery was cannulated and attached to a Statham pressure transducer and E for M Recorder. Central venous line was inserted via the right external jugular vein into the right atrium. The right and left vagosympathetic nerve trunks were exposed and attached to a nerve stimulator. An esophageal balloon was inserted and connected to a pressure transducer to record changes in intrathoracic pressure. A pneumotachograph was inserted in line with the breathing apparatus, so that continuous flow rates could be monitored. Following initial blood samples for arterial blood gases and arterial and venous histamine levels, and following baseline ventilatory volume, pressure and flow measurements, one minute of electrical stimulation was carried out with continual ventilatory measurements as well as simultaneous arterial and venous samples for histamine at/immediately following stimulation, and at 2, 5 and 10 minute intervals.

Personnel: None

Funding: Consumable
Supplies

FY 77 \$ 250.00

C-26-77 (Continued)

PROGRESS

Six dogs were studied. No significant elevations of plasma histamine were observed.

Status: Completed.

Effect of Vagal Stimulation on Canine Plasma Histamine Levels and Mast Cell Degranulation. Presented at the Fitzsimons Symposium, September 1976, Denver, Colorado.

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

INVESTIGATION PROJECT RESUME

TITLE: Pilot Study: Evaluation of Nasogastric Hyperalimentation and Peripheral Venous Hyperalimentation in Cancer Patients.

WORK UNIT NO.: C-27-76

PRINCIPAL INVESTIGATOR: Richard A. Shildt, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To gather data on two forms of hyperalimentation: nasogastric hyperalimentation and peripheral venous hyperalimentation and compare the results with a control group receiving an oral diet. This is a pilot study to determine the feasibility of hyperalimentation on the Oncology Service.

TECHNICAL APPROACH

Patients seen by the Oncology Service who are to begin chemotherapy and who have lost at least 10% of their body weight normally recorded in the pre-illness period, or who have albumin less than 8 mg%, will be asked to participate.

Patients will be randomized into three groups. Group A will be the control group receiving a diet outlined by the dietician. Group B will receive a diet outlined by the dietician and nasogastric hyperalimentation with Ensure. Group C will receive a diet outlined by the dietician and peripheral venous hyperalimentation with Intralipid and Freamine. A maximum of 24 patients, 8 in each group, will be studied.

Personnel: None

Funding: None

PROGRESS

We were unable to gather enough patients to compare a control group to intravenous and nasogastric feeding. Since our oncology population is not large enough to complete this study, the study is terminated.

Status: Terminated

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

INVESTIGATION PROJECT RESUME

TITLE: Prevalence of HBS Antigen, Carrier State and HBS Antibody in Gastroenterologists.

WORK UNIT NO.: C-30-76

PRINCIPAL INVESTIGATOR: Hugh P. McElwee, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: James L. Stammer, M.D., MAJ, MC

OBJECTIVES

To determine the prevalence of HBS antigen carrier state and HBS antibody in physicians practicing gastroenterology.

TECHNICAL APPROACH

Blood samples were collected from volunteers at annual meetings for gastroenterologists. Participants also provided a data sheet with pertinent personal and professional information. Blood samples were tested for the presence of hepatitis surface antigen and surface antibody. Test results and information from data sheets were number coded and transferred to computer files for further analysis.

Personnel: None.

<u>Funding:</u>	Consumable Supplies	Contractural Services
FY 77	-	-
FY 7T	-	-
FY 76	\$ 86.38	\$ 720.00

PROGRESS

Four hundred and seventy-eight physicians provided blood samples. Four hundred and twenty-three were gastroenterologists, fourteen were internists, four were in general practice, one was a hematologist, and 36 had other areas of of special interest. Approximately 50% of the last group were surgeons. Forty-nine participants reported a history of hepatitis and 18 of these (37%) were seropositive.

C-30-76 (Continued)

Conclusions; 1. The prevalence of hepatitis B markers in our physician group is significantly greater than that reported for a non-health care population.

2. The increased prevalence of hepatitis B markers is not significantly different from that reported for another health care population.

3. The prevalence of hepatitis B markers increases with age and years of professional experience as a gastroenterologist-endoscopist.

4. The wearing of gloves during upper endoscopy does not alter the prevalence of hepatitis B markers for gastroenterologists-endoscopists.

5. The role of endoscopy in the transmission of hepatitis B markers needs further evaluation.

Status: Completed.

McElwee, H.P. and Stammer, J.L. Prevalence of Hepatitis B Markers in Gastroenterologists and Endoscopists. *Gastrointestinal Endoscopy* 23:235, 1977.

Prevalence of Hepatitis B Markers in Gastroenterologists and Endoscopists. Presented at the William Beaumont Gastrointestinal Symposium, El Paso, Texas, March 1977; American Society for Gastrointestinal Endoscopy, Toronto, Canada, May 1977.

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

INVESTIGATION PROJECT RESUME

TITLE: Treatment of Systemic Mast Cell Disease with Cimetidine

WORK UNIT NO.: C-33-76

PRINCIPAL INVESTIGATOR: Joe A. Dean, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To measure the effect of Cimetidine, a selective H⁺ blocking agent, on recurrence of gastric ulceration, intestinal hemorrhage, pruritus and diarrhea in a patient with known systemic mast cell disease.

TECHNICAL APPROACH

The patient will be treated under the Smith, Kline and French Protocol #D01 for Cimetidine (SK&F 92334) as treatment of a special case. Under this protocol, only those seriously ill patients in whom reduction of gastric acid output may be required for their treatment and when no alternative therapy is available may be entered. Each patient will be studied on a regimen of 300 mg. q.i.d. administered with meals and h.s. Should this not completely alleviate symptoms, the dosage may be increased. Antacids may be administered p.r.n.

Personnel: None.

Funding: None.

PROGRESS

On therapy with cimetidine, the patient has had no further evidence of peptic ulcer disease or diarrhea and has had diminution of skin involvement. There has been no evidence of increased cardiopulmonary or retroperitoneal disease. He has had no known toxicity to the drug, and liver function and hematologic parameters remain stable. Cimetidine is now commercially available and therefore this study is completed.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: The Effect of Hyperbaric Carriers on the Distribution of Aminoglycoside Antibiotics in the Cerebrospinal Fluid of Dogs.

WORK UNIT NO.: C-35-76

PRINCIPAL INVESTIGATOR: E. Dale Everett, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Christopher Chaput, M.D., MAJ, MC; Thomas Rankin, M.D., LTC, MC; Theodore R. McNitt, M.D., LTC, MC; Dennis L. Stevens, M.D., MAJ, MC

OBJECTIVES

To determine the effect of hyperbaric (10% dextrose) solutions on the distribution of intrathecally administered aminoglycoside antibiotics.

TECHNICAL APPROACH

Mongrel dogs will have Ommaya reservoir placed in the cerebral ventricles. Aminoglycosides alone or aminoglycosides dissolved 10% glucose will be injected into the lumbar intrathecal space. Drug concentration at the ventricular level will be measured.

Personnel: None

Funding: None

PROGRESS

Technical difficulties encountered in placing and maintaining the Ommaya reservoirs necessitated curtailment of this project.

Status: Terminated.

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

INVESTIGATION PROJECT RESUME

TITLE: Heavy Metal Metabolism and Its Effect on Leukemias.

WORK UNIT NO.: C-1-77

PRINCIPAL INVESTIGATORS: Jerry Phillips, M.D.;
Robert P. Bowman, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Dan Marmer, M.S., MT (ASCP)

OBJECTIVES

To clearly define the cellular actions of zinc at a molecular level. Of particular interest are; 1) identification of the intracellular systems associated with zinc; 2) characterization of the mechanisms by which such systems are affected by zinc; and 3) both identification and characterization of systems in which zinc metabolism is abnormal, such as appears to be the case with leukemia lymphocytes.

TECHNICAL APPROACH

Human peripheral blood was obtained by venipuncture from 7 healthy donors and from donors with chronic lymphocytic leukemia. Purified lymphocyte populations were assessed for viability by exclusion of trypan blue, for thymus-dependent (t) lymphocytes by the ability to form rosettes with sheep erythrocytes, and for thymus-independent (b) lymphocytes by the ability to form rosettes with sheep erythrocytes coated with antibody and complement.

To assay zinc uptake, 1.5×10^6 lymphocytes were suspended in 1 ml. serum-free RPMI-1640 in culture tubes. Each culture received 10 g. (^{65}Zn)zinc transferrin. Finally, varying concentrations of either PHA or poly-L-ornithine were added. Cultures were incubated overnight at 37° in a humidified atmosphere of 5% CO_2 in air. Incubations were terminated by addition of 2 ml. ice-cold PBS² followed by centrifugation at 160xg for 10 minutes. The cell pellet was resuspended in 2 ml. ice-cold PBS and again centrifuged. This process was repeated one additional time. The final washed cell pellet was suspended in 2 ml. cold PBS and the cells collected by vacuum filtration. Radioactivity associated with the lymphocytes was then assessed. All cultures were run in duplicate.

Personnel: None.

Funding: None.

C-1-77 (Continued)

PROGRESS

The relative effects of PHA and poly-L-ornithine on zinc uptake differed between normal and CLL lymphocytes. The ratio, i.e. zinc uptake in poly-L-ornithine cultures/zinc uptake in PHA culture, appears to be characteristic for each of the lymphocyte populations used. For the seven normal donors this ratio is 1.9 ± 0.2 , while the ratio is only 0.9 ± 0.3 for the seven CLL donors. Using Student's t-test, it was determined that the difference between these two ratios is statistically significant ($P < .001$). Additionally, lymphocytes from one donor with lymphoma and one donor with Hodgkin's disease were tested and the ratios of 3.4 and 2.8, respectively, were obtained.

It is proposed that this this technique may be useful in the diagnosis of chronic lymphocytic leukemia as well as in the assessment of the efficacy of chemotherapeutic regimes.

Status: Ongoing.

Phillips, J.L., Tuley, J.A. and Bowman, R.P. Zinc uptake in normal and leukemic lymphocytes: Effect of poly-L-ornithine. J Natl Cancer Inst 58:1229, May 1977.

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

INVESTIGATION PROJECT RESUME

TITLE: Comparison of Hemodynamic Effects of Angiographic Contrast Material with Dynamic and Static Exercise.

WORK UNIT NO.: C-3-77

PRINCIPAL INVESTIGATOR: Barry R. Alter, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Joseph P. Murgo, M.D., LTC, MC

OBJECTIVES

To evaluate the usefulness of postangiographic hemodynamic data in assessing left ventricular function by comparison with the effects of standard forms of left ventricular stress in the cardiac catheterization laboratory.

TECHNICAL APPROACH

Seventy-five patients with either normal cardiovascular dynamics or a variety of cardiac diseases including coronary artery disease, valvular heart disease and cardiomyopathies, will be entered into the study. Each patient will undergo routine, control, rest, dynamic, and static exercise hemodynamic protocols currently used at Brooke Army Medical Center. Left ventricular pressure will be recorded in a manner sufficient to accurately measure peak systolic pressure, end-diastolic pressure, and left ventricular dp/dt. Other routine pressures and parameters will also be made. Three thermal dilution measurements of cardiac output will be made during each phase of the study. Prior to injection of contrast material, all parameters will be measured during controlled state. A specially designed Millar high fidelity injection catheter with recessed holes will be utilized for the injection allowing high fidelity left ventricular pressure measurements with simultaneous fluid aortic pressures. Pressures and thermal dilution cardiac output will be obtained prior to injection of the contrast material and then will be re-recorded at specific intervals following injection until all hemodynamic parameters return to baseline levels. All data will be analyzed for tempo changes, and to compare postangiographic hemodynamic changes with those following dynamic and static exercise.

Personnel: None

Funding: None

C-3-77 (Continued)

PROGRESS

Several patients have thus far been studied under the protocol, but data have been inadequate for interpretation due to technical problems. Recently a new catheter was obtained from Millar Electronics allowing simultaneous left ventricular and aortic pressures to be measured following injection. Beginning in the near future, a minimum of 2-3 patients per week will undergo the protocol.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Modified Time-Motion Study of Outpatient Flow at BAMC AMIC

WORK UNIT NO.: C-5-77

PRINCIPAL INVESTIGATOR: Richard A. Call, II, M.D., CPT, MC

ASSOCIATE INVESTIGATORS: Barry W. Wolcott, M.D., LTC, MC

OBJECTIVES

1. To determine the various processing linkages, service times, waiting times, routes, patient types, and staffing for treating patients in the general, adult, non-appointment AMIC at BAMC.
2. To provide analysis of operations of the AMIC utilizing a modified time and motion study and data reduction procedures developed by the Indian Health Service.
3. To suggest modifications in ER/AMIC medical process to provide more medically effective care with current resources.
4. To compare these process aspects at BAMC with those of other civilian and governmental clinics with similar missions but differing structure.

TECHNICAL APPROACH

Using a protocol developed by the Indian Health Service, time clocks were placed at all patient care stations within the ER/AMIC. Data were collected on 1800 patients presenting to the ER/AMIC during a one week period. The method of data collection allowed calculation of both cueing time and service time at each station throughout the ER/AMIC system. The data are entered into a computer; the program allows for search by time of patient arrival, day of patient arrival, complaint at time of arrival, initial care provide, and a variety of other variables.

Personnel: None

Funding None

C-5-77 (Continued)

PROGRESS

The initial analysis of the data has been completed giving us for the first time a profile of patient flow through the ER/AMIC. Based on this profile, we have been able to make significant alterations in staffing of various areas of the ER/AMIC and improve the flow of patients through the system. In addition, the time data assembled allows calculation of the cost of medical care for the different providers in the Clinic; information that is essential in any analysis of the utilization of physician extenders in the Emergency Department.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: The Mechanism of the Modulation of Lymphocyte Functions by Complement.

WORK UNIT NO.: C-6-77

PRINCIPAL INVESTIGATOR: Michel Laham, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Hartley A. Selfridge, SSG

OBJECTIVES

Previous work done in collaboration with Drs Richar Panush and Jacques Caldwell at the University of Florida has demonstrated that in vitro responses of human peripheral blood lymphocytes (PBL) to mitogens, as measured by the uptake of labelled thymidine (3HTdR), were significantly decreased in the presence of human Complement (C) components C₁, C₄, and C₂. The purpose of this project is to study the mechanism of this inhibition of lymphocyte functions by C.

TECHNICAL APPROACH

Human PBL are obtained by Ficoll-Hypaque sedimentation. They are further separated into T and B cell subpopulations by rosetting with EAC cells and E cells, respectively, and by a second Ficoll-Hypaque sedimentation. The separated cells are incubated with C₁, C₄, and C₂, then stimulated with various mitogens. Lymphocyte uptake of ³HThdR is measured at 24, 48 and 72 hours, respectively.

Personnel: 1 SSG (10 months)

Funding: Consumable
Supplies

FY 77 \$1,275.10
FY 7T \$ 447.70

PROGRESS

We have been able to separate T and B cell populations that are 90% pure. The dose-response curves of the separated cells to PHA, Con A, PWM have been determined. Con A was found to differentiate best between T and B

C-6-77 (continued)

cells. Initial results with C indicate that both T and B cells that are preincubated with C_{142} have a decreased uptake of 3HTdR at 72 hours. Unseparated PBL show the same trend but to a lesser degree than separated cells. After we have corroborated our initial findings, we will address ourselves to the kinetics of this inhibition of lymphocyte responses by measuring uptake of 3HTdR sequentially for up to 120 hours. Next, we will examine the effect of C_{142} on lymphokine production, specifically, leukocyte inhibitory factor (LIF).

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: The Use of Lyophilized Homografts for Creation of AV Fistula
in Dialyzed Patients.

WORK UNIT NO.: C-10-77

PRINCIPAL INVESTIGATORS: Richard H. Merrill, M.D., LTC, MC;
Bruce S. Jarstfer, M.D., COL, MC

ASSOCIATE INVESTIGATORS: Hartley A. Selfridge, SSG

OBJECTIVES

To determine whether a more effective and less expensive dialysis access procedure can be developed.

TECHNICAL APPROACH

Lyophilized homografts are to be compared against the standard bovine xenograft for creation of A-V fistula in patients requiring chronic hemodialysis. The patients are randomized and the physicians caring for the patient are blinded as to the exact appliance used. All fistula undergo weekly evaluation for dysfunction.

Personnel: 1 SSG (3 months)

Funding: Consumable
Supplies

FY 77 \$ 133.70

PROGRESS

Fifteen patients have been entered into the study with several patients passing the one year mark. It is anticipated that another five patients will be entered in this phase of the study before the code is broken and the data are analyzed. All the homografts have been saphenous veins harvested from cadavers. After twenty patients have entered the study the bovine graft will be compared to lyophilized umbilical veins in another twenty patients.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Antibody Titer Response to Swine Influenza Immunization in an Oncology Population.

WORK UNIT NO.: C-11-77

PRINCIPAL INVESTIGATOR: Richard A. Schildt, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Dan W. Luedke, M.D., MAJ, MC; Michel N. Laham, M.D., MAJ, MC; George Kasai, Ph.D., DAC

OBJECTIVES

1. To compare antibody titer response of a population of oncology patients who receive swine influenza immunization with that of normal controls and immunosuppressed patients without malignant disease.
2. To correlate the antibody titer response with immunoglobulin levels and lymphocyte counts.
3. To compare the morbidity of influenza immunized oncology patients with normal controls and immunosuppressed patients without malignant disease.
4. To record the incidence of respiratory tract and swine influenza illnesses in our immunized population.

TECHNICAL APPROACH

At the time of immunization, 10 cc of blood will be collected and the sera analyzed for swine influenza antibody titers. Twenty initial samples will be sent to the Virology Lab for complement fixation and hemagglutination titer determinations. Three and nine weeks after inoculation a second and third sample will be collected and evaluated for the factors mentioned above.

The participants will be given typewritten instructions on how to report the side effects of the inoculation and will be asked to report any viral illnesses they develop during the "flu" season (from inoculation to April). Viral illness will be defined as any respiratory symptom complex. The participant will be examined and interviewed by one of the investigators and a throat culture for virus obtained. A serum sample will be drawn three weeks after the illness and examined for a rise in swine influenza antibodies.

C-11-77 (Continued)

Personnel: None

Funding: None

PROGRESS

The Swine and Victoria titers are completed. At the present time we are running titers for increases in Hong Kong B antibodies. The data collected on the 112 patients in the study are being reviewed.

Status: Ongoing.

Immunologic Response of Oncology Patients to Influenza Immunization.
Presented to the Texas Branch of the Society of American Microbiologists,
San Antonio, Texas, 11 March 1977.

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

INVESTIGATION PROJECT RESUME

TITLE: A Prospective Study of the Usefulness of the Chest X-ray in
evaluating Patients with Acute Cough.

WORK UNIT NO.: C-19-77

PRINCIPAL INVESTIGATOR: Barry W. Wolcott, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Staff, General Medicine Service

OBJECTIVES

To determine if the use of the chest x-ray is cost-effective in the evaluation of ambulatory patients presenting with an acute cough at BAMC; to determine the value of clinical signs and symptoms and the clinician's judgment, in predicting the presence of infiltrate on chest x-ray; and to compare cough patients evaluated with a chest x-ray with cough patients evaluated without a chest x-ray, in terms of clinical outcome and the cost of care.

TECHNICAL APPROACH

Patients presenting to the ER/AMIC whose reasons for seeking evaluation include a cough are candidates for the study. After obtaining informed consent, these patients are examined by a research assistant who uses a check sheet to establish a uniform history of the present illness and past medical history. They are then evaluated by a staff physician who performs a standardized and defined physical examination and makes judgments concerning the necessity for a chest x-ray at the time of this visit. All patients are x-rayed and the x-rays are randomly shown or not shown to the staff physician. Patients are discharged home on the medical care prescribed by the staff physician and in a pre-defined period following the index visit the patients are contacted to obtain outcome and satisfaction data. All data are entered into a computer.

Personnel: None

Funding: None

PROGRESS

Over 850 patients have been included in this study. Our statisticians estimate that 2,000 patients will be required before statistical significance can be demonstrated.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of the Effectiveness of Oral Methoxsalen Followed by Longwave Ultraviolet Light (UVA 320-400 nm) in the Treatment of Psoriasis.

WORK UNIT NO.: C-23-77

PRINCIPAL INVESTIGATORS: Eric W. Kraus, M.D., CPT, MC;
Charles W. Lewis, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the efficacy of 8-methoxypsoralen (methoxsalen) and longwave ultraviolet light (PUVA) in the treatment of psoriasis.

TECHNICAL APPROACH

The patients takes 3-6 capsules of Oxsoralen by mouth depending on weight two hours prior to exposure to longwave ultraviolet light in a specially designed light box; treatment is given 2-3 times per week.

Personnel: None

Funding: None

PROGRESS

Thirteen patients have entered the study. Seven patients cleared completely and are now on maintenance therapy varying from once a week to prn. Two patients received no benefit from the treatment and were considered treatment failures. Two patients moved to another location during treatment. Two patients are currently in the initial phase of their treatment.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: The Toxicity of Aminoglycosides to Kidney Tumor Cell Lines in Tissue Culture.

WORK UNIT NO.: C-26-77

PRINCIPAL INVESTIGATOR: Dan W. Luedke, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC: James J. Plitt, M.S., SSG

OBJECTIVES

To establish various kidney tumor cell lines in vitro and to test the efficiency of kill of these tumor lines with various aminoglycosides.

TECHNICAL APPROACH

Four kidney tumor cell lines will be obtained. These lines are: 1) an autonomous kidney tumor line, 2) an estrogen-dependent kidney tumor cell line, 3) the established line BHK-21, and 4) an epithelial kidney cell line (HAK). All of these lines are malignant and all are derived from the Syrian hamster. They will be established in our laboratory and characterized as to population doubling times, cloning efficiencies, and saturation densities.

We will determine the cytotoxicity of gentamicin and paromomycin in log phase cells and in resting cells. Toxicity measurements will be performed by the usual colony counting method. After incubating cells with antibiotics, viable colonies are fixed and stained with crystal violet and counted. These in turn are compared to untreated controls to give a survival fraction. Concentration and time dependence of the toxicity will be examined for each drug in each line of cells.

Personnel: 1 SSG (4 months)

Funding: Consumable
Supplies

FY 77 \$1,414.00

C-26-77 (Continued)

PROGRESS

Preliminary studies have been carried out in Berkeley, California by Lieutenant Joseph Landolph. Data on these studies are currently being analyzed.

We are setting up a tissue culture facility at Brooke Army Medical Center to allow us to complete this project, as well as establishing a repository of cells for other investigators.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: L-dopa and the Relief of Pain in Cancer Patients.

WORK UNIT NO.: C-27-77

PRINCIPAL INVESTIGATOR: Richard A. Shildt, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: J. Dean McCracken, M.D., LTC, MC

OBJECTIVES

To better define the usefulness of L-dopa in relief of cancer pain.

TECHNICAL APPROACH

The patients for this study will be selected from the Oncology inpatient and outpatient service who have significant pain refractory to safe doses of standard narcotic medication. The patients will have documented tumor involvement of the bony skeleton or visceral organs which is responsible for the pain.

Participants in the study will be instructed to record the time and amount of prn pain medicine taken for 48 hours (Phase I). At the end of 48 hours, the patient will receive one capsule containing either L-dopa or placebo, qid, unknown to the patient or the doctors in a randomized double-blinded fashion. Pain relief, side effects, time and amount of pain medication taken on a prn basis will be recorded for 48 hours (Phase II). If there is no pain relief, the dose will be doubled and taken for another 48 hours (Phase III). All patients, both those who have obtained pain relief in Phase II and III and those who have not, will enter Phase IV. All patients will receive 1 capsule, qid, the one not taken in Phase II, for 48 hours (Phase IV). If there is no pain relief, in Phase IV the dose will be doubled and taken for an additional 48 hours (Phase V). At the end of this additional 48 hours period the study will be completed.

Personnel: None

Funding: None

C-27-77 (Continued)

PROGRESS

Terminated due to delays in obtaining approval and inadequate time to complete.

Status: Terminated.

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

INVESTIGATION PROJECT RESUME

TITLE: Tumor Immunology - Multi-test Device with Standardized Antigens to Assay Delayed Hypersensitivity Via the Skin Test.
(Collaborative Study with UTSA)

WORK UNIT NO.: C-28-77

PRINCIPAL INVESTIGATOR: James R. McDonald, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: W. T. Kniker, M.D.

OBJECTIVES

To carry out initial clinical skin testing of individual "Recall" antigens on healthy adults to establish safety and degree of delayed hypersensitivity using a new multi-test delivery unit.

TECHNICAL APPROACH

The multi-test device contains eight test sites. Antigens being used include Streptokinase, Tetanus, Diphtheria, Old Tuberculin, Candida, and glycerinated controls. These substances are used in two concentrations. The complete set of antigens at low concentration is applied to the right forearm, and the higher concentration is applied to the left forearm. The patient is evaluated at four to six hours and again at 24 and 48 hours for evidence of erythema or induration. Induration is measured in millimeters in two planes and recorded.

Personnel: None

Funding: None

PROGRESS

Initial studies have been started.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Histologic Characterization of Early Adriamycin-induced Soft Tissue Injury - Possible Therapeutic Role of Glucocorticoids.

WORK UNIT NO.: C-29-77

PRINCIPAL INVESTIGATOR: Dan W. Luedke, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Robert W. Rietschel, M.D., MAJ, MC

OBJECTIVES

1. To characterize the histopathology of Adriamycin-induced soft tissue damage after subcutaneous extravasation in rabbits.
2. To determine whether the administration of local or systemic glucocorticoids concurrent with Adriamycin will modify resultant soft tissue damage.

TECHNICAL APPROACH

Adult rabbits will be divided into five groups with two animals in each group.

Group I: Adriamycin injections will be administered to eight labeled regions on the back of both animals. Skin biopsies will be taken from the central area of injection outward to normal skin of any noted inflammation at 2, 6, 24, and 48 hours and at 1, 2 and 3 week intervals after drug injection.

Group II: Each animal will be injected with Adriamycin as per group I, followed by intradermal injections of hydrocortisone into each area previously injected with Adriamycin. Skin biopsies will be taken as in Group I.

Group III: Each animal will be given intradermal injections of hydrocortisone only. Skin biopsies will proceed as per group I.

Group IV: Each animal will be injected with Adriamycin as per Group I followed by a single injection of cortisone. Skin biopsies will be taken as per group I.

C-29-77 (Continued)

Group V: Each animal will be injected with Adriamycin as per Group I followed in 48 hours by IM cortisone daily x 3. Biopsy schedule will proceed as per group I.

Personnel: None

Funding: None

PROGRESS

This is a new study.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Immune Deficiency in Dialyzed Patients: A Chronic Model of
Acute Trauma

WORK UNIT NO.: C-32-77

PRINCIPAL INVESTIGATOR: Richard H. Merrill, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Hartley A. Selfridge, SSG; Rikki Solow, SP5

OBJECTIVES

To determine the etiology of immune depression in renal failure.

TECHNICAL APPROACH

A battery of immune function tests have been developed in this laboratory and are being applied to four classes of patients; patients with chronic renal failure, both dialyzed and managed conservatively, patients with nephrotic syndrome, patients with acute renal failure, and traumatized patients. The immune depression found in these patients is to be correlated with various aspects of nutrition such as amino acid metabolism, phosphate metabolism, etc.

Personnel: 1 SSG (3 months)

Funding: None

PROGRESS

Approximately sixty patients have been entered into the protocol. Depression of mainly cellular immunity has been found in all classes of patients to varying degrees.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Management of Patients with a Metastatic Adenocarcinoma of Unknown Origin.

WORK UNIT NO.: C-34-77

PRINCIPAL INVESTIGATOR: Peter S. Kennedy, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To determine the individual yield of various diagnostic procedures in finding the site of tumor origin in patients who present with metastatic adenocarcinoma with no obvious primary source.
2. To assess the efficacy of combination chemotherapy in palliative management of this disease as demonstrated by the percent of patients showing objective response to treatment, and by survival duration of responding vs. non-responding patients.

TECHNICAL APPROACH

Patients with adenocarcinoma from an unknown primary source are put through a series of diagnostic screening studies in an attempt to establish a diagnosis of the primary tumor. If no primary is found, treatment is begun using a 3-drug regimen which includes fluorouracil, cyclophosphamide, and adriamycin.

Personnel: None

Funding: None

PROGRESS

Eight patients have been treated with this regimen. Five have demonstrated an objective response. Five of six responding patients are alive; median survival for this group has not been reached at six months. All patients have demonstrated vomiting, alopecia and marrow suppression requiring drug dose adjustments. This protocol has been accepted for group-wide study by the Southwest Oncology Group.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Studies of Virulence and Antibiotic Sensitivity of Clinical Isolates of Rhodochrous Taxon.

WORK UNIT NO.: C-35-77

PRINCIPAL INVESTIGATOR: David R. Haburchak, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Michael M. Lieberman, Ph.D., CPT, MSC; E. Dale Everett, M.D., LTC, MC; B. Jeffery, DAC; J. Higbee, Ph.D., MAJ, MSC

OBJECTIVES

1. Speciate Rhodochrous group organisms isolated from patients at Brooke Army Medical Center.
2. Determine if clinical isolates demonstrate virulence in a guinea pig model.
3. Determine if patients or guinea pigs demonstrate precipitating antibodies to antigen of Rhodochrous, thereby further implicating possible virulence.
4. Conduct in vitro antibiotic sensitivity testing using drugs commonly employed in mycobacterial and nocardia infections, as a guide in patient management.

TECHNICAL APPROACH

Organisms will be identified and speciated by standard methods. Virulence of isolates will be ascertained by guinea pig inoculation, and determination of antibody levels to the isolates in patients and experimental animals. Antibiotic susceptibility testing will be performed with in vitro testing on solid agar based media.

Personnel: None

Funding: Consumable
Supplies

FY 77 \$ 117.00

PROGRESS

Organisms conforming to Rhodochrous taxon were isolated from three patients with known immuno-compromise under circumstances suggesting a pathogenic role for the organism. These are partially acid fast, catalase positive rods which form orange or red granular, domed colonies aerobically in 3-4 days on Sabouraud, Mueller-Hinton, and Middlebrook 7H-10 agars. They are differentiated from Nocardia by morphology and ability to degrade ethylene glycol in 7H-10 media. Identification was confirmed by CDC. Two clinical strains and a reference strain were inoculated intraperitoneally into 250 gm guinea pigs, half of which received 20 mg per day methylprednisolone intramuscularly beginning 3 days prior to inoculation. Steroid treated animals exhibited clinical illness, wide spread peritonitis and recovery of inoculated organisms, while non-steroid treated animals exhibited localized abscesses with inconstant recovery of organisms when sacrificed. This study suggests Rhodochrous may be pathogenic under conditions of immune compromise.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: The Effect of Radiotherapy on Regional Lung Function in Patients with Bronchogenic Cancer.

WORK UNIT NO.: C-36-77

PRINCIPAL INVESTIGATOR: Peter S. Kennedy, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Stephen Sorgen, M.D., MAJ, MC; A. Baker, M.D., LTC, MC; Charles Brearley, M.D., MAJ, MC

OBJECTIVES

1. To evaluate regional lung function in patients with localized, unresectable bronchogenic cancer by means of radionuclide lung scans, plus selected pulmonary function tests.
2. To compare regional lung function in patients before and serially after therapeutic super voltage irradiation in an attempt to correlate changes in RLF with response to treatment, respiratory symptoms, local disease control, and survival.

TECHNICAL APPROACH

Patients with unresectable bronchogenic cancer who are candidates for primary treatment by cobalt irradiation undergo Xenon-Technesium Ventilation-Perfusion lung scans and selected pulmonary function tests. These studies along with clinical evaluation and standard P.A. chest x-ray will be repeated serially. Changes in the results of these tests will be correlated with tumor response and recurrence patterns.

Personnel: None

Funding: None

PROGRESS

Six patients have been entered into the study. At this time all new radiotherapy patients are being referred for initiation to the study.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Electronic Size Measurements of Platelet Aggregates in Blood.

WORK UNIT NO.: C-37-77

PRINCIPAL INVESTIGATOR: Peter S. Kennedy, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: David R. Head, M.D., LTC, MC; Robert P. Bowman,
M.D., LTC, MC; A. O. Brossoit, SP5; Dan Marmer,
M.S., MT (ASCP)

OBJECTIVES

1. To establish a normal range of values for the size distribution of platelet aggregates formed in vitro in response to aggregating agents ADP, epinephrine and collagen.
2. To investigate the usefulness of Coulter methods in evaluating platelet function in patients who have a platelet count less than 100,000/mm³.
3. To determine the effects of selected cytotoxic agents including nitrogen mustard, Adriamycin, vincristine, actinomycin-D, vinblastine and mitomycin-C on platelet function in man as they may relate to the development of local venous thrombosis at the drug infusion site.

TECHNICAL APPROACH

Measurements of the size distribution of platelet aggregates formed in vitro in response to various aggregating agents using an electronic particle counter are determined. This represents a rapid, high resolution, quantitative whole blood assay for evaluating platelet function.

Personnel: None

<u>Funding:</u>	Consumable Supplies	Contractural Services
FY 77	\$ 216.60	\$ 2,375.00

PROGRESS

This is a new project

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of Eosinophilia in Dialysis Patients.

WORK UNIT NO.: C-42-77

PRINCIPAL INVESTIGATOR: Richard A. Stor, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Walter H. Whitman, M.D., MAJ, MC; Robert P. Bowman,
M.D., LTC, MC; Timothy McNamara, M.D., MAJ, MC;
David R. Head, M.D., LTC, MC

OBJECTIVES

To attempt to elucidate the incidence of eosinophilia in the dialysis population.

TECHNICAL APPROACH

All patients being entered on chronic hemodialysis and all patients currently on dialysis will be studied with 5 total eosinophil counts prior to initiation of dialysis where applicable, weekly total eosinophil counts for the next 6 weeks of dialysis, then biweekly total eosinophil counts for the next 6 months, and finally monthly total eosinophil counts until the study is completed. Serum IgE levels will be obtained prior to dialysis and after one and 6 months of dialysis.

Patients followed in the Renal Clinic with gradually declining or stable chronic renal failure with glomerular filtration rates of less than 20 ml/minute will also be studied with 5 total eosinophil counts and one baseline IgE level.

In patients with acute renal failure of various etiologies who require dialysis, an attempt will be made to get at least two total eosinophil counts prior to dialysis, twice weekly during dialysis and once weekly for four weeks after dialysis.

An allergy check list will be completed on all patients as will a list of all medications.

C-42-77 (Continued)

Immunoglobulin E levels will be determined by immunoelectrodifffusion.

Personnel: None.

Funding: None

PROGRESS

This is a new study.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Algorithm Directed Troop Medical Care (ADTMC) Project.

WORK UNIT NO.: C-47-77

PRINCIPAL INVESTIGATOR: Barry W. Wolcott, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: William H. Bell, MAJ, MSC; 1st Cavalry Division
Surgeon and Staff, Fort Hood, TX; Staffs of
Troop Medical Clinics 5, 7, and 8, Fort Hood, TX

OBJECTIVES

To take existing algorithm directed triage and health care delivery systems, adapt them to a combat arms troop environment, and test the hypothesis that medical treatment/return to duty of soldiers who need to be seen at military sick call can be expedited with no decrease in the quality of medical care provided.

TECHNICAL APPROACH

In Phase 1 of the project, Brooke Army Medical Center-validated triage algorithms will be modified for use in one of the two divisions at Fort Hood, Texas. Following the collection of background data on the sick call process in both the test and control divisions, an algorithm directed triage system will be implemented in the test division. The effects of this system will be measured through the use of time clocks and comparison with the previous system as it existed in the test division and as it still exists in the control division. The total sick call time will be measured using methodology modified to fit the two-division structure at Fort Hood.

Phase 2 of the project involves the use of validated acute care clinical algorithms by military physician extenders in the Troop Medical Clinics.

Phase 3 of the project involves the preparation and implementation of algorithmic protocols for periodic review and evaluation of active duty military personnel with documented chronic medical conditions (hypertension, diabetes, pseudofolliculitis barbae, etc.)

Personnel: None

Funding: None

C-46-77 (Continued)

PROGRESS

This is a new study.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: The Relationships of Vaginal and Cervical Flora in Pregnancy and Premature Rupture of Membranes.

WORK UNIT NO.: C-11-75

PRINCIPAL INVESTIGATOR: James E. Connerth, M.D., CPT, MC

ASSOCIATE INVESTIGATORS: Willie J. Lett, M.D., MAJ, MC; Warren N. Otterson, M.D., COL, MC; Rudi Ansbacher, M.D., COL, MC; Barry L. Davison, M.S., CPT, MSC

OBJECTIVES

To assess the possible degree of correlation between vaginal and cervical flora in pregnancy and premature rupture of membranes.

TECHNICAL APPROACH

Serial aerobic and anaerobic cultures (1st and 3rd trimester) of the vagina and cervix were taken on approximately 900 gravidas. Seventy patients with spontaneous rupture of membranes were also cultured (vagina and amniotic fluid if present).

Personnel: None

Funding: Consumable
Supplies

FY 77	-
FY 78	-
FY 76	\$2,200.00
FY 75	\$4,099.81

PROGRESS

Data gathering have been completed. A wide range of anaerobic and aerobic organisms were recovered. No definite correlation between microflora and spontaneous rupture of membranes was noted on initial review of the data. Further correlations await statistical analysis.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Correlation of Phenotypic Sex of Fetuses with Amniotic Fluid Testosterone Levels.

WORK UNIT NO.: C-20-75

PRINCIPAL INVESTIGATOR: William Sutherland, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Rudi Ansbacher, M.D., COL, MC; Edward D. Helton, Ph.D.; Harris D. Plant, SP4

OBJECTIVES

1. To determine whether testosterone levels in male fetuses, 16-20 weeks embryonic age, are significantly higher than those of female fetuses.
2. To determine whether the observed ranges of testosterone values will allow one to deduce phenotypic sex from the value of amniotic fluid testosterone.

TECHNICAL APPROACH

Fifty patients undergoing elective second trimester abortions at Brooke Army Medical Center over a six month period were surveyed. Amniotic fluid was obtained at the time the abortifacient was injected into the amniotic fluid. Assay for testosterone was performed utilizing a method which incorporates procedural details set forth by Armando de la Pena (laboratory method), Burton V. Caldwell (laboratory notes on radioimmunoassay of steroids) and Hillier, Bronsey and Cameron with only slight modification by Helton and Plant for use with liquor amnii. Following abortion, fetal sex will be determined anatomically by at least two physicians.

Personnel: SP4 (3 months)

Funding: Consumable
Supplies

FY 77	-
FY 78	-
FY 76	\$ 285.00
FY 75	\$ 436.79

PROGRESS

Amniotic fluid specimens were analyzed for testosterone by RIA technique described by Christian et al. In our study including 50 samples, there was no correlation between phenotypic sex and testosterone levels.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: The Decision to Obtain Voluntary Sterilization.

WORK UNIT NO. C-1-76

PRINCIPAL INVESTIGATOR: Margaret Clark

ASSOCIATE INVESTIGATORS: Rudi Ansbacher, M.D., COL, MC
Warren N. Otterson, M.D., COL, MC

OBJECTIVES

To study the determinants of choice of male versus female sterilization procedures. To evaluate postoperative satisfaction with the operation of choice in terms of these factors.

TECHNICAL APPROACH

A self-completion questionnaire has been given to individuals who come to the Department of Obstetrics and Gynecology and to the Department of Urology seeking information and counseling regarding voluntary sterilization. A follow-up questionnaire has been mailed to consenting individuals approximately six months after a sterilization procedure.

Personnel: None

Funding: None

PROGRESS

Final analysis of data is being performed.

Status: Ongoing.

Clark, M. The decision to obtain voluntary sterilization. Presented at a meeting of the American Sociological Association, September 1977.

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

INVESTIGATION PROJECT RESUME

TITLE: Spinal Cord Injuries: Sperm Antibodies.

WORK UNIT NO.: C-3-76

PRINCIPAL INVESTIGATOR: Rudi Ansbacher, M.D., COL, MC

ASSOCIATE INVESTIGATOR: Mauro P. Gangai, M.D., COL, MC

OBJECTIVES

To determine the incidence of sperm-agglutinating and sperm-immobilizing antibodies in the sera of 25 men after spinal cord injuries.

TECHNICAL APPROACH

Men hospitalized with spinal cord injuries or those seen in the Urology Clinic, BAMC, have a sexual history taken to determine the frequency of erections, seminal emissions, and sexual history prior to and subsequent to their injury. Ten milliliters of blood are drawn from each man, the serum is removed from the clotted blood by centrifugation, complement is destroyed by heating the serum for 30 minutes at 58° Celsius, and the serum samples are stored at below -25° Celsius until and between testing days.

The macroscopic gelatin sperm-agglutination and the sperm-immobilization test are utilized to determine the presence of circulating sperm antibodies, using pooled rabbit serum as the complement source and normal semen samples obtained from donors with at least 60 million spermatozoa per milliliter and motility above 70 percent as the antigen.

Results will be correlated with each man's history and compared to previously obtained data from men studied before and after bilateral vas ligations.

Personnel: None

Funding: None

C-3-76 (Continued)

PROGRESS

To date, nine men have been studied; the spinal cord injuries occurred between 4 and 26 years prior to interview. Their ages ranged from 21-52 years. None have had circulating sperm-agglutinating or sperm-immobilizing antibodies.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Review of Medical Decision Making in the Evaluation of Gynecological Complaints.

WORK UNIT NO.: C-14-77

PRINCIPAL INVESTIGATOR: Richard J. Bowers, M.D., CPT, MC

ASSOCIATE INVESTIGATORS: Rudi Ansbacher, M.D., COL, MC; Barry W. Wolcott, M.D., LTC, MC; Robert M. Young, M.D., CPT, MC; Robert P. Pumphrey, M.D., CPT, MC

OBJECTIVES

To determine which constellation of historical questions, physical findings, and laboratory tests are required for a physician to arrive at a correct diagnosis in patients with gynecologic complaints.

TECHNICAL APPROACH

The technical approach was conducted as described in the protocol. One hundred and sixteen patients participated in the study.

Personnel: None

Funding: None

PROGRESS

The histories from 116 patients who entered the BAMC Gyn Clinic were recorded on the algorithm checklist. The most common positive finding on the algorithm was related to a vaginal infection with symptoms of vaginal itching in 80% of the cases. Pelvic and abdominal pain were the next most common symptom in 33% of the cases.

C-14-77 (Continued)

The diagnosis of 51 patients could not be coded out in the algorithm because of their complaint as "desire for birth control pills", etc. The study does show that the Gyn Walk-In Clinic is filled by many non-emergency patrons.

The present algorithm should be revised with the above results in mind.

Status: Completed

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

INVESTIGATION PROJECT RESUME

TITLE: Maternal Cellular Immunity During Pregnancy.

WORK UNIT NO.: C-21-77

PRINCIPAL INVESTIGATOR: Roger L. Wallace, D.O., CPT, MC

ASSOCIATE INVESTIGATORS: Frank P. Wilson, D.O., CPT, MC; Robert P. Bowman, M.D., LTC, MC; Rudi Ansbacher, M.D., COL, MC; Russell W. Steele, M.D., LTC, MC; John Posch, M.S.; Dan Marmer, M.S.; I. Chapa

OBJECTIVES

To determine if cell mediated immunity is altered during pregnancy as determined by in vitro lymphocyte function studies. An attempt will be made to outline immune parameters in normal pregnant women.

Newborn infants will also be assessed clinically to establish if there is any relationship between maternal immune mechanisms during pregnancy and problems during early infancy.

TECHNICAL APPROACH

Patients from the OB clinic will be studied during their gestations and blood specimens will be collected once every two months during pregnancy for the appropriate studies. Lymphocyte function studies will include surface immunoglobulins, quantitative immunoglobulin, EAC rosettes, E rosettes, mitogen stimulation, mixed lymphocyte cultures. Comparisons will be made with previously published data and establish normal immune parameters.

Personnel: None

Funding: None

PROGRESS

Sixteen patients have been studied throughout their gestations. All values obtained for lymphocyte function studies have been within the previously established range of normal for non-pregnant patients.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Inhibition of Premature Labor with Terbutaline.

WORK UNIT NO.: C-39-77

PRINCIPAL INVESTIGATOR: Roger L. Wallace, D.O., CPT, MC

ASSOCIATE INVESTIGATORS: David L. Caldwell, M.D., CPT, MC; Rudi
Ansbacher, M.D., COL, MC; Warren N.
Otterson, M.D., COL, MC

OBJECTIVES

To study inhibitory effects of terbutaline on premature labor.

TECHNICAL APPROACH

Patients of less than 36 weeks gestation admitted to the Obstetric Service in premature labor will be initially treated with terbutaline. Terbutaline will be administered by an initial intravenous loading dose, followed by a subcutaneous dose for 24 hours, followed by a p.o. maintenance dose. During the p.o. maintenance one-half of the patients will receive an oral placebo and one-half of the patient will receive oral terbutaline.

Personnel: None

Funding: None

PROGRESS

Thirty patients with otherwise uncomplicated pregnancies and seven patients with multiple gestations and diagnosed as being in labor prior to 36 weeks gestation have been treated with terbutaline. In 34 of the 37 patients uterine activity was initially arrested with intravenous terbutaline. The average prolongation of gestation was 2.9 weeks. 45.9% of the patients delivered within 48 hours

C-39-77 (Continued)

after the terbutaline was discontinued. The gestation was prolonged beyond 36 weeks in 37.8% of the patients. None of the patients delivered infants that subsequently died of RDS. Pediatric follow-up reveals that all the infants have developed mentally and neurologically comparable to their peers.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: A Microbiologic Comparison of Therapeutic and Disc Antibody
Activity Against Selected Enteric Bacteria.

WORK UNIT NO.: C-16-75

PRINCIPAL INVESTIGATOR: Cleste N. Guerra

ASSOCIATE INVESTIGATORS:

OBJECTIVES

1. To determine the sensitivity patterns of therapeutic antibiotics and antibiotic-impregnated discs.
2. To develop and perform antibiotic sensitivity tests designed to compare the effectiveness of both laboratory methods in relation to proper patient care.
3. To provide better laboratory indices by which physicians may more accurately assess the drug of choice in treatment of patient infections.

TECHNICAL APPROACH

A comparison of results of various antibiotics (diagnostic and therapeutic) against various enteric organisms from infected patients is performed by using the plate sensitivity method (with recorded disc concentrations) and serial tube dilutions sensitivity tests (aqueous solution of drugs equivalent to the disc concentration).

Personnel: None

Funding: Capital Equipment

FY 77	-
FY 7T	-
FY 76	\$930.00

PROGRESS

This study continues to confirm the experimental design; i.e. it offers more definitive sensitivity results and provides physicians with laboratory data of practical clinical value.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of the Oxi/Ferm System for Identification of Nonfermentative Bacteria.

WORK UNIT NO.: C-9-77

PRINCIPAL INVESTIGATOR: James W. Higbee, Ph.D., MAJ, MSC

ASSOCIATE INVESTIGATORS: Thomas R. Oberhofer, LTC, MSC; Grover V. Cunningham, DAC; Joyce W. Rowen, DAC

OBJECTIVES

1. To determine the accuracy of biochemical reactions in the compartmentalized, multiple-biochemical test system in comparison to conventional tests.
2. To determine the accuracy of identification using the Oxi/Ferm System in comparison to conventional tests.
3. To determine the extent as well as the limits which can be imposed upon the test system.

TECHNICAL APPROACH

Three hundred and seventy-five cultures used in this study were stock organisms retrieved from the collection of the Special Bacteriology Subsection, as well as isolated recently recovered from primary cultures. The conduct of the OxiFerm tests followed the procedure described in the manufacturer's directions, with a few innovations. Conventional tests against which the Oxi/Ferm Reactions were compared included triple sugar iron agar for dextrose fermentation and H₂S production; rapid arginine broth for dihydrolase activity; potassium nitrate broth with inverted tube for N gas production; casitone broth with xylene extraction and peptone broth for indole production by NFB and fermentative bacteria; O-F special medium (phenol red indicator) with 1% dextrose and xylose for acidification tests of NFB and Andrade's base with 1% sugars for fermenters; Christensen's agar for urease; and Simmons' agar for citrate utilization. Results of tests were based on 48 hour incubation to coincide with 48 hour results in the Oxi/Ferm system. Susceptibility tests using the standardized single disc method were performed routinely.

C-9-77 (Continued)

Personnel: None

Funding: Consumable
Supplies

FY 77 \$ 207.48

FY 7T \$ 148.20

PROGRESS

With the exception of the anaerobic dextrose test, there were more positive tests in conventional media than in OxF. Tests for hydrogen sulfide, indole, nitrogen gas production, arginase activity, and urea hydrolysis showed over 96% agreement. Agreement was better than 92% for nitrite production, acid from xylose and acid from dextrose. Utilization of citrate and acid from anaerobic dextrose agreed less than 90% from the two methods. Overall agreement was 95.0% between the two systems.

Conclusions: The Oxi/Ferm system is a convenient, simple and rapid approach to the identification of NFB. Eight media representing nine, and possibly ten, biochemical tests are simultaneously tested in a matter of minutes. The inoculation and labeling procedure, to include streaking of a TSA plate, is considerably shorter than the time required to inoculate the equivalent conventional battery of tests. In addition, colonies can be picked directly from primary isolation plates and processed immediately.

The Oxi/Ferm system, even with its limitations of nine tests, and oxidase reaction, to identify the numerous organisms which possibly can be recovered, seems to offer a distinct advantage over the use of conventional methods.

Status: Completed.

Oberhofer, T.R., Rowen, J.W., Cunningham, G.F., and Higbee, J.W. Evaluation of the Oxi/Ferm Tube System with selected gram negative bacteria. *Journal of Clinical Microbiology* (In Press).

Evaluation of the Oxi/Ferm Tube System with Selected Gram Negative Bacteria. Presented at the annual meeting of the American Society for Microbiology, New Orleans, La., 8-13 May 1977.

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

INVESTIGATION PROJECT RESUME

TITLE: Diagnosis and Management of Hemostatic Changes in Cardiac
By-Pass Surgery.

WORK UNIT NO. C-17-77

PRINCIPAL INVESTIGATOR: David R. Head, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Richert E. Goyette, M.D., MAJ, MC; Robert P.
Bowman, M.D., LTC, MC; Olyn M. Walker, M.D.,
LTC, MC; Special Hematology Staff

OBJECTIVES

To determine the specific hemostatic changes occurring during cardiac
by-pass surgery.

TECHNICAL APPROACH

A battery of hemostatic tests will be performed on all scheduled cardiac
by-pass surgery patients within three days before surgery. These in-
clude: Protime (PT), activated partial thromboplastin time (APTT),
bleeding time (BT), platelet count (PC), split products (FSPs), thrombin
time (TT), fibrinogen (I), factor IX assay, factor VIII assay, reptilase
time (RT) if the TT is abnormal), platelet aggregation, and platelet
adhesivity (wright).

Coagulation results for each patient will be correlated with the
patient's clinical status and interpreted by standard techniques.
When abnormalities are delineated, appropriate corrective action will
be undertaken. Abnormalities noted will be tabulated for the entire
series and correlated with patient's age, status, operation, opera-
tion time, pump time, heparin dose, protamine dose, blood loss, blood
product replacement and unusual operative complications.

Personnel: None

Funding: None

PROGRESS

Approximately 150 patients have been studied thus far. We have docu-
mented routine postoperative thrombocytopenia and platelet dysfunction;
the platelet aggregometric method for evaluation of platelet function

C-17-77 (Continued)

with low platelet counts is now operational, and we plan to include this in future studies; it has been unavailable in the past. There is routine postoperative depression of Factor VIII, corrected by postoperative transfusion in most cases. In addition, we have discovered an unexpected selective prolongation of the protime postoperatively. Attempts to delineate the precise cause of the prolongation have been only partially successful to date. The deficiency is corrected by mixing with normal plasma. It is not corrected by mixing with Factor VII deficient plasma. However, Factor VII assays postoperatively have been within normal limits failing to explain the prolongation of the protime. Other possible causes include a selective inhibitor of Factor VII or an acquired deficiency of a previously undescribed factor.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Laser Nephelometric Assay of Factor VIII Antigen and Anti-Thrombin III (AT-III).

WORK UNIT NO.: C-25-77

PRINCIPAL INVESTIGATORS: David R. Head, M.D., LTC, MC;
Terry Sheehan, Ph.D., CPT, MSC

ASSOCIATE INVESTIGATORS: Robert P. Bowman, M.D., LTC, MC; Agnes Rohan, DAC; Brenda Harris, DAC; Madelyn Stewart, DAC; Dan Marmer, DAC; John Posch, DAC

OBJECTIVES

To establish a rapid immunologic assay of Factor VIII Antigen and AT-III using a laser nephelometer.

TECHNICAL APPROACH

When a satisfactory system is developed, AT-III will be determined in a series of normal and abnormal patients by the nephelometric procedure and by radioimmunodiffusion. Results of the two methods will be compared by linear regression analysis.

Factor VIII antigen determinations will be performed by nephelometry and by electroimmunodiffusion for a series of normal and deficient patients. Nephelometric results will be compared with EID results by linear regression analysis.

Personnel: None

Funding: Consumable
Supplies

FY 77 \$ 374.00

PROGRESS

Progress to date on these assay systems has been minimal. We are currently gaining familiarity with the instrument involved, Behring Laser Nephelometer. Attempts at establishing the Factor VIII Antigen Assay System have been unsuccessful due to nonspecific precipitation when the Factor VIII

C-25-77 (Continued)

antibody is added to normal and Von Willebrand's plasma. If this cannot be eliminated, we will be unsuccessful in developing the assay. We are currently trying to eliminate this problem by altering the buffer system, obtaining a purer antigen, and using more efficient containers (quartz cuvettes). There has been little progress in the antithrombin III assay to date, again because we are still becoming familiar with the Behring Nephelometer, and because of insufficient technical personnel to proceed with this project at this time.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Clinical Evaluation of a New Immunofluorometric Technique for Quantitating Antibodies to DNA in Human Serum.

WORK UNIT NO.: C-38-77

PRINCIPAL INVESTIGATOR: Stephen R. Speights, CPT, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the clinical value of a new Immunofluorometric Technique for the rapid quantitative assessment of antibodies to DNA in human serum as compared to a well-established radiq-labeled DNA binding assay.

TECHNICAL APPROACH

Parameters to be covered in this investigation included the following:

- a. Whether the two procedures could compliment each other in as far as both producing comparable results on frozen aliquots of known positive and negative specimens, considering two different antigen sources, namely, human cell-line DNA and bovine thymus DNA.
- b. Precision data, to include "within run" and "run to run" coefficients of variation on the immunofluorometric procedure.
- c. To follow course of therapy over several weeks on selected SLE patients' sera previously sent in for these and other assays, and subsequently saved as reference specimens.

Personnel: None

Funding: None

PROGRESS

The FIAX-DNA study has shown that the assay has several features of merit:

- 1) It is a standardized assay kit which eliminates the need for constant in-house quality control monitoring of components and the absence of radioisotopes eliminates problems involved in working with such substances.

C-38-77 (Continued)

2) The assay is quick, requiring less than two hours turnaround time compared to at least 24 hours for the Farr assay.

3) The FIAX-DNA test is highly sensitive and specific (five known SLE sera were found negative by the Farr assay and positive by the FIAX assay).

4) The assay is capable of high reproducibility as shown by "within run" coefficients of variation of 5.25% and 5.45% over two sets of data. The "run-to-run" coefficient of variation was 8.65%.

5) The FIAX-DNA qualitative assay correlates extremely well, with findings of 83% and 92% agreement, with two Farr assay methods of detecting anti-DNA antibody.

Status: Completed.

DEPARTMENT OF THE ARMY
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Fort Sam Houston, Texas 78234
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Hemoglobinopathy Testing of United States Army Inductees -
Analysis of Two Systems.

WORK UNIT NO.: C-44-77

PRINCIPAL INVESTIGATOR: David R. Head, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Robert P. Bowman, M.D., LTC, MC; R. Panke, M.D.,
MAJ, MC; Richert Goyette, M.D., MAJ, MC; V. Coley,
MAJ, MSC; Agnes Rohan, DAC; Madelyn Stewart, DAC;
Brenda Harris, DAC; John Posch, DAC; Dan Marmer,
M.S., DAC

OBJECTIVES

To analyze the cost per subject, error rate, feasibility for mass screening and rate of detection of abnormal hemoglobin variants with two screening systems, one based on a semiautomated dithionate screen for sickle hemoglobin and the second based on a Coulter S CBC and cellulose acetate hemoglobin electrophoresis.

TECHNICAL APPROACH

A pilot study will be conducted testing 5,000 student volunteers at the Academy of Health Sciences using two testing systems:

- a. Semiautomated dithionate testing, with confirmation of abnormal results by cellulose acetate hemoglobin electrophoresis.
- b. Coulter S CBC with reticulocyte count and cellulose acetate hemoglobin electrophoresis with densitometric A_2 quantitation, alkali denaturation hemoglobin F determine, and clarification of borderline A_2 values by column chromatography. Abnormal results will be investigated and confirmed by standard laboratory methods.

Personnel: None

Funding: None

PROGRESS

This is a new study.

Status: Ongoing

DEPARTMENT OF THE ARMY
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Fort Sam Houston, Texas 78234
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: a. Compilation of Atlas of Electron Micrographs of Known Viruses.
b. Electron Microscopic Examination of Selected Viral Cultures
for Detection of Mixed Viral Infections.

WORK UNIT NO.: C-45-77

PRINCIPAL INVESTIGATOR: George J. Kasai, Ph.D.

ASSOCIATE INVESTIGATORS: Dermott Acton, SFC; Alan Weckerling, DAC;
Steven K. Koester, DAC; Lucy Olalde, DAC

OBJECTIVES

- a. An atlas of the ultrastructural characteristics of known viral agents in tissue culture, confirmed by antibody neutralization, will be compiled. The cellular location and ultrastructural characteristics of each identified virus will be noted, and electron micrographs of representative forms will be prepared of each virus.
- b. The recognition of mixed viral infections by ultrastructural detection of more than one viral agent, and identification of the agents involved by their ultrastructure, will be attempted on unknown viral cultures that are not identifiable by present laboratory methods. Since this will be done on all ambiguous viral cultures during the period of the study, an estimate of the incidence of dual viral infections will be possible.

TECHNICAL APPROACH

- a. Patient specimens submitted for viral culture and identification will be processed by standard methods employed in the Virology Laboratory. When specific viruses are detected by neutralization of CPE, hemagglutination, or blocking virus, the cultures will be studied ultrastructurally by standard electron microscopic techniques. A general atlas of electron micrographs of viral agents in tissue culture will be accumulated.
- b. All cultures with ambiguous neutralization results will be studied by electron microscopy for the detection of viral particles. If viral particles are identified, the number of virus types present will be determined, and appropriate neutralization studies will be undertaken, as directed by their ultrastructures, to attempt to identify the viruses.

C-45-77 (Continued)

Personnel: None

Funding: None

PROGRESS

This is a new project.

Status: Ongoing.

DEPARTMENT OF THE ARMY
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CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of Cellular Immunity to the Varicella-Zoster Virus
Employing a Newly Developed Microassay Technique.

WORK UNIT NO.: C-14-74

PRINCIPAL INVESTIGATOR: Russell W. Steele, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Luis Canales, M.D., COL., MC; I.Chapa, DAC

OBJECTIVES

To examine the applicability of a newly developed microassay technique which measures cellular immunity specific to the Varicella-Zoster virus.

TECHNICAL APPROACH

Assays of Varicella-Zoster induced lymphocyte blastogenesis were accomplished with methods similar to those employed for a one way mixed lymphocyte culture. Stimulating cells include tissue culture cells persistently infected with Varicella-Zoster virus and uninfected culture cells. Counts per minute for lymphocytes incubated with the infected cells divided by counts per minute following incubation with uninfected cells determined the blastogenic index and a value of 3 or greater is considered positive in most assays. This assay has been extended to include other infectious agents including herpes virus, cytomegalic virus, influenza virus, and Sporothrix schenckii.

Personnel: 1 GS-7 (15 months)

<u>Funding:</u>	Consumable Supplies	Capital Equipment
FY 77	\$3,654.13	-
FY 7T	\$ 506.75	-
FY 76	\$2,617.10	-
FY 75	\$1,112.50	\$ 695.00
FY 74	\$ 165.00	-

C-14-74 (Continued)

PROGRESS

During the first year of this study, FY 1974, efforts were directed toward standardizing the assay and methods. A paper describing these procedures was subsequently published in the Journal of Infectious Diseases 131:528-534, 1975.

Techniques learned in this study were applied to developing blastogenic assays with various antigens. These have included sporothrix schoenkii, herpes simplex type 1, herpes simplex type 2, cytomegalovirus, and coccidiomycosis. These assays were then used to examine various aspects of disease processes.

During FY 1977, efforts have been concentrated on examining the ontogenesis of varicella-zoster infection in both the normal and compromised host. This assay was also employed to examine cell immune responses to varicella-zoster virus during treatment with adenine arabinoside.

Status: Ongoing.

Steele, R.W., Suttle, D.E., LeMaster, P.C., Patterson, F.D., and Canales, L. Screening for cell-mediated immunity in children. Amer J Dis Child 130:1218, 1976.

Eichberg, J.W., Steele, R.W., Kalter, S.S., et al. Cellular immunity in gnotobiotic primates induced by transfer factor. Cell Immunol 26:114-119. 1976.

Eichberg, J.W., Heberling, R.L., Steele, R.W., et al. Transfer factor to prevent herpes virus infection. Fed Proc (in press).

Steele, R.W. and Canales, L. Transfer factor for the prevention of varicella-zoster infection in childhood leukemia. Pediat Res 11: 506, 1977.

Plasma Infusion Correction of Opsonization for Pneumococcal Meningitis. Presented at the Pediatric Society Meeting, San Francisco, Calif., 25-30 Apr 77.

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

INVESTIGATION PROJECT RESUME

TITLE: Cellular Immunity to Herpesvirus Hominis in the Compromised Host.

WORK UNIT NO.: C-15-74

PRINCIPAL INVESTIGATOR: Russell W. Steele, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Luis Canales, M.D., COL, MC; I. Chapa, DAC

OBJECTIVES

To develop specific and reliable in vitro assays of both the afferent and efferent mechanisms of cellular immunity to Herpesvirus Hominis (HVH) and to examine response of patients with malignant disease or of patients on immunosuppressive therapy.

TECHNICAL APPROACH

A ⁵¹Cr lymphocytotoxicity microassay to cell lines persistently infected with HSV-1, HSV-2 or V-Z is being used in the study. Briefly, this technique examines lymphocyte-target cell interaction employing the infected cell lines as target cells. The quantitative release of ⁵¹Cr from the target cells is used as an index of lymphocyte mediated reactivity against the infected cells. Uninfected tissue cultures serve as controls to quantitate ⁵¹Cr release not attributed to virus itself. Specific immune release of 8% or greater is considered positive in these assays.

Personnel: 1 GS-7 (15 months)

<u>Funding:</u>	Consumable Supplies
FY 77	\$3,855.67
FY 77	\$1,176.80
FY 76	\$2,141.50
FY 75	\$ 504.00
FY 74	\$1,206.78

PROGRESS

Following initial efforts to standardize this assay of cytotoxicity to herpes group virus infected cell lines, the assay was employed in the clinical setting to investigate various aspects of medial disease. Patients with primary immune deficiency, malignancy and herpes virus infection, subacute sclerosing panencephalitis, and experimental primate animals infected with herpes virus were investigated. Two areas of greatest interest concern changes in this assay during treatment with adenine arabinoside and examination of transfer factor to prevent herpes virus infection in non-human primates. This assay was used to monitor methods of immunotherapy and disease progress and treatment.

Status: Ongoing.

Steele, R.W., Keeney, R.E., Brown, J., III and Young, E.J. Cellular immune responses to herpes group viruses during treatment with adenine arabinoside. *J Infect Dis*, Apr 1977.

Steele, R.W., et al. Prevention of herpex simplex virus type 1 fatal dissemination in primates with human transfer factor. In Transfer Factor, Basic Properties and Clinical Applications (ed. Ascher, M.S., Gottlieb, A.A. and Kirkpatrick, C.H.) Academic Press, New York, 1976.

Steele, R.W., Suttle, D.E., LeMaster, P.C. et al. Screening for cell-mediated immunity in children. *Amer J Dis Child* 130:1218-1221, 1976

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

INVESTIGATION PROJECT RESUME

TITLE: The Preparation and Purification of Dialyzable Transfer Factor
for the Treatment of Selected Infectious Diseases.

WORK UNIT NO.: C-42-74

PRINCIPAL INVESTIGATOR: Russell W. Steele, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Luis Canales, M.D., COL, MC; I. Chapa, DAC

OBJECTIVES

To evaluate the efficacy of transfer factor therapy for disseminated fungal or viral disease or tuberculosis unresponsive to the usual forms of therapy.

TECHNICAL APPROACH

Dialyzable transfer factor (TF_d) was prepared and purified from donors by the methods of Lawrence and Al-Askari. In most cases, leukocytes have been obtained by leukapheresis using a continuous-flow celltrifuge, (American Instrument Co.). Lymphocytes are separated from the cell pack using a Hypaque-Ficoll gradient, freeze thawed in the presence of DNase 10 times and TF was then dialyzed and concentrated by lyophilization. All recipients of human transfer factor are first tested for skin test and blastogenic responses to the antigens under investigation at which time, transfer factor is injected subcutaneously in the dose equivalent to 1×10^9 lymphocytes. Three days after injection skin tests are usually repeated and blood is again drawn for in vitro study.

Personnel: 1 GS-7 (15 months)

Funding: Consumable
Supplies

FY 77	\$3,141.45
FY 7T	\$ 452.50
FY 76	\$2,818.30
FY 75	\$1,331.00
FY 74	\$1,092.41

PROGRESS

During FY 1977, patients with disseminated coccidioidomycosis and primary immune deficiency have been treated. Results of such treatments appear in publications listed below. In addition, experimental animals infected with herpes simplex virus have been treated with transfer factor. Prevention of overwhelming infection with this virus has been achieved in this animal model. One patient with Shilder's disease is currently on transfer factor therapy, but no therapeutic benefit has been recognised to date.

Status: Ongoing.

Steele, R.W., Sieger, B.E., McNitt, T.R., et al. Therapy for disseminated coccidioidomycosis with transfer factor from a related donor. *Amer J Med* 61:283-286, 1976.

Steele, R.W., Eichberg, J.W., Heberling, R.L., et al. In vivo transfer of cellular immunity to primates with transfer factor prepared from human or primate leucocytes. *Cell Immunol* 22:110-120, 1976.

Steele, R.W., Britton, H.A., Anderson, C.T., and Kniker, W.T. Severe combined immunodeficiency with cartilage-hair hypoplasia: in vivo response to thymosin and attempted reconstitution. *Pediat Res* 10:555, 1976.

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

INVESTIGATION PROJECT RESUME

TITLE: A Comparison of Immunologic Parameters in Three Nonhuman Primates.

WORK UNIT NO.: C-19-75

PRINCIPAL INVESTIGATOR: Russell W. Steele, M.D., LTC, MC

ASSOCIATE INVESTIGATOR: I. Chapa, DAC

OBJECTIVES

To undertake a detailed analysis of host herpes virus interaction in nonhuman primates in an effort to find factors in each of three species of nonhuman primates which are most critical to defense against infections and oncogenic agents.

TECHNICAL APPROACH

Present studies have evaluated three primate species (baboons, cebus monkeys and marmosets) with various parameters of phagocytic, humoral and cell-mediated immune responses. Such assays have included cytotoxicity, lymphocyte blastogenesis, and lymphokine production as parameters of cellular immunity; chemotaxis, phagocytosis, bactericidal capacity of neutrophils, and antibody production to various antigens. In vivo responses of skin graft rejection, skin test reactivity and response to thymosin, transfer factor, and thymus transplants have been investigated.

Personnel: 1 GS-7 (15 months)

<u>Funding:</u>	Consumable Supplies
FY 77	\$ 890.28
FY 7T	\$ 302.05
FY 76	\$1,215.87
FY 75	\$2,750.11

C-19-75 (Continued)

Some very basic aspects of cell immune function in non-human primates have been investigated. The parameters have included mixed lymphocyte reactivity, skin graft rejection, quantitation of T and B cells using E and EAC rosettes, the effect of thymosin on in vitro assays of cellular immunity and finally responses of non-human primates to human and primate transfer factor. Much of this work has been published during FY 77 and ongoing efforts are currently examining the usefulness of transfer factor or immune RNA to prevent herpes simiri induced leukemia in marmosette monkeys.

Status: Ongoing.

Eichberg, J.W., Steele, R.W., Kalter S.S., et al. Cellular immunity in gnotobiotic primates induced by transfer factor. *Cell Immunol* 26:114-119, 1977.

Steele, R.W., Eichberg, J.W., Heberling, R.L., et al. Mixed lymphocyte reactivity and skin graft rejection in nonhuman primates. *J Med Primatol* 1976.

Eichberg, J.W., Steele, R.W., et al. Chemotaxis and phagocytosis in nonhuman primates. Submitted for publication.

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

INVESTIGATION PROJECT RESUME

TITLE: The Use of Growth Hormones in Hypopituitary Patients.

WORK UNIT NO.: C-12-76

PRINCIPAL INVESTIGATOR: Adrienne B. Butler, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Luis Canales, M.D., COL, MC; Stephen R. Stephenson, M.D., CPT, MC

OBJECTIVES

To investigate the growth response in hypopituitary patients to commercially available human growth hormone.

TECHNICAL APPROACH

Human growth hormone (CB 311) has been administered (2 units 3 times weekly, IM) for 16 months to a 13 year 10 month white female who is 8 years postresection of craniopharyngioma.

Personnel: None.

Funding: Consumable
Supplies

FY 77	-
FY 7T	-
FY 76	\$1,600.00

PROGRESS

The patient has grown 4½ inches since institution of therapy, having had essentially no growth during the previous two years. She has had some redistribution of fat, with resultant maturing of her appearance although there are no secondary sex characteristics developing. The present plan is to continue the patient on therapy until antibodies develop and growth ceases (present height is 52") and then to proceed to feminize her with exogenous estrogen and progesterone.

CB 311 is now FDA approved and is marked under the trade name Asellacrin.

Status: Completed.

DEPARTMENT OF THE ARMY
Brooke Army Medical Center
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CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Red Cell Affinity in Newborn Rabbits After Acute and Chronic Intrauterine Hypoxia.

WORK UNIT NO.: C-13-77

PRINCIPAL INVESTIGATOR: Werner N. Keidel, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Robert P. Bowman, M.D., LTC, MC; John Posch, DAC

OBJECTIVES

To determine the clinical and chemical correlates of experimental intrauterine hypoxia on the red cell 2,3 DPG levels in newborn rabbits.

TECHNICAL APPROACH

Pregnant New Zealand white rabbits are placed in a high altitude chamber and the atmospheric pressure slowly lowered over 48 hours to 470 mm Hg. The rabbits are maintained at this pressure for 7 to 10 days or until term. The animals are then removed and the fetal rabbits delivered via cesarean section under pentobarbital anesthesia. Blood is collected from the umbilical vessels and/or the thoracic aorta for hemoglobin, hematocrit, red cell 2,3 DPG and intraerythrocytic pH.

Personnel: None

Funding: Consumable
Supplies

FY 77 \$2,101.00

PROGRESS

Current funding has been consumed developing the animal model. 15-20% of the does were not pregnant because of the single exposure to the buck. Other does aborted after being moved from the breeder to the ISR animal facility. If the atmospheric pressure in the hypobaric chamber is acutely dropped to 470 mm Hg, the does usually abort. The rabbit does require administration of oxygen and IV fluids

C-13-77 (Continued)

during the operation if hypertension and shock are to be avoided. The surgery must be carried out expeditiously if the animal preparation is to remain stable and the fetuses in good condition. Studies to date have shown that the adult rabbit has a red cell 2,3 DPG at 8.82 mm/gm Hgb (N=8). The term fetus has a concentration of 2.23 mm (N=9) while the premature fetus of 24-26 days gestation has a level of 1.27 mm/gm Hgb (N=8). Normal hematologic indices have been determined for the fetal rabbits.

Status: Ongoing.

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Brooke Army Medical Center
Fort Sam Houston, Texas 78234
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: The Influence of Intrauterine Hypoxia on Neonatal Red Cell pH,
2,3 DPG and P₅₀.

WORK UNIT NO.: C-18-77

PRINCIPAL INVESTIGATOR: Werner N. Keidel, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Robert P. Bowman, M.D., LTC, MC;
Melvin Baden, M.D., COL, MC

OBJECTIVES

To determine if intrauterine hypoxia decreased neonatal red blood cell affinity for oxygen thus improving oxygen delivery to the tissues.

TECHNICAL APPROACH

Cord blood is collected at delivery for measurement of hemoglobin, hematocrit, blood gases, red cell 2,3 DPG and intraerythrocytic pH. Blood is also collected for determination of fetal hemoglobin concentration. The effective 2,3 DPG fraction is calculated by the equation:

$$\text{DPG} \times (\text{HgbA} \% + 0.4 \times \text{HgbF} \%)$$

Personnel: None

Funding: None

PROGRESS

Analysis of three different methods for determining fetal hemoglobin concentration were carried out and compared with results from column separation. The method of Chaplin et al. was most accurate for the concentration of HgbF usually found in the premature and term infant. Since the start of the study, the number of infants delivered with intra-uterine growth retardation has been quite small so that no statement can be made regarding the effects of intra-uterine hypoxia on erythrocyte 2,3 DPG.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Urinary LDH Activity and Isoenzyme Patterns in Normal, Premature,
and Term Infants.

WORK UNIT NO.: C-20-77

PRINCIPAL INVESTIGATOR: Werner N. Keidel, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: William A. Rouse, M.D., MAJ, MC

OBJECTIVES

To develop normal values for urinary lactic dehydrogenase activity and isoenzyme patterns in the premature and term infant.

TECHNICAL APPROACH

Urine is collected in Hollister urine bags on newborns during their 3 day hospitalization. An aliquot of urine is analyzed for LDH activity on a DuPont ACA Autoanalyzer and the remainder is sent to the Chemistry Section of the Dept. of Pathology for determination of the LDH isoenzyme pattern using Beckman LDH Isoenzyme kits. Part of the urine is sent for a routine urinalysis.

Personnel: None

Funding: None

PROGRESS

Forty urinary LDH assays have been determined on 27 infants. The average urinary LDH activity was 66.20 with a range of 14-370. Because of the low urinary LDH activity, it has been difficult to visualize the isoenzyme patterns on electrophoresis without first concentrating the urine.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Effects of Asphyxia on Intestinal Enzymes in Newborn Rats.

WORK UNIT NO.: C-24-77

PRINCIPAL INVESTIGATOR: Werner N. Keidel, M.D., LTC, MC

ASSOCIATE INVESTIGATORS Elliott Weser, M.D., UTSA; William B. Winborn,
UTSA

OBJECTIVES

To study the effects of asphyxia on intestinal disaccharidase activity in the newborn rat model of necrotizing enterocolitis.

TECHNICAL APPROACH

Newborn rat pups will be asphyxiated by daily enclosure in an air-tight plastic bag until they are limp, cyanotic and gasping (usually 3-5 minutes). The rat pups will be resuscitated and returned to their cages. Split litters of rat pups will be inoculated with *Klebsiella* by administering a saline suspension of bacteria. After daily asphyxia the pups will be sacrificed sequentially. The bowel will be weighed and disaccharidase activity will be measured in the duodenum, jejunum and ileum. The succus entericus will be analyzed in each segment for pH, K^+ , reducing substances and bacterial counts.

Personnel: None

Funding: None

PROGRESS

Preliminary studies using the rat model were unsuccessful. After a suitable animal model is determined, the study will be reinstated.

Status: Ongoing.

DEPARTMENT OF THE ARMY
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Fort Sam Houston, Texas 78234
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: The Use of Algorithms in the Triage of Patients in an Ambulatory Pediatric Setting.

WORK UNIT NO.: C-30-77

PRINCIPAL INVESTIGATOR: Adrienne B. Butler, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Linda Ornelas, M.D., CPT, MC; Frank P. Wilson, M.D., CPT, MC; Ana Ortiz, M.D., MAJ, MC; Luis Canales, M.D., COL, MC; Barry Wolcott, M.D., LTC, MC

OBJECTIVES

To develop and validate algorithms which can be used by paramedical personnel to triage patients in a large volume, primary care, pediatric facility.

TECHNICAL APPROACH

During the months of February and March 1977 a total of 2,028 patients were screened using triage algorithms written for the 20 chief complaints seen most frequently in the Pediatric Clinic. Triage was performed by an AMOSIST loaned from the BAMC Emergency Room with no specific pediatric training.

Following triage, the patient was seen in the usual manner by a pediatrician who was unaware of the triage disposition. The physician completed his examination, made disposition of the patient, and recorded his impression of the role he was playing in caring for the patient.

Personnel: None

Funding: None

PROGRESS

A high level of correlation with no instance of compromise of patient care by use of the algorithm was found.

C-30-77 (Continued)

Carefully written and validated algorithms, implemented by paramedics and supervised by pediatricians, can provide an acceptable alternative to either physician or nurse directed triage, freeing professionals to deliver care to those patients who most urgently need it.

Conclusions: 1. The triage algorithms are safe and accurate;

2. Since three-quarters of all patients have an acute minor illness, establishment of a PAMIC is a desirable and justifiable goal;

3. The efficiency of the system can be augmented by utilizing additional algorithms.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: A Pilot Study to Investigate in vitro and in a Guinea Pig Model the Synergistic and Antagonistic Relationship between E. Coli and P. Aeruginosa as the Pathophysiologic Basis of Acute Necrotizing Fasciitis and Myositis.

WORK UNIT NO.: C-31-77

PRINCIPAL INVESTIGATOR: Lewis F. Gold, M.D., CPT, MC

ASSOCIATE INVESTIGATORS: Russell W. Steele, M.D., LTC, MC

OBJECTIVES

1. To demonstrate in a guinea pig model the synergistic relationship between E. coli and P. aeruginosa as the pathophysiologic basis of acute necrotizing fasciitis and myositis.
2. To demonstrate in vitro and in a guinea pig model the antagonistic relationship between E. coli and P. aeruginosa manifested by the inability to recover multiple synergistic organisms utilizing routine bacteriologic techniques due to the variable concentrations of organisms resulting from differential growth rates.

TECHNICAL APPROACH

Stock cultures of Non-K-1 antigen E. coli and P. aeruginosa with known sensitivity patterns were utilized in all phases of the investigations. All cultures were inoculated on standardized McConkey's and blood agar with plates from the laboratory stock. Trypticase Soy Broth was prepared according to the manufacturer's recommendations, sterilized in 50 cc aliquots and passed through a falcon millipore filter.

Nine 450-480 gram outbred male guinea pigs were separated into three equal groups. All animals were inoculated in the same manner. The abdomen was shaved and under aseptic conditions three 0.5 cm. incisions were made through the skin. The incisions were spaced evenly over the abdomen and designated as cephalad, middle and caudad. All animals were inoculated subcutaneously along the margin of the incision with 0.1 cc E. coli (cephalad), 0.1 cc E. coli plus 0.1 cc P. aeruginosa (middle), and 0.1 cc P. aeruginosa (caudad).

Blood cultures were obtained on two animals from each group on days 1, 2, 3, 5, 7 and 9. The one remaining animal from each group was observed, without being cultured, for one month from the time of

C-31-77 (Continued)

inoculation and then sacrificed and cultured. With the evidence of abscess formation in all animals on day 3 post-inoculation, intramuscular antibiotic therapy was started. Group 1 received no therapy; group 2 received gentamicin sulfate approximately two times the MIC for E. coli but less than MIC for P. aeruginosa; group 3 received oxytetracycline at a dose greater than two times the MIC for either organism. Swab cultures of the abscesses were obtained every other day and plated on blood and McConkey's agar. The muscle beneath the abscess, lungs and liver of two animals from each group were cultured at the time of death or on day nine.

Personnel: None

Funding: Consumable
Supplies

FY 77 \$ 181.68

PROGRESS

Blood cultures were negative throughout the testing period on all animals. The areas cephalad and caudad corresponding to the pure inoculations of E. coli and P. aeruginosa, respectively, showed induration at 24 hours with complete resolution at 48 hours. No abscess formation was evident in either site on any of the animals. At postmortem examination, these sites were grossly free of infection and cultures revealed no E. coli or P. aeruginosa present. All animals developed an abscess in the middle inoculation site. Necrotizing fasciitis was not produced in any of the guinea pigs in the study.

Despite the inability to produce a necrotizing fasciitis, the existence of synergism between E. coli and P. aeruginosa was demonstrated in that only the combined inoculum produced an abscess. The cultures from group 1 indicate that the heavy growth of E. coli suppressed the growth of P. aeruginosa. This point was further supported by results in group 2 which indicate that only P. aeruginosa was recovered after the initiation of antimicrobial therapy selective against E. coli. Thus we conclude that the presence of the rapidly growing E. coli antagonizes the growth of P. aeruginosa. In group 3, treated with broad spectrum antimicrobial therapy, there was sterilization of the abscessed area by day five. This was confirmed at postmortem examination when the involved underlying muscle revealed no E. coli or P. aeruginosa.

We have shown that (1) we could not produce necrotizing fasciitis in the guinea pig model, (2) E. coli and P. aeruginosa work synergistically in the production of a subcutaneous abscess, (3) routine bacteriologic techniques may fail to identify all members of a synergistic

C-31-77 (Continued)

bacterial population due to an antagonism of one organism on the other, and (4) an abscess produced by a synergistic bacterial population can be rendered sterile if broad spectrum antimicrobial therapy is employed.

Status: Completed.

DEPARTMENT OF THE ARMY
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CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of Gallium-67 as a Scanning Agent for Malignant Neoplasms.

WORK UNIT NO.: C-141-72

PRINCIPAL INVESTIGATOR: Alton W. Baker, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To study the value of Gallium-67 as a tumor localizing agent in a variety of malignant neoplasms.

TECHNICAL APPROACH

Total body images are obtained at 24, 48 and 72 hours following intravenous administration of Gallium-67-Citrate in an attempt to demonstrate radionuclide location in malignant tumors. Cleansing enemas are commonly utilized to diminish the activity due to excretion of the radiopharmaceutical in the bowel.

Personnel: None

Funding: None

PROGRESS

We have utilized two Gallium studies with Gallium-67-Citrate obtained from Medi-Physics and looking for malignant lesions and/or inflammatory conditions. We have had good success with this agent and have found no difference between the Gallium-67-Citrate received from Medi-Physics and that of Gallium-67-Citrate received from New England Nuclear.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Clinical Evaluation of Cisternography Utilizing ¹¹¹Indium DTPA.

WORK UNIT NO.: C-35-74

PRINCIPAL INVESTIGATOR: Alton W. Baker, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate the safety and efficacy of ¹¹¹Indium DTPA for cisternography.

TECHNICAL APPROACH

Patients are considered for this investigation project when they are referred for cisternography study by the Neurology or Neurosurgery Services. ¹¹¹Indium DTPA is administered intrathecally by standard lumbar puncture. Progress of the radiopharmaceutical through the subarachnoid space into the basal cisterns is monitored via whole body scan. High resolution views of the cerebral cisterns is then accomplished at varying time intervals over a 3-4 day period. When evaluating the CSF rhinorrhea, the nose is packed to measure radioactive leakage during the study.

Personnel: None

Funding: None

PROGRESS

Twenty-five studies on patients utilizing ¹¹¹Indium DTPA to evaluate them for low pressure or non-obstructive hydrocephalus have been performed with good results.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: NEN Gallium-67 Citrate for Intravenous Administration.

WORK UNIT NO.: C-35-75

PRINCIPAL INVESTIGATOR: Alton W. Baker, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate clinically the NEN brand of Gallium-67 Citrate.

TECHNICAL APPROACH

Total body images are obtained at 24, 48 and 72 hours following intravenous administration of Gallium-67 Citrate in an attempt to demonstrate radionuclide localization in malignant tumors. Cleansing enemas are commonly utilized to diminish the activity due to excretion of the radiopharmaceutical in the bowel.

Personnel: None

Funding: None

PROGRESS

Thirty-one studies utilizing Gallium-67 Citrate obtained from New England Nuclear for investigation of neoplasms and/or inflammatory conditions have shown no significant difference between the Gallium-67 Citrate from New England Nuclear than that from Medi-Physics. This agent has proved to be of effective use in localizing inflammatory conditions and/or neoplasms.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: NEN ^{99m}Tc Stannous Glucoheptonate for Intravenous Administration.

WORK UNIT NO.: C-6-76

PRINCIPAL INVESTIGATOR: Alton W. Baker, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Broad clinical evaluation of the NEN Stannous Glucoheptonate Kit after reconstitution with ^{99m}Tc-sodium pertechnetate as a diagnostic agent for studying the kidney.

TECHNICAL APPROACH

This radiopharmaceutical will be administered intravenously for evaluating renal function and structure. Scintillation camera will be used for imaging the dynamic transit of this material into and out of the renal structures. Computer analysis will be applied for obtaining time activity histogram curves and other quantitative analysis of renal function.

Personnel: None

Funding: None

PROGRESS

Utilizing ^{99m}Tc-Stannous Glucoheptonate, 15 studies were performed on patients with satisfactory results in localizing the kidneys.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: MPI ^{99m}Tc-dimercaptosuccinic Acid for Intravenous Administration.

WORK UNIT NO.: C-14-76

PRINCIPAL INVESTIGATOR: Alton W. Baker, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Broad clinical evaluation (Phase III) of MPI kidney scintigraphin reagent after reconstitution with ^{99m}Tc-sodium pertechnetate as a diagnostic agent for studying the kidney.

TECHNICAL APPROACH

Up to 5 millicuries of ^{99m}Tc-dimercaptosuccinic acid will be administered intravenously for high resolution kidney imaging studies. A scintillation camera with high resolution collimator or pin-hole will be utilized for optimal resolving capability. Computer analysis of the imaging data will be performed when indicated by the clinical situation.

Personnel: None

Funding: None

PROGRESS

Ten studies on patients have been performed utilizing ^{99m}Tc-dimercaptosuccinic acid for localizing the kidneys as well as to evaluate renal function in burn patients.

Status: Ongoing.

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BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON TEX
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DEPARTMENT OF THE ARMY
Brooke Army Medical Center
Fort Sam Houston, Texas 78234
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Intravenous Administration of ¹³¹I-6-B-Indomethylnorcholesterol
(NP-59) for Adrenal Evaluation and Imaging.

WORK UNIT NO.: C-12-77

PRINCIPAL INVESTIGATOR: Alton W. Baker, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

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

After the IV administration of approximately 1 to 2 millicuries of I-131 labeled 6-B-Iodomethylnorcholesterol (NP-59) over a 2 to 5 minute time interval, the patient is returned in approximately 4 to 6 days for an initial scan of the body. A subsequent scan is performed at approximately 6 to 8 days and depending upon the magnitude of uptake in the adrenal glands, scanning is carried from the 8th to 10th day. At this time, when clinical judgment indicates that the scan appears to be adequate for evaluating whether the adrenals are within normal limits or abnormal, a subsequent renal scanning agent is injected IV (Tc Glucoheptonate or TC DTPA) for visualizing kidneys and noted the relationships of the kidneys to the adrenal glands.

Personnel: None

Funding: None

PROGRESS

Five scans utilizing NP-59 for adrenal evaluation have been performed. No adverse reactions have occurred. The accuracy of this agent for scanning the adrenals is encouraging.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Diastolic Augmentation Using an Intra-Aortic Balloon Pump.

WORK UNIT NO.: C-6-72

PRINCIPAL INVESTIGATOR: Robert L. Treasure, M.D., COL. MC

ASSOCIATE INVESTIGATORS: Olyn M. Walker, M.D., LTC, MC; George M. McGranahan, M.D., COL, MC

OBJECTIVES

Evaluation of an intra-aortic balloon pump providing diastolic augmentation increasing cardiac output in patients with low cardiac output due to myocardial infarction, severe cardiac disease, or following open heart surgery.

TECHNICAL APPROACH

We continue to utilize the intra-aortic balloon, primarily as an assist device in treating patients with low output syndrome following complicated open heart surgery.

Personnel: None

Funding: None

PROGRESS

The effectiveness of this device has been demonstrated, and the current mortality rate in patients in whom this device is necessary is at a very acceptable level.

Status: Ongoing.

A Five-Year Experience with the Intra-aortic Balloon Pump at Brooke Army Medical Center. Presented at the Current Trends in Cardiovascular Disease Symposium, William Beaumont Army Medical Center, El Paso, Texas, 17 May 1977.

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

INVESTIGATION PROJECT RESUME

TITLE: Biodegradable Cuffs, an Adjunct to Peripheral Nerve Repair in Dogs.

WORK UNIT NO.: C-23-75

PRINCIPAL INVESTIGATOR: Robert L. Reid, M.D., COL, MC

ASSOCIATE INVESTIGATORS: Stephen C. Boone, M.D., LTC, MC; Duane E. Cutright, D.D., COL, DC, WRAIR

OBJECTIVES

To determine the efficacy of biodegradable cuffs at the sutured site of sectioned peripheral nerves.

TECHNICAL APPROACH

Ten adult mongrel dogs were used in the study. The ulnar nerves in the forelimb and peroneal nerves in the hindlimbs were surgically exposed, transected, and repaired with 9-0 nylon epineural sutures using magnification. One side was repaired in the standard fashion and used as a control. The other side was repaired in the same fashion but in addition the anastomotic site was covered with a standard copolymer cuff whose cross-section diameter was $2\frac{1}{2}$ times that of the repaired nerve. Nerve conduction and electromyographs were conducted on all limbs at monthly intervals and at time of sacrifice. After the anastomotic site was resected, light and electromicroscopic studies were performed at Walter Reed Army Institute to determine the amount of local invasiveness of scar tissue and/or reaction in the nerve to the copolymer biodegradation.

Personnel: None

<u>Funding</u>	<u>Consumable Supplies</u>
FY 77	-
FY 76	-
FY 75	\$1,630.18

C-23-75 (Continued)

PROGRESS

All studies have been completed, and the data is currently being statistically analyzed.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: The Ocular Flora of the Burned Patient.

WORK UNIT NO.: C-32-75

PRINCIPAL INVESTIGATOR: Clarence G. Pramhus, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Thomas E. Runyan, M.D., LTC, MC
Robert B. Lindberg, Ph.D.

OBJECTIVES

1. To establish the incidence of individual micro-organisms in the conjunctival flora of the acutely burned patient.
2. To see if and how these flora are altered during treatment and convalescence and particularly during changes in the lid-conjunctival-corneal anatomical relationship.
3. To compare the flora recovered from the conjunctiva with those recovered from other sources (skin, IV sites, blood, surrounding environment).
4. To study the incidence of ocular complications resulting either directly from the burn itself or from secondary changes occurring during treatment and convalescence.
5. To look at the effectiveness of various prophylactic modalities of treatment (topical Lacrilube Ophth Oint; topical or local antibiotics and/or steroids; lid, conjunctival, and/or corneal surgery; bandage soft contact lenses).
6. To assess the efficacy of various therapeutic measures once these complications have occurred (bandage soft lenses with and without antibiotics, tarsorrhaphies, conjunctival flaps, keratoplasties).

TECHNICAL APPROACH

Fifty-three patients admitted to the USAISR over a four month period were examined by one of the investigators as soon after admission as was possible. Following ocular examination, the patients were entered into one of three major groups.

C-35-75 (Continued)

Group I consisted of 14 patients with thermal burns who had no facial or initial ocular involvement. Group II was made up of 30 patients with facial burns who had no initial ocular involvement. Group III consisted of 9 patients who had conjunctival and corneal burns in conjunction with their facial burns.

A fourth group was formed by 10 patients who developed late ocular complications. This included 8 patients who initially had no ocular problems. It also included 2 group III patients in whom corneal burns progressed to infectious corneal ulcers.

At the time of initial ophthalmological examination, a conjunctival specimen for culture and sensitivity was obtained from each eye. Bi-weekly conjunctival cultures were taken from each eye until the patient was transferred to the convalescent ward at which time weekly cultures were obtained. Concomitant cultures were routinely being taken by the ISR staff from other sites including blood, skin, respiratory tract, urine, IV sites and surrounding environment.

Patients in Group I received no ocular medication. Eight of the 30 patients in Group II were continued on neomycin-bacitracin-polymyxin B ointment four times a day. The remaining patients in this group were given either Lacri-Lube four times a day (13 patients) or no medication (9 patients). Because of the corneal epithelial defects present in Group III patients, topical broad spectrum antibiotics were immediately instituted.

Personnel: None

Funding: None

PROGRESS

One hundred and six eyes of 53 patients with severe thermal burns were studied. A dramatic shift of the normal conjunctival flora from the preponderance of S. epidermidis and corynebacterium to S. aureus and gram negative bacilli were observed. This commonly occurred on the 5th to 6th postburn day and represented colonization of the conjunctiva by bacteria recovered from other sites in the body. Despite the high incidence of Pseudomonas Aeruginosa isolates (34%) of these eyes, deleterious effects were noted in only three eyes in two patients who developed infectious corneal ulcers prior to their demise.

Status: Completed.

Pramhus, C.G., Runyan, T.E. and Lindberg, R.B.: Ocular Flora in the severely burned patient. Submitted to Annals of Ophthalmology for publication.

Runyan, T.E. and Pramhus, C.G.: The use of the hydrophillic lens in severely burned patients. Submitted to American Journal of Ophthalmology for publication.

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

INVESTIGATION PROJECT RESUME

TITLE: An Evaluation of Water Diuresis for the Prevention and Control of Recurrent Urinary Tract Infection in Women.

WORK UNIT NO.: C-34-75

PRINCIPAL INVESTIGATOR: Evelyn R. Anderson, Ph.D.

ASSOCIATE INVESTIGATORS: Mauro P. Gangai, M.D., COL, MC

OBJECTIVES

To evaluate the effect of teaching principles of fluid diuresis to females on the prevention and control of urinary tract infection.

TECHNICAL APPROACH

Nineteen patients were formally interviewed: of these, 15 were followed for a 12 month period (4 were transferred by the Army); 8 were in the control group and 7 in the experimental group. The experimental group were taught to take their specific gravity readings and record them daily along with their total fluid intake. In addition to receiving these records, the researcher made a monthly telephone contact with each patient to discuss problems, and identify any possible health problems that would contraindicate continuation in the study. The control group kept no records, but were contacted monthly for the purpose of keeping track of their urinary status.

Personnel: None

Funding: None

PROGRESS

Fifteen patients were followed for a 12 month period. The following results were obtained:

C-34-75 (Continued)

	Experimental N-7	Control N-8
Prevention (0 infection)	5	2
Control (1 infection)	0	3
Recurrence (2 or more infections)	2	3

Status: Completed

Anderson, E.R. Urinary tract infections: Increasing the nurse's role in helping the female patient with cystitis. Nursing, Apr 1977.

An Evaluation of Water Diuresis for the Prevention and Control of Urinary Tract Infection in Women. Presented to the Research Group of the Royal College of Nursing, London, England, June 1976.

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

INVESTIGATION PROJECT RESUME

TITLE: Laparoscopy Under Subarachnoid Block.

WORK UNIT NO.: C-13-76

PRINCIPAL INVESTIGATOR: Robert McPherson, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Residents and Staff, Department of Ob-Gyn

OBJECTIVES

To evaluate the effectiveness of subarachnoid block as the anesthesia of choice in laparoscopy.

TECHNICAL APPROACH

Female volunteers scheduled for laparoscopic tubal ligation under subarachnoid anesthesia will be tested at regular intervals (pre- and post-subarachnoid block to the T-6 level with pontocaine) to determine vital capacity and peak expiratory flow rates.

Pulmonary function (volumes and flow rates) will be recorded on a Donti pulmonary function analyzer during distension of the peritoneal cavity created by the usual pneumoperitoneum technique.

Personnel: None

Funding: None

PROGRESS

The principal investigator was unable to conduct this study due to a delay in the delivery of the pulmonary function analyzer. The analyzer has now arrived and the study will be conducted by a new investigator.

Status: Ongoing

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

INVESTIGATION PROJECT RESUME

TITLE: Effect of Enflurane and Halothane on Cardiovascular Function
Using Echocardiography.

WORK UNIT NO.: C-17-76

PRINCIPAL INVESTIGATOR: James E. Black, M.D., CPT, MC

ASSOCIATE INVESTIGATORS: Robert L. Watson, M.D., LTC, MC

OBJECTIVES

To assess the effects of halothane or enflurane upon the function of the cardiovascular system using a non-invasive technique.

TECHNICAL APPROACH

Three male volunteers scheduled for routine elective surgery underwent echocardiography during the induction of anesthesia with Ethrane while assessing the depth of anesthesia by determining alveolar concentrations of Ethrane utilizing a Beckman infrared analyzer.

Attempts were made at measurement of the left ventricular diameter to determine ejection fractions and cardiac output.

Personnel: None

<u>Funding:</u>	MEDCASE	Contractural Services
FY 77	-	-
FY 78	-	-
FY 76	\$1,597.75	\$7,246.00 (Cancelled)

PROGRESS

In all three patients ejection fractions were impossible to measure because induction of anesthesia caused inspiratory volume changes which made distinct ventricular diameter clarity impossible.

Status: Terminated.

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

INVESTIGATION PROJECT RESUME

TITLE: Comprehensive Rehabilitation of the Laryngectomee.
(Collaborative Study with the University of Texas at San Antonio)

WORK UNIT NO.: C-21-76

PRINCIPAL INVESTIGATOR: Sonley R. LeMay, Jr., M.D., COL, MC

ASSOCIATE INVESTIGATORS: George A. Gates, M.D.; Edmund Lauder, M.S.;
J. C. Cooper, Ph.D.

OBJECTIVES

To acquire normative data about the biological, psychological, social and employment aspects of laryngectomee rehabilitation; to demonstrate a comprehensive program of rehabilitation is more efficient than current methods; and to statistically validate the indices of successful and unsuccessful rehabilitation.

TECHNICAL APPROACH

Preoperatively, written informed patient consent is secured. Biological, biographical, psychological, social, employment and financial data are obtained. Speech data and a brief interview are recorded on videotape. Each patient is presented with standardized educational material and a criterion based test.

Postoperatively, a second auditory evaluation is made. A treatment plan is developed based on the patient's physical condition and psychological and speech evaluations. One to two hour individual and/or group speech therapy sessions are conducted weekly. Progress is assessed monthly. Three and six month follow-up evaluations are performed with respect to esophageal speech fluency and technical proficiency, psychological and social adjustment, and employment and financial status. Manometric data are again obtained at the end of six months.

Retrospective control patients undergo comparable assessment procedures as detailed in the grant proposal.

Personnel: None

Funding: None

PROGRESS

Four of seven prospective Brooke Army Medical Center patients, three males and one female, are included in the study. One patient refused participation and two others were not appropriate study group subjects.

Of the male patients, two have acquired fair to good esophageal speech, and one a minimal level of usable esophageal speech due to severe, persistent, esophageal stenosis. All three male patients have returned to preoperative positions of employment and have achieved financial and social adjustments commensurate with preoperative status. One female patient with recurrent disease requiring treatment with chemotherapy has developed no esophageal speech and has achieved a marginal social adjustment.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Effectiveness of Haloperidol Alone and in Combination with Ephedrine as a Motion Sickness Preventative.

WORK UNIT NO.: C-32-76

PRINCIPAL INVESTIGATOR: Anton J. Jirka, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Robert L. Watson, M.D., LTC, MC

OBJECTIVES

To assess by the use of the biaxial stimulation chair, the effectiveness of haloperidol alone and in combination with ephedrine in the prevention of motion sickness.

TECHNICAL APPROACH

Ten human volunteers were evaluated for the effectiveness of haloperidol, haloperidol and ephedrine in combination, ephedrine and a placebo, in preventing motion sickness produced by controlled spins in a biaxial stimulator at Brooks Aeromedical Center.

The study was randomized and double blinded with at least two weeks between spins to avoid adaptation. All subjects completed the required five spins each.

Personnel: None

Funding: None

PROGRESS

The total time of rides varied from 3 minutes to 77 minutes and a mean of 23.625 minutes. There were 3 rides which were terminated after 70 minutes due to time restriction. In the latter instances, the subjects had no indications of significant motion sickness at the time of termination. Termination of four rides was the result of frank vomiting. On two rides, individuals became drowsy to the point where they could not respond adequately to verbal stimuli.

C-32-76 (Continued)

Even though these subjects had no significant nausea, they were terminated as they were obviously incapacitated. Both prolonged drowsiness and quick recovery post-ride were frequently noted.

Preliminary statistical analysis of the data considered the total time of the rides and the time of onset of the symptoms. The only significance found was in the total time of rides between individuals and the effectiveness of ephedrine in delaying the onset of drowsiness. There were no other differences in the criteria we measured with the other drugs.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Determination of Preventive Keflin Delivered to the Site of
Total Joint Replacement.

WORK UNIT NO.: C-22-77

PRINCIPAL INVESTIGATOR: William A. McIlwain, M.D., CPT, MC

ASSOCIATE INVESTIGATORS: Neal A. Jewell, M.D.

OBJECTIVES

To determine the levels of cephalosporin delivered to the site of total joint replacement procedures: 1) To determine an exact dose/route regimen in total joint replacement; 2) to thereby devise a standardized protocol for preoperative, intraoperative and postoperative administration of preventive antibiotic in total joint replacements.

TECHNICAL APPROACH

This project involves three regimens of giving antibiotics preoperatively and intra-operatively and sampling bone, muscles, synovial fluid, and blood at time of surgery to determine the antibiotic level delivered. It is anticipated that 36 patients will be utilized in this study, 12 in each dose regimen group.

Personnel: None

Funding: None

PROGRESS

One patient has been entered into this study.

Status: Ongoing.

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

INVESTIGATION PROJECT REUME

TITLE: Human Placental Transfer of Naloxone.

WORK UNIT NO.: C-33-77

PRINCIPAL INVESTIGATOR: Barry J. Anderton, M.D., CPT, MC

ASSOCIATE INVESTIGATORS: Robert L. Watson, M.D., LTC, MC; Melvin Baden,
M.D., COL, MC; Rob G. Parrish, Ph.D., CPT, MSC,
Michael M. Lieberman, Ph.D., CPT, MSC

OBJECTIVES

To assess the degree and time course of placental transfer of Naloxone (Narcan) during normal vaginal deliveries using a new sensitive and specific radioimmune assay.

TECHNICAL APPROACH

Selected female volunteers at term who have received narcotics prior to their delivery will be given Naloxone (40 mg/kg body weight) 15 minutes prior to their delivery. Fetal cord blood will then be analyzed with a radioimmuno assay (RIA) technique for maternal-fetal transmission of Naloxone.

Personnel: None

Funding: None

PROGRESS

Rabbit antisera for Narcan RIA has been received and the study will be started in the near future.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: The Aerobic Microbiologic Flora of the Contact Lens Carrying Case.

WORK UNIT NO.: C-40-77

PRINCIPAL INVESTIGATOR: Patrick G. Paglen, M.D., CPT, USAF MC

ASSOCIATE INVESTIGATORS: Michelle Bright; Roy Kincaid; Robert Ferguson;
Joseph Madden, CPT, MSC

OBJECTIVES

To determine the aerobic microbiologic flora present in the contact lens carrying case of 100 consecutive patients seen in the BAMC Eye Clinic.

TECHNICAL APPROACH

Each patient who reports to the Eye Clinic will be questioned as to whether or not they wear contact lenses. If they wear lenses we will ask them if we may culture their lens case. If they agree, cultures will be obtained in a sterile fashion. Initially the capsule within the culturette will be burst and the damp swab will be removed by holding the culturette cap around its stem. The lens case will be swabbed once from side to side.

Personnel: None

Funding: None

PROGRESS

This is a new study.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Measurement of CO₂ Production and Humidification during Anesthesia with the Bain and Watson Circuits.

WORK UNIT NO.: C-41-77

PRINCIPAL INVESTIGATOR: Robert Rayburn, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To measure CO₂ production and humidification in children using the Mapleson D type circuit (Bain or Watson circuit).

TECHNICAL APPROACH

Twenty healthy patients (ASA Class I or II) scheduled for operative procedures requiring endotracheal anesthesia for one or more hours will be studied. As much as is possible, patients requiring blood gases for management of their surgery will be chosen for the study. Ambient room temperature and esophageal temperatures will be recorded continuously during anesthesia. Thirty minutes after initiation of anesthesia, an arterial blood gas will be drawn to confirm P CO₂ near 40 torr. Concomitant with blood gases, a record will be made of the mixed expired CO₂.

A precise measure of fresh gas flow will be determined by incorporating a pneumotachographic type flow analyzer in the inspiratory gas line for the anesthesia machine. Throughout the operation the percent humidity will be measured by means of hygrosensor placed between the endotracheal tube and the Mapleson D. circuit.

The data of all twenty patient will be compiled in order to express an average CO₂ production/m²/min and an average percentage relative humidity.

Personnel: None

<u>Funding:</u>	Capital Equipment	Consumable Supplies
FY 77	\$ 885.35	\$ 390.00

C-41-77 (Continued)

PROGRESS

This is a new project.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Inter-rater Reliability: The Voluntary Muscle Test.

WORK UNIT NO.: C-8-77

PRINCIPAL INVESTIGATOR Carleen Tortello, 2LT, SP

ASSOCIATE INVESTIGATORS: Barbara Reid, MAJ, SP

OBJECTIVES

To determine what difference, if any, exists between physical therapists' evaluations of the strength of the same muscle expressed as voluntary muscle test grades.

TECHNICAL APPROACH

A patient with a spinal cord injury five months post-trauma was chosen for this study. The injury resulted in below normal strength in the lower extremity musculature. For this study, four muscles were chosen to be tested bilaterally on the basis that they had not changed by more than one-half test grade for two months. No more than three tests were performed each day. Ten experienced physical therapists and ten students from the U.S. Army-Baylor University Physical Therapy program were instructed to perform a voluntary muscle test of the four indicated muscles using the letter grading system and then record the muscle test grades on a card.

Personnel: None

Funding: None

PROGRESS

No consistent variation could be shown between the two experimental groups except that the mean student grades were always higher than those of the experienced therapists. In general, the students showed a higher percentage of agreement which was probably due to the fact that they were all trained at the same time by the same instructors. The experienced therapists, however, came from a variety of backgrounds.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Forced Vital Capacity Following Application of Transcutaneous Nerve Stimulation.

WORK UNIT NO.: C-15-77

PRINCIPAL INVESTIGATORS: Steven A. Stratton, 2LT, SP;
Martha M. Carpenter, 2LT, SP

ASSOCIATE INVESTIGATORS: Joyce McDowell, LTC, SP; S. El-Beheri, LTC,
MSC; H. Aulick, MAJ, MSC; M. Lucas, LTC, MSC

OBJECTIVES

To determine whether transcutaneous nerve stimulation causes changes in forced vital capacity of post-thoracotomy patients before, during and after application of this stimulation.

TECHNICAL APPROACH

Twenty-one thoracotomy patients being treated at Brooke Army Medical Center were randomly assigned to the experimental or control group. A thoracotomy was defined as any incision into the chest; cardiac surgery patients were excluded. The patients ranged in age from 15 to 71 years. Three trials of forced vital capacity (FVC) were taken with both groups. With eleven patients in the experimental group, these readings were taken (1) immediately before transcutaneous nerve stimulation (TNS) application, (2) during the tenth minute of TNS, and (3) 10 minutes after completion of TNS. With the ten patients in the control group, three trials of FVC were recorded at 10 minute intervals. When possible, FVC was recorded 5 days postoperatively in an attempt to measure the long-term effect of TNS stimulation.

Personnel: None

Funding: None

PROGRESS

The data indicate that FVC did improve significantly with TNS application while without TNS there was no significant increase in FVC over the same ten minute interval. Retention of greater FVC in the experimental group 10 minutes after TNS was discontinued as well as 5 days postoperatively was not demonstrated in the study.

C-15-77 (Continued)

Conclusions: We feel this study objectively shows the potential for TNS application as an effective, conservative method for the reduction of pain following thoracic surgery by aiding chest expansion, deep breathing, coughing and upper member mobility, hopefully reducing the possibility of postoperative complications such as atelectasis or pneumonia.

Status: Completed.

Stratton, S.A. and Carpenter, M.M. Forced vital capacity following application of transcutaneous nerve stimulation. Submitted to Physical Therapy Journal of the American Physical Therapy Association for publication.

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

INVESTIGATION PROJECT RESUME

TITLE: A Comparison of Ultrasound Driven Hydrocortisone and Ultrasound Alone as Treatment of Lateral Humeral Epicondylitis.

WORK UNIT NO.: C-16-77

PRINCIPAL INVESTIGATORS: Shelley Earing, 2LT; Michele Puckett, 2LT

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if ultrasound driven hydrocortisone is as effective in treatment for humeral epicondylitis as ultrasound alone.

TECHNICAL APPROACH

Eleven subjects were included in this study. Age ranged from 25 to 59 years. There were six females and five males. One group of six patients, three females and three males, were treated with ultrasound and 1% hydrocortisone. The other group of five patients, three females and two males, were treated with ultrasound and placebo. Patients received ultrasound treatments daily for a total of ten treatments. Patients of both groups were treated with ultrasound without the hydrocortisone for the initial five treatments.

Personnel: None

Funding: None

PROGRESS

Of the 11 patients, seven were judged improved with normal active range of motion, increase in grip strength, and the patient's report of a significant decrease in pain. 83% of the patients treated with ultrasound and 1% hydrocortisone showed improvement while only 40% of those treated with ultrasound alone improved. 17% of the subjects treated with ultrasound and hydrocortisone worsened. 60% treated with ultrasound alone had no change.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: The Reduction of Low Back Pain as a Function of the Interaction of Physical Therapist and Patient. (Health Care Study)

WORK UNIT NO.: C-43-77

PRINCIPAL INVESTIGATOR: Jane E. Gierhart, LTC, AMSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To investigate the treatment of low back pain and evaluate both the physical treatment of the patient and the interaction between physical therapist and patient.

TECHNICAL APPROACH

Utilizing questionnaires furnished the MEDDAC/MEDCEN by the principal investigator, information about the patient's low back pain and the treatment will be collected. For purposes of this study, low back pain is defined as any pain of acute or chronic nature from T-10 to the tuberosity of the ischium.

Personnel: None

Funding: None

PROGRESS

This is a new study.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Child Advocacy Resources Expansion.

WORK UNIT NO.: C-8-76

PRINCIPAL INVESTIGATOR: Hubert A. Kelley, D.S.W., LTC, MSC

ASSOCIATE INVESTIGATORS: Michael F. Marley, Dir., Project CARE

OBJECTIVES

To demonstrate the effectiveness of community/Army/Air Force/Welfare Department planning in the provision to military families of broad spectrum services for the prevention, diagnosis, and treatment of child abuse and neglect.

TECHNICAL APPROACH

Ongoing conferences with military and civilian protective services staff have been held to clarify role definitions and referral procedures and to facilitate prompt intervention with troubled families.

Personnel: None

Funding: None

PROGRESS

Project CARE's findings indicate that--as in civilian life--child abuse and neglect in the military are symptomatic of broader problems involving dysfunctional, ineffective parents and families. An isolated incident of abusive behavior may be as much a cry for help as a series of incidents. Rather than focusing on assignment of blame, and labeling and stereotyping perpetrators, clinicians must make a thorough assessment of family history, dynamics, and stresses. A coordinated multidisciplinary military/civilian effort is necessary to intervene and strengthen the family's capacity to care for its children.

Status: Ongoing.

C-8-76 (Continued)

International Aspect of Child Abuse in the Military and the Army's New Role as Child Advocate. Presented at Symposium on Child Abuse, Denver, Colorado, October 1976.

Management and Supervisory Issues of Military Child Abuse Programs. Presented at the 2d Annual National Conference on Child Abuse and Neglect, 19 April 1977, Houston, Texas. Published in Conference Proceedings.

Characteristics and Management of Child Abuse and Neglect Among Military Families. Presented at the Naval Health Research Center's Military Family Research Conference, 1-3 September 1977, San Diego, California. Published in Conference Proceedings.

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

INVESTIGATION PROJECT RESUME

TITLE: Patient Attitudes. A Preliminary Study. (Health Care Study)

WORK UNIT NO.: C-47-77

PRINCIPAL INVESTIGATOR: Barbara M. Nardi

ASSOCIATE INVESTIGATOR: Hubert A. Kelley, D.S.W., LTC, MSC

OBJECTIVES

To begin to isolate those factors bearing on a patient's ability to cope with the conditions of hospitalization. It is hoped that the results of this initial study will (1) demonstrate the effectiveness of the survey instrument and (2) show the emergence of a pattern of factors influencing "successful" and "unsuccessful" patient behavior.

TECHNICAL APPROACH

Patient interviews will be carried out at Beach Pavilion, BAMC. The sample will consist of one group of adults ages 20 through 50, and a second group age 51 and above. One hundred patients will be included in the study.

Personnel: None

Funding: None

PROGRESS

This is a new project.

Status: Ongoing.

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

APPENDIX A

SOUTHWEST ONCOLOGY GROUP PROTOCOLS

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

INVESTIGATION PROJECT RESUME

TITLE: Radiotherapy-Chemotherapy (MOPP) for Stages I and II A and B Hodgkins.

WORK UNIT NO.: SWOG 781

PRINCIPAL INVESTIGATOR: Robert P. Bowman, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: J. Dean McCracken, M.D., LTC, MC

OBJECTIVES

To compare total nodal radiotherapy and involved field radiotherapy plus MOPP chemotherapy in patients with Stages I and II A and B Hodgkin's disease.

TECHNICAL APPROACH

At the time of registration of the patient, randomization to one or two treatment programs will be made: (1) total nodal radiation or (2) involved field radiation followed by MOPP chemotherapy. Therapy will be according to the schedule outlined in the study protocol.

PROGRESS

Since the last report, no new patients have entered the study. Therefore, the study is closed.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: POMP Combination Chemotherapy of Adult Acute Leukemia.

WORK UNIT NO.: SWOG 920

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate the frequency of remission induction in adult acute leukemia.

TECHNICAL APPROACH

Adult patients with acute leukemia are treated with a combination of 5-mercaptopurine (Purinethol), vincristine (Oncovin), methotrexate and prednisone (POMP) for remission induction and maintenance.

PROGRESS

No new patients have been entered on this protocol since the last progress report. Therefore, the study is closed.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Combination Chemotherapy of Multiple Myeloma in Previously Untreated Patients.

WORK UNIT NO.: SWOG 7305/7306

PRINCIPAL INVESTIGATOR: Robert P. Bowman, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Hayden G. Braine, M.D.

OBJECTIVES

1. To evaluate the frequency and degree of response from treatment with a melphalan-adriamycin-prednisone combination (MAP), a melphalan-cyclophosphamide-prednisone combination (MCP), and a melphalan-cyclophosphamide-BCNU-prednisone combination (MCBP) in patients with previously treated multiple myeloma.
2. To compare the results with recent historical controls of patients treated with other melphalan-prednisone combinations.

TECHNICAL APPROACH

Dosage and treatment schedule will conform to the schema outlined in the study protocol.

PROGRESS

SWOG 7305 - This phase of the protocol was completed in October 1975.

SWOG 7306 - While none of the arms appear to be superior to historical controls with melphalan-prednisone, considerable information is available on the relationship of tumor mass to response and survival. The study has been completed, and a manuscript is being prepared by the Southwest Oncology Group.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Remission-Induction for Adult Acute Leukemia with Ten-Day OAP;
Remission-Maintenance with OAP vs. OAP plus BCG.

WORK UNIT NO.: SWOG 7316

PRINCIPAL INVESTIGATOR: Robert P. Bowman, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare the effectiveness of 5-day maintenance OAP with 5-day maintenance OAP plus BCG in prolonging the duration of complete remission of patients achieving a complete remission on 10-day induction which was followed by 5-day OAP consolidation.

TECHNICAL APPROACH

Following complete remission after the second induction course of OAP, the patient receives three consolidation courses of 5-day OAP therapy.

PROGRESS

No new patients have been entered on this protocol since the last progress report. Therefore, the study is closed.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Combination Immunotherapy and Chemotherapy in Localized Osteogenic Sarcoma.

WORK UNIT NO.: SWOG 7317

PRINCIPAL INVESTIGATOR: Robert P. Bowman, M.D., LTC, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Evaluation of the efficacy of the combination of transfer factor and combination chemotherapy (COMPADRI II - cyclophosphamide, oncovin, methotrexate, melphalan and adriamycin) in localized osteogenic sarcoma.

TECHNICAL APPROACH

Transfer factor will be administered in dosage levels of two units per day for a total of eight units to be given prior to the initiation of chemotherapy completing the administration 48 hours prior to treatment. Thereafter, during the 250 day outlined chemotherapy treatment plan, the transfer factor will be given during lapses in chemotherapy, 14 days from day one of the pulses of therapy and in the amount of 2 units per day for 2 days or 4 units total. The patient will receive approximately 40 units by the end of the prescribed 350 day course.

Chemotherapy will be administered according to the protocol plan.

PROGRESS

Since the last progress report, no new patients have been entered on this study. Therefore the study is closed at BAMC.

SWOG results indicate there are 35 patients who have been at risk for 24 months. Two have died of methotrexate toxicity, 17 have developed metastases and 16 remain disease free. These patients were registered prior to January 1975. Of 29 patients registered after January 1975, 9 have developed metastases and 20 remain disease free.

Status: Completed at BAMC.

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

INVESTIGATION PROJECT RESUME

TITLE: Remission-Induction for Adult Acute Lymphocytic Leukemia with Adriamycin, Vincristine and Prednisone Remission-Maintenance with Methotrexate and 6-Mercaptopurine Reinforcement with Prednisone and Vincristine.

WORK UNIT NO.: SWOG 7401

PRINCIPAL INVESTIGATOR: Robert P. Bowman, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Hayden G. Braine, M.D.

OBJECTIVES

1. To evaluate the effectiveness of adriamycin, vincristine and prednisone in the induction of remission in acute lymphocytic leukemia in adults.
2. To evaluate the following remission maintenance program: daily 6-mercaptopurine and weekly methotrexate, plus periodic reinforcement with prednisone and vincristine.

TECHNICAL APPROACH

Patients who have received no prior adriamycin and who have ALL with at least 30% blasts in the marrow are eligible for entry into the study. Only adults 15 years of age or older will be studied. Approximately 37 patients will be entered. The remission-induction and remission-maintenance phases will be administered according to instructions in the study protocol.

PROGRESS

To date there have been a total of 57 patients registered, 37 ALL's and 20 AML's. Thirty of the ALL's and 17 of the AML's are evaluable. Patients with complete remission total 23/30 (77%) of ALL and 3/17 (18%) of AML. The combination is effective for induction remission of ALL. However, the protocol does not contain specific prophylactic therapy for CNS and several patients relapsed with that. The combination is ineffective for the reinduction of patients with AML; the few patients who obtained a complete response had relatively short remissions of 1 month, 1½ months and 6 months.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Cis-platinum in Lymphomas and Multiple Myeloma.

WORK UNIT NO.: SWOG 7413

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

To evaluate the activity of cis-diamminedichloroplatinum (II) NSC-119875, (CACP) in patients with refractory Hodgkin's and non-Hodgkin's lymphoma and in refractory multiple myeloma.

TECHNICAL APPROACH

CACP, 75 mg/M², will be given as a single rapid intravenous injection every three weeks. An adequate trial will consist of two courses and all patients will be followed for the six week period. If there is evidence of tumor response or stable disease the drug may be discontinued at three week intervals indefinitely. With evidence of progression after two courses of the agent, the patient will go off study.

PROGRESS

Case accrual for this protocol was poor in both lymphoma and myeloma categories. However, several positive leads were observed with cis-Platinum. There was one complete and one partial remission in Hodgkin's disease (of five cases registered) and one stable and one progressive disease of the two evaluable myeloma cases. One investigator has observed a high cure rate with cis-Platinum in a mouse myeloma which is

SWOG 7413 (Continued)

highly responsive to alkylating agents (Adj-PC5). These observations on platinum will be taken as positive leads for incorporation of this agent into combinations for myeloma patients in relapse. Because of the one positive bit of information, it was recommended that cis-Platinum be explored in Hodgkin's disease.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Chemoimmunotherapy of Acute Leukemia in Adults.

WORK UNIT NO.: SWOG 7416/7417

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

1. To determine whether with the use of sequential or simultaneous adriamycin and ARA-C there is significant difference in their ability to induce complete remission.
2. To study the effects of combination chemotherapy and immunotherapy on the duration of remission and survival in patients with acute leukemia.
3. To identify those patients with ALL vs AML who are vincristine and prednisone responsive.

TECHNICAL APPROACH

Patients fulfilling the criteria for treatment will be divided into two different categories, depending on their peripheral circulating blast count. Category 1 is for those patients with a circulating blast count of less than 30,000. Category 2 is for those patients with a circulating blast count equal to or greater than 30,000/cu. ml. Approximately 96 patients will be entered into each group. Therapy will be in accordance with the schema outlined in the study protocol.

The study has been amended to exclude the vincristine and prednisone arm.

PROGRESS

Three hundred and ninety-seven patients were partially or fully evaluable. The response rate overall was 59% which was slightly higher than the 54% complete remission rate reported in the 10-day OAP study. The response rate to VP treatment in first induction was 22%; however, when subsequent responses to second induction are considered, VP patients had a total response rate of 62%. Considering all patients postamendment, the complete response rate was 57% for both treatment arms. Combining

SWOG 7416/7417 (Continued)

patients pre- and postamendment who received simultaneous or sequential treatment as first induction treatment, the complete remission rates were identical at 57%.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Chromomycin in Multiple Myeloma.

WORK UNIT NO.: SWOG 7423

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

To investigate the effectiveness of Chromomycin A₃ in the treatment of advanced multiple myeloma.

TECHNICAL APPROACH

Chromomycin, 0.75 mg/M², will be given daily as 10-20 minute infusion in 50-100 ml D5W through an established running IV for five days. This will be repeated every three weeks.

It is estimated that 14 evaluable patients will be adequate to determine whether 20% response will be expected at 5% rejection error. Approximately 25 will estimate this response rate with a standard error of ±8%.

PROGRESS

Since chromomycin has only shown evidence of nephrotoxicity in myeloma patients and no hint of response, the study has been closed.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Combination Chemotherapy Utilizing BCNU, Hydroxyurea and DTIC (BHD) with and without BCG, and DTIC with BCG in the Treatment of Patients with Disseminated Malignant Melanoma.

WORK UNIT NO.: SWOG 7424/7425

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

To compare the effectiveness of BHD (3-drug regimen) alone, BHD in combination with BCG, and DTIC in combination with BCG for remission induction, duration of remission and survival in patients with disseminated malignant melanoma.

TECHNICAL APPROACH

Since BCNU, DTIC and hydroxyurea are principally myelosuppressive, dosage and time intervals were calculated to avoid the maximum toxicity occurring at the same time. Separate randomizations are set up for patients with normal and impaired bone marrow reserve, as well as for patients with brain metastases and liver metastases.

Treatment will be in accordance with the schema outlined in the study protocol.

PROGRESS

There were 317 patients who were fully or partially evaluable. The complete plus partial response rate was 30% (28/93) for BHD, 28% (32/116) for BHD + BCG, and 19% (20/108) for DTIC + BCG. There are no statistically significant differences in response rate among the three treatment programs ($p = .13$). If all patients receiving BHD are combined and paired with those receiving DTIC + BCG, the response rates are 29% and 19%, respectively. This characteristic (receiving BHD or not) is related to response ($p = .05$).

SWOG 7424/7425 (Continued)

The patient characteristics significantly related to CR + PR rate at a 5% level were: age, stage at diagnosis, performance status, and liver involvement. Favorable patients were those who were 30 to 59 (28% CR + PR rate), who were stage 0 at diagnosis (53% CR + PR rate), who were asymptomatic and active (38% CR + PR rate) and who had no liver involvement (38% CR + PR rate).

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Chemoimmunotherapy in Non-Hodgkin's Lymphoma.

WORK UNIT NO.: SWOG 7426/7427

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

1. To compare the effectiveness of two chemotherapy regimens or chemoimmunotherapy for remission induction in previously untreated non-Hodgkin's lymphoma patients.
2. To evaluate systematic restaging of clinical remissions.
3. To test the value of continued maintenance immunotherapy vs. no maintenance treatment for complete remissions.
4. To test the effectiveness of continued treatment with chemoimmunotherapy for partial remissions.

TECHNICAL APPROACH

Therapy will follow the schema outlined in the study protocol.

PROGRESS

Fifty-two percent of the randomized patients have had a complete response (CR) and an additional 32% have had a partial response (PR) giving a CR + PR rate of 84%. Three hundred of these randomized patients now have a final evaluation. Their CR rate is 59% and their CR + PR rate is 83%.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Methyl CCNU-Adriamycin for Patients with Metastatic Sarcomas.

WORK UNIT NO.: SWOG 7431

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To determine the efficacy of combination chemotherapy using Methyl CCNU for metastatic sarcomas in patients who have prior refractoriness for cyclophosphamide, vincristine and/or Actinomycin D.
2. To determine the remission duration pattern of patients under study comparing intermittent and continuous administration of adriamycin in those patients initially induced into remission with Methyl CCNU and adriamycin.

TECHNICAL APPROACH

Approximately 80 patients will be studied over a period of 18-24 months. Dosage and treatment schedule will conform with the schema outlined in the study protocol.

PROGRESS

The overall response rate is 40% but only one complete response was observed and there is relatively brief duration of response of only three months. There were two advantages to this combination: The gastrointestinal toxicity was less than with A-DIC and it is possible to give good doses of Adriamycin with MeCCNU. But, it was apparently not active in CNS disease. Mixed response patients had an increase of CNS disease with diminishing peripheral disease. No activity in Kaposi sarcoma was seen.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: VBAP in Multiple Myeloma (Vincristine, BCNU, Adriamycin and Prednisone).

WORK UNIT NO.: SWOG 7432

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

To evaluate the frequency and degree of response with VCR, BCNU, adriamycin, prednisone combination (VBAP) in patients who failed to respond or relapsed on alkylating agents with or without prednisone.

TECHNICAL APPROACH

Patients with the diagnosis of multiple myeloma are eligible who have received Melphalan or Cytoxan with or without Prednisone and have recovered from previous toxicity. The study was amended to allow VBAP treatment for all patients relapsing on any SWOG protocol and to include lymphoma patients.

Treatment was in accordance with the schema outlined in the study protocol.

PROGRESS

In patients who have relapsed following response to Melphalan and/or Cytoxan, there seems to be a solid response rate of about one out of three (33%). In patients that have had "adequate" induction therapy with either BCNU and/or adriamycin there does not seem to be a response with VBAP. If the patient has not had adequate treatment with BCNU and/or adriamycin there are some responders. Toxicity seems to be more related to the status of the patient than the toxicity to the drugs involved in this protocol.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: 5-FU + Mitomycin-C vs. 5-FU + MeCCNU in GI Malignancies.

WORK UNIT NO.: SWOG 7434

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To determine and compare the toxicity and effectiveness of two combination chemotherapies in GI carcinomas.
2. Compare the results with the results observed in SWOG 7302.

TECHNICAL APPROACH

All histologically proven surgically incurable gastrointestinal carcinomas with clinically definable measurable lesions are eligible.

Treatment is as outlined in the study protocol.

PROGRESS

The only patient subgroups in which response rates by treatment differ are in the disease sites of pancreas and other-GI. In each of these sites, 5-FU + Mitomycin-C has shown some evidence of having a higher response rate than 5-FU + MeCCNU. No response rate differences have been detected for colon or stomach patients.

Length of survival for colon patients does not differ significantly by treatment overall, nor in any of the following subgroups: no measurable

SWOG 7434 (Continued)

disease, measurable disease, or no liver involvement. The only exception for colon patients was in the subgroup with liver involvement wherein 5-FU + MeCCNU had significantly longer survival.

The overall survival comparison by treatment does not yet show a significant difference in any of these other subgroups: stomach, pancreas, or other GI patients.

Survival of the colon responders and/or those who are stable does not differ by treatment. The colon CR + PR patients survive significantly longer than the stable patients on both arms combined, but not individually. The colon CR + PR group survives significantly longer than the nonresponders on both arms combined, and on each arm separately.

The overall median survival time of measurable colon patients on this study (9.7 months) represents an increase (40%) over that achieved by similar patients on the previous study, SWOG 7302 (median = 6.9 months), which is very significant both statistically and clinically.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Piperazinedione in Malignant Lymphoma or Myeloma.

WORK UNIT NO.: SWOG 7435

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

1. To establish the objective tumor response rates, both partial and complete, for patients with refractory lymphomas, and the duration of such responses.
2. To establish the objective tumor response rates and their durations in patients with refractory multiple myeloma.

TECHNICAL APPROACH

Since the primary purpose of the study is to estimate the effectiveness of Piperazine in patients with Hodgkin's disease, non-Hodgkin's lymphoma, and multiple myeloma, sufficient patients will be entered into the study to obtain reasonably precise estimates of the complete and partial remission rates. Thus the study will proceed until at least 24 patients have been studied in each disease category. Therapy will be in accordance with the scheme outlined in the study protocol.

PROGRESS

The case accrual for this study was quite low. There is evidence that the compound is active in lymphoma. However, since there have been no case entries since the last report, the study is closed.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Cis-platinum for GU-GYN Malignancies, Phase II.

WORK UNIT NO.: SWOG 7438

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

To evaluate the activity of cis-diamminedichloroplatinum (II) NSC 119876, CACP) in patients with malignant diseases of the genitourinary and gynecologic organs.

TECHNICAL APPROACH

CACP, 75 mg/M², as a single intravenous injection will be administered every 3 weeks. A minimum of 15 patients in each histologic subtype will be studied.

PROGRESS

A total of 93 patients have entered the study, and several are still to early for evaluation. Little or no activity is shown for kidney, transitional cell tumors, prostate and uterus, although the number of patients for these locations is still small. The response rates for testes and ovary are somewhat inferior to published observations, being 33% and 18%, respectively.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Skin Test Protocol for Evaluation of Cellular Immunity in Patients with Neoplasia.

WORK UNIT NO.: SWOG 7475

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To determine if response to chemotherapy, duration of remission or survival of patients with cancer correlate with cellular immune competence as judged by skin test evaluation prior to therapy.
2. To determine which skin tests are ideal for this type of immunocompetence.
3. To delineate more clearly by means of three types of skin tests the immunologic defect in the cancer patient.

TECHNICAL APPROACH

Patients who have not received chemotherapy in the prior three month period and who are to be registered on a SWOG therapy protocol are eligible for entry into this protocol.

Skin tests are administered as outlined in the study protocol.

PROGRESS

Four hundred and eight skin tests have been registered and are broken down by diseases as follows: melanoma-128; colon cancer-43; lymphoma-24; breast cancer-30; sarcoma-18; myeloma-9; Hodgkin's disease-21; leukemia-40; ovarian cancer-7; brain tumors-8; miscellaneous-29. Detailed correlation with prognosis, duration of survival and response rate are pending.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Cycloctidine in Melanoma, Phase II.

WORK UNIT NO.: SWOG 7504

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

To determine the effect of cycloctidine chemotherapy on the frequency, magnitude and duration of tumor regression, and on the survival of patients with disseminated malignant melanoma.

TECHNICAL APPROACH

A minimum of 25 patients will be studied. Cycloctidine will be administered as outlined in the study protocol.

PROGRESS

Thirty patients have been registered, and 12 are too early to evaluate. Therefore, there were 18 patients evaluable for this study, with 1 short partial remission, 5 nonresponders, and 12 with increasing disease. Toxicity was definitely evident with four patients showing grade 4 leukopenia and grade 4 thrombocytopenia and one patient showing grade 5 thrombocytopenia. Therefore the doses used were adequate. The median

SWOG 7504 (Continued)

time to thrombocytopenia was day 13 with leukopenia being day 20. Since the response rate appears to be minimal and enough patients have been accrued, the study is closed.

Status: Completed.

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

INVESTIGATION PROJECT RESUME

TITLE: Piperazinedione: In Patients with metastatic Malignant Melanoma,
Phase II.

WORK UNIT NO.: SWOG 7506

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

To investigate the efficacy of Piperazinedione in patients with metastatic malignant melanoma.

TECHNICAL APPROACH

A minimum of 25 patients will be entered into the study. The initial dose of Piperazinedione will be 12 mg/M² administered by intravenous infusions q 3 weeks for patients with adequate marrow reserve. Inadequate marrow reserve will receive initial dose of 9 mg/M² IV infusion q 3 weeks. Courses will be administered at 3-week intervals as tolerated. Subsequent courses should not be repeated until the nadir of blood counts has been reached, and the counts are recovering. Subsequent doses of Piperazinedione will be adjusted in relation to nadir blood counts according to the schedule outlined in the study protocol.

PROGRESS

Patient accrual is small. It is too early to evaluate the data.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: 5-FU, MeCCNU + Radiotherapy with or without Testolactone for
Localized Adenocarcinoma of the Exocrine Pancreas.

WORK UNIT NO.: SWOG 7509

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

1. To evaluate the effect on survival of intensive radiotherapy and chemotherapy (5-FU and MeCCNU) of localized pancreatic adenocarcinoma.
2. To evaluate any beneficial effect of testolactone when added to this regimen.

TECHNICAL APPROACH

Patients with histological confirmation of adenocarcinoma of the exocrine pancreas with localized disease are eligible for enrollment in this study protocol.

Treatment regimen is as outlined in the schema accompanying the study protocol.

PROGRESS

Of the 21 patients evaluable on this study, 9 have expired with a median survival of 16 weeks. Of all patients on study, median survival to date is 25 weeks. Six patients have survived >140 weeks with 5 continuing on study maintaining stable disease status or better. The influence of Teslac on survival cannot be determined as yet.

Toxicity has been observed in all patients on study and is mainly hemologic. Greatest toxicities observed were grade 4 in 4 patients,

SWOG 7509 (Continued)

grade 3 in 8 patients, grade 2 in 8 patients, and grade 1 in 1 patient. Many patients (1) on study are greater than 70 years of age with median age of all patients on study 64 years. However, toxicity appeared just as severe in younger patients as in those >64 years with most patients having numerous drug dosage delays and omissions secondary to hematologic toxicity. One drug related death has been reported. By omitting MeCCNU dose at day 43 toxicity should diminish.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Adjuvant Chemotherapy for Patients with Locally Advanced Adenocarcinoma of the Large Bowel.

WORK UNIT NO.: SWOG 7510

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To determine the effectiveness of the combination of MeCCNU + 5-FU as ajuvant chemotherapy.
2. 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 regimen will conform with the schema outlined in the study protocol.

PROGRESS

The chemotherapy alone limb had relapses at 6 months, 8 months, and 12 months and no deaths to date. In this limb, there was a 95.7% chance of having no evident disease at 6 months (1 relapse of 23 patients). The survival curve indicates a 58.0% chance of being disease-free (and a 100% chance of being alive) at 17 months--the duration of longest follow-up.

SWOG 7510 (Continued)

The chemotherapy plus BCG limb includes a single patient who relapsed at 4 months and died at 5 months and a second patient who relapsed at 10 months. The curvival curve indicates a 97.2% chance of being clinically disease-free from 4 months up to 10 months where the likelihood falls to 64.8% where it stays through 13 months (the longest follow-up on this limb).

The patient who died was one of 26 on the chemotherapy plus BCG limb who were followed for 5 months or more. This indicates that 96.2% on this limb are alive at 5 months. If we combine both limbs of the study, a total of 59 were followed for five months, and 58 of them (98.3%) are alive. The literature indicates that 5% of patients such as these, but without any adjuvant therapy, should be expected to be dead by 6 months. Thusfar, we have a total of 44 patients (21 on one limb; 23 on the other) who have been at risk to die by 6 months. Five percent of 44 is 2.2 patients "expected" to die in accordance with the historical experience. Therefore, the observation that only one of the 44 did die suggests that this adjuvant therapy may be exerting a favorable effect.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Baker's Antifol in GI Malignancies.

WORK UNIT NO.: SWOG 7512

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

To determine the efficacy of Baker's Antifol in gastrointestinal malignancies.

TECHNICAL APPROACH

Therapy will be administered in accordance with the schema outlined in the study protocol.

PROGRESS

A review of the study indicates that 250 mg/M² of Baker's antifol in patients with good liver function, objective remissions can be obtained in patients with colorectal carcinoma (3/30). It was stressed again by investigators that in patients with poor liver functions unpredictable toxicity can be expected, and therefore these should not be treated with BAF. In patients who tolerated BAF well on the first treatment, the importance of drug escalation was stressed. At least

SWOG 7512 (Continued)

one of the three patients showing tumor response developed clearcut response only after drug escalation was accomplished as outlined by the protocol. Inasmuch as the purpose of this study was to get an approximate estimate of the response rate of treated categories, it is felt the study should be closed for colorectal carcinoma but should remain open as a second line therapy for all other gastrointestinal tumors, limited to patients with good liver function.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: VP-16 in Adults with Metastatic Adenocarcinoma of the Breast.

WORK UNIT NO.: SWOG 7514

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

To determine the efficacy of VP-16 in adult patients with metastatic adenocarcinoma of breast.

TECHNICAL APPROACH

Eligibility: Patients with a histologically confirmed diagnosis of adenocarcinoma of the breast with metastasis who are not eligible for studies of higher priority.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

The initial dose of VP-16 was raised from 45 mg/M² to 75 mg/M². At this time, there have not been sufficient patients to evaluate the effect of this change in the protocol.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Phase III Study of Squamous Cell Carcinoma of the Head and Neck Region.

WORK UNIT NO.: SWOG 7519

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC: Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

To determine whether a three drug combination treatment program will give a superior response rate and/or a longer remission duration than methotrexate alone in patients with squamous cell carcinoma of the head and neck region.

TECHNICAL APPROACH

Eligibility: Patients with histologically proven advanced squamous cell carcinoma of the head and neck region not amenable to other forms of therapy, not previously treated with nitrosourea, methotrexate or bleomycin.

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

PROGRESS

The response (CR + PR) rate on the Methotrexate arm (13/33 = 39%) was higher, but not significantly so ($p = .271$) than that achieved on the MTX + MeCCNU + Bleo arm (7/27 = 26%). It is interesting to note that the distribution of patients by performance status (PS) was significantly different between the two treatment arms of this study. The pretreatment PS was known for 27 patients who received Methotrexate alone, and 25 patients who received the three-drug combination. Of these 27 Methotrexate patients, 25 (93%) were in the PS 0-1 group,

SWOG 7519 (Continued)

whereas only 15 (60%) of the 25 patients treated with the three-drug combination were PS 0-1. This difference is statistically significant with $p = .005$, indicating that a more prognostically favorable group had accrued to the single drug arm of this study.

Survival appears to be better on the Methotrexate alone arm than on the three-drug arm of the study. This may reflect the fact that patients with a more favorable performance status in general accrued to the Methotrexate arm than to the three-drug arm.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Phase II Study of Galactitol in Advanced Cancer Patients.

WORK UNIT NO.: SWOG 7520

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC: Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

To determine the efficacy and toxicity of Galactitol in the treatment of advanced carcinoma.

TECHNICAL APPROACH

Eligibility: Patients with measurable metastatic disease not eligible for studies of higher priority or other potentially more effective drugs.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

Patient entry has been very slow. One of six evaluable patients with squamous cell cancer has responded.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Combination Chemotherapy with or without Immunotherapy in High Risk Melanoma Patients: An Adjuvant Study.

WORK UNIT NO.: SWOG 7521

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To determine efficacy of BHD in preventing recurrence of disease and prolonging survival of patients who have received definitive surgical treatment for their primary lesion.
2. To determine the efficacy of BHD + BCG in preventing metastases and prolonging the disease-free interval.
3. To determine the immunocompetence of these patients.

TECHNICAL APPROACH

Eligibility: All patients with histologically confirmed diagnosis of malignant melanoma previously untreated with chemotherapy or radiotherapy who are within 4 weeks of surgical excision of active disease.

Treatment will follow the schema outlined in the study protocol.

PRGRESS

This protocol is relatively new. At this time the results are such that there is no indication as to what the ultimate outcome of the study will be.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

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

WORK UNIT NO.: SWOG 7522

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

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.

TECHNICAL APPROACH

Eligibility: All patients with confirmed diagnosis of benign phase CML not previously treated with any of the agents used in this study.

Treatment will follow the schema outlined in the study protocol.

PROGRESS

Twenty-seven patients have been registered. However, it is too early to evaluate the results of the treatment program.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Treatment of Advanced Large Cell Undifferentiated and Adenocarcinoma of the Lung Using the Combination of Methotrexate and Methyl CCNU.

WORK UNIT NO.: SWOG 7523

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

To determine the effectiveness, response rates, and duration of response of Methotrexate and Methyl CCNU in large cell undifferentiated and adenocarcinoma of the lung.

TECHNICAL APPROACH

Eligibility: Patients with diagnosis of large cell undifferentiated or adenocarcinoma of the lung with extensive disease and no prior treatment with nitrosourea or methotrexate.

Treatment will follow the schema outlined in the study protocol.

PROGRESS

Using only the fully evaluable patients, the complete + partial response rates by cell types are: 7/56 = 13% for adenocarcinoma, and 4/26 = 15% for undifferentiated large cell patients. Several comparisons of survival have been made. The survival of all adenocarcinoma patients (median = 112 days) is not at all significantly different ($p = .599$) from that achieved by large cell patients (median = 110 days).

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

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

WORK UNIT NO.: SWOG 7524

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To compare the effectiveness of chemotherapy alone vs. chemoimmunotherapy for remission induction in Stages III and IV ovarian and endometrial carcinoma.
2. To test the effectiveness of chemotherapy plus immunotherapy vs. chemotherapy in maintaining complete remissions.
3. To test effectiveness of continued chemotherapy plus immunotherapy vs. chemotherapy in inducing complete remission or maintain partial remissions in patients with occult disease at restaging or in patients achieving only partial remission during 12 month induction therapy.

TECHNICAL APPROACH

Eligibility: 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 follow the schema outlined in the study protocol.

PROGRESS

Patient accrual has been slow for the endometrial cancer. Although the current analysis strongly suggests that BCG will increase the partial response rate of ovarian cancer patients to adriamycin-cyclophosphamide, it is too early to determine if this increase is real or will translate into improved survival or disease-free survival.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Treatment of Patients for Early Testicular Cancer with Irradiation and Chemotherapy with Vinblastine and Bleomycin.

WORK UNIT NO.: SWOG 7525

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To determine if a combination of irradiation and chemotherapy can improve the two year disease free interval and five year survival in certain morphologic subtypes of IB and II nonseminomatous testicular tumors.
2. To determine with sequence of irradiation and chemotherapy more favorably influences remission maintenance, survival and possibly cure. In part, this will be done by compression of the AFIP classification which excludes pure seminomas and choriocarcinomas.

TECHNICAL APPROACH

Eligibility: Previously untreated patients with histologically proven Stage IB and II pure embryonal, pure teratocarcinomas, mixed cell types with seminomatous elements.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

This study will require several years of observation and patient registration. All patients registered are still alive. It is too early to analyze results of therapy.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Immune Evaluation of Lymphoma in Unmaintained Remission.

WORK UNIT NO.: SWOG 7580

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To evaluate the immune status of patients with lymphoma who have been successfully treated and are in remission without therapy.
2. To correlate the presence of immune deficits with histologic type of lymphoma, pathologic stage, types of therapy, and interval since therapy.
3. To correlate the immunologic profile with long term follow-up of patients in terms of disease relapse, second malignancy, and duration of survival.

TECHNICAL APPROACH

Eligibility: Any patient with histologically proven Hodgkin's or non-Hodgkin's lymphoma, who has completed therapy and has had at least 3 months of unmaintained remission.

Evaluation will be carried out in accordance with the schema outlined in the study protocol.

PROGRESS

Fifty-nine patients have been registered. The study will continue until 100 patients have been completely evaluated with recall and neoantigen skin tests, PHA skin tests, and KLH antibody studies.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Effect of Schedule of Activity of 5-Azacytidine in Acute Leukemia.

WORK UNIT NO.: SWOG 7603

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

To compare the activity and toxicity of single dose vs. continuous 5-day infusions of 5-Azacytidine in patients with acute leukemia.

TECHNICAL APPROACH

Eligibility: Patients with bone marrow diagnosis of acute leukemia who are ineligible for or who have relapsed on a leukemia protocol of higher priority.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

Because of the activity of 5-Azacytidine against acute myelogenous leukemia in adults and its minimal toxicity when administered as a continuous infusion at a dose of 200 mg/M²/day for 5 days, further experience is needed with this regimen.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Chemotherapy of Disseminated Testicular Cancer with Vinblastine, Bleomycin, Cis-Platinum, Chlorambucil and Actinomycin-D.

WORK UNIT NO.: SWOG 7610

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To determine the effectiveness of Vlb, Bleo, and Cis-platinum in remission induction.
2. To determine the duration of remission with a maintenance combination of chlorambucil and actinomycin-D, alternating with Vinblastine.

TECHNICAL APPROACH

Eligibility: Patients of an age with Stage III metastatic testicular carcinoma who have not been previously treated with any of the selected agents.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

There has been complete response in 10 of 21 (48%) evaluable patients and partial response in 7. Duration of responses are as follows: teratoma 3+, 1+ months; embryonal 5+, 4+, 3+, 2+, 2+, 2+, 2+ months; and seminoma-embryonal 2+ months.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Cis-Platinum for Refractory Sarcomas.

WORK UNIT NO.: SWOG 7611

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

To determine the efficacy of cis-platinum in the treatment of patients with advanced sarcomas refractory to Adriamycin combinations.

TECHNICAL APPROACH

Eligibility: Patients with a biopsy confirmed diagnosis of soft tissue or bony sarcoma and no eligible for a higher priority protocol. Patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

Sufficient patients have not been entered into this study to accurately evaluate results. The study will remain open to determine if any significant antitumor activity exists.

Status: Ongoing

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

INVESTIGATION PROJECT RESUME

TITLE: Combined Preoperative Adjuvant Therapy in Rectal Carcinoma.

WORK UNIT NO.: SWOG 7618

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To determine if adjuvant preoperative radiotherapy and chemotherapy will yield a higher incidence than expected of Duke A lesions in a high risk group.
2. To determine the survival of patients with an without regional node metastases.

TECHNICAL APPROACH

Eligibility: Patients with carcinoma of the rectum judged by the surgeon to have clinically resectable disease by abdominoperineal resection.

Therapy will conform to the schema outlined in the study protocol.

PROGRESS

Approximately 140 patients are necessary for this randomized study between preoperative radiotherapy vs. preoperative radiotherapy plus systemic chemotherapy to detect a 20% increase in Duke A lesions (expected incidence 25%) in either of the two treatment arms. It is too early to analyze results at this time.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of Ftorafur in the Treatment of Metastatic Adenocarcinoma of the Colon and Rectum.

WORK UNIT NO.: SWOG 7619

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

To determine the efficacy of Ftorafur in disseminated adenocarcinoma of the colon and rectum.

TECHNICAL APPROACH

Eligibility: Patients must have biopsy proven adenocarcinoma arising from the colon or rectum and have clinically measurable recurrent or disseminated disease.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

Twelve patients are evaluable. One is improved, eight are stable, and three have increased disease. It is anticipated that 50 patients will be studied (25 patients with liver metastases and 25 patients without).

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Chemotherapy or Chemotherapy + Immunotherapy Following Initial Surgery and/or Radiotherapy for Treatment of Early Squamous Cell Carcinoma.

WORK UNIT NO.: SWOG 7620

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. 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 chemotherapy or chemoimmunotherapy after initial surgery, radiotherapy or combination approach have resulted in no clinically evident disease.
2. To accumulate immunologic data in treated and untreated patients with this malignancy.

TECHNICAL APPROACH

Eligibility: Patients with no evidence of clinical disease three months after completion of surgery or irradiation.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

There is an insufficient number of evaluable patients at this time.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Adriamycin vs. Adriamycin plus Cis-Platinum in Transitional Cell Bladder Carcinoma.

WORK UNIT NO.: SWOG 7624

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

To compare the efficacy of Adriamycin vs. Adriamycin + Cis-platinum in recurrent or disseminated transitional cell bladder carcinoma.

TECHNICAL APPROACH

Eligibility: Patients with histologically proven T₄ transitional cell bladder carcinoma, T₃ if there is a general contraindication to radical surgery; recurrent or residual cases after surgery, radiotherapy or both; and M₁ cases of liver, osseous, pulmonary, or other metastasis.

Therapy will follow the schema outlined in the study protoco.

PROGRESS

Eleven patients have been registered; however, it is too early to evaluate the results.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Combined Chemotherapy for Advanced Sarcoma of the Bone and Mesothelioma Utilizing Rubidazone and DTIC.

WORK UNIT NO.: SWOG 7625

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To determine the efficacy in terms of rate of response of combination chemotherapy with the 2-drug regimen, RubiDIC (Rubidazone + DIC) in patients with metastatic sarcomas of bone and mesothelioma.
2. To determine the duration of remission and survival pattern of patients on this study and compare them with that of patients with metastatic bone sarcomas and mesothelioma on previous SWOG or M.D. Anderson Hospital protocols using adriamycin containing regimens.
3. To determine the toxicity of the regimen especially with regard to cardiac toxicity.

TECHNICAL APPROACH

Eligibility: Patients with a biopsy-confirmed diagnosis of bony sarcoma or mesothelioma with measurable metastases who have already received appropriate surgical therapy and who have not received prior adriamycin, daunorubicin, rubidazone, DIC or BIC are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

This is a new study.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: ROAP Induction of Chemotherapy for Acute Leukemia Patients Over the Age of 50.

WORK UNIT NO.: SWOG 7626

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., MAJ, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To determine the efficacy of the 4-drug combination chemotherapy regimen ROAP (rubidazone, vincristine, arabinosyl cytosine and prednisone) in remission induction chemotherapy in patients with acute leukemia over the age of 50.

To determine the toxicity of the regimen.

TECHNICAL APPROACH

Eligibility: All patients age 50 or greater with a diagnosis of acute leukemia who have received no extensive prior therapy (defined as one course or less 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. Absolute infiltrate is defined as the total blast cell percentage (%) multiplied by the bone marrow cellularity percentage divided by 100.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

This is a new study.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Combined Chemotherapy/Radiotherapy/Immunotherapy for Oat Cell
Cancer of the Lung.

WORK UNIT NO.: SWOG 7628

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

To use combination chemotherapy, local radiotherapy, and maintenance chemotherapy or chemoimmunotherapy in the treatment of oat cell carcinoma of the lung in order to improve the quality and duration of survival.

TECHNICAL APPROACH

Eligibility: Histologically proven diagnosis of oat cell carcinoma or small cell undifferentiated carcinoma of the lung.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

Twenty-three patients have been registered; however, no data are available for analysis. Case accrual is satisfactory to date.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Cis-Platinum in Refractory Epidermoid Carcinoma of the Head
and Neck.

WORK UNIT NO.: SWOG 7629

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

To determine the efficacy and toxicity of cis-platinum and mannitol
in the treatment of refractory epidermoid head and neck carcinoma.

TECHNICAL APPROACH

Eligibility: Patients with epidermoid carcinoma of the head and neck
region with measurable disease, who are not eligible for protocols of
higher priority.

Therapy is administered according to the schema outlined in the study
protocol.

PROGRESS

Insufficient data for analysis at this time.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Chemotherapy of Advanced Prostatic Cancer.

WORK UNIT NO.: SWOG 7630

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

1. To compare rate of response of hydroxyurea versus adriamycin + cytoxan.
2. Compare the duration of survival in patients with nonmeasurable disease.
3. To estimate the response rate to each crossover regimen.

TECHNICAL APPROACH

Eligibility: All patients with advanced Stage D prostatic cancer who have not received hydroxyurea, adriamycin or cyclophosphamide.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

Insufficient data available for analysis at this time.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Rubidazone in Adults with Previously Treated Acute Leukemia and Patients with CML Blast Transformation.

WORK UNIT NO.: SWOG 7633

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To determine the efficacy of rubidazone in adult patients with previously treated acute leukemia and in patients with CML blast transformation.
2. To determine the toxicity of the drug in the above patients with special reference to patients having prior therapy with adriamycin.

TECHNICAL APPROACH

Eligibility: Adult patients with acute leukemia having had prior chemotherapy and patients with CMLBT will be eligible.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

This is a new study.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of MeCCNU plus BTGdR and Mitomycin-C plus BTGdR
in the Treatment of Refractory Disseminated Colorectal
Carcinoma.

WORK UNIT NO.: SWOG 7634

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

To evaluate the effectiveness of MeCCNU plus BTGdR vs. Mitomycin-C
plus BTGdR for remission induction or for relapsing patients from
prior chemotherapy.

TECHNICAL APPROACH

Eligibility: All patients with disseminated colorectal carcinoma who
are not eligible for studies of higher priority.

Therapy will be administered in accordance with the schema outlined in
the study protocol.

PROGRESS

This is a new study.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Combined Modality Treatment for Limited Squamous Carcinoma of the Lung.

WORK UNIT NO.: SWOG 7635

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke, M.D., MAJ, MC

OBJECTIVES

1. To determine whether chemotherapy with adriamycin and/or immunotherapy with levamisole, improve median survival of split-course radiotherapy used alone in the treatment of patients with limited extent, squamous bronchogenic carcinoma.
2. To determine the qualitative and quantitative toxicity of each treatment regimen.

TECHNICAL APPROACH

Eligibility: All patients with a histologically confirmed diagnosis of limited squamous carcinoma of the lung are eligible provided they have received no previous chemotherapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

This is a new study.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Hexamethylmelamine in Advanced Breast Cancer.

WORK UNIT NO.: SWOG 7636

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

1. To determine the responsiveness of patients to hexamethylmelamine.
2. To determine whether pyridoxine given prophylactically will prevent the neuropathy associated with long-term hexamethylmelamine administration.

TECHNICAL APPROACH

Eligibility: Patients with advanced breast cancer not eligible for a higher priority SWOG study.

Therapy will be administered in accordance with the schema outlined in the study protocol.

PROGRESS

This is a new study. It is anticipated that 50 patients will satisfy the statistical requirements of the study; i.e., response rate with standard error of $\pm 7.5\%$.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Adriamycin, Mitomycin-C, and 5-FU in Gastric Carcinoma.

WORK UNIT NO.: SWOG 7639

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

1. To determine and to document both the response rates and the toxicities of two different combinations of Adriamycin, Mitomycin-C and 5-Fluorouracil in the management of surgically incurable adenocarcinoma of the stomach.
2. To compare the effectiveness of these two regimens.

TECHNICAL APPROACH

Eligibility: Patients must have unresectable gastric adenocarcinoma and an objectively measurable lesion. No prior exposure is permitted to Adriamycin, Daunomycin, Mitomycin-C or Porfiromycin. If previous chemotherapy has been given, full recovery from its effects must have been achieved before this regimen is started.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

This is a new study.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

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

WORK UNIT NO.: SWOG 7703

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

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

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

Therapy will follow the schema outlined in the study protocol.

PROGRESS

This is a new study.

Status: Ongoing.

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

INVESTIGATION PROJECT RESUME

TITLE: Chemotherapy/Immunotherapy for Multiple Myeloma.

WORK UNIT NO.: SWOG 7704

PRINCIPAL INVESTIGATOR: J. Dean McCracken, M.D., LTC, MC

ASSOCIATE INVESTIGATORS: Peter S. Kennedy, M.D., MAJ, MC; Dan W. Luedke,
M.D., MAJ, MC

OBJECTIVES

1. To compare the effectiveness of three intermittent pulse chemotherapy combinations VMCP + VCAP vs. VMCP + VBAP vs. MP for induction of remissions in previously untreated patients with multiple myeloma.
2. For patients proven to have at least a 75% tumor regression after induction, to compare the value of 12 months of chemoimmunotherapy maintenance VMCP + Levamisole in comparison to VMCP alone.
3. To establish baseline and serial data on immunologic status in these patient groups.

TECHNICAL APPROACH

Eligibility: On previously untreated patients with multiple myeloma (all stages) are eligible; without prior cytotoxic chemotherapy.

Therapy will follow the schema outlined in the study protocol.

PROGRESS

This is a new study.

Status: Ongoing.

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