

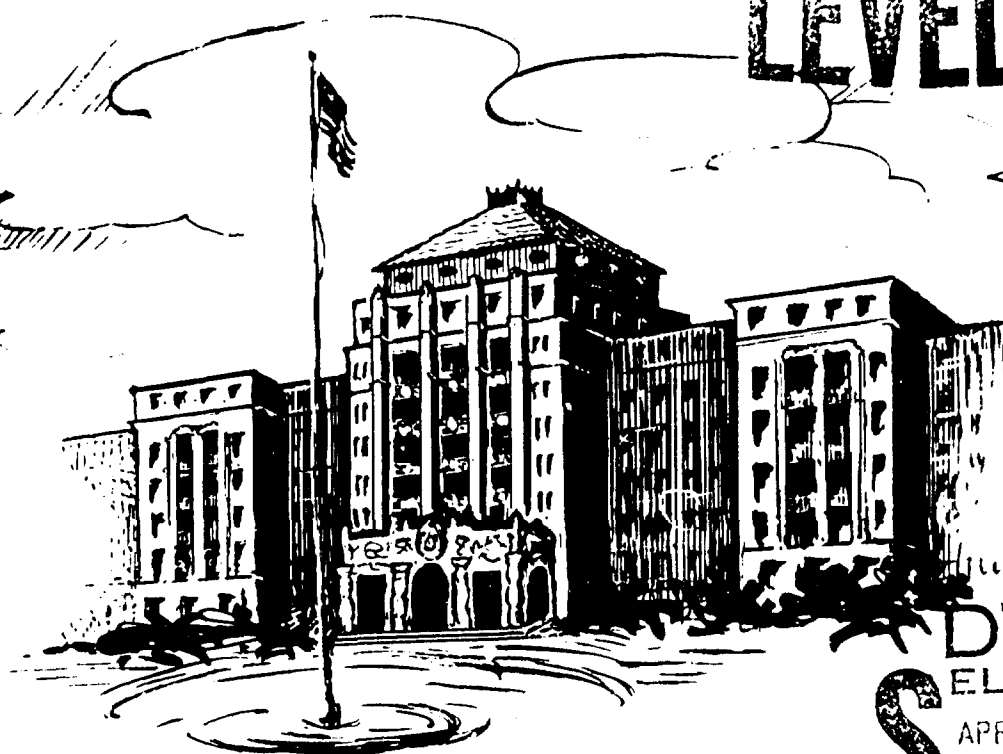
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DEPARTMENT OF CLINICAL INVESTIGATION

Annual Research Progress Report

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FISCAL YEAR 1980

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REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER MED-300	2. GOVT ACCESSION NO. AD-A097 213	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) ANNUAL RESEARCH PROGRESS REPORT, Fiscal Year 1980		5. TYPE OF REPORT & PERIOD COVERED ANNUAL - FY 80
7. AUTHOR(s) JAMES H. ANDERSON, JR., M.D. Major, MC		6. PERFORMING ORG. REPORT NUMBER
9. PERFORMING ORGANIZATION NAME AND ADDRESS Department of Clinical Investigation Brooke Army Medical Center Fort Sam Houston, Texas 78234		8. CONTRACT OR GRANT NUMBER(s)
11. CONTROLLING OFFICE NAME AND ADDRESS Commander Brooke Army Medical Center Fort Sam Houston, Texas 78234		10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS
14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office) Office of The Surgeon General Department of the Army Washington, D.C. 20314		12. REPORT DATE 1 Oct 1980 13. NUMBER OF PAGES 122857 15. SECURITY CLASS. (of this report) Unclassified 15a. DECLASSIFICATION/DOWNGRADING SCHEDULE
16. DISTRIBUTION STATEMENT (of this Report) APPROVED FOR PUBLIC RELEASE; DISTRIBUTION UNLIMITED		
17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report) ... N/A		
18. SUPPLEMENTARY NOTES The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.		
19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Clinical Investigations, all medical specialties Investigational protocols Publications, Presentations (at national, international, and regional science meetings) Detail Summary Sheets to include status and key words. (continued on reverse side)		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee and registered with the Department of Clinical Investigations during Fiscal Year 1980 and other known presentations and publications by the Brooke Army Medical Center staff. The research protocols described were conducted under the provisions of AR 40-38, as amended, Clinical Investigation Program; AR 40-7 Use of Investigational Drugs in Humans-(continued on reverse side)		

Block 19. Key Words

Southwest Oncology Group
Gynecology Oncology Group
Polycythemia Vera Study Group

Block 20. Abstract

USAMRDC 70-25, Use of Volunteers as Subjects of Research; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports; and BAMC Memo 40-98, Clinical Investigation Service (pending revision), to insure the medical well-being, preservation of rights and dignity of human subjects who participated in these investigational studies.

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FOREWORD

Clinical investigation is in serious trouble. Medical researchers should be regarded as an "endangered species". The gains of FY 80 and the promises for FY 81 might be compared to Cheyne-Stokes respiration. Symptoms of the problems in clinical research are evident in both the civilian and military arenas. The profound decline in research oriented physicians (50% decrease from 1968 to 1975) is reflected in the decreased number of NIH research awards to physicians in the last decade (44% in 1966 to 23% in 1978 - during which time the success rate for MD applicants remained constant). The impact on military medicine has been dramatic in both the Health Services Command and the Medical Research and Development Command. Three Clinical Investigation Services (later Departments) had no permanent chief during FY 1980. BAMC was one of these institutions. Publications and presentations decreased slightly from FY 79 at BAMC.

There are many factors which deter the physician from clinical investigation - the logarithmic increase in federal (and DOD) regulations governing human, animal and even in vitro research, the declining number of academic physicians serving as role models and stimulators of young physicians, instability of financial resources, lack of facilities and public pressure toward provision of direct patient care (despite the insistence of Medicare and Blue Cross, I am a physician - not a "provider"). These same problems are faced by military physicians. Thus far we have been no more successful in finding solutions than our civilian counterparts. This is unfortunate.

Names of our major medical facilities, William Beaumont, Walter Reed, etc., reflect the contributions military physicians have made in clinical investigation. Sir Alexander Fleming's clinical investigations have contributed to the reduction of both combat and noncombat mortality perhaps more than any other discovery. The primary point is - Clinical Investigation is not a "luxury" - it is the very foundation from which better health care for everyone can be obtained. Clinical Investigation must be supported, not only financially, but with interest and devotion of time by the hospital staff, the Commander and the higher Commands.

It is to the credit of each individual in the Department of Clinical Investigation that the past year was as productive as it was. Their interest, time and talents are the real assets of the department. BG Andre J. Ognibene's support of Clinical Investigation is unparalleled and continues to be a prime factor in the recruitment of new staff members. LTC Charles Thornsvarð was outstanding in his leadership of the Department as Acting Chief for the first eleven months of FY 80. MAJ David Burleson did an exceptional job as Laboratory Director. Special appreciation is due Mrs. Dodie Bratten whose unique contributions and talents have made not only this annual report possible but without whom the Department would cease to function effectively.



JAMES H. ANDERSON, JR., M.D.

Major, MC

Chief, Department of Clinical Investigation

UNIT SUMMARY - FISCAL YEAR 1980

A. Objectives

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

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

B. Technical Approach

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

C. Staffing

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Thornsvard, Charles T.*	LTC	60Z00	Acting Chief
Anderson, James H., Jr.**	MAJ	61C00	Chief, Endocrinologist
Burleson, David G.	MAJ	68C00	Laboratory Director/Biochemist
Lieberman, Michael M.	CPT	68A00	Microbiologist
Madonna, Gary S.	CPT	68A00	Microbiologist
Loyd, Charles M.	SFC	92B3R	Sr Med Lab Sp, NCOIC
Sinegal, John H.	SSG	92B2R	Med Lab Sp
Ebrahim, Fatima	SSG	92B2R	Med Lab Sp
Hunter, Deborah J.	SP5	01H2R	Biological Science Asst
Kelly, Jack	SP4	92B10	Med Lab Sp
Wolcott, Karen	SP4	92B10	Med Lab SP
	GS11	00334	Computer Sp
Strong, GERALYN	GS9	01320	Chemist
Chapa, Isidoro	GS7	00645	Med Lab Tech
Bratten, Dodie	GS7	01087	Editorial Asst

*Acting Chief, September 78 to August 79

**Assigned as Chief, 13 August 79.

D. Funding

Type	Fiscal Year 79	Fiscal Year 80
Civilian personnel to include benefits	70,068.00	72,855.00
Consumable supplies	45,666.08	58,362.87
Civilian contracts to include consultants	1,226.55	13,405.60
TDY	2,160.00	4,830.00
Publications	1,985.21	4,961.63
Noninvestment equipment (Minor MEDCASE)	3,000.00	-
Other OMA		
OMA Total	127,105.84	154,415.10
MEDCASE	104,014.39	37,894.25
Other		
Military	109,000.00	157,000.00
Total	340,120.23	349,309.35

E. Progress

<u>Protocol Disposition FY 80</u>			
	<u>Terminated</u>	<u>Completed</u>	<u>Ongoing to FY 81</u>
FY 73			1
FY 74			1
FY 75		1	1
FY 76			1
FY 77	2	5	3
FY 78	2	7	4
FY 79	2	15	11
FY 80	<u>4</u>	<u>14</u>	<u>24</u>
	10	42	46

Group Protocol Dispositions FY 80

	<u>Terminated</u>	<u>Completed</u>	<u>Ongoing FY 81</u>
SWOG	10	23	63
GOG	1	2	20
PVSG	<u>5</u>	<u>1</u>	<u>4</u>
	16	26	87

F. Problems

The "meat" of the problem areas encountered in the Department of Clinical Investigation at BAMC is what we refer to as SPaM - SPACE, PERSONNEL and MONEY. There is no need to go into a long dissertation as to what can be done about them - it seems they are here to stay, however recipe suggestions for meat tenderizers will be gratefully accepted.

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Code:

Project Number - C*-1⁺-78⁻

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

C - Completed
 O - Ongoing
 T - Terminated

P - Published
 SP - Submitted for Publication
 PR - Presentation

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Allen, R.C. Lucigenin chemiluminescence. Second International Symposium on Luminescence, La Jolla, Calif., 26-28 Aug 80. (C)

Allen, R.C. Use of chemilumigenic probes in the study of polymorphonuclear leukocyte redox metabolism. Second European Conference on Phagocytic Leukocytes, Trieste, Italy, 15-18 Sep 80. (C)

Hunter, D.J., Allen, R.C. Oxygen-dependent Streptococcus faecalis chemiluminescence: The importance of metabolism and medium composition. Second International Symposium on Luminescence, La Jolla, Calif., 26-28 Aug 80. (C)

Lieberman, M.M., Wright, G.L., Wolcott, K.M. Relationship between a Pseudomonas ribosomal vaccine and outer membrane proteins. American Society for Microbiology, Miami Beach, Fla., 13 May 80. (C)

Lieberman, M.M. Research on Pseudomonas ribosomal vaccines: Preparation of polyvalent antisera. Pseudomonas Society, American Society for Microbiology, Miami Beach, Fla., 12 May 80. (C)

Madonna, G.S., Allen, R.C. Shigella sonnei phase I and phase II: The role of classical and alternate complement activation in opsonification. American Society for Microbiology, Miami Beach, Fla., 12 May 80. (C)

DEPARTMENT OF MEDICINE

Thornsvard, C.T. Hematology-oncology in Europe for U.S. Armed Forces 1975-1978. Association Military Surgeons United States, San Diego, Calif., Oct 79.

Allergy-Immunology

Ramirez, D.A., Evans, R., III. Adverse reactions to venom immunotherapy. American Academy of Allergy, Atlanta, Ga., 19 Feb 80.

Laham, M.N. Increased total respiratory resistance in allergic asthmatics during skin testing. American Academy of Allergy, Atlanta, Ga., 19 Feb 80.

Cardiology

Murgo, J.P. Dynamic aortic valve gradients and hypertrophic cardiomyopathy. 52nd Scientific Sessions, American Heart Association, Dallas, Tex., Nov 79. (C)

Murgo, J.P. Chairman, Sessions on Clinical Research - Laennec Society, 52nd Scientific Sessions of the American Heart Association, Dallas, Tex., Nov 79. (C)

Murgo, J.P. Panel member, 29th Annual Sessions of the American College of Cardiology. Physiologic basis of heart sounds and murmurs. Houston, Tex., Mar 80. (C)

Murgo, J.P. Grand Rounds, Texas Heart Institute, St. Luke's Episcopal Hospital, Houston, Tex. Ejection dynamics in "obstructive" and "nonobstructive" hypertrophic cardiomyopathy. Mar 80. (C)

Murgo, J.P. Right and left heart ejection dynamics in pericardial tamponade. Pericardial disease symposium sponsored by the Pennsylvania Chapter of American Heart Association and the University of Pittsburgh, Pittsburgh, Penn., May 80. (C)

Murgo, J.P. Resting subvalvular pressure gradients in valvular AS. 9th Annual Association of Army Cardiology Meeting, Letterman Army Medical Center, San Francisco, Calif., May 80. (C)

Murgo, J.P. Evaluation of the time course of relaxation in man. 9th Annual Association of Army Cardiology Meeting, Letterman Army Medical Center, San Francisco, Calif., May 80. (C)

Murgo, J.P. Visiting Professor, The Medical University of South Carolina, Charleston, South Carolina. (1) Grand Rounds - The ejection dynamics of obstructive and nonobstructive hypertrophic cardiomyopathy. (2) Research seminar - The mechanisms of pulsus paradoxus in pericardial tamponade. June 80. (C)

Murgo, J.P. Research Seminar: New techniques on the latest measurement and information processing in medicine. University of California at Los Angeles, Los Angeles, Calif., Aug 80. (C)

Alexander, M.D. Congenital aneurysm of the atrial septum: An unusual clinical presentation. 9th Annual Association of Army Cardiology Meeting, Letterman Army Medical Center, San Francisco, Calif., May 80.

Bloom, K.R., et al. The use of Technetium 99m labeled macro-aggregates for the evaluation of differential pulmonary blood flow in congenital heart disease with obligatory right to left shunting. 9th Annual Association of Army Cardiology Meeting, Letterman Army Medical Center, San Francisco, Calif., May 80.

Craig, W.E. Time course of relaxation in normal man at rest, during exercise and with isoproterenol. 52nd Scientific Sessions of the American Heart Association, Nov 79.

Dermatology

Lewis, C.W. Topical corticosteroids. AMA Winter Scientific Meeting, San Antonio, Tex., 13-14 Jan 80.

Lewis, C.W. Common hair problems. AMA Winter Scientific Meeting, San Antonio, Tex., 13-14 Jan 80.

Lewis, C.W. Warts. AMA Winter Scientific Meeting, San Antonio, Tex. 13-14 Jan 80.

Lewis, C.W. Hand dermatitis. AMA Winter Scientific Meeting, San Antonio, Tex., 13-14 Jan 80.

Lewis, C.W. Contact dermatitis and drug eruptions. AMA Winter Scientific Meeting, San Antonio, Tex., 13-14 Jan 80.

Emergency Medicine

Thompson, N.J. Military EMS and interfacing with civilian EMS systems. 55th TPHA Annual Meeting, San Antonio, Tex., 26 Feb 80.

Gastroenterology

Block, D.K., Brown, J.D., Ownesby, L.C. Singultus and the Mallory-Weiss syndrome. Ninth Annual William Beaumont Gastrointestinal Symposium, El Paso, Tex., 20 Mar 80.

Infectious Disease

Carpenter, J.L. Treatment of chancroid. Interscience Conference on Antimicrobial Agents and Chemotherapy, Boston, Mass., Oct 79.

Oncology

McCracken, J.D. Intra-arterial 5-FU chemotherapy combined with radiation therapy for the treatment of localized adenocarcinoma of the pancreas. American Pancreatic Assoc., Inc. and National Pancreatic Cancer Project, Kansas City, Kan., Nov 79. (C)

White, J.E., McCracken, J.D., Chen, T.T., and the Southwest Oncology Group. Radiation therapy in limited oat cell carcinoma of the lung. American Society of Clinical Oncology, New Orleans, La., Mar 80. (C)

Cowan, J.D., Von Hoff, D.D. Use of a human tumor stem cell assay system to screen retinoids for antineoplastic activity. 20th Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, La., 22-24 Sept 80.

DEPARTMENT OF NURSING

Butke, D.N. Acid-base balance/disturbances. American Association of Critical Care Nurses, San Antonio, Tex., 15-16 Nov 79.

DEPARTMENT OF PATHOLOGY

Cerezo, L. Classification of the acute leukemias. 4th Annual Meeting, Society of Armed Forces Medical Laboratory Scientists, San Antonio, Tex., Nov 79.

Cerezo, L. Lymphoblastic crisis in polycythemia vera. ASCP-CAP Meeting, Las Vegas, Nev., Oct 79.

Cerezo, L. FAB acute leukemia workshop. Fall Southwest Oncology Group Meeting, Phoenix, Ariz., 6 Sept 80.

DEPARTMENT OF PEDIATRICS

Wilson, L.O. Algorithm-directed triage: The first year. American Academy of Pediatrics, Section on Military Pediatrics, San Francisco, Calif., Oct 79. (C)

Squires, M.D. Biblical prospectives on adolescents and their problems. The Baptist General Convention, Baylor University, Waco, Tex., 24-26 Jun 80.

DEPARTMENT OF PSYCHIATRY

Worthington, E.R. Female adjustment in the modern army. Seventh Psychology in the DOD Symposium, USAF Academy, Colorado Springs, Colo., Apr 80.

Worthington, E.R. Volunteer army and initial adjustment. Seventh Psychology in the DOD Symposium, USAF Academy, Colorado Springs, Colo., Apr 80.

Worthington, E.R. Psychology training for Olympic athletes. 88th Annual American Psychological Association Convention, Montreal, Can., Sept 80.

Worthington, E.R. Analysis of sexual assaults at a major military post. 88th Annual American Psychological Association Convention, Montreal, Can., Sept 80. (C)

Blankenship, D.G. The evolution of a multidisciplinary human relations program at a large medical center. American Psychological Association Convention, Montreal, Can., 3 Sept 80.

DEPARTMENT OF RADIOLOGY

Telepak, R.J. Non-cardiac 7 pinhole tomography. Picker Tomography Symposium, Denver, Colo., 14 Mar 80.

Telepak, R.J. Cardiac and non-cardiac 7 pinhole tomography. Texas Association of Physicians in Nuclear Medicine, Houston, Tex., 17 May 80.

Telepak, R.J. Non-cardiac 7 pinhole tomography, its strengths and weaknesses. Lettermay Army Medical Center Present Concepts in Radiology Course, San Francisco, Calif., 29 May 80.

DEPARTMENT OF SURGERY

Anesthesiology and Operative Service

Anderton, B.J. Hyperpyrexia. Clinical Symposium for ANC Nurse Anesthetists, HSC, Fort Sam Houston, Tex., 29 Apr 80.

Casperton, T. Anesthesia for cardiac patient. Clinical Symposium for ANC Nurse Anesthetists, HSC, Fort Sam Houston, Tex., 30 Apr 80.

Edsall, D. Anesthesia for patients with COPD. Clinical Symposium for ANC Nurse Anesthetists, HSC, Fort Sam Houston, Tex., 1 May 80.

Tewis, H.D. Epidural anesthesia. Clinical Symposium for ANC Nurse Anesthetists, HSC, Fort Sam Houston, Tex., 1 May 80.

Weddel, S.J. Serum levels following epidural administration of morphine and correlation with relief of post surgical pain. Society of Obstetrical Analgesia and Perinatology, Boston, Mass., May 80. (C)

General Surgery

Rosenthal, D* Surgical approach to the adrenal gland. Gary Wratten Symposium, Walter Reed Army Medical Center, Washington, D.C.

Rosenthal, D* Feminizing tumor of the adrenal cortex. Gary Wratten Symposium, Walter Reed Army Medical Center, Washington, D.C.

Rosenthal, D* Colonic polyps - An overview. Robert B. Brown Surgical Symposium, National Naval Medical Center, Bethesda, Md.

Rosenthal, D* E.E.A. anastomosis experience. U.S.U.H.S.-Mexican Surgical Combined Meeting, Washington, D.C.

Rosenthal, D* A diagnostic dilemma, gastrointestinal vs. vascular disease. Gastrointestinal Symposium, William Beaumont Army Medical Center, El Paso, Tex.

Rosenthal, D* Antibiotic choice in nonoperative management of acute diverticulitis. U.S.U.H.S. Surgical Symposium.

*Presentations made while assigned at Walter Reed Army Medical Center.

Spebar, M.J. Adjuvant hyperbaric oxygen in the management of fungal infections of the burn wound. Fifth Conference on the Clinical Applications of Hyperbaric Oxygen, San Diego, Calif., June 80.

Spebar, M.J. Air embolism. Annual Meeting of the Military Vascular Society, Bethesda, Md., Dec 79.

Young, R.N. Tetanus revisited and updated. Academy of Pediatrics, San Francisco, Calif., 16-18 Oct 79.

Young, R.N. Newer concepts in the treatment of surgical infections. San Francisco, 10-11 Nov 79.

Young, R.N. Anterior chest wall melanomas. Military Plastic Surgery Symposium, 22-26 Jan 80.

Young, R.N. Anterior chest wall melanomas. Southwest Surgical Congress, Colorado Springs, Colo., 5-8 May 80.

Jarstfer, B.S. The occluded internal carotid artery. Military Vascular Surgery Symposium, 13-14 Dec 79.

Neurological Surgery

Gendell, H.M., Jannetta, P.J. Neurovascular compression of the ventrolateral medulla: Theoretical considerations and experimental model. Congress of Neurological Surgery, Las Vegas, Nev., Oct 79.

Segal, R., Gendell, H., Canfield, D. et al. Hemodynamic changes induced by pulsatile pressure applied to the left ventro-lateral medulla. Congress of Neurological Surgery, Las Vegas, Nev., Oct 79.

Ophthalmology

Griffith, D.G. Management of intravitreal lens material. Walter Reed Biennial Short Course in Ophthalmology, Washington, D.C., Apr 80.

Griffith, D.G. Vitrectomy. Satellite Television Services, Brooke Army Medical Center, Fort Sam Houston, Tex., Aug 80.

Mauldin, M. Bietti's tapetoretinal degeneration without marginal corneal dystrophy: Crystalline retinopathy. Bascom Palmer Eye Institute, Miami, Fla., 20-22 Jun 80.

Orthopaedic Surgery

Mayer, H.A., Jr. Transtrochanteric anterior rotational osteotomy of the femoral head. Society of Military Orthopaedic Surgeons, San Francisco, Calif., 26 Nov - 2 Dec 79.

Williams, R.D. Concepts and uses of the "Roto Rest" treatment table. Society of Military Orthopaedic Surgeons, San Francisco, Calif., 26 Nov - 2 Dec 79.

Parr, T.J. Nonorbital osteosarcoma following bilateral retinoblastoma: A case report and review of the literature. Society of Military Orthopaedic Surgeons, San Francisco, Calif., 26 Nov - 2 Dec 79.

Baker, C.L., Jr. Acute posterolateral rotatory instability. American Academy of Orthopaedic Surgeons, Atlanta, Ga., 7-12 Feb 80.

Baker, C.L., Jr. Results" Acute posterolateral rotatory instability. Philosophy of the Knee with Hughston II Meeting, Pine Mountain, Ga., 13-17 Apr 80.

Williams, R.D. Soft tissue injuries of the ankle. State Meeting of the Podiatry Association, San Antonio, Tex., 6 Jun 80.

Otolaryngology

Price, J.C. Soft tissue trauma. Maxillofacial Trauma Workshop, The University of Texas Health Science Center at San Antonio, Nov 79.

Price, J.D. Visiting consultant, Madigan Army Medical Center, Racoma, Wash., Dec 79.

Price, J.D. Diagnostic decision making: Current concepts. San Antonio Ophthalmology and Otolaryngology Meeting, 23 Feb 80.

Price, J.C. Rehabilitation of paralyzed face. Corpus Christi Otolaryngology Society, Corpus Christi, Tex., 29 May 80.

Cardiotheracic Surgery

Collins, G.J., Jr. Heparin utilization during arterial revascularization. Robert B. Brown Surgical Symposium, Bethesda, Md., 25 Sep 80.

Collins, G.J., Jr. Sympathectomy - Its role in modern vascular surgery. Robert B. Brown Surgical Symposium, Bethesda, Md., 25 Sep 80.

Collins, G.J., Jr. Fibromuscular dysplasia of the carotid artery management. Robert B. Brown Surgical Symposium, Bethesda, Md., 26 Sep 80.

Urology

Arnold, F.S., Spence, C.R., Solomon, H.D., Gangai, M.P. Pre-TRUP prognostic aid and post-TURP diagnostic aid. Kimbrough Urological Seminar, Nov 79.

ORAL SURGERY SERVICE

Shelton, D.W., Schow, S.R., Watson, R. Movie "Techniques in Outpatient General Anesthesia". American Association of Oral and Maxillofacial Surgeons, New Orleans, La., Oct 79.

Schow, S.R. Treatment of mandibular fractures. Short Course in Oral and Maxillofacial Surgery, Letterman Army Institute of Research, The Presidio, Calif.

Schow, S.R. Small segment maxillary and mandibular osteotomies. Short Course in Oral and Maxillofacial Surgery, Letterman Army Institute of Research, The Presidio, Calif.

SOCIAL WORK SERVICE

Allen, J.D. Addressing the mental health needs of youth - A challenge to the health care delivery system. Current Trends in Army Social Work, San Antonio, Tex., 17-21 Mar 80.

Sorensen, E.C. Training mental hygiene consultation service personnel for combat readiness: The division social worker's responsibility. Current Trends in Army Social Work, San Antonio, Tex., 17-21 Mar 80.

Detail Summary Sheet

Date: 1 Oct 80	Proj No: C-7-77	Status: Completed
TITLE: The Development of a Gram-Negative Bacterial Vaccine for Laboratory Animals.		
Start Date: Sep 76	Est Comp Date: Dec 79	
Principal Investigator: Michael M. Lieberman, Ph.D., CPT MSC	Facility: Brooke Army Medical Center	
Dept/Sec: Department of Clinical Investigation	Associate Investigators: Donna DeSoto, SP5 Gwendolyn Wright, SP5 Karen Wolcott, SP4	
Key Words: Vaccine Gram-Negative (<u>Pseudomonas aeruginosa</u>) Laboratory Animals		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:\$9700.00	Periodic Review Results:
Objective: To develop a safe and effective, broad-spectrum, gram-negative bacterial vaccine for laboratory animals.		

Technical Approach: The initial phase of the project encompassed the development of a ribosomal vaccine for several serotypes of Pseudomonas aeruginosa. The bacteria were grown in broth culture, harvested and washed by centrifugation, and subjected to ultrasonic disruption for preparation of crude extracts. The ribosomes were isolated from the extracts by ammonium sulfate fractionation and ultracentrifugation. Isolated ribosomes were chemically analyzed for protein and RNA content and tested for immunogenicity in mice. Mice were 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 were also challenged. The percentage of mice that survive 48 hours post challenge are scored to determine the extent of protection afforded by the vaccine.

In addition, the vaccine was used to immunize rabbits and the rabbits bled to obtain immune serum. The immune serum was then tested by injecting it into mice which were subsequently challenged by inoculation with live bacteria. Mice injected with pre-immune rabbit serum were also included in the challenge as controls. The challenged mice were then scored for survival as above in order to determine the ability of the immune serum to confer passive protection against Pseudomonas to the mice.

Progress: Passive protection of mice against Pseudomonas aeruginosa using specific antisera and immunoglobulin fractions induced by immunizing rabbits with a ribosomal vaccine has been accomplished. The results demonstrated that protection by the ribosomal vaccine against challenge with live organisms can be serum mediated. Previous work has shown that the vaccine can be separated into two components on the basis of molecular weight and that both the higher

C-7-77 (continued)

(peak A)- and lower (peak B)-molecular-weight fractions were capable of inducing active immunity in mice. The present report indicates that both fractions are also capable of eliciting the production of mouse-protective antibody in rabbits. Agar gel diffusion with antisera to peaks A and B or unfractionated vaccine indicated a common antigenic component among them in addition to an extra antigen in unfractionated vaccine not present in peak B. Passive hemagglutination with antisera to peaks A and B demonstrated high-titer agglutinating antibody only with antiserum to peak A when a method of erythrocyte sensitization for lipopolysaccharide antigens was used. Also, passive hemagglutination was greatly inhibited by small amounts of lipopolysaccharide prepared from the same organism from which the vaccine was made. Both antisera to peaks A and B fixed complement with either A or B antigens. Antisera to peaks A and B, when reacted with peak B antigen, had about the same complement fixation titer (as determined by a quantitative complement fixation test). However, when peak A antigen was used, antiserum to peak A had about twice the complement fixation titer that antiserum to peak B had. These results are consistent with previous observations which suggest that the ribosomal vaccine contains lipopolysaccharide in addition to an unidentified immunogenic principle associated with ribosomes. Furthermore, this immunogen was present in both peaks A and B, but detectable amounts of lipopolysaccharide were present only in peak A. The relative importance of the immunoglobulin G (IgG) and IgM classes of antibodies was also compared. The results indicated that both IgG and IgM isolated from immune rabbit serum are protective in mice. Only IgG precipitated with the vaccine in agar gel diffusion, but both IgG and IgM were active in passive hemagglutination and in complement fixation. The passive hemagglutination titer of the IgM was higher than that of the IgG, but the complement fixation titer of the IgG was higher than that of the IgM. The mouse-protective capability of the IgG and IgM was about the same.

Detail Summary Sheet

Date: 27 Oct 80	Proj No: C-25-78	Status: Ongoing
TITLE:		
Determination of Opsonizing Antibody in People Receiving Polyvalent Pneumococcal Vaccine.		
Start Date: 30 May 78	Est Comp Date:	
Principal Investigator:	Facility:	
Robert C. Allen, M.D., Ph.D., CPT, MC	Brooke Army Medical Center	
Dept/Sec:	Associate Investigators:	
Department of Clinical Investigation	Deborah J. Hunter, SP5	
Key Words:		
Pneumococcal vaccine		
Opsonification		
<u>Streptococcus</u> species		
Chemiluminescence		
Accumulative MEDCASE	Est Accumulative	Periodic
Cost:	OMA Cost: \$943.27	Review Results: Continue

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

Technical Approach: Pre- and postimmunization sera were obtained from patients undergoing immunization against Streptococcus pneumoniae using polyvalent pneumococcal vaccine (Pneumovax^R MSD). These sera are being tested for opsonic activity directed against a number of serotypes of Streptococcus pneumoniae as well as other streptococcal species. A highly sensitive chemiluminescent assay has been developed for quantification of neutrophil (PMNL) leukocyte O₂-red-x metabolism, and this technique is being applied to quantification of the rate of opsonification for these sera.

Progress: The sera have been collected and are presently undergoing testing. Preliminary results indicate that titration of each serum specimen will be required for accurate assessment of opsonic activity. Optimum stabilization of the microbe antigen (i.e. formalin treatment) is also being investigated.

Some interesting observations have already been made in the course of the investigation. These include observations with regard to the mechanism for PMNL and non-PMNL oxidative microbicidal action against streptococcal microbes.

Detail Summary Sheet

Date: 27 Oct 80 Proj No: C-35-78 Status Completed

TITLE:

The Molecular Pathology of Alpha Toxin from Clostridium Perfringens upon Polymorphonuclear Leukocyte (PMNL) Function

Start Date: 15 Aug 78

Est Comp Date: Jul 82

Principal Investigator:

Facility:

Robert C. Allen, M.D., Ph.D., CPT, MC

Brooke Army Medical Center

Dept/Sec:

Associate Investigators:

Department of Clinical Investigation

Geralyn L. Strong, DAC

Key Words:

Deborah J. Hunter, SP5

Phospholipase C

Jack Kelly, SP4

Clostridium perfringens

Bacterial toxins

Oxidative microbicidal action

Accumulative MEDCASE

Est Accumulative

Periodic

Cost:

OMA Cost:\$14079.15

Review Results:

Objective: To study membrane alterations of PMNL resulting from the action of α --toxin of C. perfringens.

Technical Approach: Clostridium perfringens alpha toxin, phospholipase C, and other clostridial toxins were purified by electrophoretic and column separation techniques. The action of these toxins on the PMNL was investigated using radioisotopic techniques for measurement of carbohydrate metabolism and chemiluminescence for assessment of oxidative microbicidal activity. The effects of direct O_2 -associated microbicidal action on anaerobic and aerobic microbes was also investigated.

Progress: Activation of PMNL metabolism was detected using various C. perfringens toxins. However, the activating substance does not appear to be exclusively phospholipase C. The exact nature of these activating toxins is presently under further investigation by Dr. D. L. Stevens at the V.A. Hospital, Boise, Idaho.

Direct O_2 -dependent, non-PMNL oxidative damage was observed from certain anaerobically poisoned microbes. This damage was associated with a measurable chemiluminescence.

Detail Summary Sheet

Date: 27 Oct 80	Proj No: C-5-79	Status: Ongoing
TITLE: Assessment of Opsonic Capacity and Phagocyte Functionality in Microliter Quantities of Whole Blood		
Start Date: 5 Jan 79	Est Comp Date: Jul 82	
Principal Investigator: Robert C. Allen, M.D., Ph.D., CPT, MC	Facility: Brooke Army Medical Center	
Dept/Sec: Department of Clinical Investigation	Associate Investigators: Deborah J. Hunter, SP5 Jack Kelly, SP4	
Key Words: Microbicidal activity Complement Immunoglobulin Chemilumigenic probes Redox metabolism		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:\$8747.00	Periodic Review Results: Continue

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

Technical Approach: The use of two difficult high quantum yield, oxidizable substrates for quantification of phagocyte O_2 -redox activity in whole blood has been achieved. Both luminol, 5-amino-2,3-dihydro-1,4-phthalazinedione, and lucigenin, 10,10'-dimethyl-9,9'-biacridinium dinitrate, have been employed in this manner. Other substrates are also under investigation. A technique for titration of serum opsonic capacity, based on the rate of activation of PMNL O_2 -redox metabolism has also been established using chemilumigenic probes.

Progress: The use of chemilumigenic probes for assessment of PMNL metabolic activity has been successfully developed as a microtechnique requiring less than one microliter of whole blood per assay. Furthermore, the use of chemically and physically different probes has afforded a method for differentiating O_2 -redox activity with respect to location and type of oxidant involved. Two distinct activities have been established for the PMNL.

Application of probe amplified PMNL chemiluminescence to the quantification of serum opsonic capacity has resulted in development of a method for titration of specific immunoglobulins and serum complement activities using microliter quantities of serum.

Detail Summary Sheet

Date: 1 Oct 80 Proj No: C-8-79 Status: Ongoing

TITLE:

The Measurement of Cyclic Nucleotide Levels in Purified Populations of Lymphocytes Incubated with Mitogens.

Start Date: 6 Feb 79	Est Comp Date: Jun 82
Principal Investigator: David G. Burleson, Ph.D., MAJ, MSC	Facility: Brooke Army Medical Center
Dept/Sec: Department of Clinical Investigation	Associate Investigators: John H. Sinegal, SSG
Key Words: Cyclic nucleotide levels T and B cells Mitogens	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$4134.41
	Periodic Review Results: Continue

Objective: To purify guinea pig lymphocytes on density gradients into functional subpopulations and measure intracellular levels of cyclic AMP and cyclic GMP after incubation of the purified cells with the mitogens for T and B Cells.

Technical Approach: Guinea pig lymph node cells are separated into seven (7) fractions using discontinuous gradients of 40-75% Percoll. The purified cells are exposed to various lectins and at different time periods the cells are lysed with a precipitating reagent and the cyclic nucleotides extracted. The extracts are purified by HPLC and analyzed by radioimmunoassay. Cyclic AMP and cyclic GMP levels are then correlated with the mitogenicity of the lectin, time of incubation and the cell type. Cell populations are characterized by Wright's stain and observation under a microscope for general morphology and by rosetting techniques for T and B cell identification.

Progress: A procedure for isolation of seven (7) populations of cells using discontinuous gradients of Percoll has been developed. Sedimentation velocity techniques of separation using an ultracentrifuge rotor have also been investigated. However, currently available purification techniques have not been adequate to remove interfering substances from the cell extracts. Completion of the project must await acquisition of a High Pressure Liquid Chromatograph for adequate purification of the cell extracts prior to measurement of cyclic nucleotides by radioimmunoassay.

Detail Summary Sheet

Date: 1 Oct 80		Proj No: C-26-79	Status: Ongoing
TITLE: Studies on the opsonization and phagocytosis of Invasive and Non-invasive <u>Shigella</u> species by Polymorphonuclear Leukocytes (PMNL).			
Start Date: 6 Nov 79		Est Comp Date: Nov 81	
Principal Investigator: Gary S. Madonna, M.S., CPT, MSC		Facility: Brooke Army Medical Center	
Dept/Sec: Department of Clinical Investigation		Associate Investigators: Robert C. Allen, M.D., Ph.D. CPT, MC Michael M. Lieberman, Ph.D. CPT, MSC	
Key Words: <u>Shigella sonnei</u> Polymorphonuclear leukocytes (PMNL) Chemiluminescence (CL)			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:\$2951.23	Periodic Review Results: Continue	

Objective: To investigate the role of specific (postimmunization) sera in effecting opsonization and microbicidal action of PMNL against various invasive and noninvasive strains of Shigella sonnei and Shigella flexneri. The opsonic role of complement alone (alternative pathway) and in the presence of immune sera (classical pathway) will be investigated.

Technical Approach: Shigella sonnei phase I synthesize a complete lipopolysaccharide (LPS) necessary for virulence whereas spontaneous occurring phase II bacteria synthesize an incomplete LPS and are uniformly avirulent. Shigella flexneri 2a also undergoes a colonial change from translucent (T) to opaque (O) colonies with concomitant loss of virulence. Differences in serum requirements (antibody and complement) necessary for opsonification of these organisms and resultant phagocytosis, stimulation of polymorphonuclear leukocyte (PMNL) microbicidal metabolism and phagocytic killing are studied.

Serum is obtained from rabbits before (normal rabbit serum) and after (immune) a two week daily series of injections using formalin-treated bacterial suspensions. For studies in which the individual opsonic roles of IgM and IgG is determined, serum is precipitated with $(NH_4)_2SO_4$ and the immunoglobulin separated by using a Sepharose 6 B-packed glass column.

Stimulation of PMNL O_2 -redox metabolism as required for oxidative killing is measured by chemiluminescent technique using luminol as a chemilumigenic substrate. Measurement of this PMNL chemiluminescence (PMNL-CL) is accomplished using a Beckman LS 150 scintillation counter. Killing of virulent and avirulent organisms by the bactericidal action of serum or microbicidal action of PMNL is determined by a viable bacterial-colony count method.

Progress: Shigella sonnei phase I and phase II differ distinctly in their susceptibility to direct killing by serum and serum opsonic requirements necessary for activation of PMNL O_2 -redox metabolism and PMNL microbicidal

C-26-79 (continued)

killing. S. sonnei phase I is resistant to direct complement-mediated killing by serum whereas S. sonnei phase II is susceptible. Opsonification of S. sonnei phase I is restricted to the antibody dependent classical pathway of complement activation. Only after opsonification with specific phase I antibody and complement was phase I capable of stimulating PMNL-CL and microbicidal action. This specific recognition system was not required for S. sonnei phase II. Stimulation of PMNL microbicidal metabolism by phase II was effected by activation of complement in the absence of specific immune serum.

Detail Summary Sheet

Date: 1 Oct 80	Proj No: C-38-79	Status: Ongoing
TITLE: The Effect of Prostaglandin Synthesis Inhibitors on <u>in vitro</u> Suppressor Cell Activity in Lymphocytes from Patients with Common Variable Agammaglobulinemia.		
Start Date: Sep 79	Est Comp Date: Oct 82	
Principal Investigator: David G. Burleson, Ph.D., MAJ, MSC	Facility: Brooke Army Medical Center	
Dept/Sec: Department of Clinical Investigation	Associate Investigators: Michel N. Laham, M.D., MAJ, MC Charles M. Loyd, SFC	
Key Words: Agammaglobulinemia T-cell Suppressor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$4141.84	Periodic Review Results: Continue

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

Technical Approach: Human peripheral blood lymphocytes (HPBL) from normal individuals and patients with common variable agammaglobulinemia are incubated independently and in combination in the presence of pokeweed mitogen for six days. Various cultures are also incubated in the presence of prostaglandin synthesis inhibitors. After six days of culture, the cells are harvested and plated on slides in agar. Immunoglobulin cells are detected using the reverse hemolytic plaque assay. This involves plating HPBL with sheep red blood cells (SRBC) coated with protein A. The agarose coated slides containing the cells are incubated in anti human immunoglobulin and complement to develop the plaques. The plaques are then counted under a low power microscope. Increased number of plaques indicate decreased lymphocyte suppressor activity. Plaque counts of normal patient and combined cultures are compared to determine the presence of suppressor cell activity. Suppressed cultures incubated with prostaglandin synthesis inhibitors are evaluated for release from suppressor activity.

Progress: The principal technician for this project has been trained in Dr. Peter Lipsky's laborator, Dallas, Texas, to do the reverse hemolytic plaque assay. Extensive preliminary testing has shown that the plaque assay is now working and patients are being contacted to participate in the study.

Detail Summary Sheet

Date: 1 Oct 80	Proj No: C-4-80	Status: Ongoing
TITLE: The Development of a <u>Pseudomonas aeruginosa</u> Vaccine for Laboratory Animals, Phase II.		
Start Date: 10 Jan 80	Est Comp Date: Jan 83	
Principal Investigator: Michael M. Lieberman, Ph.D., CPT, MSC	Facility: Brooke Army Medical Center	
Dept/Sec: Department of Clinical Investigation	Associate Investigators: Gwendolyn Wright, SP5 Karen Wolcott, SP4 Fatima Ebrahim, SSG	
Key Words: <u>Pseudomonas aeruginosa</u> Vaccine		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$3926.52	Periodic Review Results: Continue
Objective: To develop a safe and effective, multivalent, <u>Pseudomonas aeruginosa</u> vaccine and hyperimmune globulin for laboratory animals.		

Technical Approach: Ribosomal vaccines are prepared as described previously (C-7-77) from all available serotypes of P. aeruginosa. Rabbits are divided into two groups and each group is immunized with half the total number of vaccine preparations. (prior to immunization the rabbits are bled to obtain pre-immune sera.) After the immunization schedule, rabbits are bled for the immune sera. Groups of mice are injected with the multivalent antisera and then challenged with live cultures of randomly chose clinical isolates of P. aeruginosa. Mice are scored for percentage of survivors for each challenge culture. The percentage of clinical isolates of Pseudomonas against which statistically significant protection was achieved by the multivalent anti-sera is calculated.

Progress: Significant protection was achieved against 34 of 40 strains tested (85%). Included among these strains against which protection was achieved were four mucoid strains. In addition, the degree of cross-protection attainable by the ribosomal vaccines was investigated. The results obtained indicated that these vaccines are generally serotype specific.

Detail Summary Sheet

Date: 28 Oct 80	Proj No: C-28-73	Status: Ongoing
TITLE: The Simultaneous Determination of Instantaneous Aortic Flow, High Fidelity Intracardiac Pressures, Intracardiac Phonocardiography, Echocardiographic Dimensions and Derived Indices in Man.		
Start Date: 6 Mar 73	Est Comp Date: Dec 80	
Principal Investigator Joseph P. Murgo, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Cardiology	Associate Investigators: John P. Giolma, Ph.D., CPT, MSC Wm. Craig, M.D., MAJ, MC Julio Bird, M.D., CPT, MC N. Westerhoff, Ph.D.	
Key Words: Instantaneous aortic flow Cardiac catheterization Intracardiac phonocardiography		
Accumulative MEDCASE Cost: \$364,730.54	Est Accumulative OMA Cost: \$15984.00	Periodic Review Results: Update by 1 Jan 81

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.

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. The evaluation includes strip chart echocardiography to determine the patient's suitability for certain aspects of the protocol. 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 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.

Progress: Progress during FY 80 was hampered to a great extent by the loss of CPT Giolma from active duty and the transfer of our computer specialist to HSC.

C-28-73 (continued)

This affected most seriously the full utilization of the HP 1000 computer which was delivered during this fiscal year. In addition, our research assistant was lost by transfer out of CONUS. As a result, personnel turnovers affected progress during this fiscal year in a very significant manner.

However, at the time of this progress report, a multidisciplinary team of scientists and research assistants has been identified for the coming fiscal year. These include a full time Ph.D. cardiovascular physiologist, a Ph.D.-M.D. cardiovascular scientist (fluid dynamicist), a military computer scientist, a civilian computer specialist, a research assistant and a programmer analyst.

Despite the problems generated above, significant progress was still made with the final acceptance of four major scientific articles, one case report, four new abstracts, three book chapters, three additional papers submitted for publication and ten presentations.

Detail Summary Sheet

Date: 15 Oct 80 Proj No: C-9-75 Status: Ongoing

TITLE:

Clinical Outpatient Algorithm Validation - A Pilot Study.

Start Date: 30 Sep 74	Est Comp Date: Aug 81
Principal Investigator: Barry W. Wolcott, M.D., LTC, MC	Facility: Brooke Army Medical Center
Dept/Sec: Department of Medicine/Emergency Medicine	Associate Investigators: Richard M. Tompkins, M.D.
Key Words: Algorithm Validation	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

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

Technical Approach: This large study has multiple components subtended by its title. Currently these include the management of ankle trauma in the BAMC Emergency Room, validation of algorithms for dysuria and gastrointestinal complaints in the BAMC Adult Emergency Room, validation of a pediatric URI algorithm in the Pediatric Acute Care Clinic, and development of an on-line microprocessor assisted triage and AMOSIST encounter system (first in the Pediatric Acute Care Clinic and then in the BAMC Emergency Department).

Progress: Ongoing studies continue to produce useful data with publications being accepted in a variety of reference journals.

Detail Summary Sheet

Date: 7 Oct 80 Proj No: C-29-75 Status: Completed

TITLE:

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

Start Date: L Apr 75	Est Comp Date: Sep 80
Principal Investigator: Rilard L. DeVillez, M.D., LTC USAR	Facility: Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology	Associate Investigators:
Key Words: Anhidrotic ectodermal dysplasia Erythroderma Transepidermal water loss	

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

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.

Progress: The dynamics of heat loss by two patients with classic anhidrotic ectodermal dysplasia were studied. Both were active in high school athletics and avoided heat injuries by various forms of behavior modification.

Elevated core and skin temperature measurements were found at rest in comfortable environments. In a warm environment 35-45% of the heat generated was lost by radiation. Heat loss in control subjects was 9% by radiation, 17% by conduction/convection, and 67% by evaporation. The dry routes of heat dissipation used by the anhidrotic patients were inadequate to prevent a rise in core temperature.

Since we have had no new patients during the past year, we have elected to consider the protocol as completed.

Detail Summary Sheet

Date: 22 Sep 80 Proj No: C-23-76 Status: Ongoing

TITLE:

Demonstration of a Testosterone Binding Protein in Semen.

Start Date: 25 Feb 76		Est Comp Date: Sep 81
Principal Investigator: Albert M. Thomason, M.D., COL, MC		Facility: Brooke Army Medical Center
Dept/Sec: Department of Medicine/Endocrinology		Associate Investigators:
Key Words: Testosterone binding protein Electrophoresis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$35.00	
		Periodic Review Results: Continue
Objective: To demonstrate a testosterone binding protein in semen.		

Technical Approach: Electrophoresis of testosterone-labeled semen on polyacrylamide gels and isolation of the labeled band.

Progress: So far, a labeled protein band has not been isolated. A different approach using slab gels and a C¹⁴ labeled testosterone is ongoing.

Detail Summary Sheet

Date: 28 Oct 80 Proj No: C-3-77 Status: Terminated
TITLE:

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

Start Date: Jul 76	Est Comp Date:
Principal Investigator: Joseph P. Murgu, M.D., COL, MC	Facility: Brooke Army Medical Center
Dept/Sec: Department of Medicine/Cardiology	Associate Investigators:
Key Words: Hemodynamic Effects Angiographic Contrast Material Dynamic Exercise Static Exercise	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Review Results: Terminate

Objective: 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: Following left ventriculography performed at the time of cardiac catheterization, serial measurement of the following parameters will be made: pulmonary capillary wedge, pulmonary arterial, right ventricular, right atrial, left ventricular, and aortic pressures; serial thermal dilution cardiac output; pulmonary artery and aortic flow velocity signals. These parameters will be compared to those obtained in the resting and steady exercise states. In order to carry out the project, a special high fidelity left ventricular injection catheter has been designed.

Progress: The problems encountered with the performance of the special high fidelity injection catheter are still unresolved.

Detail Summary Sheet

Date: 24 Oct 80 Proj No: C-6-77 Status: Ongoing
 TITLE:

Mechanism of Modulation of Lymphocyte Responses by Complement.

Start Date: 15 Sep 76	Est Comp Date: Jul 81
Principal Investigator: Michel N. Laham, M.D., MAJ, MC	Facility: Brooke Army Medical Center
Dept/Sec: Department of Medicine/Allergy-Immunology	Associate Investigators: David G. Burleson, Ph.D., MAJ, MSC Charles M. Loyd, SFC Fatima Ebrahim, SSG
Key Words: Complement Cell Mediated Immunity	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:\$2150.00
	Periodic Review Results: Continue

Objectives: To determine whether the cleavage of complement component C2 by activated C1 and C4 takes place in the fluid phase.

To determine whether generation of breakdown products of C2 correlates with the modulatory effect on lymphocytes.

To investigate the effect of intact vs cleaved C2 on the generation of suppressor T cells.

Technical Approach: C2 is exposed to active C1 and C4 in the fluid-phase and residual C2 activity is sequentially assayed using a standard hemolytic assay for C2. Simultaneously, lymphocytes are exposed to active C1, C4 and C2, and aliquots are sequentially sedimented and resuspended in fresh tissue culture medium without complement, then stimulated with mitogen and antigen.

The plaque forming cell assay (PFC) will be used as outlined in project #C-28-79 to examine the effect of C2 and C2 cleavage products on suppressor T cell activity. We will also look at the effect of C2 or PWM-induced immunoglobulin synthesis.

Progress: So far, we have been able to demonstrate fluid-phase consumption of C2 by C1 and C4 in complement fixation buffer but not in tissue culture medium. We have also been able to demonstrate a sequential increase in lymphocyte inhibition with progressively longer exposures to active C1, C4 and C2 prior to culture with mitogen. The next step will be to demonstrate a direct correlation between these two phenomena. Lymphocytes may have to be exposed to C1, C4 and C2 in complement fixation buffer first. Then as C2 is cleaved, aliquots of cells will be washed and resuspended in tissue culture medium for subsequent stimulation with mitogen. Finally, Dr. Burleson and I are just now in the process of adapting the suppressor cell assay to the specific purpose of scrutinizing C2 activity in that system.

Detail Summary Sheet

Date: 15 Oct 80 Proj No: C-19-77 Status: Completed

TITLE:

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

Start Date: 5 Jan 77	Est Comp Date: Sep 80
Principal Investigator: Barry W. Wolcott, M.D., LTC, MC	Facility: Brooke Army Medical Center
Dept/Sec: Department of Medicine/Emergency Medicine	Associate Investigators: N. Joe Thompson, M.D., LTC, MC
Key Words: Chest x-ray Acute cough	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objective: To determine when 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 BAMC ER/AMIC with complaints including acute coughs were selected for the study. Those selected received a standardized history and physical examination, and all received chest x-rays. Physicians seeing these patients were asked to request chest x-rays as they felt clinically indicated, but were randomly shown both x-rays they did and did not request. A four week outcome study was carried out on each patient following his discharge from the clinic. Computer analysis allows search for combinations of historical and physical findings at index visit which are predictive of x-rays which result in changes in the clinician's behavior.

Progress: The information gathered in this study has been used to modify the management of patients in the BAMC Emergency Room who have presented with acute cough and a decrease in the chest x-ray utilization for evaluation of those patients with no decrement to quality of their care.

Detail Summary Sheet

Date: 1 Oct 80	Proj No: C-23-77	Status: Ongoing
TITLE: Oral Methoxalen Followed by Longwave UV Light Effectiveness in the Treatment of Psoriasis.		
Start Date: 19 Jan 77	Est Comp Date: Indefinite	
Principal Investigator: Eric W. Kraus, M.D., MAJ, MC	Facility: Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Dermatology	Associate Investigators: Charles W. Lewis, M.D., COL, MC Richard M. Storm, M.D., CPT, MC	
Key Words: Psoriasis Longwave ultraviolet light (PUVA)		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objective: To determine the efficacy of 8-methoxypsoralen (methoxsalen) and longwave ultraviolet light (PUVA) in the treatment of psoriasis.		

Technical Approach: Patients are given a prescribed dosage of 8-methoxypsoralen (methoxalen) two hours prior to long-wave ultraviolet light exposure. The amount of light energy applied to the skin is gradually increased to obtain clinical clearing of the skin disease and to promote pigmentation (tanning) of the skin. The eyes are protected by special ultraviolet glasses that block out penetration of ultraviolet. The light dosage is carefully regulated to prevent a sunburn reaction of the skin. All patients receive initial laboratory screening studies and ophthalmologic evaluation and follow-up examinations at regular intervals.

Progress: Since the last report, five new patients have entered into the study. Three patients have had palmoplantar psoriasis and two have had plaque type psoriasis. Four of the five patients had greater than 95% clearing of their lesions. The fifth patient demonstrated approximately 75% clearing but was unable to achieve additional benefit.

Detail Summary Sheet

Date: 15 Oct 80 Proj No: C-46-77 Status: Completed
TITLE:

Algorithm Directed Troop Medical Care (ADTMC) Project.

Start Date: 23 Aug 77	Est Comp Date:
Principal Investigator: Barry W. Wolcott, M.D., LTC, MC	Facility: USAH Fort Hood, Texas
Dept/Sec: Department of Medicine	Associate Investigators:
Key Words: Algorithm Medical care	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: 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.

Progress: This project introduced an algorithm-directed care system into the care of active duty military personnel and was studied by comparison at each phase of the implementation of the test unit with a control unit receiving medical care in a standard format.

Progress: The results of this study have been used to create Health Service Command's Ambulatory Patient Care Model #21 which is now available for the care of active duty patients in all HSC activities.

Detail Summary Sheet

Date: 1 Oct 80	Proj No: C-1-78	Status: Ongoing
TITLE: Tetracycline-induced Ultraviolet Fluorescence of Pathologic Pulmonary Tissues as Viewed Through the Fiberoptic Bronchoscope.		
Start Date: Oct 77	Est Comp Date: Oct 81	
Principal Investigator: Michael Natalino, M.D., MAJ, MC	Facility: Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Pulmonary	Associate Investigators: John R. Holcomb, M.D., MAJ, MC Joseph Matthews, M.D., LTC, MC	
Key Words: Fluorescence Tetracycline-induced Fiberoptic Bronchoscope		
Accumulative MEDCASE Cost: \$6407.00	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objective: To establish whether <u>in vivo</u> tetracycline labeling can be used to aid the endoscopist in locating pathologic pulmonary tissues when viewed through a fiberoptic bronchoscope incorporating an ultraviolet light source.		

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

Progress: We have recently obtained the ultraviolet light source for our fiberoptic bronchoscope, with the proper ultraviolet fiberoptic bundle. To date, no patients have been studied under this protocol; however, as we have just received the materials, we will begin the study in the near future.

Detail Summary Sheet

Date: 20 Oct 80 Proj No: C-5-78 Status: Completed

TITLE:

The Effect of Sodium Nitroprusside Infusion on Hemoglobin Oxygen Carrying Patterns in Man.

Start Date: Oct 77	Est Comp Date:
Principal Investigator: Stephen H. Humphrey, M.D., MAJ (P), MC	Facility: Brooke Army Medical Center
Dept/Sec: Department of Medicine/Cardiology	Associate Investigators:
Key Words: Oxygen Sodium Nitroprusside	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objective: To determine the effect of sodium nitroprusside infusion on the ability of hemoglobin to carry oxygen.

Technical Approach: 5 cc of arterial blood were withdrawn in a heparinized syringe before and at intervals during sodium nitroprusside infusion given for clinical indications. For each specimen, determinations of blood oxygen content, total hemoglobin (cyanmethemoglobin method), methemoglobin concentration, and hemoglobin oxygen carrying capacity were made, and the results plotted against time as well as against immediate and cumulative infused doses.

Progress: Significant decrease in hemoglobin oxygen carrying capacity related to rate of drug infusion was observed. There was no significant change in methemoglobin concentrations suggesting that other hemoglobin species, perhaps cyanmethemoglobin, were formed precluding normal oxygen carrying patterns.

Detail Summary Sheet

Date: 22 Oct 80 Proj No: C-10-78 Status: Completed

TITLE:

Serum ACTH Levels in Lung Cancer Patients.

Start Date: 19 Jan 78		Est Comp Date:
Principal Investigator: Merrill S. Kies, M.D., MAJ, MC		Facility: Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators:
Key Words: Serum ACTH Lung cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine if serum ACTH levels are abnormally elevated in lung cancer patients.

To determine if elevated serum ACTH levels correlate with disease recurrence in lung cancer patients who have undergone attempted curative surgical resection.

To determine if serum ACTH levels correspond to clinical disease activity in patients with oat cell carcinoma treated medically.

Technical Approach: ACTH levels in two groups of lung cancer patients and controls were studied. Group A consisted of 20 consenting patients with histologically proven oat cell carcinoma of the lung. Group B was composed of 20 patients considered for definitive surgical treatment of suspected or proven primary non-oat cell lung cancer. If no malignancy was found at surgery, the patient was placed in the control group. Group C was composed of patients undergoing exploratory thoracotomy for suspected lung cancer who at surgery were not found to have lung cancer.

Pretreatment ACTH levels were obtained on all patients. In Group A patients, a second assay was obtained if the patient achieved a complete remission of all clinical evidence of disease. Serial ACTH levels were obtained every two months until relapse occurred. Group B patients had ACTH levels performed at 4 weeks postoperatively and again if clinical relapse occurred.

Progress: The data analysis has been completed and a manuscript is being prepared for submission for publication. However, since the principal investigator is no longer in the Army, the complete results of this study are not available.

Detail Summary Sheet

Date: 1 Oct 80 Proj No: C-14-78 Status: Completed

TITLE:

Evaluation of Amantadine in the Prophylaxis of Influenza A/USSR/77.

Start Date: 28 Feb 78	Est Comp Date:
Principal Investigator	Facility
David W. Potts, M.D., MAJ, USAF MC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Medicine/Infectious Disease	Dennis L. Stevens, M.D.
Key Words:	
Influenza A/USSR/77	
Amantadine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To document the clinical and epidemiologic characteristics of influenza A/USSR/77 infection in a young adult population and to evaluate the effect of amantadine on the incidence, duration and clinical manifestations of influenza infection and on the subclinical infection rate.

Technical Approach:

Progress: This protocol was kept open in order to study additional patients in the event of an Influenza A/USSR/77 outbreak in January and February 1980. This did not occur, and therefore, it was decided to consider the study completed with the results as reported in the FY 79 Annual Report.

Detail Summary Sheet

Date: 1 Oct 80 Proj No: C-24-78 Status: Terminated

TITLE:

Benzoyl Peroxide in the Treatment of Superficial Mycoses.

Start Date: 30 May 78	Est Comp Date:
Principal Investigator: John J. Jucas, M.D., MAJ, MC	Facility: Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objective: To evaluate the efficacy of benzoyl peroxide in a double blind study comparing the active agent against its vehicle in the treatment of various superficial fungal infections. These will include tinea versicolor, tinea corporis, tinea pedis, tinea cruris, and tinea unguinum.

Technical Approach: A double blind compared study for the efficacy of benzoyl peroxide in the treatment of the above infections was planned. A commercial benzoyl peroxide was to be compared against its vehicle.

Progress: This study was terminated due to delay in obtaining FDA approval of the vehicle.

Detail Summary Sheet

Date: 1 Oct 80 Proj No: C-26-78 Status: Completed
TITLE:

Antibody Response to Pneumococcal Vaccine in Adult Patients with Malignant Disease.

Start Date: 30 May 1978	Est Comp Date:
Principal Investigator: Richard A. Shildt, M.D., LTC, MC	Facility: Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: J. Dean McCracken, M.D., COL, MC James Boyd, M.D., MAJ, MC
Key Words: Pneumococcal vaccine Antibody response	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To compare antibody responses in a population of oncology patients immunized with pneumococcal vaccine with that of normal controls.

To further clarify the optimum time to immunize patients receiving cytotoxic agents.

To obtain baseline data regarding efficacy of pneumococcal vaccine in selected patient populations.

Technical Approach: On-hundred-forty patients were vaccinated with Pneumovax and antibody titers determined.

Progress: Patients with plasma cell dyscrasis showed a poor response to pneumococcal vaccine when compared to normal controls. Controls had a significant increase in antibody titers ($p < .003$) whereas myeloma patients did not ($p = .07$). Myeloma patients showed 2-fold antibody titer rises to all 12 antigens, but most of the postimmunization titers in the myeloma group were lower than the preimmunization titers in the control group.

Results were essentially the same in the other tumor types studied.

Detail Summary Sheet

Date: 1 Oct 80 Proj No: C-9-79 Status: Ongoing

TITLE:

Evaluation of Antidiar, Lomotil and Placebo in Acute Diarrheas

Start Date: 6 Feb 79		Est Comp Date: Jan 81
Principal Investigator: Leonard Duran, M.D., CPT, MC		Facility: Brooke Army Medical Center
Dept/Sec: Department of Medicine/Gastroenterology		Associate Investigators: Ernest L. Sutton, M.D., LTC, MC Dwayne Bohman, M.D., MAJ, MC
Key Words: Acute diarrhea Antidiar Lomotil Placebo		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

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

Progress: Currently, approximately 70 patients have been entered on the study. The plan is to continue the study until at least 100 to 120 patients have been entered into the study and then complete statistical analysis regarding the use of Antidiar versus Lomotil for acute diarrheal illness.

Detail Summary Sheet

Date: 30 Sep 80 Proj No: C-13-79 Status: Ongoing
TITLE:

Headache and Back Pain Clinical Algorithm Validation, Cost Analysis and AMOSIST Reliability.

Start Date: 22 Mar 79	Est Comp Date: Sep 81
Principal Investigator Robert D. Slay, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Emergency Medicine	Associate Investigators: N. Joe Thompson, M.D., LTC, MC
Key Words: Algorithm AMOSIST	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To determine if new clinical algorithms, used to evaluate and treat patients presenting with acute headache and back pain, utilized by physician extenders, can be validated as effective in an outpatient population.

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

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

Technical Approach: Approximately 1,000 adult patients with a chief complaint of headache and 1,000 adult patients with a chief complaint of back pain triaged to and evaluated by AMOSISTS will constitute the study population. Approximately 10% of each group will be randomly triaged to an internist (study physician), who will complete the same data base, add any comments he sees fit, and without the algorithm logic, will assign the patient a diagnosis and prescribe therapy. The AMOSISTS will utilize the current BAMC headache/back pain algorithms, data collection check list and TAB approved headache/back pain treatment protocols in evaluating these patients. A non-physician research assistant will be responsible for follow-up. They will be responsible for contacting the patient 4 or 6 weeks after the patient's initial visit and completing a telephone interview checklist which includes the duration of the illness, the appearance of new symptoms, the time lost from normal activity and the level of patient's satisfaction with the care received. These checklists will then be reviewed, and specific data will be obtained and recorded on a chart review check list for later analysis.

Progress: To date, 425 back pain and headache entries have been validated by AMOSIST and 189 validated by a physician. The goal is 500 in each.

Detail Summary Sheet

Date: 12 Oct 80 Proj No: C-14-79 Status: Ongoing

TITLE:

Immunoglobulin Regulation in Rheumatic Disease.

Start Date: Mar 79	Est Comp Date: Indefinite
Principal Investigator Gordon Willey, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Rheumatology	Associate Investigators: I. Jon Russell, M.D.
Key Words: Rheumatic disease Immunoglobulin regulation	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objective: To further characterize the physicochemical properties of amplifier factor in patients with systemic lupus erythematosus, rheumatoid arthritis, dermatopolymyositis, progressive systemic sclerosis, Sjogren's syndrome and sarcoidosis, and to study the cellular interactions responsible for its function.

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

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

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

Detail Summary Sheet

Date: 27 Oct 80 Proj No: C-17-79 Status: Completed

TITLE:

Neutrophil Chemotaxis and Phagocytic Activity in Psoriasis Vulgaris.

Start Date: 30 May 79	Est Comp Date: Sep 80
Principal Investigator Charles S. Fulk, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/ Dermatology	Associate Investigators: Robert C. Allen, M.D., Ph.D., CPT, MC Deborah J. Hunter, SP5
Key Words: Psoriasis Polymorphonuclear leukocyte Chemotaxis Complement	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:\$949.59
	Periodic Review Results:

Objective: To research the functional dynamics of neutrophil chemotaxis and phagocytic activity in psoriasis vulgaris patients as compared to psoriatics undergoing treatment with 8-methoxypsoralen and ultraviolet light (PUVA) and nonpsoriatic controls.

Technical Approach: Peripheral blood polymorphonuclear leukocytes (PMNL) were obtained from eleven patients and fifteen controls. These PMNL were tested for under-agarose chemotactic response using a variety of stimuli. The PMNL were also tested for stimulated O_2 -redox activity as measured by chemiluminescence. The sera from patients and controls were titrated for serum opsonic capacity, and tested for their capacity to generate chemotactic factors. Complement components such as C3, C4 and factor B were quantified by radial immunodiffusion and rocket immunoelectrophoresis.

Progress: Eleven psoriatic patients and controls were studied. The PMNL from the psoriatics showed increased ($p < 0.05$) chemotaxis relative to the nonpsoriatic controls. Sera from ten different psoriatics were more effective than controls ($p < 0.01$) with respect to generation of chemotactic factor upon exposure to zymosan.

Serum opsonic capacity and antigenic levels of complement components also appear to be elevated in psoriatic sera. These data will be subject to statistical analysis before formal presentation.

Detail Summary Sheet

Date: 30 Sep 80	Proj No: C-21-79	Status: Completed
TITLE: A Controlled Clinical Trial Comparing the Efficacy and Safety of Amcinonide (0.1% Cream) with Betamethasone Valerate (0.1% Cream) in Patients with Psoriasis.		
Start Date: 11 Jun 79	Est Comp Date:	
Principal Investigator Charles W. Lewis, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Dermatology	Associate Investigators: Eric W. Kraus, M.D., MAJ, MC	
Key Words: Psoriasis Double blind trial		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
Objective: Assessment of the efficacy and safety of amcinonide (0.1% cream) as compared with betamethasone valerate (0.1% cream) in the treatment of psoriasis without the use of occlusive dressings.		

Technical Approach: This is a double blind clinical trial comparing amcinonide cream to valisone cream.

Progress: Thirty patients were treated in a double blind study of topical amcinonide 0.1% cream vs. betamethasone valerate 0.1% cream. There were no adverse reactions, and the drug was considered beneficial in the therapy of psoriasis.

Detail Summary Sheet

Date: 6 Oct 80 Proj No: C-34-79 Status: Ongoing

TITLE:

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

Start Date: 9 Aug 79	Est Comp Date: Indefinite
Principal Investigator Charles W. Lewis, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology	Associate Investigators: J.R. Cook, M.D., MAJ, MC
Key Words: Lichen planus	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To determine the efficacy of TCIS cream (0.015%) in lichen planus without occlusion.

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

Technical Approach: Patients with lichen planus are dispersed two coded tubes of medication labeled for use on right and left sides of the body. Medication is applied to the same area on each side, e.g., forearms. Response to treatment is compared right vs. left, at two weeks and four weeks. The study is concluded at four weeks and graded response to therapy is reported on standardized forms provided.

Progress: Five patients have entered and completed study. No adverse reactions have been encountered, and treatment has been considered beneficial.

Detail Summary Sheet

Date: 3 Nov 80 Proj No: C-35-79 Status: Ongoing

TITLE:

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

Start Date: Aug 79	Est Comp Date: Indefinite
Principal Investigator Kenneth R. Bloom, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgu, M.D., COL, MC
Key Words: Patent Ductus Arteriosus Cyanotic congenital heart disease	

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

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

Progress: One infant has been treated over the past year, and he did well initially. However, the child did not survive surgery. The study is ongoing pending approval of the drug by FDA.

Detail Summary Sheet

Date: 25 Sep 80 Proj No: C-36-79 Status: Completed

TITLE:

Stability of Cytarabine in Bicarbonate Infusion Solutions.

Start Date: 28 Sep 79	Est Comp Date:
Principal Investigator Bruce R. Harrison, CPT, MSC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cytarabine Sodium bicarbonate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To ascertain the stability of cytarabine in normal infusion solutions containing sodium bicarbonate.

Technical Approach: Clinical concentrations of cytarabine in D5W with and without NaHCO_3 added were scanned to determine maximum absorbance. Changes in UV absorbance in the described solutions of cytarabine were determined using spectrophotometry.

Progress: The initial phase of testing involved spectrophotometric analysis (271 nm) of cytarabine solutions with and without the addition of NaHCO_3 (pH = 8.3). Tests performed up to 216 hours after the addition of NaHCO_3 indicated no loss of absorbance (stability of cytarabine). The second phase involved testing the cytarabine for loss of absorbance in solutions with increased pH (range 9-11) adjusted with NaOH. These tests also showed no loss of absorbance over a period up to 175 days.

Detail Summary Sheet

Date: 23 Sep 80 Proj No: C-37-79 Status: Ongoing

TITLE:

Ankle Trauma Study.

Start Date: Sep 79	Est Comp Date: Spe 82
Principal Investigator N. Joe Thompson, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Emergency Medicine	Associate Investigators: Barry W. Wolcott, M.D., LTC, MC Robert Highley, M.D. James Bushyhead, M.D. Robert Wood, M.D.
Key Words: Trauma Algorithm	

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

Technical Approach: All patients with ankle injuries excluding certain high risk patients and known fracture are offered study. The patient is examined and the physician predicts likely diagnosis. Patient is x-rayed and those with fractures are deleted from the study. The physician again predicts, special studies are performed, and the patient returns within 48 hours to another physician, who again predicts likely diagnosis. At this time, informed consent is obtained. They are then placed in one of four groups on a random basis.

Progress: Currently >300 of 900 felt required for statistical accuracy have been completed. Already we can eliminate one-third of ankle studies (x-rays) previously felt necessary. Patient acquisition has not been as rapid as originally anticipated.

Detail Summary Sheet

Date: 6 Oct 80 Proj No: C-1-80 Status: Terminated

TITLE:

Plasmapheresis in the Treatment of Psoriasis and Other Skin Diseases
Characterized by Immune-Complex Formation.

Start Date: 15 Nov 79	Est Comp Date:
Principal Investigator Larry D. Hudson, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology	Associate Investigators: Charles W. Lewis, M.D., COL, MC Lizardo Cerezo, M.D., MAJ, MC
Key Words: Plasmapheresis Psoriasis Immune-Complex	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To find a simple treatment for patients with psoriasis and other cutaneous disorders currently unresponsive to topical therapy.

Technical Approach:

Progress: No suitable patients available for study during the past year.

Detail Summary Sheet

Date: 22 Sep 80 Proj No: C-3-80 Status: Completed

TITLE:

Chest X-ray Ordering Pattern - Modification and Patient Care.

Start Date: 7 Jan 80	Est Comp Date:
Principal Investigator	Facility
Donald J. Gordon, M.D., LTC, MC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Medicine/Emergency Medicine	James Bushyhead, M.D.
Key Words:	
Chest x-ray	
URI algorithm	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To study and determine (1) the effect of the newly indorsed URI algorithm on intern physician chest x-ray (CXR) ordering frequency; (2) the effect on CXR ordering frequency after a training film; (3) the effect of a simple thought-provoding questionnaire which must be filled our prior to ordering CXRs on CXR ordering frequency; (4) if a decrease in CXR ordering can be achieved through training alone; (5) can a CXR frequency decrease be achieved without a decrease in quality care; (6) the effect of intern training on their ordering pattern.

Technical Approach: The study period extended thru two 14-week periods. During that time more than 8900 patients presented with URI's and were screened to the AMIC clinic which is manned by in-house trained physician extenders (AMCSISTS).

During Phase I, data were gathered, and in phase II, a questionnaire was introduced.

Progress: Over a 28 week period, 9047 patients wich acute upper respiratory complaints were seen at the Brooke Army Medical Center's Acute Minor Illness Clinic. A new URI algorithm was introduced requiring greater physician input to CXR ordering which resulted in a 10% decrease in CXR's without diminution of patient care. The CXR ordering frequencies were 6% + 3% overall for the 65% of URI patients presenting with cough; of the 25% of the cough patients requirng intern intervention, 21% received CXRs. Intern CXR ordering frequencies were unaffected by 30% increase in patient load nor by the introduction of thought-provoking questionnaire which had to be completed prior to getting a CXR.

Detail Summary Sheet

Date: 3 Nov 80 Proj No: C-5-80 Status: Ongoing

TITLE:

Lopressor Intervention Trial.

Start Date: Jan 80	Est Comp Date: Sep 82
Principal Investigator Joe M. Moody, Jr., M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgo, M.D., COL, MC
Key Words: Myocardial infarction Lopressor	
Accumulative MEDCASE Cost:	Est Accumulative DMA Cost:
	Periodic Review Results: Continue

Objective: To determine the efficacy of Metoprolol (Lopressor^R) in reducing the incidence of overall and cardiac death in survivors of recent myocardial infarction.

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

Progress: Nine patients have been enrolled to date, with follow-up periods up to eight months. There have been no adverse effects of medication, no recurrent myocardial infarctions and no deaths.

Detail Summary Sheet

Date: 1 Oct 80 Proj No: C-6-80 Status: Ongoing

TITLE:

Clotting Studies in Liver Disease.

Start Date: 24 Jan 80	Est Comp Date: Jan 81
Principal Investigator Charles T. Thornsvard, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine	Associate Investigators: John F. Schultheiss, M.D., LTC, MC Thomas F. O'Meara, M.D., MAJ, MC Barbara Reeb, DAC
Key Words: Prothrombin time Vitamin K	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

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

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

Progress: Four patients with liver disease have demonstrated the applicability of this test in predicting vitamin K response.

Detail Summary Sheet

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

TITLE:

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

Start Date: 24 Jan 80	Est Comp Date: Sep 81
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology	Associate Investigators: Gary Wikert, M.D., CP, MC John J. Posch, Jr., DAC
Key Words: Prostatectomy Coagulation system Fibrinolytic system	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:\$3,923.31
	Periodic Review Results: Continue

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

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

Technical Approach; To date, we have standardized all the laboratory tests that will be needed in this protocol. This has included the development of several new techniques in the field of coagulation testing with the use of chromogenic substrates. Testing on 50 normal controls has established the normal ranges for the test to be utilized in this study. Our only technical problem has been the standardization of fibrinolytic activity of the urine; this is a quite variable test and may have to be deleted from the study.

Progress: To date, two patients have been registered on the study. Accrual to this study has been slow due to schedule changes which Dr. Wikert incurred in his residency program. However, he is now once again on the Urology Ward Service at BAMC, and we expect accrual of patients to continue with adequate numbers achieved in 1981.

Detail Summary Sheet

Date: 26 Sep 80		Proj No: C-10-80	Status: Ongoing
TITLE: The Value of Immunotherapy with Dermatophagoides Mite Extract in the Treatment of House Dust Allergy.			
Start Date: 3 Mar 80		Est Comp Date: Mar 83	
Principal Investigator Daniel A. Ramirez, M.D., MAJ, MC		Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Allergy-Immunology		Associate Investigators:	
Key Words: Immunotherapy Dermatophagoides mite extract House dust allergy			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue	
Objective: To asses the value of immunotherapy with Dermatophagoides mite extract in the treatment of house dust allergy.			

Technical Approach: A double blind randomized study, using commercial mite extract versus placebo in patients with house dust allergy, will be done.

Progress: This is a cooperative study originally from Wilford Hall Medical Center. Patients are being gathered at BAMC. We are waiting to receive the coded extracts and placebo from WHMC.

Detail Summary Sheet

Date: 3 Oct 80 Proj No: C-13-80 Status: Terminated

TITLE:

Hemodynamic Effects and Clinical Correlates of the Hepatojugular Reflux Test.

Start Date: 18 Mar 80	Est Comp Date:
Principal Investigator Ronald G. Albright, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Internal Medicine	Associate Investigators:
Key Words: Hepatojugular Reflux	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objective: To answer the following questions: A. What are the hemodynamic effects of the hepatojugular reflux test? B. Do these hemodynamic changes vary in states of abnormal cardiac function? C. Is the presence of an abnormal hepatojugular reflux test predictive of specific cardiac pathophysiology?

Technical Approach:

Progress: Project cancelled due to transfer of principal investigator.

Detail Summary Sheet

Date: 23 Oct 80	Proj No: C-17-80	Status: Ongoing
TITLE: Role of Digoxin in Preventing Myocardial Toxicity in Cancer Patients Receiving Adriamycin.		
Start Date: 6 Jun 80	Est Comp Date: Jun 81	
Principal Investigator Steven A. Madden, M.D., CPT, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Kenneth R. Bloom, M.D., LTC, MC J. Dean McCracken, M.D., COL, MC	
Key Words: Digoxin Myocardial toxicity Adriamycin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objective: To determine whether digoxin, administered prior to and during Adriamycin-containing chemotherapy regimens, reduces the incidence and extent of myocardial toxicity in cancer patients.		

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

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

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

Progress: A total of 39 patients have been entered on this study. Secondary to early patient death, technical difficulties in performing echocardiograms on some of the patients, and discontinuance of Adriamycin at total doses of less than 150-200 mg/M² in some patients, approximately one third of the patients entered will be evaluable.

Detail Summary Sheet

Date: 26 Sep 80	Proj No: C-23-80	Status: Ongoing
TITLE: An Evaluation of Local Anesthetic Skin Testing and Progressive Challenge in Patients with a History of an Adverse Reaction to Local Anesthetics		
Start Date: 24 Jun 80	Est Comp Date: Fy 82	
Principal Investigator Danie A. Ramirez, M.D., MAJ, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Allergy-Immunology	Associate Investigators:	
Key Words: Local anesthetic skin testing Challenge Adverse reaction		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objective: To confirm the safety and usefulness of this approach in a large number of patients with histories of previous suspected adverse reactions to local anesthetics.		

Technical Approach: Patients with histories of adverse reactions to local anesthetics are being studied. A skin test, challenge (up to 2.0 cc of full strength) approach is used.

Progress: This is a cooperative Army study originally from Fitzsimons Army Medical Center. Patients are currently being tested and enrolled in the study.

Detail Summary Sheet

Date: 26 Sep 80 Proj No: C-24-80 Status: Ongoing

TITLE:

Establishment of a Plasma Bank for Oncology Patients.

Start Date: 30 Jun 80		Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology-Oncology		Associate Investigators: Glenda Sutton, R.N., CPT, ANC John M. Rembold, CPT, MSC John J. Posch, Jr., DAC
Key Words: Plasma Bank Oncology patient		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
		Periodic Review Results: Continue
Objective: To collect and freeze plasma samples from patients with cancer.		

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

Progress: Ninety specimens have been collected to date. It is anticipated that we will continue at an accrual rate of approximately 50-60 new patients per year.

Detail Summary Sheet

Date: 7 Oct 80 Proj No: C-35-80 Status: Ongoing

TITLE:

Double-blind Parallel Comparison of Sulconazole Nitrate 1% Solution and Clotrimazole 1% Solution in the Treatment of Tinea Cruris.

Start Date: 1 Jul 80	Est Comp Date: Sep 81
Principal Investigator Charles W. Lewis, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology	Associate Investigators: Eric W. Kraus, M.D., MAJ, MC
Key Words: Tinea cruris Sulconazole nitrate Clotrimazole	

Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:	Periodic Review Results: Continue
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Objective: To determine the safety and efficacy of sulconazole nitrate 1% solution in the once-a-day, three-week treatment of tinea cruris in adult men and women as compared to 1% clotrimazole solution.

Technical Approach: KOH and fungus cultures are done. An unknown medication (either 1% sulconazole nitrate or 1% clotrimazole) is applied once daily to affected skin. After 2 and 3 weeks, repeat KOH and fungus cultures are done. Treatment is stopped at the end of 3 weeks if KOH is negative and the patient re-evaluated in 4 weeks. If KOH is positive the patient is removed from the study and given alternate treatment.

Progress: Ten patients entered into the study; however, one patient dropped out one day after joining. Six patients have completed three weeks or more and are to be evaluated at seven weeks. Three patients have not yet completed two weeks. There have been no adverse reactions to the medication.

Detail Summary Sheet

Date: 7 Oct 80 Proj No: C-36-80 Status: Ongoing

TITLE:

Double-blind Parallel Comparison of Sulconazole Nitrate 1% Solution and Placebo Solution in the Treatment of Tinea Versicolor.

Start Date: 1 Jul 80	Est Comp Date: Jul 81
Principal Investigator Charles W. Lewis, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Dermatology	Associate Investigators: Eric W. Kraus, M.D., MAJ, MC
Key Words: Tinea versicolor Placebo Sulconazole Nitrate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objective: To determine the safety and efficacy of sulconazole nitrate 1% solution in the once-a-day, three-week treatment of tinea versicolor in adult men and women as compared to placebo solution.

Technical Approach: Patients are seen initially and at 2, 3 and 7 weeks. KOH and wood light exam are done at each visit. An unknown medication (1% sulconazole nitrate or placebo) is applied once daily for three weeks. If KOH is positive at the three week visit, the study is stopped. If KOH is negative at the three week visit, medication is stopped and the patient re-evaluated in 7 weeks.

Progress: Eighteen patients have entered the study. Eight patients have completed the study, one patient has withdrawn from the study, and nine patients have not completed the study. There have been no adverse reactions to the medication.

Detail Summary Sheet

Date: 27 Oct 80	Proj No: C-37-80	Status: Ongoing
TITLE: Assessment of Granulocyte Function and Serum Opsonic Capacity in Nephrology Patients Undergoing Dialysis.		
Start Date: 28 Jul 80	Est Comp Date: Jul 82	
Principal Investigator Lucius D. Wright, M.D., MAJ, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Nephrology	Associate Investigators: Robert C. Allen, M.D., Ph.D., CPT, MC	
Key Words: Dialysis Polymorphonuclear leukocyte Redox metabolism Chemilumigenic probes		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:\$827.30	Periodic Review Results: Continue
Objectives: To assess granulocyte function in nephrology patients undergoing dialysis.		

To assess serum opsonic capacity in these patients.

To investigate the relationship between dialysis-associated activation of complement and the neutropenia observed during the initial phase of dialysis.

To assess peritoneal macrophage function in patients undergoing peritoneal dialysis.

Technical Approach: The number and specific activity (O_2 -redox activity) of circulating granulocytes during various phases of hemodialysis will be investigated using microliter quantities of whole blood. Serum specimens from dialysis patients will also be collected and titrated for specific and nonspecific opsonic capacity.

Both methodologies are based upon the research described in Project #C-5-79.

Progress: This is a relatively new project and only five pre- and post-dialysis sera have been titrated for opsonic capacity to date. The measurement of granulocyte function will begin in late fall, 1980.

Detail Summary Sheet

Date: 28 Oct 80 Proj No: C-41-80 Status: Ongoing

TITLE:

The Effect of Nutrition on the Humoral-Phagocytic Axis.

Start Date: 26 Aug 80	Est Comp Date: Jun 81
Principal Investigator Steven Cohen, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology-Oncology	Associate Investigators: Robert C. Allen, M.D., Ph.D., CPT, MC
Key Words: Humoral-phagocyte axis Chemiluminescence Nutritional repletion	Richard A. Shildt, M.D., LTC, MC

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To evaluate the microbicidal activity of the humoral-phagocytic axis of host immune defense using chemiluminescence techniques in malnourished patients.

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

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

Progress: This is a new study, and no reportable data are available.

Detail Summary Sheet

Date: 28 Oct 80 Proj No: C-42-80 Status: Ongoing

TITLE:

Solumedrol for the Treatment of Acute Myocardial Infarction

Start Date: 9 Sep 80	Est Comp Date: Aug 81
Principal Investigator Francis R. D'Silva, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgo, M.D., COL, MC
Key Words: Myocardial Infarction Solumedrol	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objective: To evaluate the efficacy of two pharmacologic IV doses of Solu-medrol in reducing the mortality and morbidity associated with acute myocardial infarction.

Technical Approach: All patients admitted to the coronary care unit less than 12 hours since the onset of their chest pain would be potential subjects for study. Those patients with left ventricular failure defined by rales not cleared on coughing or redistribution of pulmonary blood flow compared to normal on a chest x-ray or radiographic evidence of pulmonary edema are eligible. After obtaining informed consent, Solumedrol or placebo will be given intravenously in a randomized double blind fashion over a 20 minute period. The end points will be morbidity which will be assessed by vital signs and complications such as shock, failure, arrhythmia and other complications and overall condition. X-rays and electrocardiograms will be done at one week, one month three months and six months.

Progress: This is a new study.

Detail Summary Sheet

Date: 16 Sep 80 Proj No: C-39-77 Status: Terminated

TITLE:

Inhibition of Premature Labor with Terbutaline.

Start Date: May 77		Est Comp Date:
Principal Investigator Thomas Howard, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics-Gynecology		Associate Investigators:
Key Words: Premature labor Terbutaline		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Objective: To study inhibitory effects of terbutaline on premature labor.		Periodic Review Results:

Technical Approach:

Progress: Since suspension by FDA, Astra Pharmaceutical Co. and other producers of Terbutaline have become somewhat less enthusiastic in pursuing toxicity studies to satisfy FDA demands. Also, Ritodrine is now approved for use and will be instituted here.

Detail Summary Sheet

Date: 17 Sep 80 Proj No: C-39-78 Status: Completed
TITLE:

A Comparison Study of Cesarean Section.

Start Date: Sep 78	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics-Gynecology	Associate Investigators: Milton H. Leman, M.D., COL, MC
Key Words: Cesarean section Febrile morbidity	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To determine if postoperative Cesarean section febrile morbidity can be reduced by operative technique or prophylactic antibiotics.

Technical Approach: Twenty-four patients, in whom the decision to perform a primary low cervical transverse Cesarean section was made, were randomly selected for extraperitoneal approach. These patients were not selected based on any parameters known to either increase or decrease postoperative infectious morbidity.

Progress: Of the twenty-four extraperitoneal procedures, five postoperative infections were diagnosed: three wound infections and two cases of endo-parametritis. The pathogens were no different from those usually found, and the clinical courses of these infected patients were also not unusual. The postoperative infectious morbidity in this group of twenty-four patients is calculated to be 20% which is significantly lower than the 37%-40% current national average.

Detail Summary Sheet

Date: 29 Oct 80 Proj No: C-12-79 Status: Ongoing

TITLE:

Clinicopathologic Study of Uterine Vascular Changes with and without Hormonal Influence.

Start Date: Mar 79	Est Comp Date: Jun 81
Principal Investigator Charles V. Wilson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics-Gynecology	Associate Investigators: Milton H. Leman, M.D., COL, MC
Key Words: Uterine vascular changes Oral contraceptive	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objective: To study the association of intimal thickening of uterine arteries with oral contraceptive use in women undergoing hysterectomy with and without cervical and uterine pathology.

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

Progress: Thirty patients have been entered on the study. However, the two pathologists participating in the study are no longer assigned to BAMC and no pathological data are available for this report.

Detail Summary Sheet

Date: 13 Oct 80 Proj No: C-8-80 Status: Completed

TITLE:

A Study of the Effects of Nursing Intervention on the Outcome of Lactation.

Start Date: 21 Jan 80	Est Comp Date:
Principal Investigator Mindy Tinkle, R.N.	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Nursing intervention Lactation Primipara	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objective: To determine if information and support given by the professional nurse during the immediate postpartum period increases the mother's success at breast feeding as measured six weeks postpartum by questionnaire.

Technical Approach: Ten primiparas who indicated a desire to breast-feed their infants comprised the sample of this study to determine the effects of nursing intervention on the outcome of lactation. The sample was divided into a control and an experimental group on the basis of their date of delivery. The experimental group received intensive assistance and teaching about breast-feeding during their hospital stay from a professional nurse, while the control group received the nursing assistance routine provided on the unit.

Progress: There was no significant difference in the success at breast-feeding between the two groups. Of the nine mothers whose success could be evaluated, only three were still breast-feeding at six weeks postpartum. Three mothers quit breast-feeding before their hospital discharge, while three more mothers quit by the second week postpartum. Such factors as a lack of prenatal preparation, unsupportive families, and a lack of a strong desire to breast-feed appeared to influence the success rate.

Detail Summary Sheet

Date: 16 Oct 80	Proj No: C-15-80	Status: Ongoing
TITLE: Fluorouracil Cream vs Podophyllum in the Management of Vulvar Condyloma Accuminatum.		
Start Date: 28 Mar 80	Est Comp Date: Jun 81	
Principal Investigator John E. Miers, M.D., CPT, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Obstetrics-Gynecology	Associate Investigators: Milton H. Leman, M.D., COL, MC	
Key Words: Vulvar condyloma accuminatum Podophyllum Fluorouracil cream		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objective: To determine whether Fluorouracil Cream is a better therapeutic agent with less side effects and toxicity than Podophyllum.		

Technical Approach: Participants in the study will be divided into two groups. To insure the groups are scientifically comparable, they will be stratified based on the size and number of lesions. Group I will be treated with 5% Fluorouracil Cream for 5 days each week x 4 weeks. Group II will receive application of Podophyllum once each week x 4 weeks. Responses will be recorded weekly x 4 weeks.

Progress: We have temporarily stopped placing patients on this study because of (1) poor compliance and (2) losing too many patients to follow-up. We are presently trying to reconstruct the study to avoid these problems.

Detail Summary Sheet

Date: 12 Sep 80	Proj No: C-16-80	Status: Terminated
TITLE: A Prospective Randomized Study of Vaginal and Abdominal Delivery of the Low Birth Weight Frank Breech Infant.		
Start Date: 28 Mar 80	Est Comp Date:	
Principal Investigator Thomas H. Howard, M.D., LTC, MC	Facility	
Dept/Sec: Department of Obstetrics-Gynecology	Associate Investigators:	
Key Words: Vaginal delivery Abdominal delivery Low birth weight frank breech fetus		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
Objective: To determine whether the uncomplicated low birth weight frank breech (LBWFrBr) breech presentation in labor should be delivered by cesarean section or vaginal delivery in order to minimize maternal and neonatal risks.		

Technical Approach:

Progress: This was a collaborative study with the other MEDCFNs. Brooke Army Medical Center had no patients present during the study period who met the criteria for consideration for the protocol. Two patients (total) were collected among all the medical centers participating.

This study was discontinued due to lack of eligible patients. This was a common finding at all the medical centers participating.

Detail Summary Sheet

Date: 16 Oct 80 Proj No: C-45-77 Status: Completed

TITLE:

Compilation of Atlas of Electron Micrographs of Known Viruses.

Start Date: 23 Aug 77	Est Comp Date:
Principal Investigator George J. Kasai, Ph.D.	Facility Brooke Army Medical Center
Dept/Sec: Department of Pathology/Microbiology	Associate Investigators: Terry Knight, 1LT, MSC Lucy Acalda, DAC Thomas R. Perez, DAC Steven Koester, DAC
Key Words: Viruses Electron micrographs	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To compile an atlas of electron micrographs of known viruses for purposes of facilitating identification of unknown isolates obtained from patients' specimens.

Technical Approach: Known viruses grown in susceptible tissue culture cell lines were subjected to the standard procedures of electron microscopy specimen preparations and micrographs were prepared for future use. Known viruses were checked by serum neutralization procedures using standardized sera obtained from commercial domestic suppliers or from the Center for Disease Control in Atlanta, GA.

Progress: Electron micrographs of all of the known viruses in the virology unit's stock viruses collection have been completed. These are being used as aids to identify unknown isolates that cannot be neutralized by the complex bank of antisera stored in the Virology unit.

The compiled micrographs has permitted a group classification of unknown viruses and has also facilitated identification of mixed infections.

Micrographs produced in this investigation will gain increased importance as additional and improved rapid EM techniques are developed to aid the physician in patient treatment. Additionally, electron micrographs of viral particles, from the examination of tissue, can be an aid to the pathologist in documenting a disease condition or cause of death.

Detail Summary Sheet

Date: 28 Oct 80 Proj No: C-33-78 Status: Completed

TITLE:

Oxauracil Typing of Herpesvirus simplex Type I and II Clinical Isolates.

Start Date: 19 Jul 78	Est Comp Date:
Principal Investigator	Facility
Lawton A. Seal, CPT, MSC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Pathology	Richard M. Jamison, Ph.D.
Key Words:	
<u>Herpesvirus simplex</u>	
Oxauracil	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$313.00	Periodic Review Results:
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Objectives: To evaluate the efficacy of Oxauracil in the differentiation of HSV clinical isolates (wild strains) using tissue culture cell lines currently available in the Virology Laboratory.

To establish a new and rapid procedure for typeing HSV wild strains, thereby reducing the time required to obtain reliable results.

Technical Approach: The purpose of this study was to compare the efficiency of Oxauracil with specific antiserum neutralization and fluorescent antibody staining techniques in the typing of clinical isolates of HSV. Thirty clinical isolates of HSV were typed (as to HSV-I or HSV-II) by the methods stated above in several tissue culture cell lines.

Progress: A rapid simple method for the typing of wild HSV isolates based on selective inhibition of HSV-II replication by the pyrimidine analogue Oxauracil (2H-1,3-oxazine-2,6(3H)-dione) was developed. Chi-square analysis of the results of typing of 30 wild strains by serum neutralization tests, immuno-fluorescence and oxauracil-inhibition indicates no significant difference in assessment of types to the isolates. The oxauracil-inhibition test obviates confusion of typing resulting from use of immune sera containing cross-reactive antibodies. We conclude oxauracil typing is a simple, rapid, and precise test which can be performed in any laboratory capable of isolating HSV.

Detail Summary Sheet

Date: 20 Oct 80 Proj No: C-9-80 Status: Ongoing
TITLE:

Identification of T-cell Leukemias-Lymphomas with Heterologous Antisera.

Start Date: Jan 80	Est Comp Date: Feb 81
Principal Investigator Lizardo Cerezo, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Pathology	Associate Investigators: Isidoro Chapa, DAC
Key Words: T-cell lymphoid neoplasms Non-T leukemias-lymphomas	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

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

Technical Approach: Lymphocytes from both blood and lymph node tissue will be isolated using Ficoll-Hypaque centrifugation. T cells will be harvested from the isolates by the E rosetting technique of Dean et al. Rabbits will be immunized intravenously with 2 to 4 x 10⁷ T cells and boosted in similar fashion 14 days later. They will be bled 7 days after the boost. Rabbit sera complement will be deactivated by heating at 56°C for 30 minutes. Undiluted and multiple dilutions of the antisera will be tested with normal peripheral blood lymphocytes by indirect immunofluorescence and a two-stage microlymphocytotoxicity assay. The results will be compared with the percentage of E-rosetting cells in the same samples. In this fashion, the proper antisera titers will be determined.

Progress: The initial phase of the study (antisera development) has taken longer than anticipated. Two rabbits have died. Currently ten rabbits are active: 4 injected with human peripheral blood T-cells; 3 injected with human CLL B-cells; and 3 injected with homogenized human brain with incomplete Freund's adjuvant. One rabbit is producing high titer antisera against T-cells. We will continue to periodically give him booster injections, harvest his sera and freeze it in aliquots for future use. The specificity and activity of this batch of antisera has been confirmed at another institution using a lymphocytotoxic assay.

Detail Summary Sheet

Date: 20 Oct 80 Proj No: C-12-80 Status: Ongoing

TITLE:

Cytochemistry of Epithelial Neoplasms.

Start Date: 3 Mar 80	Est Comp Date: Mar 81
Principal Investigator Lizardo Cerezo, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Pathology	Associate Investigators: Bruce Wellman, M.D., MAJ, MC
Key Words: Epithelial neoplasms Cytochemistry	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objectives: To study multiple cytochemical parameters of epithelial neoplasms and thereby determine if cytochemical profiles may contribute to the accurate diagnosis of these tumors. The study would also evaluate the feasibility and reliability of cytochemistry of postmortem tissues.

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

Progress: Twenty-nine cases of epithelial tumors have been received and evaluated cytochemically. These include eight cases of infiltrating duct carcinoma which have fallen into two cytochemically distinct groups: Non-specific esterase positive (by either one or both stains) and negative. We are now in the process of comparing the morphologic and ultrastructural features of these two groups of breast cancer.

Two cases of thyroid cancer with specific esterase activity have been detected (naphthol AS-D chloroacetate esterase). This was not detected in any other tumor tissue type and may turn out to be a useful marker for properly diagnosing poorly differentiated metastatic thyroid cancer.

Detail Summary Sheet

Date: 7 November 1980		Proj No: C-21-80	Status: Ongoing
TITLE: <u>In Vitro</u> Demyelination and Remyelination of Cultured Mammalian Central Nervous Tissue.			
Start Date: 7 May 1980		Est Comp Date: June 1981	
Principal Investigator Roby P. Joyce, M.D., MAJ, MC		Facility Brooke Army Medical Center	
Dept/Sec: Department of Pathology		Associate Investigators: Jacqueline Longbotham, M.D., CPT, MC	
Key Words: Demyelination Remyelination Central Nervous Tissue		Terry J. Knight, MS, 1LT, MSC	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: \$805.25	Periodic Review Results: Continue	
Objective: To establish at Brooke Army Medical Center the capability to study demyelination and remyelination of mammalian central nervous tissue in a reliable cell culture laboratory model.			

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

Progress: The successful culture of myelinated mammalian central nervous tissue represents the conclusion of this portion of the project. The next phase will involve in vitro demyelination of the cultured neurons using sera from mice affected by experimental Allergic Encephalomyelitis (EAE). Before this second phase of experimentation can be pursued, the visualization and photographic documentation of changes in the colonies must be improved. Technical assistance is being provided by the Medical Photography Section but the greatest handicap is the lack of phase contrast visualization capability with our present inverted tissue culture microscope.

Detail Summary Sheet

Date: 26 Sep 80 Proj No: C-11-80 Status: Completed
 TITLE:

Analysis of Sexual Assaults at Fort Sam Houston.

Start Date: Mar 80	Est Comp Date:
Principal Investigator	Facility
E.R. Worthington, Ph.D., LTC, MSC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Psychiatry/Mental Health	
Key Words:	
Sexual assaults	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To analyze all sexual assaults officially reported in 1978 to provide information leading to better preventive measures.

Technical Approach: Data relating to the victim and the circumstances surrounding the crime were extracted from records of the emergency room of the medical center and the post law enforcement investigative agency. All information collected was coded for processing thereby insuring the anonymity of the victim. There were 39 females and one male. The data were analyzed using two categories of victims; military and non-military, and three categories of data source, hospital or law agency or both.

Progress: The data collected demonstrated that certain patterns are present involving both the victim and the circumstances. The victim generally is young (20-22 years old), mostly an active duty caucasian, single, female, Private, undergoing military training. Typically, the assault involves circumstances where the female is especially vulnerable such as being with a newly found acquaintance, or accepting rides from strangers or alone walking, at a club or at a party. Most assaults occur late at night and on the weekend. There are also significant differences between the married female soldier assault victim (older and always attacked in her residence) and the single female soldier victim (younger and more vulnerable to attack by where she is when the assailant first makes contact with her).

Detail Summary Sheet

Date: 1 Oct 80 Proj No: C-35-74 Status: Ongoing

TITLE: Clinical Evaluation of Cisternography Utilizing ¹¹¹Indium DTPA.

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

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objective: To evaluate the safety and efficacy of ¹¹¹Indium DTPA for cisternography.

Technical Approach: Cisternograms using ¹¹¹Indium DTPA are being done to diagnose subarachnoid blocks, presence of abnormal CSF circulation (especially backward flow into the lateral ventricles as seen in communicating hydrocephalus), and CSF leaks such as rhinorrhea or otorrhea. The radionuclide is introduced intrathecally via an LP and then images performed at approximately 6, 24 and even 48 hours later. Cotton pledgets in the nostrils and ears are inserted and counted to check for CSF leakage in appropriate cases.

Progress: The use of ¹¹¹Indium DTPA for cisternography has yielded very useful clinical and diagnostic information in four patients studied this past year.

Recently, an updated protocol was submitted and is pending reapproval.

Detail Summary Sheet

Date: 1 Oct 80		Proj No: C-12-77	Status: Ongoing
TITLE: Intravenous Administration of ¹³¹ I (NP 59) for Adrenal Evaluation of Imaging.			
Start Date: 15 Nov 76		Est Comp Date: Not known	
Principal Investigator Robert J. Telepak, M.D., LTC, MC		Facility Brooke Army Medical Center	
Dept/Sec: Department of Radiology/Nuclear Medicine		Associate Investigators: Roswell N. Beck, Jr., M.D., MAJ, MC Ronald K. McCauley, M.D., MAJ, MC	
Key Words: Adrenal scan, NP-59			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue	

Objective: Clinical evaluation of NP-59 as a diagnostic agent for the detection of adrenal-cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

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

Progress: During the past year, three patients were scanned. One patient had activity seen only in the left adrenal gland consistent with the patient's clinically suspected diagnosis of adrenal adenoma. Another patient had visualization of both adrenal glands with more than usual activity consistent with bilateral adrenal hyperplasia.

Detail Summary Sheet

Date: 1 Oct 80	Proj No: C-22-78	Status: Ongoing
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TITLE:

Technetium-99m-pyridoxylideneglutamate (99m-Tc-PG) for Diagnosis of Hepatobiliary Disease.

Start Date: Apr 77	Est Comp Date: Sep 82
Principal Investigator Robert J. Telepak, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Radiology/Nuclear Medicine	Associate Investigators: Roswell N. Beck, Jr., M.D., MAJ, MC Ronald K. McCauley, M.D., MAJ, MC
Key Words: Biliary scan	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objective: To evaluate the clinical efficacy of Tc-99m-PG as a diagnostic hepatobility and gallbladder agent.

Technical Approach: The patient is injected with 15 millicuries of 99m Technetium labeled pyridoxylideneglutamate with images obtained approximately every 5 minutes in the anterior projection. In normal persons, activity is promptly seen in the liver and then concentrates in the biliary tree with visualization of the gallbladder usually by 30 minutes after injection and evidence of activity within the bowel shortly thereafter. The scan is most useful for evaluating acute cholecystitis in which the gallbladder is not visualized because of obstruction of the cystic duct. The scan is also very useful for evaluating patency of the biliary tree into the bowel and also for evaluating surgical anastomoses and shunts involving the biliary tree. As with all other biliary scanning agents tried to date, the visualization of the biliary tree becomes very difficult with increasing liver dysfunction, especially high serum bilirubin levels. This is because of the liver's inability to process the agent into bile and thereby enables the biliary tree and gallbladder to be visualized.

Progress: During the past year 107 patients were scanned. The study has been very well received by clinicians to date and has been of quite high diagnostic value. It represents a very safe, rapid, and non-invasive evaluation of the biliary system. Used in conjunction with ultrasonography of the gallbladder and biliary tree, it provides complimentary information that in many instances has provided diagnostic information on patients and eliminated the need for invasive and more dangerous studies such as the intravenous cholangiogram, percutaneous transhepatic cholangiogram, or surgery. There have been no reactions to the Tc-99m-PG to date and none are expected. Some patients have

C-22-78 (continued)

experienced transient mild discomfort associated with injection of cholecystokinin (an already approved and commonly used drug for biliary system stimulation). Cholecystokinin is only used in those patients in whom it is indicated and such side effects as mentioned above are not considered to adverse drug reactions.

Detail Summary Sheet

Date: 1 Oct 80	Proj No: C-22-80	Status: Ongoing
TITLE: Correlation of Epidurography with Anatomical Investigation of the Lumbar Spinal Canal.		
Start Date: 23 Jun 80	Est Comp Date: Jun 81	
Principal Investigator Nadi S. Hibri, M.D.	Facility Brooke Army Medical Center	
Dept/Sec: Department of Radiology	Associate Investigators: Robert C. Harris, M.D., CDR, USNMC Howard Gendell, M.D., MAJ, MC	
Key Words: Epidurography Herniated nucleus pulposus		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objective: To gain a better understanding of the relationship of a herniated nucleus pulposus to the epidural and subarachnoid spaces.		

Technical Approach: After routine autopsy has been done on the cadaver, epidurography, as well as myelography, will be done using the same techniques employed on patients with the exception of mixing coloring material (Methylene blue for the epidural space and red Latex for the subarachnoid space). After radiographs are taken, the cadaver will be transferred again to the autopsy suite and dissection of the spinal canal done.

Progress: None. We have not been able to find adequate cooperation in obtaining consent for examination of the spine on autopsy permits. Further effort in this regard will be attempted.

Detail Summary Sheet

Date: 29 Oct 80 Proj No: C-18-79 Status: Terminated

TITLE:

Evaluation of Oxytrode Sensor and the Clinical Utility of Concurrent Continuous Measurement of Arterial and Central Venous PO₂.

Start Date: Apr 78 Est Comp Date:

Principal Investigator Facility

Richard C. Traugott, M.D. Brooke Army Medical Center

Dept/Sec: Associate Investigators:

Department of Surgery/Cardiothoracic

Key Words:

Oxytrode sensor

Arterial PO₂

Central venous PO₂

Accumulative MEDCASE Est Accumulative Periodic

Cost: OMA Cost: Review Results:

Objective: To evaluate accuracy, safety, feasibility, and clinical utility of the Oxytrode Sensor for continuous measurement of arterial and mixed venous PO₂ during cardiopulmonary bypass surgery.

Technical Approach: No information available.

Progress: The study was done and the data given to a statistician for evaluation. We have been unable to obtain the final evaluation of the data, and therefore the study is terminated.

Detail Summary Sheet

Date: 15 Oct 80	Proj No: C-21-78	Status: Ongoing
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TITLE:

Clinical Study of Intraocular Lenses.

Start Date: Feb 78	Est Comp Date: Unknown
Principal Investigator Calvin E. Mein, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/Ophthalmology	Associate Investigators: John Gearhart, M.D., MAJ, MC Leighton Whitsitt, M.D., LTC, MC Arthur Glover, M.D., MAJ, MC
Key Words: Intraocular lenses Cataract extraction	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objective: To establish the safety and effectiveness of this device for use in human subjects according to guidelines recommended by the Food and Drug Administration ophthalmic advisory panel.

Technical Approach: Continuous monitoring of patients undergoing cataract extraction with insertion of intraocular lenses has been continued to satisfy the requirements of Part 812, Title 2 of Code of Federal Regulations (Investigational Device Exemptions). Specific controls to facilitate the evaluation of the safety and efficiency of the intraocular lens are an integral part of the clinical study design.

Progress: from 1 Feb 78 to 1 Oct 80, 106 intraocular lenses have been inserted and monitored (preoperatively, operatively and postoperatively) according to the evaluation standards established by the investigational plans for McGhan, Coburn and Surgidev Medical Corporations. Over 85% of patients studied thus far have received vision of 20/40 or better postoperatively.

Detail Summary Sheet

Date: 5 Aug 80 Proj No: C-3-79 Status: Terminated

TITLE:

Dantrolene Sodium IV for Reduction of Lethal Effects of Malignant Hyperthermia Crisis.

Start Date: 8 Nov 78	Est Comp Date: 5 Aug 80
Principal Investigator	Facility
Richard R. Ritter, M.D., COL, MC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Surgery/Anesthesia-Operative	
Key Words:	
Malignant hyperthermia	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objective: To ascertain the potential of dantrolene sodium IV for reduction of the lethal effects of the malignant hyperthermia crisis in affected patients.

Technical Approach: Dantrolene sodium is injected intravenously in doses of 1 mg/kg until tachycardia or arrhythmia is relieved or muscle tone or temperature decreases. Further infusions at the same dose level may subsequently be indicated if the heart rate increases or again becomes irregular or if the muscle tone or temperature again increases.

Progress: No indication for the use of this protocol has developed during this review period. The investigational drug has been released for general usage by the Food and Drug Administration for the treatment of malignant hyperthermia crisis.

Detail Summary Sheet

Date: 22 Apr 80 Proj No: C-15-79 Status: Completed
TITLE:

Analgesic Effect of Epidurally Administered Morphine.

Start Date: Apr 79	Est Comp Date: 22 Apr 80
Principal Investigator Stephen J. Weddel, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/Anesthesia-Operative	Associate Investigators: Richard R. Ritter, M.D., COL, MC
Key Words: Epidural morphine Analgesia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To evaluate the analgesic effect of extradural administration of morphine and its potential side effects to include vascular reabsorptive levels.

Technical Approach: Following major surgery with continuous epidural block as the primary anesthesia, 5 or 10 mg/70kg body weight of preservative-free morphine sulfate was administered through the epidural catheter when the patient noted the onset of post-surgical pain. Serum morphine levels were determined at intervals between 5 and 240 minutes post-injection using liquid chromatography with electrochemical detection, and analgesic effectiveness was assessed using a linear pain analogue scale and the subjective response of the patient.

Progress: The mean peak serum level resulting from the 10mg/70kg dose was 49.7 ± 35.6 ng/ml, and the mean serum levels declined to 5.4 ± 4.8 ng/ml over the four hour post-injection period. The 5mg/70kg dose resulted in a mean peak serum level of 28.0 ± 20.6 ng/ml with mean serum levels declining to 2.1 ± 1.6 over the four hour post-injection period.

Average onset of significant analgesia was 15 minutes post-injection. Duration of adequate analgesia varied from four hours to several days, the mean being 37.9 hours for those receiving 5mg/70kg and 51.6 hours for those receiving 10mg/70kg.

C-15-79 (continued)

Side effects included pruritis easily ameliorated with diphenhydramine, and urinary retention. Respiratory depression which developed in one patient was reversed with naloxone without notable effect on the duration or intensity of the analgesic response to the epidural morphine.

This study demonstrates the analgesic effectiveness of and the serum morphine levels consequent to the epidural administration of morphine, and supports the concept of a selective spinal analgesic action.

Detail Summary Sheet

Date: 26 Sep 80 Proj No: C-32-79 Status: Terminated

TITLE:

Effects of Antiplatelet Therapy in Carotid Endarterectomy.

Start Date: Aug 79	Est Comp Date:
Principal Investigator	Facility
Vernon T. Deal, M.D., MAJ, MC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Surgery/General Surgery	Bruce S. Jarstfer, M.D., COL, MC
Key Words:	
Carotid Endarterectomy	
Antiplatelet Therapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To determine intraoperative blood loss and to quantitate postoperative blood loss by estimate of wound hematoma volume in patients receiving or not receiving antiplatelet therapy in the perioperative period.

Technical Approach: Double blinded administration of ASA vs placebo to patients will begin 6 days prior to carotid endarterectomy. Careful measurement of intraoperative blood loss will be carried out, and postoperative wound complications will be evaluated.

Progress: The number of carotid endarterectomies was somewhat curtailed in March of this year with the loss of COL Bruce S. Jarstfer, our vascular chief. In addition, patient compliance or acceptance of the protocol once adequately explained to them has been very small; most patients elected not to participate in the study. Since the arrival of MAJ Michael J. Spebar, chief of vascular surgery, we have instituted a protocol for intraoperative administration of Reomacrodex during carotid endarterectomy which makes pointless the estimation of any blood loss with respect to platelet function. For these reasons, completion of this protocol is no longer possible.

Detail Summary Sheet

Date: 26 Sep 80 Proj No: C-2-80 Status: Completed
 TITLE: An Open Study Evaluation of Butorphanol as a Premedicant Coadministered with Diazepam and Glycopyrrolate, as a Supplement to Balanced Anesthesia, and as a Postoperative Analgesic.

Start Date: 15 Nov 79	Est Comp Date:
Principal Investigator	Facility
Barry J. Anderton, M.D., MAJ, MC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Surgery/Anesthesia-Operative	Richard R. Ritter, M.D., COL, MC
Key Words:	Robert V. DeVore, Jr., M.D., CPT, MC
Preanesthetic medication	
Analgesic	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To evaluate butorphanol tartrate (Stadol^R) as a preanesthetic medication used in conjunction with diazepam and glycopyrrolate using an open experimental design employing hospitalized presurgical patients.

To gain additional experience using butorphanol tartrate as a supplement to balanced anesthesia in combination with N₂O:O₂ and pancuronium and/or tubocurare.

To gain additional experience and evaluation of butorphanol in postoperative pain in these patients.

Technical Approach: Patients undergoing abdominal or vaginal surgical procedures who met the eligibility criteria for this study were divided into two groups. Group 1 received glycopyrrolate, butorphanol IM, and valium orally; and group 2 received glycopyrrolate and butorphanol IM as a premedication one hour prior to their surgical procedure. Prior to induction of anesthesia, patients were evaluated by the method of Dundee for excitement, apprehension and sedation. Patients then received D tubocurare for defasciculation, butorphanol and thiopental for induction, and succinyl. Requirements for additional butorphanol were determined by a change in the patient's vital signs.

Following completion of the procedure and return to wakefulness, the patient was extubated and transferred to the recovery room for observation. Subsequently, the patient was transported to the ward and the butorphanol continued postoperatively until the patient was able to take oral medications, they experienced a severe side effect, or required to be removed from the study.

Progress: A total of 52 patients were admitted to the study. Patients in both study groups were similar in respect to age, body weight, sex and race. The average age was 43.9 years and the average weight 147.2 pounds.

The premedication was considered excellent or good if a marked or moderate amount of sedation was present without apparent apprehension or excitement.

C-2-80 (continued)

If slight apprehension or excitement were present, the premedication was felt to be satisfactory, and if moderate or marked amounts of excitement or apprehension was present, this was considered a poor premedication. Utilizing this criteria, butorphanol was considered to be a satisfactory or better premedication in 85% of the patients studied. Group 2, premedicated with butorphanol (3 mg/70 kg), appeared to have fewer episodes of apprehension or excitement than group 1 (butorphanol and valium) but appeared less heavily sedated.

We found butorphanol to be a satisfactory premedication in 85% of our patients and thought it compared favorably with other currently used medications.

We were impressed with butorphanol during general anesthesia. Inductions were smooth and the anesthetic course uncomplicated in all patients. Maintenance of anesthesia did require greater supplementation with a potent inhalational agent, Enflurane, in those patients not receiving valium premedication, despite the amount of butorphanol administered to both groups being nearly identical.

As expected from a longer acting analgesic, the duration of pain relief following cessation of anesthesia was greater than if a shorter acting analgesic had been employed. In our patients this averaged 491 minutes. Seventy percent of patients thought that their pain relief was either good or excellent postoperatively. Amnesia was excellent in all patients following induction.

Detail Summary Sheet

Date: 30 Oct 80 Proj No: C-14-80 Status: Ongoing

TITLE:

Abdominal Wound Closure

Start Date: Mar 80		Est Comp Date: Indefinite
Principal Investigator Paul C. Vose, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/General Surgery		Associate Investigators: General Surgery Residents Michael J. Spebar, M.D., MAJ, MC
Key Words: Running suture Interrupted suture Wound closure		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
		Periodic Review Results: Continue

Objective: To determine if there is a difference in wound closures performed by interrupted or running suture techniques on the fascial layers.

Technical Approach: All abdominal operations on the General Surgery Service will be randomized into two closure groups: (1) continuous running prolene or (2) interrupted neurilon or wire. The type of closure will be determined in the operating room by a random process similar to flipping a coin. All patients in the study will be analyzed to determine the following: (a) wound disruption with relation to type of closure; (b) incisional hernia secondary to type of closure; (c) relationship if any of wound disruption of incisional hernia related to type closure and wound infection; (d) time of closure per cm of wound for each type of closure.

Progress: This study has not been started due to retirement of principal investigator. A new investigator will be appointed in the near future.

Detail Summary Sheet

Date: 26 Sep 80 Proj No: C-20-80 Status: Ongoing

TITLE:

Evaluation of St. Jude Prosthetic Heart Valve

Start Date: May 80	Est Comp Date: Unknown
Principal Investigator George F. Schuchmann, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Surgery/Cardiothoracic	Associate Investigators:
Key Words: Prosthetic Heart Valve	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Periodic Review Results: Continue	
Objective: Clinical evaluation of the S. J. Medical bi-leaflet, center opening cardiac valve prosthesis.	

Technical Approach: This project would involve replacment of diseased heart valves with the entirely pyrolitic carbon prosthesis using routine operative technique. The flow characterizations of this experimental design are particularly desirable for patients with a small annulus.

Progress: I choose to use this experimental prosthesis only in patients where standard prostheses would result in residual stenosis of the involved valve. We have not encountered such a patient since this protocol was approved. Thus, no data have been accumulated.

Detail Summary Sheet

Date: 1 Oct 80 Proj No: C-4-79 Status: Completed

TITLE:

Efficacy of Epirizole in the Treatment of Swelling Accompanying Dental Surgery.

Start Date: 5 Jan 79

Est Comp Date: May 80

Principal Investigator:

Facility:

Starling R. Schow, D.M.D., LTC, DC

Brooke Army Medical Center

Dept/Sec:

Associate Investigators:

Department of Dentistry/Oral Surgery

Key Words:

Epirazole

Swelling

Dental Surgery

Accumulative MEDCASE

Est Accumulative

Periodic

Cost:

OMA Cost:

Review Results:

Objective: To determine if epirizole therapy, as compared to placebo, will prevent or significantly decrease the swelling this accompanies third molar extractions.

To evaluate the safety of epirizole therapy by close observation of the patients concerning organs, organ systems, clinical laboratory values and side effects and adverse reactions.

Technical Approach: The study has been conducted within the parameters outlined in the clinical protocol. To date a total of six patients have completed study strictly within the outlines of the protocol. Data were collected daily and relayed via telephone-computer transmission to the sponsor, Marion Laboratories, for analysis.

Progress: A total of six patients were treated at Brooke Army Medical Center according to the protocol format. There was no significant difference in either clinical or laboratory results with any of these patients.

This project and four similar projects in other hospitals failed to produce any significant results. Therefore, Marion Laboratories elected to discontinue the study.

Detail Summary Sheet

Date: 1 Oct 80		Proj No: C-40-80	Status: Ongoing
TITLE: Evaluation of PO ₂ Changes Associated with Intravenous Sedation for Out-patient Oral Surgery			
Start Date: 1 Nov 80		Est Comp Date: Jun 81	
Principal Investigator: Richard A. Kraut, LTC, DC		Facility: Brooke Army Medical Center	
Dept/Sec: Department of Dentistry/Oral Surgery		Associate Investigators: Sterling R. Schow, LTC, DC Ricney F. Newhouse, LTC, DC B. Michael Kulikowski, MAJ, DC	
Key Words: PO ₂ changes Intravenous Sedation Oral Surgery			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue	

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

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

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

1. ECG - a cardiac monitor utilizing a 2 channel oscilloscope with cardioverter/defibrillator connected in line.
2. A respiratory monitor with a digital rate display and a graphic display on the 2nd channel of the oscilloscope.
3. An automatic hands-off blood pressure monitor set for readings every two minutes.
4. A continuous cutaneous oxygen monitor.

Progress: This study cannot be started until the Cutaneous PO₂ monitor, a MEDCASE item, has been acquired.

Detail Summary Sheet

Date: 31 Oct 80 Proj No: C-43-77 Status: Completed
TITLE:

The Reduction of Low Back Pain as a Function of the Interaction of Physical Therapist and Patient.

Start Date: May 77	Est Comp Date:
Principal Investigator	Facility
Jane E. Gierhart, Ph.D., LTC, SP	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Physical Therapy	
Key Words:	
Low back pain	
Physical therapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

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: Ten U.S. Army medical treatment facilities participated in this study. The patients were referred to physical therapy with or without a physician's evaluation. The physical therapists evaluated their own patients and planned the treatment according to their expertise and assessment of the low back pain. The treatment regime was followed until discontinued by the therapist. The Fundamental Interpersonal Relations Orientation-Behavior Test was completed at the beginning of the study. Utilizing questionnaires furnished by the principal investigator, information about the patient's low back pain and treatment was collected.

Progress: The findings of the study are as follows:

1. Patients' favorable perceptions of their physical therapist are related to the successful treatment of low back pain.
2. Physical therapists' positive expectation and opinions regarding the patient's successful relief of low back pain symptoms are related to treatment outcome.
3. Total compatibility, as measured by the Fundamental Interpersonal Relations Orientation-Behavior Test, is not as important to treatment outcome as the ongoing interaction between therapist and patient based on perceptions, expectations, and opinions of the other's behavior.

C-43-77 (continued)

4. In comparison with previous studies, symptomatic treatment may provide the patient with low back pain faster relief than time alone, regardless of the modality used.

Detail Summary Sheet

Date: 31 Oct 80 Proj No: C-19-79 Status: Completed

TITLE:

The Relationship Between Grip Size of a Tennis Racquet and the Incidence of Tennis Elbow Symptoms in Female Tennis Players.

Start Date: Jun 79	Est Comp Date:
Principal Investigator Kathleen S. Zurawel, 2LT, AMSC	Facility academy of Health Sciences
Dept/Sec: Physical Therapy	Associate Investigators:
Key Words: Tennis elbow	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objective: To determine the relationship between tennis elbow symptoms in female tennis players and variances in racquet grip size from true grip size of the individual as determined by measuring from the proximal palmar crease of the hand along the radial border of the ring finger to its tip.

Technical Approach: Forty-five women from San Antonio tennis clubs were surveyed to determine the relationship between grip size of tennis racquets and the incidence of tennis elbow symptoms in female tennis players. The survey was conducted by researcher questionnaire in which participants were asked their age, number of years playing tennis, amount of lesson time, size of racquet used, and whether or not they had ever ceased playing tennis for at least a week secondary to elbow pain. The subject's racquet hand was then measured using Nirschl's method (the distance from the proximal palmar crease of the hand along the radial border of the ring finger to its tip).

Progress: There was no correlation between the simple presence or absence of tennis elbow and the fact that a tennis player consistently uses a racquet whose grip is greater or less than his palm size. However, a significant correlation is indicated when the larger positive differentials are examined as a single contributing factor. At the same time it is further indicated that tennis elbow occurs irrespective of age or the presence of a correlation between tennis elbow and simple racquet size controlling for age.

Detail Summary Sheet

Date: 31 Oct 80	Proj No: C-20-79	Status: Completed
TITLE: Quality Assurance in Physical Therapy: An Attitudinal Survey on Specialization and Mandatory Continuing Education.		
Start Date: Jun 79	Est Comp Date:	
Principal Investigator Michael B. Hammond, 2 LT, AMSC	Facility Academy of Health Sciences	
Dept/Sec: Physical Therapy	Associate Investigators:	
Key Words: Physical therapy Continuing education		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
Objectives: To determine the attitudes of selected American Physical Therapy Association (APTA) members on the issues of specialization and mandatory continuing education.		

To assess significant differences in the attitudes of selected APTA members on specialization and mandatory continuing education according to demographical data.

Technical Approach: The attitudes of physical therapists on two key issues of quality assurance were studied: specialization and mandatory continuing education. Questionnaires were mailed to a random sample of two hundred therapists from the Texas Chapter of the American Physical Therapy Association (AOTA). A demographic survey accompanied the questionnaires.

Progress: A 41% response allowed statistically significant conclusions to be drawn. To assess demographic data, a profile was compiled of the typical respondent to include number of years employed as a therapist, employment setting, income level, educational level and degree of involvement in the APTA. Most respondents subscribed to the concepts of both specialization and mandatory continuing education as beneficial to quality physical therapy. Most respondents considered themselves moderately well acquainted with these two key issues of quality assurance.

Detail Summary Sheet

Date: 31 Oct 80	Proj No: C-24-79	Status: Completed
TITLE: Input by Clinical Faculties into the Curriculum Content and Design of Entry-Level Physical Therapy Programs.		
Start Date: Jun 79	Est Comp Date:	
Principal Investigator Neva C. Gaskins, 2LT, AMSC	Facility Academy of Health Sciences	
Dept/Sec: Physical Therapy	Associate Investigators:	
Key Words: Physital therapy programs Curriculum content		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
Objective: To determine the extent of input clinical faculties have in the Physical Therapy academic curriculum content and design.		

Technical Approach: Questionnaires were sent to the clinical educational coordinators of 400 randomly-selected clinical facilities in the United States which sponsor entry-level PT student affiliations. Planning of academic curriculum content, design, and sequence was considered.

Progress: The 173 returned questionnaires indicated that more than 75% of the clinical faculties did not actively participate in the academic curriculum planning and that 80.3% of the clinical educational coordinators who completed the questionnaire personally desired more input into the academic curriculum planning. Further study on the subject was indicated.

Detail Summary Sheet

Date: 31 Oct 80 Proj No: C-25-79 Status: Completed

TITLE:

Survey of Participation of U.S. Army Physical Therapists in Continuing Education.

Start Date: Jul 79		Est Comp Date:
Principal Investigator Richard P. Bozzio, 1LT, AMSC		Facility Academy of Health Sciences
Dept/Sec: Physical Therapy		Associate Investigators: Debra I. Chang, 2LT, AMSC
Key Words: Physical therapists Continuing Education		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
		Periodic Review Results:

Objectives: To determine the percentage of U.S. Army physical theapists who participated in continuing education during calendar year 1978.

To develop a profile of the "typical Army physical therapist" based on the factors influencing their participation.

Technical Approach: One hundred fifty-eight questionnaires were sent to active duty U.S. Army physical therapists in the continental United States, Alaska and Hawaii to determine the number of physical therapists who participated in various forms of continuing education (CE) during the calendar year 1978 and the factors that influenced their participation.

Progress: One hundred five of these questionnaires (66.5%) were returned within six weeks. Rresults revealed that the average age of U.S. Army Physi- cal therapists is 34.2 years and that 61.6% have been practicing for 10 years or less. Attendance at short courses was considered to be the most effec- tive method of CE by 69.6% of the therapists. Participation in in-service activities was rated as the second most effective method of CE.

The two most preferred areas of special interest were orthopaedics and sports medicine while geriatrics and pediatrics were the least preferred areas.

Detail Summary Sheet

Date: 31 Oct 80 Proj No: C-27-79 Status: Completed

TITLE:

Biofeedback Treatment of Extensor Lag After Total Knee Arthroplasty Compared with Standard Rehabilitation Technique: Effects on Time of Recovery.

Start Date: Jul 79	Est Comp Date:
Principal Investigator Gary Hague, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Sec: Physical Therapy	Associate Investigators: Richard Petersen, 2LT, AMSC
Key Words: Extensor lag Total knee arthroplasty Rehabilitation	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To determine if electromyographic (EMG) biofeedback when used as an adjunct to a standard rehabilitation program for total knee arthroplasty patients is effective in reducing the amount of time needed to correct extensor lag.

Technical Approach: Electromyographic biofeedback was evaluated as an adjunct to a standard rehabilitation program for total knee arthroplasty patients to determine its effectiveness in decreasing the time needed to correct extensor lag. Total knee arthroplasty patients who exhibited significant extensor lag immediately postoperatively were accepted for the study and randomly divided into control and experimental groups. Both groups participated in a standard rehabilitation program; however, the experimental group was also administered electromyographic biofeedback with quadriceps strengthening exercises. Goniometric measurements of active and passive extension at the affected knee were taken immediately postoperatively and at subsequent seven day periods to determine results.

Progress: Because of problems encountered and unexpected variables which arose during data collection, it was decided to forego analysis of study results.

Investigation into why so many problems arose and so many variables were not controlled resulted in the awareness that proper technique in preparation of a valid study was not carried out.

Detail Summary Sheet

Date:	3 Nov 80	Proj No:	C-28-79	Status:	Completed
TITLE:					
Effect of Transcutaneous Electrical Nerve Stimulation on Quadricep and Hamstring Muscle Power in Patients with Symptomatic Chondromalacia Patellae.					
Start Date:	Jul 79	Est Comp Date:			
Principal Investigator		Facility			
Robin E. Yates, 2LT, AMSC		Academy of Health Sciences			
Dept/Sec:		Associate Investigators:			
Physical Therapy					
Key Words:					
Transcutaneous Electrical Nerve Stimulation					
Chondromalacia Patellae					
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:			
Objective: To evaluate any change in quadricep and hamstring muscle power in patients with painful chondromalacia after an application of transcutaneous electrical nerve stimulation (TENS) to recommended knee patients.					

Technical Approach: TENS on quadricep femoris strength was evaluated in patients with symptomatic chondromalacia patellae. The treatment and control group each contained six subjects. The strength of each subjects' quadricep was measured in foot pounds of torque on an isokinetic dynamometer over a three-day period. Interposed between two such measurements on the second day, was an application of TENS to treatment subjects and a rest period for control subjects.

Progress: Statistical analysis showed a significant difference between the mean torques before and after TENS on the second day. This suggests that TENS may have an immediate effect of suppressing pain associated with chondromalacia which then enables the quadriceps to develop a greater amount of torque. No carry-over effect, however, was observed one day later.

Detail Summary Sheet

Date: 3 Nov 80 Proj No: C-29-79 Status: Completed

TITLE:

The Relationship Between the Pain of Chondromalacia Patellae and Knee Range of Motion.

Start Date: Jul 79	Est Comp Date:
Principal Investigator	Facility
Mary Petlin, 2LT, AMSC	Academy of Health Sciences
Dept/Sec:	Associate Investigators:
Physical Therapy	
Key Words:	
Chondromalacia Patellae	
Knee range of motion	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objective: To determine what portion of the normal range of knee motion, between 90 degrees of flexion and zero degrees of extension, is painful for patients with chondromalacia patellae when exercising against maximum resistance.

Technical Approach: Six subjects with diagnosed chondromalacia patellae were tested on the Cybex II isokinetic dynamometer.

Progress: A range of 0.91 to 30.0 degrees of knee flexion was discovered to produce the greatest pain for these subjects while working against maximal resistance. This range does not correlate with that range of motion previously reported in the literature as that causing the greatest compressive force between the patella and the femur. This fact also contraindicates the use of the short-arc quad exercise in the treatment of patients with chondromalacia patellae.

Detail Summary Sheet

Date: 3 Nov 80 Proj No: C-30-79 Status: Completed

TITLE:

A Study of Mastectomy Patients: Psychological Adjustment Problems and What Can Be Done to Help.

Start Date: Jul 79	Est Comp Date:
Principal Investigator Diana Felten, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Sec: Physical Therapy	Associate Investigators: Joan Beebe, 2LT, AMSC
Key Words: Mastectomy Psychological problems	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To investigate the psychological problems and concerns encountered by the mastectomy patient as she seeks to adjust to the loss of a breast and the diagnosis of cancer.

To determine beneficial sources of help to include internal psychological coping mechanisms such as positive thinking and external sources such as group or family support.

Technical Approach: Twenty-four women responded to a 35 question survey which provided them with possible reactions to problems, and possible solutions to resolving these problems.

All of the women, ranging in age from 44 to 74, were between 1 and 5 years postmastectomy. The study group consisted of 19 married women and five single women, including divorcees and widows. All of them have reportedly accepted their mastectomies.

Progress: The problems encountered most frequently were depression, a sense of mutilation, lymphedema, concern of the daughters about their own future, anger, despair, fear of future check-ups, denial of true feelings, and insomnia. The two most common reactions to these problems were fear and anger, followed by shame, crying and depression. Husbands and other family members, doctors, friends, and religion were the most frequently mentioned sources of help used by these women as they attempted to overcome their problems. The Reach to Recovery Program and nurses were also found to be helpful.

C-30-79 (continued)

It was concluded that mastectomy patients would benefit during their adjustment period if the husband and other family members were also involved in the surgery preoperatively so that they could be maximally supportive and understanding of the woman as she adjusted to a difficult situation.

Detail Summary Sheet

Date: 3 Nov 80	Proj No: C-31-79	Status: Completed
TITLE:		
TENS Applied at an Acupuncture Point to Facilitate Recovery of Post-operative Knee Patients		
Start Date: Aug 79	Est Comp Date:	
Principal Investigator Barry L. Karalfa, 2LT, AMSC	Facility Academy of Health Sciences	
Dept/Sec: Physical Therapy	Associate Investigators: J. Wesley McWhorter, 2LT, AMSC	
Key Words: Acupuncture TENS		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the effectiveness of TENS applied via an acupuncture point in reducing pain therapy allowing a faster recovery of postoperative knee patients.

Technical Approach: Six patients were entered into the study. All of the patients followed the stanard treatment procedure employed by the clinic. In addition, those in the experimental group received TENS for 20 minutes prior to treatment while the control group received a placebo TENS treatment. Two electrodes were placed at the acupuncture points for the knee which are located on the border of the middle and lower part of the line connecting the ear lobe and the mandibular angle, and on the foot at the metatarsal head of the little toe. A Pain Suppressor Model GL 106 A TENS was used for both groups. In order to determine the operational amplitude, the output was increased until a sensation was percevied. Once a sensation was perceived, the output for the experimental group was lowered to a point where the stimulation was no longer felt. Their treatment was then given at this level. The unit used by those in the placebo group was turned off once they had experienced a sensation. These procedures were followed with the patient prior to each treatment session.

Progress: Due to unforeseen circumstances and the small sample size, the data accumulated could not be statistically treated with any decree of validity. In order to obtain a population of six patients, several operative procedures were included in the study as postoperative knee patients making it difficult to obtain correlative data.

Detail Summary Sheet

Date: 3 Nov 80 Proj No: C-33-79 Status: Completed

TITLE:

Heart Rate Response to the Valsalva Maneuver when Performed During Exercise.

Start Date: Aug 79	Est Comp Date:
Principal Investigator Mary Reidelbach, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Sec: Physical Therapy	Associate Investigators:
Key Words: Valsalva Maneuver Heart Rate Exercise	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objective: To evaluate the effects of the Valsalva maneuver on heart rate when performed during the partial sit-up exercise in normal subjects.

Technical Approach: Heart rate response of eleven normal subjects was determined by calculating the ratio of maximal tachycardia to maximal bradycardia (the Valsalva ratio) during a simulated Valsalva maneuver, a partial sit-up exercise, and the Valsalva maneuver combined with the partial sit-up exercise. Heart rate was determined by measuring the distance between R-waves of an electrocardiograph taken through the duration of the experiment.

Progress: Statistical analysis of obtained data demonstrated a significant difference between the effects of the Valsalva maneuver and the partial sit-up exercise alone on heart rate. Significant difference also existed between the Valsalva maneuver combined with sit-up and the sit-up alone, while no significant difference was found between the Valsalva maneuver alone and in combination with the partial sit-up exercise. It was not determine if these differences were due to some type of carry-over effect such as fatigue or practice.

Detail Summary Sheet

Date: 4 Nov 80	Proj No: C-25-80	Status: Ongoing
TITLE: Transcutaneous Electrical Nerve Stimulation to Control Postoperative Knee Pain.		
Start Date: Jun 80	Est Comp Date: Oct 80	
Principal Investigator Stephen P. Shandera, 2LT, AMSC	Facility Academy of Health Sciences	
Dept/Sec: Physical Therapy	Associate Investigators:	
Key Words: Transcutaneous Electrical Nerve Stimulation Postoperative Knee Pain		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objective: To evaluate a treatment method, TENS, as a way to control post-operative knee pain.		

Technical Approach: Nine patients who had undergone reconstructive knee surgery were entered into the study. Patients were asked to use the TENS machine whenever pain interred with reading, watching TV, sleeping, etc. Pain intensity before and after use of TENS was indicated on a vertical numerical scale from one to ten. Analgesics were available upon request and data on intake of pain medication was recorded in each patient's chart.

Progress: Data collection completed. Results are being analyzed.

Detail Summary Sheet

Date: 4 Nov 80 Proj No: C-26-80 Status: Completed

TITLE:

Effect of Seat Height on Oxygen Consumption During Bicycle Ergometer Work.

Start Date: Jun 80	Est Comp Date:
Principal Investigator	Facility
Joseph P. Boden, 2LT, AMSC	Academy of Health Sciences
Dept/Sec:	Associate Investigators:
Physical Therapy	
Key Words:	
Bicycle Ergometer	
Oxygen consumption	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objective: To evaluate the use of the bicycle ergometer as a cardiorespiratory conditioning tool through examination of the effects of seat height on oxygen consumption.

Technical Approach: Ten normal subjects between the ages of 21 and 30, both male and female, were used in this study. Subjects cycles on a Tuntari bicycle ergometer at a workload of 125 watts and 50 rpms at seat heights of 95, 100 and 105 percent of ischium to floor leg lengths. Expired gases were collected in a Collins 120 liter gasometer when the subjects reached steady state. Gases were analyzed for oxygen content on a mass spectrometer.

Progress: The mean values for oxygen consumption were 1.63, 1.54, and 1.62 liters/minute, respectively. Statistical analysis revealed no significant differences between the values. It was concluded that small (5% of leg length) variation in seat height from the optimum 100% height did not significantly affect efficiency of exercise as measured by oxygen consumption.

Detail Summary Sheet

Date: 4 Nov 80	Proj No: C-27-80	Status: Completed
TITLE: Forced Expiratory Volume Measurements on a Collins Spirometer: Preliminary Evaluation of Consistent and Accurate Measurements as a Function of Patient Adjustment.		
Start Date: Jun 80	Est Comp Date:	
Principal Investigator Margaret S. Campbell, 2LT, AMSC	Facility Academy of Health Sciences	
Dept/Sec: Physical Therapy	Associate Investigators: Trancy Jan Schmidt, 2LT, AMSC	
Key Words: Forced expiratory volume Collins spirometer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
Objective: To evaluate the patient adjustment period on a Collins spirometer, a measuring tool for evaluation of patients with chronic lung disease.		

Technical Approach: Thirty normal subjects, between the ages of 18 and 46, both male and female, with no past history of tobacco use in any form were used in the study. Fifteen forced expiratory volume measurements during the first second of expiration were calculated from the fifteen forced vital capacity maneuvers performed by each subject.

Progress: The results indicate the existance of a patient adjustment period in obtaining maximum forced expiratory volume measurements during the first second of expiration. However, there proved to be no significant difference between the values of any two maneuvers. Therefore, the existence of a patient adjustment period has no affect on accurate and consistent spirometric measurements using a Collins spirometer.

Detail Summary Sheet

Date: 4 Nov 80 Proj No: C-28-80 Status: Completed

TITLE:

Supportive Effectiveness of Ankle Taping with and without Underwrap:

A Comparative Study.

Start Date: Jun 80	Est Comp Date:
Principal Investigator	Facility
Lawrence Rush, 2LT, AMSC	Academy of Health Sciences
Dept/Sec:	Associate Investigators:
Physical Therapy	Richard T. Peters, 2LT, AMSC
Key Words:	
Ankle taping	
Underwrap	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To evaluate the technique of ankle wrapping for restriction of the extremes of range of motion.

To compare the effectiveness of tape applied directly to skin with tape using an underwrap in the reduction of supination at the ankle.

Technical Approach: Eight subjects were randomly assigned to a control group, having their ankles taped without foam underwrap. Eight subjects were randomly assigned to an experimental group, having their ankles taped with foam underwrap. Three measurements of ankle supination were taken on two separate occasions for each subject: 1) prior to taping, 2) immediately after taping, and 3) after participation in a 30-minute, half-court basketball game. Ankle supination was measured using a Leighton Flexometer.

Progress: A comparison of measurements taken pre-taping and post-exercise in both groups resulted in no significant difference in reduction of supination of the ankle. The findings of this study indicate that foam underwrap does not increase the restrictive effects of ankle taping.

Detail Summary Sheet

Date: 4 Nov '80		Proj No: C-29-80	Status: Completed
TITLE: Effect of Push-ups on Upper Body Strength in Women as Measured by Cardiopulmonary Resuscitation Compressions.			
Start Date: Jun 80		Est Comp Date:	
Principal Investigator Michael J. Marchese, 2LT, AMSC		Facility Academy of Health Sciences	
Dept/Sec: Physical Therapy		Associate Investigators: Margaret Peters, 2LT, AMSC	
Key Words: Push-ups Upper body strength Cardiopulmonary Resuscitation Compressions			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:	

Objective: To test the effectiveness of push-ups in increasing the upper body strength of women as measured by the performance of Cardiopulmonary Resuscitation (CPR) compressions.

Technical Approach: The efficacy of a modified male push-up for increasing upper body strength in women was investigated. The modified push-up utilized differed from regular male push-ups in that the eccentric contraction lasted for six seconds. A quasi-experimental design was used to randomly divide 54 female volunteers into long-term experimental, short-term experimental and control groups. The control group performed regular female push-ups throughout the four week study, while the experimental groups executed modified male push-ups. Performance was measured by the number of successful cardiopulmonary resuscitation compressions completed during two nine-minute observations.

Progress: Although a correlated sample t-test showed a significant performance increase in the long-term experimental group, confounding variables prevented generalization of these results. The investigators postulated that modified male push-ups could be effective, but further research was needed to prove this.

Detail Summary Sheet

Date: 4 Nov 80	Proj No: C-30-80	Status: Ongoing
TITLE: An Analysis of Factors Involved in Encouraging Research Among Physical Therapists.		
Start Date: Jun 80	Est Comp Date: Oct 80	
Principal Investigator Cary C. Bucko, 2LT, AMSC	Facility Academy of Health Sciences	
Dept/Sec: Physical Therapy	Associate Investigators:	
Key Words: Research Physical Therapists		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objective: To provide a data-base for planning, administrative decision making, and/or policy formation.		

Technical Approach: This study utilizes a research questionnaite to analyze the factors involved in encouraging research among Physical Therapists.

Progress: Statistical analysis of the data is nearing completion.

Detail Summary Sheet

Date: 4 Nov 80		Proj No: C-31-80	Status: Completed
TITLE: Analysis of the Attitudes of Members of the American Physical Therapy Association Concerning the Practice of Physical Therapy without Practitioner Referral.			
Start Date: Jun 80		Est Comp Date:	
Principal Investigator Nancy L. Tupper, 2LT, AMSC		Facility Academy of Health Sciences	
Dept/Sec: Physical Therapy		Associate Investigators:	
Key Words: Physical Therapy Practitioner referral			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:	
Objective: To provide a data base about attitudes of members of the APTA concerning practice of physical therapy independent of practitioner referral.			

Technical Approach: Questionnaires were sent to a total of 646 members of the American Physical Therapy Association who were either members of a specified leadership group or a random sample of the organization's membership. The names and addresses of all members were obtained from the American Physical Therapy Association.

Progress: A significant difference in opinion was found between the APTA leaders and the random members surveyed, ($p < .1$). Forty-six percent of the leaders surveyed were in favor of treatment independent of referral compared to 30 percent of the general membership surveyed with this opinion. Three demographic characteristics of the therapists surveyed seemed to be significantly related to opinion on treatment without referral. These demographic traits were: whether the respondent has ever served as an APTA officer, whether he/she attended the 1980 APTA House of Delegates meeting, and the type of diagnosis received with referrals.

Detail Summary Sheet

Date: 4 Nov 80		Proj No: C-32-80	Status: Completed
TITLE: Trunk Length Changes Related to Intervertebral Disc Expansibility as a Function of Age.			
Start Date: Jun 80		Est Comp Date:	
Principal Investigator Mark C. Sanderson, 2LT, AMSC		Facility Academy of Health Sciences	
Dept/Sec: Physical Therapy		Associate Investigators: Lawrence E. Gallagher, 2LT, AMSC	
Key Words: Trunk length changes Intervertebral disc			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:	

Objective: To supplement the currently existing knowledge on the subject of intervertebral disc expansibility within the realm of anatomical/biomedical sciences.

Technical Approach: Sixty individuals varying in age from 20 to 59 years, with no history of previous back injury or trauma, were studied to determine the effect that age has upon the expansibility of the intervertebral disc. When compressional forces are released or absent from the discs, as in recumbent rest, they imbibe fluid and therefore expand. The resultant change in disc width can be measured as a general change in trunk length. Pre-sleep/rest and post-sleep/rest measures were taken on each subject and these findings were analyzed to determine the degree of expansion of their intervertebral discs in relation to their age.

Progress: There was a significant decrease in the expansion of the discs with increasing age. Our findings suggest that a significant amount of variance can be accounted for with age.

Detail Summary Sheet

Date: 4 Nov 80 Proj No: C-33-80 Status: Completed

TITLE:

Analysis of Crutch Length Estimation Methods.

Start Date: Jun 80	Est Comp Date:
Principal Investigator Stephen C. Allison, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Sec: Physical Therapy	Associate Investigators:
Key Words: Crutches Crutch fitting	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To eliminate the perceived arbitrariness in the use of various crutch length estimation methods and to establish whether any of the six methods chosen to investigate might be proven statistically to be more accurate than the others.

Technical Approach: Forty adult subjects had their axillary crutch lengths estimated using six estimation methods, and then each subject was measured for actual (ideal) crutch length. Each of the six estimation methods was then analyzed for accuracy.

The six estimation methods included in the study are as follows: 1) calculation of 77% of the subject's reported height, 2) calculation of 77% of the subject's measured height, 3) calculation of the subject's reported height minus 16 inches, 4) calculation of the subject's measured height minus 16 inches, 5) measurement of the subject's armspan from the elbow to the longest opposite fingertip, and 6) measurement from a point on the supine subject's chest wall to a point anterolateral to the subject's foot, using an original footboard measuring device.

Progress: Using a variety of statistical tests, a significant correlation between accuracy and method of estimation was found. The calculation of 77% of measured height was found to be the most accurate.

Detail Summary Sheet

Date: 4 Nov 80 Proj No: C-34-80 Status: Completed
 TITLE:

Relationship of Relative Hand Size and Hand Dominance.

Start Date: Jun 80	Est Comp Date:
Principal Investigator Kathryn A. Kelley, 2LT, AMSC	Facility Academy of Health Sciences
Dept/Sec: Physical Therapy	Associate Investigators:
Key Words: Hand size Hand dominance Volumetric measurement	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Review Results:

Objective: To evaluate the efficacy of standard therapeutic procedure utilized among physical therapists in the treatment of edema formation in the hand.

Technical Approach: Thirty adult subjects' hands were measured by volumetric displacement method to discover any consistent difference in hand size as related to hand dominance. The values (in ml) were analyzed to establish the existence of a significant difference in hand sizes.

Progress: The results indicate that the dominant hand, whether right or left, was statistically significantly larger than the non-dominant hand. The fine motor skill of writing caused sufficient hypertrophy in the intrinsic hand muscles to account for this difference. Allowances for this difference in hand size should be considered when comparing hand size while assessing edema formation or muscle atrophy.

Detail Summary Sheet

Date: 4 Nov 80	Proj No: C-38-80	Status: Completed
TITLE: Alterations in the Normal Carrying Angle in Little League and Pony League Baseball Pitchers as a Result of Inordinate Pitching.		
Start Date: Aug 80	Est Comp Date:	
Principal Investigator Lroi Sue Apple, 2LT, AMSC	Facility Academy of Health Sciences	
Dept/Sec: Physical Therapy	Associate Investigators: Michael D. Apple	
Key Words: Cubitus valgus deformity Goniometer Carrying angle		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
Objective: To determine and to what degree pitching causes cubitus valgus deformity in the young baseball pitcher.		

Technical Approach: Twenty-one Little League baseball pitchers between the ages of 11 and 16 were measured to determine any valgus deformity in the pitching arm (determine by comparing the pitching arm to the opposite arm). Next, 16 volunteers who had never played league ball were measured. These boys were also between 11 and 16 years of age. No one subject had a history of any fractures to the humerus, radius or ulna, nor any past elbow surgery. Additional data included the number of innings each of the pitchers (experimental group) pitched this past season. This information was supplied by the coaches of the teams involved after consulting their "scorebooks".

Progress: A multiple regression test showed that there was essentially no correlation between deformity and age nor between age and amount of pitching done. It appears that competitive pitching in young boys has no significant effect on the elbow.

Detail Summary Sheet

Date: 4 Nov 80	Proj No: C-39-80	Status: Completed
TITLE: Influence of Manual Massage, Moist Heat, and Electrical Stimulation on Trunk Flexibility: Effect on Trunk Flexion.		
Start Date: 26 Aug 80	Est Comp Date:	
Principal Investigator Edith Eubanks, 2LT, AMSC	Facility Academy of Health Sciences	
Dept/Sec: Physical Therapy	Associate Investigators:	
Key Words: Manual massage Moist heat Electrical stimulation Trunk flexion		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To compare the relative effectiveness of manual massage, manual massage following the application of moist heat, and electrical stimulation applied in combination with moist heat in increasing trunk flexibility in normal human subjects.

Technical Approach: The subjects, four females and two males, ranged in age from 21 to 28 years. They were randomly treated with the specified modalities with the treatment and measurement techniques standardized. The finger to floor measurement of trunk flexibility was used.

Progress: Results showed that there was no significant difference in the flexibility produced by each modality.

Detail Summary Sheet

Date:	4 Nov 80	Proj No:	C-18-80	Status:	Terminated
TITLE:					
Double-Blind Efficacy Trial of Topical 70% DMSO Gel vs Placebo (1%) in the Treatment of Acute Ankle Sprain.					
Start Date:			Apr 80		
Principal Investigator			Est Comp Date:		
Thomas Parr, M.D., MAJ, MC			Facility		
Dept/Sec:			Reynolds Army Hospital		
Department of Surgery/Orthopaedic			Associate Investigators:		
Key Words:			Michael J. Benoit, M.D.		
Acute ankle sprain					
DMSO gel					
Placebo					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results:	

Objective: To determine whether the efficacy of topical treatment with 70% DMSO gel in acute sprains of the ankle can be demonstrated. A comparison of 70% and 1% DMSO gels, applied topically will be made. The 1% DMSO gel is intended to serve as the placebo control. Techniques for assessing changes in pain, tenderness and swelling will be employed.

Technical Approach: This is a double blind study comparing 70% DMSO gel to 1% DMSO gel, measuring patient acceptance, ankle range of motion, subjective pain, and amount of swelling. This procedure involved admitting the patient to the hospital and obtaining laboratory studies on various enzymes and other chemistries, to include glucose, BUN, creatinine, uric acid, phosphate, calcium, total protein, albumin, SGOT, and bilirubin. Pre and post study chemistries were obtained.

Progress: The study has been abandoned at the request of the Food and Drug Administration and Wallace Laboratories. It was difficult to find patients who were willing to come into the hospital for a full week simply for treatment of an ankle sprain. As a result, it was difficult to obtain the patient population needed for a valuable study. This study is abandoned in lieu of a different study, also with DMSO, which will not require hospitalization or expensive laboratory studies. This new study has been approved by the FDA.

Detail Summary Sheet

Date: 4 Nov 80	Proj No: C-19-80	Status: Ongoing
TITLE: Autotransfusion in Penetrating Trauma - The Feasibility of Processing Contaminated Blood.		
Start Date: Apr 80	Est Comp Date:	
Principal Investigator John D. Rumisek, M.D., CPT, MC	Facility Reynolds Army Hospital	
Dept/Sec: Department of Surgery/General Surgery	Associate Investigators:	
Key Words: Autotransfusion Penetrating trauma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

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

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

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

APPENDIX A
Southwest Oncology Group

Detail Summary Sheet

Date: 4 Nov 80	Proj No: SWOG 7510	Status: Ongoing
TITLE: Adjuvant Chemotherapy for Patients with Locally Advanced Adenocarcinoma of the Large Bowel.		
Start Date: FY 76	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Adjuvant chemotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
Objectives: To determine the effectiveness of the combination of MeCCNU + 5-FU as adjuvant chemotherapy.		

To judge whether oral BCG adds to effectiveness.

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

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

Progress: This study was designed to compare 5-Fu + MeCCNU vs 5-FU + MeCCNU + BCG with respect to disease-free survival. Subsequently the protocol was amended to add a third control arm of patient who would receive no further treatment beyond the initial surgery.

The three curves are not significantly different; however, they do favor the chemotherapy + immunotherapy arm. The difference becomes greater after the first year post surgery. Carcinoembryonic antigen (CEA) levels are a potentially useful prognostic factor since there is a significantly decreasing disease free interval (DFI) with increasing baseline CEA levels. Patients who received chemotherapy + immunotherapy lived a shorter period of time after relapse than those who received chemotherapy only. Overall survival in patients treated with chemoimmunotherapy is better than in those treated with chemotherapy alone, but this applies only to those patients who have relapsed and an overall survival of 24 months vs 18 months in favor of chemoimmunotherapy as shown by survival curves.

Detail Summary Sheet

Date: 4 Nov 80	Proj No: SWOG 7521	Status: Ongoing
TITLE: Combination Chemotherapy with or without Immunotherapy in High Risk Melanoma Patients: An Adjuvant Study.		
Start Date: FY 76	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Chemotherapy Immunotherapy Melanoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

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

To determine the immunocompetence of these patients.

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

Therapy will follow the schema outlined in the study protocol.

Progress: There continues to be slow accrual on the Class I portion of this study. One hundred and sixteen patients have been registered on this portion, of which 95 are evaluable. Forty-six of these patients are on the BHD arm, the other 49 are on the no-treatment arm. There is a 15% relapse rate on the BHD arm, and a 24% relapse rate on the no treatment arm.

One hundred and ninety-four patients were registered on the Class II portion. Ninety-four patients were on the BHD arm and 91 patients were on the BHC + BCG arm. BCG did not seem to help as patients on this arm had a shorter disease-free interval than those that received BHD alone. Survival from start of therapy is worse with BCG.

The study remains open for the Class I portion.

Detail Summary Sheet

Date:	4 Nov 80	Proj No:	SWOG 7522	Status:	Ongoing
TITLE:					
Chemotherapy, Splenectomy with or without Immunotherapy in the Treatment of Chronic Myelogenous Leukemia					
Start Date:			FY 76		
Principal Investigator			Est Comp Date: unknown		
J. Dean McCracken, M.D., COL, MC			Facility		
Dept/Sec:			Brooke Army Medical Center		
Department of Medicine/Oncology			Associate Investigators:		
Key Words:			Richard A. Shildt, M.D., LTC, MC		
Chronic Myelogenous Leukemia			John D. Cowan, M.D., MAJ, MC		
Chemotherapy					
Splenectomy					
Immunotherapy					
Accumulative MEDCASE		Est Accumulative		Periodic	
Cost:		OMA Cost:		Review Results: Continue	
Objective: 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: All patients with confirmed diagnosis of benign phase CML not previously treated with any of the agents used in this study are eligible.

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

Progress: A total of 117 patients have been entered into this study. The data are currently undergoing analysis.

Detail Summary Sheet

Date: 4 Nov 80 Proj No: SWOG 7524 Status: Ongoing

TITLE:

Chemotherapy in Stages III and IV Ovarian and Endometrial Cancer

Start Date: FY 76	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Ovarian cancer Endometrial Cancer Chemotherapy	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To compare the effectiveness of chemotherapy alone vs chemo-immunotherapy for remission induction in Stages III and IV ovarian and endometrial carcinoma.

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

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

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

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

Progress: The endometrial portion of this study has remained open, and the accrual rate is slow due to the relative rarity of the tumor. The response rates between the AC and AC + BCG arms are 37% and 40%, respectively. Ninety percent of the cases have undergone pathology review, and no histological difference was noted between the two arms. There exists an imbalance in prognostic factors between the two arms (Stage IV patients on AC arm all have lung involvement whereas those on the AC + BCG arm exhibit more liver involvement). Currently an evaluation of survival in Stage III patients is being undertaken.

One hundred and eighty-six ovarian cancer patients were registered on this protocol. Both objective response rate and median survival duration

SWOG 7524 (continued)

were favorably affected by BCG skin reactivity. Those patients on AC + BCG who experienced 4⁺ skin reactivity had an 80% PR + CR rate, and those with 2⁺ - 4⁺ skin reactivity had a median survival duration of 25 months.

Detail Summary Sheet

Date: 4 Nov 80 Proj No: SWOG 7630 Status: Completed

TITLE:

Chemotherapy of Advanced Prostatic Cancer.

Start Date: FY 77	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Prostatic cancer Chemotherapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objectives: To compare rate of response of hydroxyurea vs adriamycin + cytoxan.

To compare the duration of survival in patients with nonmeasurable disease.

To estimate the respon. rate to each crossover regimen.

Technical Approach: All patients with advanced Stage D prostatic cancer who have not received hydroxyurea, adriamycin, or cyclophosphamide are eligible.

Therapy will be administered in accordance with the schema outlined in the study protocol.

Progress: The hydroxyurea arm has been adequately tested and shows little activity with a PR rate of 4.5% (/22). The adriamycin + cyclophosphamide arm, however, showed a PR rate of 4/18 or 22%. This data gives evidence that the A + C arm needs further testing.

Detail Summary Sheet

Date: 4 Nov 80 Proj No: SWOG 7632 Status: Ongoing

TITLE:

Combined Modality for Recurrent Breast Cancer.

Start Date: FY 77	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, MD., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Breast cancer Hormonal therapy Chemotherapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

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

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

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

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

Progress: The response to tamoxifen in premenopausal patients is 32%, in postmenopausal cases 42%, and in castrated patients 39%. Chemotherapy overall response is 47%. Response duration to tamoxifen is 57 weeks. Responses in the chemotherapy portion last a median of 44 weeks. Median survival on the chemotherapy portion is one year. The overall survival is 114 weeks for postmenopausal and 93 weeks for premenopausal and for castrated patients.

Detail Summary Sheet

Date: 5 Nov 80 Proj No: SWOG 7635 Status: Completed

TITLE:

Combined Modality Treatment for Limited Squamous Carcinoma of the Lung.

Start Date: FY 77	Est Comp Date:
Principal Investigator	Facility
J. Dean McCracken, M.D., COL, MC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Medicine/Oncology	Richard A. Shildt, M.D., LTC, MC
Key Words:	John D. Cowan, M.D., MAJ, MC
Squamous carcinoma	
Chemotherapy	
Toxicity	
Accumulative MEDCARE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objectives: 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.

To determine the qualitative and quantitative toxicity of each treatment regimen.

Technical Approach: 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 are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No significant differences have been observed by treatment with respect to either response rates or toxicity. There are too few responding and relapsing patients to permit comparison of response duration by treatment. In general, length of survival does not differ by treatment although there are some exceptions. Two possible exceptions might be the mildly significantly longer survival on either XRT alone, or on XRT plus adriamycin as compared to XRT + levamisole + adriamycin. By combining appropriate treatment arms, it can be determined that levamisole does not confer any therapeutic advantage at all.

Detail Summary Sheet

Date: 5 Nov 80 Proj No: SWOG 7701 Status: Completed
TITLE:

CIA vs Ifosfamide Alone in Extensive Squamous Lung Cancer.

Start Date: FY 78	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Squamous lung cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objectives: To determine if Ifosfamide, Adriamycin, CCNU is a more effective combination than Ifosfamide alone or in combination with Adriamycin in the treatment of patients with extensive non-oat cell carcinoma of the lung who are not eligible for curative radiotherapy.

To measure the relative efficacy of this regimen on survival.

To determine the qualitative and quantitative toxicity of the regimen.

Technical Approach: All patients with a histologically confirmed diagnosis of extensive non-oat cell carcinoma of the lung are eligible, provided they have received no previous chemotherapy.

Therapy will be in accordance with the schema outlined in the study protocol.

Progress: No significant differences in response rates among the three treatment arms have been detected. As a result of the substantial number of patients available on the Ifosfamide treatment arm, we are able to conclude with 95% certainty that the true (unknown) response rate in extensive non-oat cell carcinoma of the lung to this drug is not higher than 20%. Response rates do not differ significantly by prior XRT status, by cell type, or by performance status. The response rate for squamous cell patients on this study (13%) is lower, but not significantly so, than for patients on the predecessor study SWOG 7439 (20%).

Detail Summary Sheet

Date: 5 Nov 80 Proj No: SWOG 7703 Status: Ongoing
TITLE:

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

Start Date: FY 77	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Glioma Radiation therapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Review Results:

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: Preliminary response rates differ markedly - 33% for BCNU, 13% for Procarbazine and 43% for DTIC. Median survival times are 45, 35 and 49 weeks, respectively.

Detail Summary Sheet

Date: 5 Nov 80 Proj No: SWOG 77Q4 Status: Completed
 TITLE:

Chemotherapy/Immunotherapy for Multiple Myeloma

Start Date: FY 77	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Malignant melanoma Chemotherapy Immunotherapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objectives: To compare the effectiveness of three intermittent chemotherapy combinations VMCP + VCAP vs VMCP + VBAP vs MP for induction of remission in previously untreated patients with multiple myeloma.

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.

To establish baseline and serial data on immunologic status in these patient groups.

Technical Approach: Only previously untreated patients with multiple myeloma (all stages) are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Response rates in fully evaluable patients was 54%, 49% and 44% from VMCP/VCAP, VMCP/VBAP and MP, respectively ($p > .20$). Median duration of response for VMCP + Levamisole was about 9 months longer than for patients treated only with VMCP. The advantage from the added Levamisole resulted, in part from the low relapse rate during the first year of consolidation for those on Levamisole in comparison with those not receiving this immunomodulator. Levamisole should be continued indefinitely with the VMCP in patients who require long-term maintenance after completing one year on VMCP-Levamisole.

Tentative conclusion at present is that Levamisole appears to augment the efficacy of VMCP in maintenance therapy of multiple myeloma.

Detail Summary Sheet

Date: 5 Nov 80 Proj No: SWOG 7706 Status: Completed
 TITLE: Combination Chemotherapy for Stages III and IV Ovarian Carcinoma
 Resistant to Adriamycin-Cyclophosphamide or Single Alkylating Agent.

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

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To use a combination of 5-FU, Hexamethylmelamine and Platinum in an attempt to reduce complete and partial clinical remissions in patients with Stages III and IV ovarian carcinoma who have failed to respond to or have relapsed following remission from Adriamycin-Cyclophosphamide therapy.

To use a combination of 5-FU, Hexamethylmelamine, Platinum and Adriamycin to induce complete and/or partial remissions in patients with Stages III and IV ovarian carcinoma who have failed on or relapsed from previous alkylating agent therapy.

Technical Approach: Only patients with pathologic Stages III or IV ovarian carcinoma who have failed on prior Adriamycin-Cyclophosphamide or alkylating agent therapy will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Fifty percent of the fully evaluable patients on the three-drug study and 60 percent on the four-drug study are still alive. The median survival duration from the start of treatment for fully evaluable patients on the three-drug study was 12.8 months and for patients on the four-drug study 11.9 months. Median survival from the time of diagnosis for fully evaluable patients on the three-drug study was 27.3 months and for those on the four-drug study 26.9 months.

Detail Summary Sheet

Date: 5 Nov 80 Proj No: SWOG 7713/14 Status: Ongoing

TITLE:

Chemoimmunotherapy in non-Hodgkin's Lymphoma.

Start Date: FY 78		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chemoimmunotherapy Non-Hodgkin's Lymphoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
		Periodic Review Results:

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

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

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

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

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

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: It is too early to draw any conclusions from the data collected.

Detail Summary Sheet

Date: 5 Nov 80 Proj No: SWOG 7717 Status: Ongoing

TITLE:

Management of Patients with Metastatic Adenocarcinoma of Unknown Primary.

Start Date: FY 78	Est Comp Date: Nov 80
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Unknown Primary Metastatic Adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

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

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

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

Progress: Patients with metastatic adenocarcinoma with no obvious primary source are eligible for diagnostic evaluation. In addition, they should meet the following Criteria:

1. Should have histopathologic confirmation of their disease.
2. Patients must have measurable disease and an expected survival of six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: On the combination therapy arm there are 3/16 responders vs 0/19 on the single agent arm. Final analysis of data is in progress.

Detail Summary Sheet

Date: 5 Nov 80 Proj No: SWOG 7719 Status: Completed

TITLE:

Addition of CCP and Bleomycin to VBAP in Relapsing and Resistant Myeloma Patients.

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

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To evaluate the frequency, degree and duration of response with Cis-Platinum (DDP) and Bleomycin (Bleo) added to Vincristine-BCNU-Adriamycin-Prednisone combination (VBAP) to combinations of Melphalan and/or Cyclophosphamide with Prednisone (M/C+P).

To compare results with previous SWOG trials of VBAP in such patients.

Technical Approach: Patients with the diagnosis of multiple myeloma who are no longer responding to or have not responded to Melphalan/Cyclophosphamide with Prednisone therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: The 30% frequency of a 50% myeloma protein reduction for relapsing patients was similar to that from VBAP indicating no apparent advantage from the added DDP and Bleomycin. The median survival for those patients who "responded" to either VBAP or VBAP + DDP + Bleomycin was about 9 months longer than that for "non-responders".

Detail Summary Sheet

Date: 5 Nov 80 Proj No: SWOG 7720 Status: Terminated

TITLE:

Management of Oligoblastic Leukemia.

Start Date: FY 78		Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Oligoblastic leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To collect data on the clinical course of patients with acute oligoblastic (smoldering) leukemia, a subgroup of acute leukemia patients who do not meet the requirements of the current Southwest Oncology Group chemotherapy protocol which requires greater than a 50% absolute leukemia infiltrate.

To compare the randomly assigned immuno-stimulant effect of Levamisole on half this group of patients as opposed to those receiving no specific treatment.

To maintain data on those patients in this group who subsequently attain a marrow status, which qualified them to transfer to active chemotherapy protocols.

Technical Approach: Any previously untreated patient with a diagnosis of acute non-lymphocytic leukemia (excluding blast crisis of CGL), whose absolute marrow blast cellularity is less than 50%, should be registered in this study.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed due to lack of patient enrollments.

Detail Summary Sheet

Date: 5 Nov 80 Proj No: SWOG 7723 Status: Completed

TITLE:

Diglycoaldehyde in Adult Acute Leukemia, Phase II Study.

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

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To evaluate the responses of adult acute leukemia to diglycoaldehyde.

To study the toxicity of the drug.

Technical Approach: Patients with all cell types of acute leukemia will be eligible for the study. They will be in relapse after an initial response to other therapies or they may have failed to respond.

Therapy will follow the schema outlined in the study protocol.

Progress: Diglycoaldehyde has shown essentially no activity in the 26 patients entered on this study.

Detail Summary Sheet

Date: 5 Nov 80 Proj No: SWOG 7724 Status: Completed
 TITLE:

Diglycoaldehyde in Metastatic Malignant Melanoma, Phase II Study.

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

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objective: To evaluate the response of metastatic malignant melanoma to diglycoaldehyde.

To study the toxicity of the drug.

Technical Approach: Patients with disseminated disease who have relapsed or are resistant to regimens in a higher priority will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No responses were seen in the patients entered on this study.

Detail Summary Sheet

Date: 5 Nov 80		Proj No: SWOG 7725	Status: Ongoing
TITLE: Continuous 5-Drug Induction with Intermittent CMPF vs CMPF + Levamisole for Maintenance in Patients with Estrogen Receptor Breast Cancer			
Start Date: FY 78		Est Comp Date:	
Principal Investigator		Facility	
J. Dean McCracken, M.D., COL, MC		Brooke Army Medical Center	
Dept/Sec:		Associate Investigators:	
Department of Medicine/Oncology		Richard A. Shildt, M.D., LTC, MC	
Key Words:		John D. Cowan, M.D., MAJ, MC	
Estrogen receptor			
Breast cancer			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:	

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

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: The overall CR + PR rate is 51% in the induction stage. There are more responses in the ER-, 65% vs 42% for the ER unknown or not stated. In the maintenance phase, 126 patients are entered, 76 evaluated so far and 50 have relapsed. There is no difference in length of response or survival.

Detail Summary Sheet

Date: 5 Nov 80 Proj No: SWOG 7726 Status: Completed
TITLE:

Chemotherapy of Advanced Carcinoma of the Breast with Rubidazone.

Start Date: FY 78	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chemotherapy Carcinoma of the breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To determine the efficacy and toxicity of Rubidazone as determined by response rate and median duration of response in patients with disseminated carcinoma of the breast who have not received prior therapy with Adriamycin or other anthracycline antibiotics alone or in combination.

Technical Approach: All patients not eligible for higher priority Southwest Oncology Group studies with histologically proven advanced metastatic carcinoma of the breast who had not previously received Adriamycin or other anthracycline antibiotics are eligible. Patients must have a life expectancy of at least six months.

Progress: Rubidazone appears to offer little in the treatment of advanced carcinoma of the breast.

Detail Summary Sheet

Date: 5 Nov 80		Proj No: SWOG 7727	Status: Ongoing
TITLE: Combination Chemoimmunotherapy Utilizing BCNU, Hydroxyurea and DTIC with Levamisole vs DTIC plus Actinomycin-D in the Treatment of Patients with Disseminated Malignant Melanoma.			
Start Date: FY 78		Est Comp Date:	
Principal Investigator		Facility	
J. Dean McCracken, M.D., COL, MC		Brooke Army Medical Center	
Dept/Sec:		Associate Investigators:	
Department of Medicine/Oncology		Richard A. Shildt, M.C., LTC, MC	
Key Words:		John D. Cowan, M.D., MAJ, MC	
Chemoimmunotherapy			
Malignant melanoma			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:	

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: One hundre and seventy-five patients have been registered on this protocol, of which 141 are evaluable. There appears to be no difference between the three treatment arms in regard to response rate. Patients treated with BHD + Levamisole have shorter remission durations than those patients on the other two arms, although this is not statistically significant. In survival, however, there is a statistically significant advantage for the DTIC + Actinomycin-D arm over the other two arms.

Those patients less than 40 years of age do best with the BHD + Levamisole arm; those from 40-60 years of age do best with the BHD arm; and those older than 60 do significantly better with the DTIC + Actinomycin-D arm.

Detail Summary Sheet

Date: 5 NOV 80 Proj No: SWOG 7730 Status: Completed

TITLE:

Cis-diamminedichloroplatinum in Refractory Disseminated Malignant Melanoma.

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

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To determine the efficacy of high intermittent doses of cis-diamminedichloroplatinum in patients with advanced malignant melanoma refractory to higher priority protocol(s).

To determine the nature and extent of toxicity of this agent with the use of IV hydration only or IV hydration and mannitol diuresis.

Technical Approach: Patients with histologically confirmed diagnosis of malignant melanoma are eligible. Patients must have metastatic disease and measurable lesion(s) refractory to higher priority protocol(s) for malignant melanoma. Expected survival should be a minimum of 10 weeks

Therapy will follow the schema outlined in the study protocol.

Progress: There are 67 evaluable patients on this study. Two responses out of 32 patients have been reported on the limb without Mannitol, and 5 responses out of 34 patients have been reported on the limb with Mannitol. Median time to response was 3 courses of Cis-platinum.

Detail Summary Sheet

Date: 5 Nov 80 Proj No: SWOG 7734 Status: Terminated

TITLE:

Rubidazone in Relapsing Lymphoma Patients Previously Untreated with Anthracycline Derivatives.

Start Date: FY 78	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Anthracycline Derivatives Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objectives: To determine the efficacy, in terms of response rate, duration of response and survival, of the anthracycline antibiotic rubidazone in previously treated patients with Hodgkin's or non-Hodgkin's lymphoma.

To determine the maximum tolerated single dose in lymphoma patients.

To determine the critical cumulative cardiotoxic dose of rubidazone.

Technical Approach: Patients with histological diagnosis of Hodgkin's disease or non-Hodgkin's lymphoma who are not eligible for higher priority SWOG studies and who have had no prior anthracycline derivatives are eligible. Patients must have expected survival of six weeks or more.

Progress: This study was closed due to poor patient accrual.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7735 Status: Completed
TITLE:

Anguidine in Advanced Gastrointestinal Malignancies.

Start Date: FY 78	Est Comp Date:
Principal Investigator	Facility
J. Dean McCracken, M.D., COL, MC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Medicine/Oncology	Richard A. Shildt, M.D., LTC, MC
Key Words:	John D. Cowan, M.D., MAJ, MC
Gastrointestinal malignancies	
Response	
Survival	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Review Results:

Objectives: To determine the efficacy of anguidine and survival in terms of response rate and median duration of response, in the treatment of advanced gastrointestinal malignancies.

To observe any factors predisposing to excessive myelosuppression and for other toxicities not observed during Phase I studies of this drug.

Technical Approach: All patients with histologically proven gastrointestinal malignancies coming off studies with higher priority are eligible. Patients must have surgically incurable disease and objectively measurable parameters.

Therapy will follow the schema outlined in the study protocol.

Progress: Neither anguidine nor anguidine + 5-FU appeared to be of benefit.

Detail Summary Sheet

Date: 6 Nov 80	Proj No: SWOG 7738	Status: Completed
TITLE: Combination Chemotherapy of Pancreatic Adenocarcinoma with Mitomycin-C, 5-Fluorouracil and Streptozotocin		
Start Date: FY 78	Est Comp Date:	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Chemotherapy Pancreatic adenocarcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine and document the response rates and toxicities of mitomycin-C, streptozotocin, and 5-FU compared to mitomycin-C and 5-FU in the management of disseminated pancreatic adenocarcinoma.

Technical Approach: Patients with measurable and nonmeasurable disease will be eligible for this study. Patients with distant metastases (liver, peritoneum, etc.) and/or those in whom extension of the disease is outside of a port size greater than 15 x 15 cm. are also eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One hundred and forty patients have been registered on this study. The response rate is higher for the 3-drug arm ($p = .04$); this translates into a slightly better survival. Responders on the 3-drug arm do survive much longer ($p = .02$) than non-responders in patients with measurable disease.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7765 Status: Ongoing

TITLE:

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

Start Date: FY 79	Est Comp Date:
Principal Investigator	Facility
J. Dean McCracken, M.D., COL, MC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Medicine/Oncology	Richard A. Shildt, M.D., LTC, MC
Key Words:	John D. Cowan, M.D., MAJ, MC
Soft tissue sarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been amended to include bony as well as soft tissue sarcomas. Thirty patients have been registered on this study, and of these 11 are evaluable. There has been 1 PR, 1SD and 9 failures.

Detail Summary Sheet

Date: 6 Nov 80	Proj No: SWOG 7801	Status: Completed
TITLE: Combined Chemotherapy for Advanced Gastrointestinal Malignancies, Phase II Pilot Study.		
Start Date: FY 78	Est Comp Date:	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Gastrointestinal malignancies Response rate		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
Objective: To determine the antitumor effect of anguidine as measured by response rate and survival, in combination with 5-FU in patients with advanced gastrointestinal malignancies.		

Technical Approach: Only patients with histologically proven adenocarcinoma arising in the liver, gallbladder, biliary tree, exocrine pancreas, stomach, small intestines, colon and rectum are eligible. Patients must not have had prior exposure to fluorinated pyrimidines or anguidine.

Therapy will follow the schema outlined in the study protocol.

Progress: Combining Anguidine with 5-FU appears to be of no benefit.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7802 Status: Terminated

TITLE:

Adjuvant Therapy of Soft Tissue Sarcomas with Radiation Therapy + Combination Chemotherapy.

Start Date: FY 79	Est Comp Date:
Principal Investigator	Facility
J. Dean McCracken, M.D., COL, MC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Medicine/Oncology	Richard A. Shildt, M.D., LTC, MC
Key Words:	John D. Cowan, M.D., MAJ, MC
Soft tissue sarcoma	
Radiation therapy	
Chemotherapy	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To determine whether combination chemotherapy with A-DIC can improve the results in terms of disease-free survival produced by adjuvant radiotherapy in patients with soft tissue sarcomas Stage IIB and III at high risk for recurrent disease.

To determine any difference in toxicity between patients receiving coost radiation therapy to the scar with Cobalt 60 or electron beam.

To determine any difference in local recurrence rate of disease-free survival between patients with adequate surgery and those without adequate surgery.

Technical Approach: Patients with biopsy confirmed diagnosis of soft tissue sarcoma with Stage IIB or III who have undergone complete conservative surgical resection of the primary tumor and have no evidence of disease are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: The study is closed because of slow patient accrual.

Detail Summary Sheet

Date: 6 Nov 80		Proj No: SWOG 7804	Status: Ongoing
TITLE: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma.			
Start Date: FY 78		Est Comp Date:	
Principal Investigator		Facility	
J. Dean McCracken, M.D., COL, MC		Brooke Army Medical Center	
Dept/Sec:		Associate Investigators:	
Department of Medicine/Oncology		Richard A. Shildt, M.D., LTC, MC	
Key Words:		John D. Cowan, M.D., MAJ, MC	
Gastric adenocarcinoma			
Chemotherapy			
Disease-free interval			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:	

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been slow. Registration was temporarily halted on this study while new randomization techniques were being explored. Registration has now been reopened.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7805 Status: Completed
TITLE:

Medroxyprogesterone Acetate (MPA) Plus Yoshi 864 in Adult Patients with Adenocarcinoma of the Kidney.

Start Date: FY 79	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Adenocarcinoma of Kidney	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objective: To determine the response rate and survival of patients with metastatic adenocarcinoma of the kidney to combined therapy with Yoshi 864 and Medroxyprogesterone Acetate (MPA).

Technical Approach: Only patients who have recurrent or metastatic adenocarcinoma of the kidney will be acceptable. Objectively measurable disease is required.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirty patients have been evaluated. There has been one partial response of one month's duration. Hematologic toxicities have been mild to moderate. The results need to be analyzed further before the drug is discounted.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7806 Status: Ongoing

TITLE:

Cis-Platinum in Refractory Epidermoid Carcinomas of the Esophagus.

Start Date: FY 78	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Cis-Platinum Refractory epidermoid carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To determine the response rate and survival, with some degree of precision, utilizing cis-diamminodichloroplatinum II (CACP) in the treatment of patients with squamous cell carcinoma of the esophagus which is growing despite more standard therapy.

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

Therapy will follow the schema outlined in the study protocol.

Progress: To date there are two complete remissions and four partial remissions in the 15 patients evaluable. This study will continue until 25 patients have been entered and are evaluable.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7807 Status: Completed

TITLE:

Cis-platinum in Refractory Epidermoid Carcinoma of the Lung.

Start Date: FY 78	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC Joan D. Cowan, M.D., MAJ, MC
Key Words: Refractory epidermoid carcinoma Lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To determine the response rate and survival in patients with epidermoid carcinomas of the lung who have demonstrated refractoriness to previous therapy utilizing Cis-platinum.

Technical Approach: To be eligible for this study, patients must have epidermoid carcinoma of the lung confirmed, preferably by biopsy, although positive cytology is acceptable. Measurable disease is a requirement of this study.

Therapy will follow the schema outlined in the study protocol.

Progress: This study produced an overall response rate of 19% in patients with squamous histology. There appears to be a much higher response rate in poorly differentiated squamous lesions, and none were seen in adeno and large cell carcinoma.

Detail Summary Sheet

Date: 6 Nov 80	Proj No: SWOG 7808	Status: Ongoing
TITLE: Combination Modality Treatment for Stage III and IV Hodgkin's Disease MOPP 6.		
Start Date: FY 79	Est Comp Date:	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Hodgkin's disease		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To attempt to increase the complete remission rate induced with MOP-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a partial response at the end of six cycles of MOP-BAP.

To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when complete response has been induced with six cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Eligible patients must have a histological diagnosis of Hodgkin's which must be classified by the Lukes and Butler system.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-eight patients are fully or partially evaluable, but only ten patients have completed six cycles of chemotherapy. Of these, four were in clinical CR, four in clinical PR, one insufficient data, and one no response. Six patients have completed restaging. Response post restaging was: 2 CR, 3PR, 1 NRS.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7809 Status: Completed

TITLE:

Maytansine Therapy of Advanced Breast Cancer.

Start Date: FY 79	Est Comp Date:
Principal Investigator	Facility
J. Dean McCracken, M.D., COL, MC	Brooke Army Medical Center
Dept/Ser:	Associate Investigators:
Department of Medicine/Oncology	Richard A. Shildt, M.D., LTC, MC
Key Words:	John D. Cowan, M.D., MAJ, MC
Breast cancer	
Maytansine	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objective: To evaluate the effectiveness of Maytansine in terms of response rate and survival in patients with breast cancer resistant to standard therapeutic modalities.

Technical Approach: All patients will have histologically proven breast cancer resistant to known effective agents and no eligible for higher priority Southwest Oncology Group protocols. They should have an expected survival of six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Maytansine shows a low degree of activity and is unworthy of further investigation.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7811 Status: Ongoing
TITLE:

Brain Metastases Protocol.

Start Date: FY 79	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Brain metastases	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To determine the effectiveness of combined radiation therapy and metronidazole (Flagyl) in the treatment of patients with brain metastases from primary malignancies outside the central nervous system, compared with radiation therapy alone, as determined by objective response (brain and/or CAT scan) and/or increase in functional neurologic level and duration of response.

To determine the toxicity of multiple dose administration of metronidazole and radiation therapy.

Technical Approach: To be eligible for this study, patients must have histologic proof of a primary malignancy. There must be clinical suspicion of brain metastases documented by isotope brain scan and/or CAT scan. Patients must either have measurable disease on brain/CAT scan and/or neurologic status level of 2-4. Patients must have an expected survival time of at least one month.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirteen patients have entered this study. Four of four evaluable patients have shown partial response.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7812 Status: Completed
 TITLE:

Anguidine in CNS Tumors

Start Date: FY 79	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Central Nervous System (CNS) tumors Glioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Review Results:

Objectives: To determine the antitumor activity of anguidine in the treatment of malignant gliomas relative to clinical response and survival.

To observe for expected and unexpected adverse effects and for factors important in producing these effects.

To determine the antitumor activity of anguidine in the treatment of malignant brain tumors in children and adolescents relative to clinical response and survival.

Technical Approach: Patients with histologically confirmed primary central nervous system tumors of the following histological types are eligible: Astrocytoma, grade III and IV; ependymoma; oligodendroglioma; and medulloblastoma. Patients under 21 years of age with clinical diagnosis of recurrent brain stem glioma following radiation therapy will also be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Fourteen patients have been registered on this study. Seven are evaluable with one PR, one NR and five patients with increasing disease. The study is closed to the Adult Division.

Since this study was registered at BAMC as an Adult Division protocol, the study is considered completed.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7813 Status: Ongoing

TITLE:

Ifosfamide in the Treatment of Resistant Disseminated Malignant Melanoma.

Start Date: FY 80	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Disseminated malignant melanoma Ifosfamide	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To determine the response rate and survival of ifosfamide in patients with disseminated malignant melanoma who are either ineligible for higher priority studies or who have become resistant to standard therapy or a higher priority program.

To determine the qualitative and quantitative toxicity of ifosfamide in patients with disseminated melanoma.

Technical Approach: All patients with histologically confirmed diagnosis of disseminated malignant melanoma who are not eligible for higher priority protocols or who have failed on standard regimens or higher priority programs are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has accrued six patients, five of whom are evaluable. There has been one partial response and one possible partial response reported. The study is too early to evaluate.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7814 Status: Completed

TITLE:

Comparison of Methotrexate and Cis-platinum for Patients with Advanced Squamous Cell Carcinoma of the Head and Neck Region.

Start Date: FY 79	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Review Results:

Objective: To determine whether cis-platinum will give a superior response rate and/or a longer remission duration than methotrexate in patients with squamous cell carcinoma of the head and neck region.

Technical Approach: Patients who have histologically proven advanced squamous cell carcinoma of the head and neck region which is not amenable to other forms of therapy and who have measurable tumor lesions are eligible. It is considered that all patients meeting these requirements have advanced disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Of the 122 patients entered on this study, 100 are thus far either fully or partially evaluable. The most common sites are the tongue, nasopharynx, pharynx, and larynx. The overall response rates for fully + partially evaluable patients is 20% for the MTX arm and 9% for Cis-platinum. Mucositis was the most common toxicity seen in the MTX arm. Each arm had one drug-related death. The median survival is 24 and 17 weeks, respectively.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7817 Status: Ongoing

TITLE:

Treatment of Advanced Germ Cell Neoplasms of the Testis.

Start Date: FY 79	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Germ cell neoplasm of testis	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To determine in a randomized fashion the effectiveness of cis-diamminedichloroplatinum (DDP) given in the conventional low-dose schedule daily x 5 days versus high-dose intermittent treatment in remission induction of disseminated testicular cancer, when combined with vinblastine and bleomycin.

To determine the survival of patients who achieve a partial remission and are rendered disease-free by surgical removal of residual disease and maintained on the same chemotherapy as patients who achieved complete remission status on chemotherapy alone.

To determine the effectiveness of cyclophosphamide, actinomycin-D, adriamycin and vinblastine in the maintenance of remission status.

To document the nature and extent of the hemtologic and nonhematologic side effects of the various drug combinations.

Technical Approach: All patients with metastatic testicular cancer of germinal cell origin regardless of prior radiation therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Seventy-nine patients have been registered on this study. Thirty-eight have received low dose DDP and 41 have received high dose DDP. The response data are still very preliminary and there does not seem to be a significant difference between the two arms.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7820 Status: Completed

TITLE:

Maytansine in Advanced Sarcoma, Phase II.

Start Date: FY 79	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Sarcoma Maytansine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

objectives: To determine the antitumor effect as measured by response rate and median duration of response of maytansine against sarcoma.

To determine the nature of the toxicity of maytansine administered on a weekly dosage schedule.

Technical Approach: To be enrolled in this study, patients should have biopsy proven incurable sarcoma and must not be eligible for any other protocol of higher priority and an expected survival of at least six weeks. Patients must have measurable disease.

Twenty-five patients will be entered into this study, which will permit estimation of the response rate with a standard error not greater than 0.10.

Progress: This phase II trial of maytansine against drug refractory sarcomas failed to demonstrate useful clinical activity.

Detail Summary Sheet

Date: 6 Nov 80 Proj No: SWOG 7821 Status: Completed

TITLE:

Evaluation of Maytansine in the Treatment of Relapsing Hodgkin's and Non-Hodgkin's Lymphoma.

Start Date: FY 79	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Hodgkin's lymphoma Non-Hodgkin's lymphoma	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To determine the antitumor effect of maytansine against advanced Hodgkin's and non-Hodgkin's lymphoma.

To determine the nature and extent of toxicity of maytansine administered on a weekly basis.

Technical Approach: To enter this study, patient's should have biopsy proven Hodgkin's disease or non-Hodgkin's disease, and must not be eligible for a higher priority protocol. Patients must have clearly measurable disease and an expected survival of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-five patients have been entered on this study. Five are too early to evaluate and eighteen are evaluable. Only one PR has been noted. Therefore, this Phase II trial of maytansine is closed.

Detail Summary Sheet

Date: 4 Feb 81 Proj No: SWOG 7823/4/5/6 Status: Ongoing

TITLE:

ROAP-AdOAP in Acute Leukemia

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chemotherapy Immunotherapy Adult acute leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objectives: To compare the efficacy of the 4-drug combination chemotherapy regimen, ROAP (Rubidazone, vincristine, arabinosyl cytosine, and prednisone) to AdOAP (the same combination using Adriamycin in place of Rubidazone) in adult acute leukemia, as determined by remission rate, remission duration and survival.

To determine the comparative toxicity of these regimens.

To determine whether late intensification therapy at 9 months after complete remission will improve long-term, disease-free survival.

To determine whether immunotherapy using levamisole for 6 months after 12 months of complete remission on chemotherapy improves disease-free survival.

To determine the effects of intrathecal Ara-C on the incidence of CNS leukemia.

To determine reproducibility of the FAB/histologic classification and correlation to response to therapy in 200 consecutive cases of acute leukemia.

To study the effects of intensive supportive care in the management of acute leukemia.

Technical Approach: All patients over 15 with a diagnosis of acute leukemia who have not received extensive therapy (defined as more than one course of any other chemotherapeutic agent or combination of agents) will be eligible for this study. The diagnosis of acute leukemia will be made on bone marrow smear, clot section and/or biopsy. An absolute infiltrate of 50% leukemic cells or greater is required.

Progress: At present 287 patients are registered. The initial problems with inevaluable patients have diminished significantly. But, many cases still are not evaluable because there is insufficient information. There does not

SWOG 7823/4/5/6 (continued)

appear to be any significant difference between ROAP and AdOAP. This is important because the manufacture of Rubidazone is being discontinued.

Detail Summary Sheet

Date: 4 Feb 81 Proj No: SWOG 7827 Status: Ongoing

TITLE:

Combined Modality Therapy for Breast Carcinoma, Phase III

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Receptor positive (ER+) Chemotherapy	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy.

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

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

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

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

Technical Approach: All patients must have had a radical or modified radical mastectomy with histologically proven breast cancer and with one or more pathologically proven axillary nodes. Primary neoplasm and clinically apparent axillary disease must be completely removed. Pretherapy studies must reveal no evidence of metastatic disease or involvement of the other breast. Patients with postoperative radiation therapy are eligible but will be randomized and evaluated separately. Therapy will follow the schema outlined in the protocol.

Progress: There are 102 patients on this study with only 6 patients on the chemotherapy + oophorectomy arm. There is good registration for ER- and very brisk registration for ER+. The study was amended to add lumpectomy + radiotherapy patients.

Detail Summary Sheet

Date: 5 Feb 81 Proj No: SWOG 7828 Status: Ongoing
TITLE:

Combined Modality Therapy for Extensive Small-Cell Carcinoma of the Lung.

Start Date: FY 79		Est Comp Date: Unknown
Principal Investigator		Facility
J. Dean McCracken, M.D., COL, MC		Brooke Army Medical Center
Dept/Sec:		Associate Investigators:
Department of Medicine/Oncology		Richard A. Shildt, M.D., LTC, MC
Key Words:		John D. Cowan, M.D., MAJ, MC
Small-cell carcinoma		
Toxicity		
Accumulative MEDCASE	Est Accumulative	Periodic
Cost:	OMA Cost:	Review Results: Continue

Objectives: To improve the complete response rate and long-term, disease-free survival of patients with extensive small-cell carcinoma of the lung.

To define, quantitate and quantify the toxicity of each regimen employed.

Technical Approach: There must be a diagnosis by the institutional pathologist of small-cell, undifferentiated carcinoma of the lung. Extensive small-cell carcinoma includes the following: 1) Any patient with evidence of metastatic spread beyond the hemithorax and supraclavicular nodes on either side; 2) Any patient with a cytology-positive pleural effusion; and 3) Any patient with prior radiation therapy to the primary tumor who presents with evidence of recurrent disease.

Patients meeting the above eligibility criteria will receive one of three treatment programs. Treatment program A consists of two standard drugs--Vincristine and Methotrexate. Treatment program B consists of Vincristine plus Adriamycin and Cyclophosphamide. Treatment program C consists of Vincristine, Adriamycin and Cytosin plus VP-16. Therapy will follow the schema outlined in the study protocol.

Progress: This study has not shown any evidence of survival improvement over the results of previous studies. This may be related to the omission of chest radiation therapy.

Detail Summary Sheet

Date: 5 Feb 81 Proj No: SWOG 7830 Status: Terminated

TITLE:

Carcinoembryonic Antigen as an Indicator for Second Look Surgery in Colorectal Cancer, a Randomized, Prospective Clinical Trial, Phase III.

Start Date: FY 79	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Carcinoembryonic antigen Duke's B and C colorectal cancer	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To determine whether serial carcinoembryonic antigen (CEA) assays, following curative surgery, for Duke's B and C colorectal cancer leads to earlier detection of recurrence than standard follow-up procedures.

To determine whether recurrence detected through elevated CEA values, plus "standard clinical follow-up", leads to an improvement in the percentage of patients converted to no evidence of disease status following a second look surgery as opposed to recurrence detected by "standard" clinical means alone.

To determine whether there is a difference in crude survival between the CEA follow-up group and the standard follow-up group.

Technical Approach: To be eligible, the patient must have a completely resected Duke's B or C adenocarcinoma of the colon or rectum. Careful attention should be given to the examination of the liver. Suspicious areas should be biopsied to rule out metastatic disease. CEA values at 30 days post-initial resection must be normal, i.e., nonsmokers <2.5 ng/ml, smokers <5.0 ng/ml. Patients may be entered on the basis of institutional CEAs done 4-6 weeks post-op with normal defined above.

Eligible patients will be placed in one of two follow-up plans. Plan A - Patients placed on this regimen will be closely monitored for the development of recurrent disease by means other than CEA with physical examinations, blood chemistry tests, nuclear medicine scans and x-rays at intervals from every two months to one year. Plan B is the same as Plan A with the exception that a CEA blood test will be done every two months for two years.

Progress: The surgical protocol for CEA as an indicator for second-look surgery was closed because of inadequate patient registration. It appeared biased, as the value of CEA is already too well established to perform such a study.

Detail Summary Sheet

Date: 5 Feb 81 Proj No: SWOG 7832 Status: Ongoing
TITLE:

Evaluation of Chlorozotocin in Lung Cancer.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chlorozotocin Lung cancer	
Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:
	Periodic Review Results: Continue

Objectives: To determine whether chlorozotocin has significant activity as determined by response rate and median duration of response, against small cell, large cell, adenocarcinoma or squamous carcinoma of the lung.

To observe for toxicities of chlorozotocin not yet described and better define the known toxicities.

To determine factors predisposing to excessive toxicity to this agent.

Technical Approach: To be eligible, the patient must have histologically proven lung cancer and must have measurable lesions. Patient must be off all prior anticancer treatment for at least three weeks and recovered from all acute toxicities of prior treatment.

The anticipated accrual rate to this study is 8-10 eligible patients/month. At this rate it would be feasible to accrue the necessary 120 response-evaluable patients allowing for an overall inevaluability rate of 20-25%.

Therapy will follow the schema outlined in the study protocol.

Progress: It is too early to evaluate chlorozotocin's role in each cell type. Two patients with adenocarcinoma have shown partial response after their first course.

Detail Summary Sheet

Date: 5 Feb 81 Proj No: SWOG 7833 Status: Completed

TITLE:

Chlorozotocin in Gastrointestinal Cancer.

Start Date: FY 79	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chlorozotocin Gastrointestinal cancer	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To determine whether chlorozotocin has significant activity as determined by response rate and median duration of response against colon, pancreatic, hepatic and gastric adenocarcinoma.

To observe for toxicities of chlorozotocin not yet described and better define known toxicities.

To determine factors predisposing to excessive toxicity of this agent.

Technical Approach: The patient must have histologically proven gastrointestinal cancer which is unresponsive to standard forms of treatment or for which standard treatments have proven of little or no value.

Therapy will follow the schema outlined in the study protocol.

Progress: Adequate cases have been accrued to determine that this agent is no more active than other nitrosoureas; however, toxicities may not be as severe.

Detail Summary Sheet

Date: 5 Feb 81		Proj No: SWOG 7835	Status: Terminated
TITLE: High Dose Vincristine, Prednisone, Hydroxyurea and Cytosine Arabinoside (HOAP) in the Blastic Phase of Chronic Granulocytic Leukemia, Phase III.			
Start Date: FY 79		Est Comp Date:	
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Chronic granulocytic leukemia Blastic phase			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:	

Objectives: To evaluate the effectiveness, as determined by remission rate, of the combination of high-dose vincristine, prednisone, hydroxyurea, and cytosine arabinoside (HOAP) for remission induction in patients with the blastic phase of chronic granulocytic leukemia.

To compare the effectiveness of this regimen in myeloid versus lymphoid blastic transformation and in patients with poor prognostic characteristics, namely hyperdiploidy and lack of terminal deoxynucleotidyl transferase (TdT).

To evaluate the value, as determined by median duration of remission and survival, of an intensive intermittent regimen of cytosine arabinoside, prednisone, and vincristine in the maintenance of remission.

Technical Approach: All patients with chronic granulocytic leukemia in whom a diagnosis of blastic crisis has been made are eligible for this study. In addition, they must exhibit the following: 1) Increasing leukocyte count with or without progressive anemia and/or thrombocytopenia, resistant to conventional drugs used in the chronic phase of the disease; 2) more than 25% blasts, plus granulocytes in the bone marrow and/or peripheral blood; 3) progressive enlargement of the spleen in nonsplenectomized patients.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed due to poor patient accrual.

Detail Summary Sheet

Date: 5 Feb 81	Proj No: SWOG 7836	Status: Terminated
TITLE: Combination Chemotherapy for Metastatic Epidermal Carcinoma of the Anal Canal, Phase II.		
Start Date: FY 79	Est Comp Date:	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Chemotherapy Epidermal carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the antitumor effect of bleomycin, adriamycin, mitomycin-C, and 5-FU, as measured by response rate and survival, in epidermal carcinoma of the anal canal.

To use the patient accrual capabilities of the Southwest Oncology Group to gather sufficient patients in this relatively uncommon tumor to arrive at a statistically valid response rate.

Technical Approach: To be eligible for this study, all patients must have histologically proven metastatic squamous cell carcinoma of the anal canal or metastatic cloacogenic carcinoma.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed due to poor patient accrual.

Detail Summary Sheet

Date: 5 Feb 81 Proj No: SWOG 7841 Status: Ongoing

TITLE:

Phase II-III Comparison of FAM vs FAM + Vincristine vs Chlorozotocin in the Treatment of Advanced Gastric Adenocarcinoma.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chemotherapy Gastric adenocarcinoma Chlorozotocin	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To determine whether or not vincristine increases the effectiveness (as determined by response rate and survival) of 5-FU plus mitomycin-C plus Adriamycin (FAM) in the treatment of advanced, previously untreated gastric adenocarcinoma.

To determine the efficacy, as determined by response rate and survival of chlorozotocin in the treatment of previously untreated gastric adenocarcinoma.

To determine by crossover, after relapse or failure on FAM, V-FAM or chlorozotocin, the effectiveness as determined by response rate and survival, of the alternate treatment in advanced gastric adenocarcinoma with prior therapy.

To determine the toxicities of such treatments.

Technical Approach: Patients must have histologically proven adenocarcinoma, Stage IV in extent, to be eligible for this study. They must not have received prior chemotherapy nor should they have received radiotherapy within four weeks of entry. Patients must have a minimum life expectancy of 6 weeks and a performance status of 0-3 in order to be eligible.

The Phase II evaluation of chlorozotocin will require entry of 35 eligible patients. The Phase III comparison of FAM vs V-FAM will attempt to detect a 25% increase in response rate on the latter arm.

Progress: Sixty patients have been registered. Chlorozotocin is inactive, with no responses in nine fully evaluable patients. This arm of the study is closed. There have been no complete remissions in this study, and there appears to be a six month median survival for patients entered.

Detail Summary Sheet

Date: 5 Feb 81	Proj No: SWOG 7861	Status: Completed
TITLE: Combined Therapy with Celiac Artery Infusion 5-FU plus Radiation Therapy Followed by Mitomycin-C and 5-FU Maintenance Chemotherapy for Treatment of Localized Adenocarcinoma of the Exocrine Pancreas.		
Start Date: FY 79	Est Comp Date:	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Exocrine pancreas, adenocarcinoma Celiac artery infusion		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To evaluate the effect on survival in localized pancreatic cancer by utilizing direct celiac artery infusion of 5-FU combined with radiation therapy and Mitomycin, 5-FU maintenance therapy.

To establish the toxicities of this multimodality in a pilot study and test feasibility for widespread cooperative group use.

Technical Approach: Eligibility criteria is as follows: 1) histological confirmation of adenocarcinoma of the exocrine pancreas; 2) tumor margin as outlined by radiopaque clips to create a port size not greater than 225 cm² (approximately 15x15 cm). Alternately, patients are eligible if a similar port can be constructed based on arteriographic findings or with ultrasonography. Patients with local extension of disease into stomach, vertebral body, liver or lymph node are eligible for this study as long as the field size meets the stated criteria.

Therapy will follow the schema outlined in the study protocol.

Progress: Radiotherapy _ intra-arterial chemotherapy in localized pancreatic cancer appeared well tolerated in the pilot study. Poor survival data compared to more aggressive studies and unavailability of arterial line radiologic support in all institutions has led to dropping this program from Phase III considerations.

Detail Summary Sheet

Date: 5 Feb 81 Proj No: SWOG 7863 Status: Ongoing

TITLE:

Concurrent Chemotherapy-Radiation Therapy of Selected Head and Neck Cancer.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Head and neck cancer Radiation therapy Chemotherapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Review Results: Continue

Objectives: To assess the local and systemic toxicity of the concurrent administration of the chemotherapeutic agents, bleomycin and hydroxyurea, with super voltage radiotherapy in the treatment of locally advanced squamous cancer of the head and neck.

To determine the maximum tolerated dose of both chemo-and radiotherapy when given according to the proposed regimen.

Technical Approach: Patients with locally advanced squamous cell carcinoma of the head and neck who are candidates for definitive or palliative radiotherapy are eligible. Patients must have histologic confirmation of their disease and must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Thus far 39 patients have been registered, 8 of which are too early to evaluate and 4 who have been rendered inevaluable. Of the 27 fully or partially evaluable patients, the CR + PR is 89%. Median duration of response is 20 weeks.

Detail Summary Sheet

Date: 5 Feb 81 Proj No: SWOG 7902 Status: Ongoing
TITLE:

Combined Modality Therapy for Head and Neck Cancer.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Head and neck cancer Chemotherapy Radiation therapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objectives: To compare the survival of Stage III and IV squamous cell carcinoma of the tongue, oral cavity, tonsil, oropharynx, hypopharynx and larynx subjected to radiation therapy followed by surgical excision, if possible, vs survival of patients subjected to chemotherapy with Cis-platinum, Oncovin and Bleomycin (COB), followed by radiation therapy and surgical excision if possible.

To determine the incidence and extent of complications arising from chemotherapy and radiotherapy followed by head and neck surgery vs radiotherapy and head and neck surgery.

Technical Approach: Previously untreated patients with a histologically confirmed diagnosis of advanced inoperable squamous cell carcinoma of the head and neck, Stages III and IV, of the oral cavity, tongue, tonsil, oropharynx, hypopharynx and larynx are eligible. There must be an evaluable lesion(s). Patients must have a life expectancy of 6 weeks or greater.

Therapy will follow the schema outlined in the study protocol.

Progress: This study will objectively look at survival, quality of survival and toxicity. At this time it is too early for analysis of data.

Detail Summary Sheet

Date: 5 Feb 81		Proj No: SWOG 7903	Status: Terminated
TITLE: Advanced (Stages III and IV) Hodgkin's Disease: Remission Induction with CHOP: Groupwide Study for MOPP Failures without Prior Anthracyclines, Phase II Study.			
Start Date: FY 79		Est Comp Date:	
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Hodgkin's disease Chemotherapy			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:	

Objectives: To evaluate the effectiveness, as determined by response rate, of the CHOP combination of chemotherapy for remission induction in patients with advanced (Stages III or IV) Hodgkin's disease who have not had prior chemotherapy and in those with prior MOPP (no anthracyclines).

To assess the length of unmaintained remissions after intensive induction with ten courses of treatment with CHOP and after documentation of complete response (CR) by restaging.

To evaluate the degree of noncross-resistance of CHOP in MOPP failures in terms of remission induction, duration of remission and survival.

To compare the toxicities and side effects of the CHOP regimen to those of MOPP.

Technical Approach: Patients must have histologic diagnosis of Hodgkin's disease classified by the Lukes and Butler System in order to be eligible. They must have stage of disease classified by Ann Arbor staging criteria and must be clinical or pathological Stages III or IV if previously untreated. Relapsing patients may have any extent of disease, however, staging procedures sufficient to gauge response are required.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed due to slow patient accrual.

Detail Summary Sheet

Date:	5 Feb 81	Proj No:	SWOG 7904	Status:	Ongoing
TITLE: Hexamethylmelamine vs FAC in Advanced Transitional Cell Bladder Carcinoma in Patients with Impaired Renal Function, Phase II-III					
Start Date:			FY 79		
Principal Investigator			Est Comp Date:		
J. Dean McCracken, M.D., COL, MC			Unknown		
Dept/Sec:			Facility		
Department of Medicine/Oncology			Brooke Army Medical Center		
Key Words:			Associate Investigators:		
Transitional cell bladder carcinoma			Richard A. Shildt, M.D., LTC, MC		
			John D. Cowan, M.D., MAJ, MC		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results:	
				Continue	
Objective: To compare the efficacy (response rate) of hexamethylmelamine vs FAC (5-Fluorouracil, Adriamycin and Cyclophosphamide) in locally recurrent or disseminated transitional cell bladder carcinoma, in patients with impaired renal function, with crossover upon treatment failure.					

Technical Approach: Patients with histologically proven T₄ transitional cell bladder carcinoma, if there is a contraindication to radical surgery or radiotherapy, and recurrent or residual cases after surgery, radiotherapy or both; and M₁ cases with liver, osseous, pulmonary or other metastases are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Seven patients have entered an initial treatment arm and one patient has crossed-over from FAC to hexamethylmelamine. The cross-over patient has expired. It is too early for analysis of the remaining patient data.

Detail Summary Sheet

Date: 5 Feb 81 Proj No: SWOG 7906 Status: Ongoing

TITLE:

Multidrug Adjuvant Chemotherapy in Non-Metastatic Osteosarcoma - Comparison of Compadri I with Compadri V, Phase III.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Osteosarcoma, nonmetastatic	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To compare disease-free survival in patients with nonmetastatic osteosarcoma treated with (a) Compadri-I using cyclophosphamide, vincristine, phenylalanine mustard, and Adriamycin with (b) those treated by Compadri-V using high-dose methotrexate with citrovorum factor in addition to those drugs mentioned above.

To determine pronostic differences in the subtypes of osteogenic sarcoma.

For patients undergoing treatment on the Compadri-V arm, to evaluate the effect of preoperative high-dose methotrexate on the amputation specimen.

Technical Approach: All patients with histologically established diagnosis of osteosarcoma without metastases may be registered for the study. Patients must be registered before amputation.

Therapy will follow the schema outlined in the study protocol.

Progress: This protocol is also registered as SWOG 7929. This protocol (7906) is for pediatric registrations and 7929 is for adult registrations.

No patients have been entered on the study.

Detail Summary Sheet

Date: 5 Feb 81 Proj No: SWOG 7907 Status: Terminated

TITLE:

VP-16-213 in Acute Monocytic and Myelomonocytic Leukemias, Phase II.

Start Date: FY 79	Est Comp Date:
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Monocytic leukemia Myelocytic leukemia CP-16	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To evaluate the effectiveness of VP-16 in the induction of remission in acute monocytic leukemia and myelomonocytic leukemia in relapse.

To evaluate remission maintenance with VP-16.

Technical Approach: Patients of all ages with the diagnostic criteria of acute monocytic leukemia or acute myelomonocytic leukemia in relapse after previous treatment are eligible, provided that VP-16 has not been given to them previously. Cytomorphology must conform with the diagnosis of acute myelomonocytic leukemia or acute monocytic leukemia.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed due to poor patient accrual.

Detail Summary Sheet

Date: 5 Feb 81	Proj No: SWOG 7908	Status: Terminated
TITLE: Vinblastine Sulfate in the Management of Resistant Chronic Myelogenous Leukemia, Phase II.		
Start Date: FY 79	Est Comp Date:	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Myelogenous leukemia Vinblastine sulfate		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
Objective: To determine the incidence, quality and duration of responses to vinblastine sulfate among previously treated patients with chronic myelogenous leukemia.		

Technical Approach: Chronic myelogenous leukemia patients previously treated with radiation therapy and/or alkylating agent (single or combination) and failing due to drug resistance are eligible. Patients must have progressive disease, and must be off previous chemotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed due to poor patient accrual.

Detail Summary Sheet

Date: 5 Feb 81		Proj No: SWOG 7910	Status: Ongoing
TITLE: Evaluation of Estrogen-Antagonist in the Management of Refractory Large Bowel Tumors, Phase II.			
Start Date: FY 79		Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Estrogen receptors Colorectal tumor			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue	

Objective: To help judge whether there is any therapeutic significance in humans to the laboratory observation that some colorectal tumors, in men and women, have estrogen receptors as determined by response rate to tamoxifen.

Technical Approach: Patients with biopsy confirmed diagnosis of adenocarcinoma of the large bowel are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Of nine evaluable patients, two have shown improvement. The protocol has been amended to only allow for the entry of patients who had had ER determinations.

Detail Summary Sheet

Date: 5 Feb 81 Proj No: SWOG 7911 Status: Completed

TITLE:

Phase II Evaluation of Gallium Nitrate in Soft Tissue and Bone Sarcomas.

Start Date: FY 79	Est Comp Date:	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Bone sarcomas Gallium nitrate Soft tissue sarcomas		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the efficacy of gallium nitrate in patients with soft tissue and bone sarcomas, who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of this drug.

Technical Approach: All patients no eligible for higher priority studies with histologically proven incurable advanced soft tissue and bone sarcomas are eligible. Patients must have a life expectancy of at least 6 weeks and must have clearly measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty patients have been entered on this study, and nine are evaluable. There have been no responses, consequently this study is closed.

Detail Summary Sheet

Date: 5 Feb 81	Proj No: SWOG 7912	Status: Ongoing
TITLE: Gallium Nitrate in Patients with Malignant Lymphoma - Hodgkin's and Non-Hodgkin's, Phase II.		
Start Date: FY 79	Est Comp Date: Unknown	
Principal Investigator: J. Dean McCracken, M.D., COL, MC	Facility: Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Hodgkin's lymphoma Non-Hodgkin's lymphoma Gallium nitrate		
Accumulative MEDCASE Cost:	Est Accumulative UMA Cost:	Periodic Review Results: Continue
Objectives: To determine the efficacy, as measured by response rate, of gallium nitrate in patients with malignant lymphoma, both Hodgkin's and non-Hodgkin's types, in patients who have received prior therapy and are not eligible for higher priority studies.		

To determine the nature and degree of toxicity of this drug.

Technical Approach: All patients with malignant lymphoma who are not eligible for higher priority protocols are eligible. Patients must have a life expectancy of at least 6 weeks and clearly measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: There appears to be some efficacy with this agent in lymphoma patients. Of the 15 patient registrations, two patients have achieved a partial response.

Detail Summary Sheet

Date: 5 Feb 81 Proj No: SWOG 7915 Status: Ongoing

TITLE:

Combination Chemotherapy in the Therapy of Advanced Carcinomas of the Salivary Glands.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chemotherapy Salivary gland carcinoma	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objective: To determine, and to document, the efficacy, as determined by the response rate, of a combination of Adriamycin, Cytosan, and 5-Fluorouracil in the chemotherapeutic management of advanced, rapidly growing, epithelial tumors of the salivary glands not amenable to surgery or radiotherapy.

Technical Approach: Patients with biopsy-confirmed diagnosis of carcinoma arising in one of the major or minor salivary glands are eligible. The tumor must be aggressively and actively growing and all rational surgical and radiotherapy alternatives must have been exhausted.

Therapy will follow the schema outlined in the study protocol.

Progress: This protocol was temporarily suspended in October 1979 and has been reopened. It is too early for statistical analysis of registrants.

Detail Summary Sheet

Date: 5 Feb 81	Proj No: SWOG 7916	Status: Ongoing
TITLE: Phase II Evaluation of Gallium Nitrate in Metastatic Urological Malignancies: Testicular, Bladder, Prostate and Kidney		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ MC	
Key Words: Metastatic urological malignancies Gallium nitrate		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the efficacy of Gallium Nitrate, as determined by response rate, duration of response and survival, in patients with metastatic urological malignancies which include: testicular, bladder, prostate and kidney; who have failed on higher priority treatment protocols.

Technical Approach: All patients no eligible for higher priority SWOG studies with histologically proven, incurable, advanced, metastatic urological malignancies are eligible. Patients should not have had more than two previous types of combination or single agent chemotherapy trials. Patients must have a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: To date, there have been six kidney and one bladder patients entered. No kidney toxicity has been seen. Patient accrual has been slow.

Detail Summary Sheet

Date: 5 Feb 81	Proj No: SWOG 7917	Status: Ongoing
TITLE: Gallium Nitrate in Previously Treated Patients with Metastatic Cancer, Phase II.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Metastatic breast cancer Gallium nitrate		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the efficacy (as determined by response rate and median duration of response) of Gallium Nitrate in metastatic carcinoma of the breast who have failed standard therapy.

To determine if an initially positive Gallium scan predicts response.

Technical Approach: To be eligible, patients must have histologic proof of breast cancer currently stage IV in extent. There must be measurable disease. Patients must not be eligible for higher priority protocols and should have had a previous trial with appropriate standard therapies (cooper's regimen and/or hormonal manipulation).

Therapy will follow the schema outlined in the study protocol.

Progress: Fourteen patients have been entered. Eleven are evaluable and no responses have been seen. Toxicity has been minimal.

Detail Summary Sheet

Date: 5 Feb 81 Proj No: SWOG 7918 Status: Ongoing

TITLE:

Evaluation of m-AMSA in Lymphoma - Hodgkin's and Non-Hodgkin's.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Hodgkin's lymphoma Non-Hodgkin's lymphoma m-AMSA	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objectives: To determine the antitumor activity as determined by response rate and duration of response of m-AMSA used in a single dose schedule in patients with Hodgkin's and non-Hodgkin's lymphoma, who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of this drug.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven, advanced Hodgkin's or non-Hodgkin's lymphoma are eligible. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirty-seven patients have been registered on this protocol. It is too early for data analysis.

Detail Summary Sheet

Date: 5 Feb 81	Proj No: SWOG 7920	Status: Ongoing
TITLE: m-AMSA in Hepatocellular Carcinoma, Gallbladder Carcinoma and Bile Duct Carcinomas, Phase II.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Hepatocellular carcinoma Gallbladder carcinoma Bile duct carcinoma m-AMSA		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the efficacy of m-AMSA at a dose of 120 mg/M² IV every three weeks in producing regressions or remissions in patients with hepatocellular, bile duct, and gallbladder carcinoma.

Technical Approach: All patients who have histologically confirmed hepatocellular carcinoma, gallbladder carcinoma or bile duct carcinoma beyond hope of surgical cure are eligible. There must be histologic proof of residual, recurrent or metastatic carcinoma. Patients must have measurable disease and a life expectancy of at least 4 weeks.

Progress: Twenty patients have been registered; however, it is too early to evaluate the data.

Detail Summary Sheet

Date: 5 Feb 81		Proj No: SWOG 7921	Status: Ongoing
TITLE: Methyl-Gloxyl BIS-Guanylhydrazone (MGBG) in Metastatic Carcinoma of the Breast.			
Start Date: FY 80		Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Breast carcinoma Methyl-Gloxyl BIS-Guanylhydrazone			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue	
Objectives: To determine response rate and remission duration with weekly intravenous therapy using MGBG in patients with carcinoma of the breast who have failed on higher priority treatment protocols.			

To define the qualitative and quantitative toxicity of this regimen.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven, incurable, advanced, metastatic carcinoma of the breast are eligible. Patients must have clearly measurable disease and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Fourteen patients have been registered on this protocol. It is too early for data analysis.

Detail Summary Sheet

Date: 5 Feb 81	Proj No: SWOG 7922	Status: Ongoing
TITLE: Combination of CTX, Adria and Cis-Platinum vs m-AMSA in Patients with Advanced Transitional Cell Cancer of the Urinary Bladder with Good Renal Function, Phase II-III.		
Start Date: FY 81	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Transitional cell bladder cancer		

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To determine the response rate to the combination chemotherapy of CAP vs m-AMSA in patients with advanced transitional cell carcinoma of the urinary bladder not amenable by surgical resection and/or radiotherapy, who have good renal function.

To determine the response rate to CAP vs m-AMSA after failure or progression on either arm upon crossover to the alternate treatment arm.

Technical Approach: Patients with histologic diagnosis of transitional cell carcinoma of the urinary bladder, Stage IV, or patients who have failed on previous surgery and/or radiotherapy are eligible. Patients must have measurable disease and a life expectancy of at least 8 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Four patients have been registered. It is too early for data analysis.

Detail Summary Sheet

Date: 5 Feb 81	Proj No: SWOG 7923	Status: Ongoing
TITLE: Gallium Nitrate in Metastatic Squamous Cell Carcinoma and/or Local Recurrent Squamous Cell Carcinoma of the Head and Neck.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Gallium nitrate Squamous cell carcinoma of head and neck		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the efficacy as determined by response rate of Gallium Nitrate in patients with metastatic squamous cell carcinoma and/or local recurrent squamous cell carcinoma of the head and neck who have failed on higher priority treatment protocols.

To determine if Gallium scan results may be predictive of anti-tumor effect.

Technical Approach: All patients not eligible for higher priority SWOG protocols with histologically proven, incurable, advanced, metastatic squamous cell carcinoma or local recurrent squamous cell carcinoma of the head and neck are eligible. Patients must have clearly observable and/or measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Seven patients have been entered thus far. It is still too early for a meaningful analysis.

Detail Summary Sheet

Date: 5 Feb 81	Proj No: SWOG 7924	Status: Ongoing
TITLE: Multimodal Therapy for Limited Small Cell Carcinoma of the Lung, Phase III.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Small cell carcinoma of lung		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the efficacy of sequentially alternating mutually noncross-resistant, multidrug regimens in remission induction and intensification therapy in patients with limited small cell lung cancer.

To determine the value of chest radiotherapy added to intensive systemic chemotherapy in reducing chest recurrences and in improvement of survival.

To determine the relative efficacy and toxicity of low-dose, extensive chest radiation when used in close chronologic sequence with systemic multi-agent chemotherapeutic regimens.

To determine whether radiotherapy ports should be set according to tumor size prior to or after induction chemotherapy.

To determine the value of combined systemic chemotherapy and radiotherapy in the control of bulky chest disease.

Technical Approach: Patients with histologically or cytologically proven small cell carcinoma of the lung will be eligible for this study. All patients must have so-called "limited disease".

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 6 Feb 81	Proj No: SWOG 7925	Status: Ongoing
TITLE: Chemoimmunotherapy in Stages III and IV Ovarian Carcinoma: A-C plus BCG, vs A-C plus Cis-Platinum, vs A-C plus Cis-Platinum plus BCG, Phase III.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Ovarian carcinoma Chemoimmunotherapy		

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To compare the effectiveness of A-C + BCG vs A-C + Cis-Platinum for remission and induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma.

To compare the effectiveness of A-C + Cis-Platinum vs A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival in patients with Stage III and IV ovarian carcinoma.

To compare the effectiveness of A-C + BCG vs A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma.

To compare the toxicities of the A-C + BCG, A-C + Cis-Platinum and A-C + Cis-Platinum + BCG regimens.

Technical Approach: Only patients with epithelial type neoplasms will be eligible for this study. The patient must have histologically confirmed diagnosis of ovarian carcinoma.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirty-seven patients have been entered on this study which at this time are too early to evaluate.

Detail Summary Sheet

Date: 6 Feb 81 Proj No: SWOG 7927/8 Status: Ongoing

TITLE:

Chemotherapy for Multiple Myeloma, Phase III.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Multiple myeloma Chemotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
		Periodic Review Results: Continue

Objectives: To compare the effectiveness of four different drug combinations for remission induction in previously untreated patients with multiple myeloma.

For patients with a 75% tumor reduction, to evaluate the role of 12 months of chemotherapy maintenance with VCP or VCP plus levamisole, when compared with previous experiences.

Technical Approach: Only previously untreated patients with the diagnosis of multiple myeloma will be eligible for this study. Patients should have objective evidence of and be symptomatic from complications due to myeloma.

Therapy will follow the schema outlined in the study protocol.

Progress: About 50 patients have been registered on this protocol. Responses have occurred in all treatment groups. However, the major purpose of this study is to define the value of long-term levamisole treatment and to evaluate the results from a VCP combination.

Detail Summary Sheet

Date: 6 Feb 81	Proj No: SWOG 7934	Status: Ongoing
TITLE: Evaluation of Acridinylamino-Methanesulfon-M-Anisidide (AMSA) in Metastatic Squamous Carcinoma of the Head and Neck, Phase II.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator	Facility	
J. Dean McCracken, M.D., COL, MC	Brooke Army Medical Center	
Dept/Sec:	Associate Investigators:	
Department of Medicine/Oncology	Richard A. Shildt, M.D., LTC, MC	
Key Words:	John D. Cowan, M.D., MAJ, MC	
Adridinylamino-Methanesulfon-M-Anisidide		
Head and neck, metastatic squamous carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the antitumor activity, response rate and duration of response in patients with metastatic squamous cell carcinoma of the head and neck who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of this drug.

Technical Approach: All patients not eligible for higher priority SWOG studies, with histologically proven, incurable, advanced squamous cell carcinoma of the head and neck are eligible. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Eight patients have been registered. However, it is too early for data analysis.

Detail Summary Sheet

Date: 6 Feb 81		Proj No: SWOG 7935	Status: Ongoing
TITLE: Chemotherapy of Functioning and Nonfunctioning Islet Cell Carcinoma with Chlorozotocin.			
Start Date: FY 80		Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Islet cell carcinoma Chlorozotocin			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue	
Objectives: To study the response of functioning and non-functioning islet cell carcinomas to chlorozotocin.			

To obtain pathology materials for review on all patients entered into this study.

Technical Approach: Eligible patients must have biopsy-proven islet cell carcinoma nor amenable to further surgical therapy, and a minimum life expectancy greater than 6 weeks. All patients must have objectively measurable disease or a significant biochemical abnormality specific for their islet cell tumor.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, and it is too early for data analysis.

Detail Summary Sheet

Date: 6 Feb 81	Proj No: SWOG 7936	Status: Ongoing
TITLE: Evaluation of Mitomycin-C + Vincristine + Bleomycin + Cis-Platinum vs Mitomycin-C + Cis-Platinum vs Cis-Platinum in the Treatment of Disseminated Carcinoma of the Uterine Cervix, Phase II.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator	Facility	
J. Dean McCracken, M.D., COL, MC	Brooke Army Medical Center	
Dept/Sec:	Associate Investigators:	
Department of Medicine/Oncology	Richard A. Shildt, M.D., LTC, MC	
Key Words:	John D. Cowan, M.D., MAJ, MC	
Uterine cervix carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response rate, duration of responses, and survival of (1) cis-platinum alone, (2) cis-platinum combined with mitomycin-C, and (3) cis-platinum with mitomycin-C, vincristine, and bleomycin, in patients with advanced squamous cell carcinoma of the cervix no longer amenable to surgery or radiation therapy.

To document the nature and extent of the hematologic and non-hematologic side effects of the above three drug regimens.

Technical Approach: All patients with incurable squamous cell carcinoma of the uterine cervix who are not candidates for surgery or radiotherapy and are not eligible for higher priority SWOG studies are eligible. Patients must have no uncontrolled active or potentially active site of infection, must have at least one measurable lesion and must have a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been entered on this protocol. It is too early for analysis.

Detail Summary Sheet

Date: 6 Feb 81	Proj No: SWOG 7937	Status: Ongoing
TITLE: Evaluation of m-AMSA in Metastatic Carcinoma of the Genitourinary Tract Except Renal Carcinoma, Phase II.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Metastatic genitourinary tract carcinoma m-AMSA		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the antitumor activity of AMSA, as determined by response rate, duration of response, and survival, in patients with metastatic carcinoma of the genitourinary tract who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of this drug.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven, incurable, advanced, metastatic carcinoma will be eligible. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study, and it is too early for data analysis.

Detail Summary Sheet

Date: 6 Feb 81		Proj No: SWOG 7940/1/3		Status: Ongoing
TITLE: Evaluation of 5-FU vs a Phase II Drug in Metastatic Adenocarcinoma of the Large Bowel, Phase II-III.				
Start Date: FY 80		Est Comp Date: Unknown		
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center		
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC		
Key Words: Metastatic adenocarcinoma of large bowel MGBG Gallium Nitrate				
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue		

Objectives: To determine the relative activity of a phase II drug (MGBG SWOG 7941, Gallium Nitrate SWOG 7943) in previously untreated patients with disseminated colon and rectal cancer.

To compare the survival of patients with disseminated colon cancer receiving a Phase II agent (MGBG/Gallium Nitrate) as first therapy to the survival of patients receiving fluorinated pyrimidine 5-Fluorouracil (5-FU) therapy first.

To determine the effect of a previously administered Phase II drug on the response rate seen with 5-FU in patients with disseminated colon and rectal cancer.

Technical Approach: Eligible patients must have biopsy proven adenocarcinoma arising from the colon or rectum. Patients must have clinically measurable recurrent or disseminated disease to qualify for the study. Obstructive lesions in the colon and rectum must have been bypassed or adequately maintained by decompression measures. Patients must have a life expectancy of at least 10 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. Initially MGBG and Gallium Nitrate will be evaluated. Indicine-N-oxide and DHAD are scheduled for subsequent evaluation.

Detail Summary Sheet

Date: 6 Feb 81 Proj No: SWOG 7956 Status: Ongoing

TITLE:

Study of Postinfarction Nephrectomy and Medroxyprogesterone Acetate (Depo-Provera) in Metastatic Renal Cell Carcinoma.

Start Date: FY 80

Est Comp Date: Unknown

Principal Investigator

Facility

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

Brooke Army Medical Center

Dept/Sec:

Associate Investigators:

Department of Medicine/Oncology

Richard A. Shildt, M.D., LTC, MC

Key Words:

John D. Cowan, M.D., MAJ, MC

Metastatic renal cell carcinoma

Postinfarction nephrectomy

Depo-Provera

Accumulative MEDCASE

Est Accumulative

Periodic

Cost:

OMA Cost:

Review Results: Continue

Objectives: To determine the response rate and survival patterns in patients with disseminated renal cell carcinoma treated with postinfarction nephrectomy.

To determine the response rate and survival patterns of patients with disseminated renal cell carcinoma who relapse or do not respond to postinfarction nephrectomy when treated with Depo-Provera.

Technical Approach: Patients with measurable disseminated renal cell carcinoma who have not had removal of the primary cancer and in whom the metastatic disease is not resectable at the time of nephrectomy are eligible. Patients must have an expected survival of at least 3 months.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. It is too early to report any meaningful results.

Detail Summary Sheet

Date: 6 Feb 81	Proj No: SWOG 7958	Status: Ongoing
TITLE: Evaluation of m-AMSA in Metastatic or Recurrent Epithelial Carcinomas of the Female Genital Tract.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Epithelial carcinoma of female genital tract m-AMSA		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the antitumor activity of AMSA in patients with metastatic or recurrent epithelial carcinomas of the ovary, endometrium, cervix, vagina or vulva who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of AMSA in patients treated by the split-course three-day schedule.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven incurable, advanced, metastatic or recurrent epithelial carcinoma of the ovary, endometrium, cervix, vagina or vulva are eligible. Patients must have clearly measurable disease and a life expectancy of 6 weeks.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 6 Feb 81	Proj No: SWOG 7959	Status: Ongoing
TITLE: Evaluation of Methyl-Gloxyl Bis-Guanylhydrazone (MGBG) in Metastatic Renal Carcinoma.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Metastatic renal carcinoma Methyl-Gloxyl Bis-Guanylhydrazone (MGBG)		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objectives: To determine the response rate and remission duration with weekly intravenous therapy using MGBG in patients with metastatic renal carcinoma.		

To define the qualitative and quantitative toxicity of this regimen.

Technical Approach: Eligible patients are those with a histologically proven diagnosis of incurable, advanced, metastatic renal cell carcinoma. All patients must have measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 6 Feb 81 Proj No: SWOG 7960 Status: Ongoing
TITLE:

Colchicine in Refractory Hodgkin's Disease, CLL, Lung and Breast Cancer.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Refractory Hodgkin's, CLL, Lung and Breast Cancer Cochicine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objectives: To determine the maximum dose of colchicine which may be safely administered on a once weekly basis.

To determine the response rate (standard error $\pm$ 10%) to weekly, intravenous cholchicine in each of the tumor types tested.

To determine quantitative and qualitative toxicity of the drug on this schedule.

Technical Approach: Patients with chronic lymphocytic leukemia, Hodgkin's disease, breast and lung cancer (both small and non-small cell) are potential candidates for this study after they have developed progressive disease on SWOG protocols of higher priority. They must have a life expectancy of at least 6 weeks and a Performance Status of 0-3. Measurable disease is desirable but not required.

It is estimated that 30 patients in each category will need to be entered in order to have 25 patients which are response-evaluable.

Therapy will follow the schema outlined in the study protocol.

Progress: There are only three patients registered. This study was originally written as a pilot study and will soon be made a Groupwise study for patients with refractory CLL only.

Detail Summary Sheet

Date: 6 Feb 81		Proj No: SWOG 7965	Status: Ongoing
TITLE: Treatment of Early Squamous Cell Carcinoma of the Head and Neck with Initial Surgery and/or Radiotherapy Followed by Chemotherapy vs No Further Treatment, Phase III.			
Start Date: FY 80		Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken		Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Squamous cell carcinoma of head and neck Radiotherapy Chemotherapy			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue	

Objective: To determine if the disease-free interval and survival of patients in high risk categories of squamous head and neck cancer can be improved by adjuvant methotrexate after initial surgery, radiotherapy or both have resulted in no clinically evident disease.

Technical Approach: Patients with histologically proven squamous cell carcinoma of the head and neck who have been rendered clinically disease free by surgery or radiotherapy are eligible. Patients must be entered within three months of completion of radiotherapy or surgery.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 6 Feb 81		Proj No: SWOG 7969	Status: Ongoing
TITLE: Hepatic Infusion and Systemic Combination Chemotherapy in the Treatment of Unresectable Hepatoma, Phase II.			
Start Date: FY 80		Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Hepatoma, unresectable Chemotherapy			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue	
Objective: To determine the remission rate seen with induction chemotherapy consisting of intra-arterially infused 5-FUDR, Adriamycin and Streptozotocin in patients with hepatocellular carcinoma.			

Technical Approach: Patients with a histologically confirmed diagnosis of unresectable hepatocellular carcinoma which is localized to the liver are eligible. Patients with local extension of tumor into contiguous organs are eligible. Patients must not have received prior chemotherapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 6 Feb 81 Proj No: SWOG 7980 Status: Ongoing

TITLE:

Study of Cis-Platinum for Recurrent Gliomas.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Gliomas, recurrent Cis-Platinum	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objectives: To determine the efficacy of the chemotherapeutic agent cis-diammine dichloroplatinum (DDP) in the treatment of gliomas recurrent after prior therapy with irradiation (plus or minus chemotherapy).

To determine the duration of response and survival of patients receiving this therapy.

Technical Approach: All patients with gliomas (grade I-IV) who have recurred following cranial irradiation will be eligible. It is essential that patients have evaluable lesions on either CT or radionuclide brain scan.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. It is too early for data analysis.

Detail Summary Sheet

Date: 6 Feb 81	Proj No: SWOG 7982	Status: Ongoing
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TITLE:

Chlorozotocin in the Treatment of Advanced Sarcomas.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Sarcomas Chlorozotocin	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objective: To determine whether chlorozotocin in a dose of 120 mg/M² has significant activity in sarcomas by determination of response rate and duration.

To describe toxicities of chlorozotocin not yet defined.

Technical Approach: Eligible patients must have biopsy proven advanced bony or soft tissue sarcoma. Patients must have measurable disease and an expected survival of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. Therefore, it is too early for data analysis.

Detail Summary Sheet

Date: 6 Feb 81	Proj No: SWOG 7983	Status: Ongoing
TITLE: Radiation Therapy in Combination with CCNU in Patients with Incompletely Resected Gliomas of the Brain, Grade I and II.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Glioma Radiation therapy CCNU		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objectives: To compare the survival of patients with incompletely resected Grade I and II gliomas treated with radiation alone versus radiation and CCNU.		

To compare the effectiveness of radiation therapy versus radiation therapy plus CCNU for remission induction and duration of remission.

Technical Approach: Patients with histologically confirmed primary brain tumors of the following histologic types are eligible: Astrocytoma, Grade I and II with incomplete tumor resection. Patients who have had surgery with histologic diagnosis within the previous six weeks are eligible.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 6 Feb 81 Proj No: SWOG 7985 Status: Ongoing

TITLE:

Combined Modality Treatment for ER- Breast Cancer, Phase III.

Start Date: FY 80		Est Comp Date: Unknown
Principal Investigator		Facility
J. Dean McCracken, M.D., COL, MC		Brooke Army Medical Center
Dept/Sec:		Associate Investigators:
Department of Medicine/Oncology		Richard A. Shildt, M.D., LTC, MC
Key Words:		John D. Cowan, M.D.
Breast cancer		
Estrogen receptor negative (Er-)		
Accumulative MEDCASE	Est Accumulative	Periodic
Cost:	OMA Cost:	Review Results: Continue

Objectives: To compare disease-free interval and survival among control group Stage I (and Stage II node negative) breast cancer patients who tumors are determined to be ER- at the time of mastectomy, versus Stage I (and Stage II node negative) ER- patients treated with adjuvant CMFV for 6 months.

To document recurrence patterns among untreated patients with Stage I breast cancer whose tumors are determined to be ER- at the time of mastectomy.

Technical Approach: All female patients having had a radical, modified radical or total mastectomy, or segmental mastectomy with axillary node dissection for potentially curable, histologically proven breast carcinoma, whose axillary nodes are negative for tumor, and whose estrogen receptor assay on the primary tumor is less than 10 femtomoles/mg cytosol protein are eligible for this study. Patients must be registered within 28 days of mastectomy. Patients with previous oophorectomy are eligible provided the oophorectomy was not performed for tumor.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was modified to an intermittent drug regiment to be given for six months - Cytosan, 5-FU, Methotrexate, Vincristine vs surgery alone.

No patients have been entered at this time.

Detail Summary Sheet

Date: 6 Feb 81 Proj No: SWOG 7990 Status: Ongoing
TITLE:

Testicular Cancer Intergroup Study.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Testicular cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objectives: To compare the disease-free survival and overall survival for surgery alone (with chemotherapy for relapsers) vs surgery plus early adjuvant chemotherapy in patients with resectable Stage II testicular cancer.

To register and follow patients with non-seminoma, non-choriocarcinoma stage I testicular cancer, to define prognostic variables which may predict recurrence in this stage group.

To define the difference in disease-free rates and patterns of recurrence based upon histologic subtypes and extent of disease on initial presentation.

To evaluate the role of marker substances such as human chorionic gonadotropin, alpha-fetoprotein and lactic dehydrogenase in the early detection and management of recurrences in patients with stage I and stage II testicular carcinoma.

To evaluate the accuracy of lymphangiogram, CAT scans and ultrasound studies for staging of retroperitoneal nodal involvement.

Technical Approach: Patients with histologically confirmed carcinoma of the testis, stage I or stage II, are eligible. Patients should enter the study between two and four weeks after lymphadenectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been slow. Insufficient data have been collected for reporting purposes.

Detail Summary Sheet

Date: 6 Feb 81	Proj No: SWOG 8001	Status: Ongoing
TITLE: Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Acute lymphoblastic leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To evaluate the effectiveness as determined by the complete remission rate of the L10 protocol using Vincristine, Prednisone and Adriamycin for induction, followed by intensive consolidation in the treatment of acute ALL.

To compare the effect on remission duration and survival of two maintenance regimens: the L10 "eradication" regimen vs cyclic therapy with POMP-COAP-OPAL.

To determine the reproducibility of the FAB histologic classification and correlation to response to therapy of ALL in adults.

Technical Approach: Patients are eligible with the diagnosis of acute lymphoblastic leukemia who satisfy the following criteria: A) Absolute infiltration of the marrow with >50% blasts; b) Absolute infiltration is defined as the total blast cell percentage (%) multiplied by the bone marrow cellularity percentage divided by 100; B) If the absolute infiltrate is 30-49%, evidence of progressive disease prior to entering the study will be required.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 6 Feb 81 Proj No: SWOG 8003 Status: Ongoing

TITLE:

Evaluation of MGBG in Non-Oat Cell Cancer of the Lung, Phase II.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Non-Oat cell cancer of lung MGBG	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To determine the response rate and remission duration with weekly intravenous therapy using MGBG in patients with non-oat cell carcinoma of the lung who have failed on higher priority treatment protocols.

To define the qualitative and quantitative toxicity of this regimen.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven, incurable, advanced metastatic non-oat cell carcinoma of the lung are eligible. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 6 Feb 81 Proj No: SWOG 8004 Status: Ongoing

TITLE:

Evaluation of DHAD in Soft Tissue and Bone Sarcomas, Phase II.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Sarcoma, soft tissue and bone DHAD	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To determine the efficacy, by response rate, of Dihydroxyanthracenedione (DHAD) in patients with soft tissue and bone sarcomas, who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of this drug used in a single dose every three-week schedule.

Technical Approach: All patients must have histologically proven, incurable soft tissue or bone sarcomas, not eligible for higher priority SWOG studies, in order to be eligible for study. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: DHAD appears to be a potentially active Phase II agent for sarcoma. For statistical reasons, this study may accrue a few more patients than what is usual for a single agent, phase II study.

Detail Summary Sheet

Date: 6 Feb 81 Proj No: SWOG 8008 Status: Ongoing

TITLE:

Evaluation of Dihydroxyanthracenedione (DHAD) in Refractory Breast Cancer, Phase II.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Breast cancer Dehydroxyanthracenedione (DHAD)	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objectives: To determine the response rate and remission duration of refractory breast cancer in patients treated with anthracenedione used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: Eligible patients must have pathologically verified histologic diagnosis of breast cancer. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 6 Feb 81		Proj No: SWOG 8009	Status: Ongoing
TITLE: Evaluation of DHAD in Patients with Refractory Small Cell Lung Cancer, Phase II.			
Start Date: FY 80		Est Comp Date: Ongoing	
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center	
Dept/Sec: Department of Medicine/Oncology		Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC	
Key Words: Small cell lung cancer DHAD			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue	
Objectives: To determine the response rate and remission duration of refractory small cell lung cancer in patients treated with DHAD used in a single dose every three-week schedule.			

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: Eligible patients must have pathologically verified histologic diagnosis of small cell lung cancer. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 6 Feb 81 Proj No: SWOG 8010 Status: Ongoing

TITLE:

Evaluation of DHAD in Advanced Prostate Cancer, Phase II.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Prostate cancer DAHD	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objectives: To determine the response rate and remission duration in patients with prostate cancer treated with DHAD used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: Eligible patients must have pathologically verified histologic diagnosis of prostate cancer. All patients must have measurable or evaluable disease.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 6 Feb 81 Proj No: SWOG 8011 Status: Ongoing

TITLE:

Evaluation of DHAD in Patients with Advanced Renal Cell Carcinoma, Phase II.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Renal cell carcinoma DHAD	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To determine the response rate and duration of response in patients with advanced renal cell carcinoma treated with DHAD used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II Study.

Technical Approach: All patients with advanced renal cell carcinoma not eligible for higher priority protocols are eligible. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 6 Feb 81 Proj No: SWOG 8014 Status: Ongoing
TITLE:

Colchicine in Refractory Chronic Lymphocytic Leukemia, Phase I-II.

Start Date: FY 80	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Oncology	Associate Investigators: Richard A. Shildt, M.D., LTC, MC John D. Cowan, M.D., MAJ, MC
Key Words: Chronic lymphocytic leukemia Colchicine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objectives: To determine the maximum dose of colchicine that may safely be administered on a once weekly basis.

To determine the response rate standard error (+/- 10%) in patients with chronic lymphocytic leukemia.

To determine quantitative and qualitative toxicity of the drug colchicine administered on a once weekly basis.

Technical Approach: Patients with chronic lymphocytic leukemia who have demonstrated progressive disease on studies of higher priority are eligible. Patients must have recovered from toxicities resulting from prior treatment before the initiation of treatment with colchicine.

Therapy will follow the schema outlined in the study protocol.

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

APPENDIX B
Gynecology Oncology Group

Detail Summary Sheet

Date: 6 Feb 81	Proj No: GOG 22	Status: Completed
TITLE: A Randomized Comparison of Melphalan Alone vs Adriamycin and Cyclophosphamide vs Hexamethylmelamine and Melphalan in Patients with Ovarian Adenocarcinoma: Suboptimal Stage III, Stage IV & Recurrent Equivalent to Stages III & IV.		
Start Date: FY 78	Est Comp Date:	
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:	
Key Words: Ovarian adenocarcinoma.		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
Objective: To determine if combination chemotherapy is more effective than Melphalan alone in achieving remission and improving survival in Stage IV and suboptimal patients with Stage III ovarian cancer.		

Technical Approach: Patients who have been diagnosed as primary Stage III suboptimal and Stage IV and all recurrent cases of ovarian adenocarcinoma are eligible. The Melphalan alone arm has been discontinued.

Therapy will follow the schema outlined in the study protocol.

Progress: Both combination regimens appear to be more active than Melphalan alone in producing complete responses. Adriamycin plus Cyclophosphamide has a slightly higher response rate, while the Melphalan and Hexamethylmelamine combination is oral and avoids cardiac risk and alopecia.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: GOG-24	Status: Ongoing
TITLE: Treatment of Women with Cervical Cancer Stage IIB, IIIB, IVA, Confined to the Pelvis and/or Para-aortic Nodes with Radiotherapy Alone vs Radiotherapy plus Immunotherapy (Phase II).		
Start Date: FY 78	Est Comp Date: Unknown	
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:	
Key Words: Cervical cancer Radiotherapy Immunotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objective: To assess the therapeutic effectiveness of immunotherapy (intravenous C-parvum) used concomitantly with radiation in patients with advanced carcinoma of the uterine cervix.		

Technical approach: Patients with histologically confirmed, previously untrated carcinoma of the uterine cervix (adenocarcinoma or squamous carcinoma) are eligible.

Therapy will be in accordance with the schema outlined in the study protocol.

Progress: It is too early to draw any conclusions with regard to improved survival; however, some interesting data are accumulating with regard to adverse effects. The therapeutic value of C-parvum will be determined and if the results warrant, this mode of therapy will be compared with other regimens which show promise.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: GOG-25	Status: Ongoing
TITLE: A Randomized Comparison of Melphalan Therapy Alone vs Melphalan plus Immunotherapy (C. Parvum) in the Treatment of Women with Stage III (Optimal) Epithelial Carcinoma of the Ovary (Phase II).		
Start Date: FY 78	Est Comp Date: Unknown	
Principal Investigator	Facility	
Milton H. Leman, M.D., COL, MC	Brooke Army Medical Center	
Dept/Sec:	Associate Investigators:	
Department of Obstetrics and Gynecology		
Key Words:		
Epithelial carcinoma, ovary		
Immunotherapy		
C. Parvum		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objective: To determine the efficacy of adjuvant nonspecific immunotherapy to standard alkylating agent therapy in patients with Stage III optimal carcinoma of the ovary.		

Technical Approach: Patients in "optimal" category (3 cm or less greatest diameter of residual tumor(s) with proven primary Stage III epithelial cancer of the ovary) who have undergone tumor-reductive surgery will be included in the study.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no significant difference when the duration of progression-free interval and survival are compared by therapy. When progress-free interval and survival are compared by size of residual tumor at surgery, both are statistically significant at the .05 level.

Detail Summary Sheet

Date: 9 Feb 81 Proj No: GOG-26 Status: Ongoing

TITLE:

Master Protocol for Phase II Drug Studies in Treatment of Advanced, Recurrent Pelvic Malignancies.

Start Date: FY 78	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Pelvic malignancies Chemotherapy	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objective: This protocol constitutes a Phase II design outlining the procedures that will be performed to screen for activity of new agents of drug combinations in patients with advanced recurrent pelvic malignancies. Its intent is to determine the efficacy of chemotherapeutic agents in patients whose advanced malignancies have been resistant to high priority methods of treatment.

Technical Approach: This is a study of multiple chemotherapeutic agents. Therapy will follow the schema outlined in the study protocol. Agents to be used in this study include: Piperazinedione, Cis-platinum, VP-16, Galacticol, Baker's Antifol, ICRF-159, Maytansine, m-AMSA and Yoshi 864.

Progress: Cis-platinum has marked activity as first line chemotherapy of squamous cell carcinoma of the cervix and is active as second line therapy of advanced ovarian carcinoma at the dose and schedule tested. The drug appears to be inactive against endometrial carcinoma but may have limited activity in the therapy of sarcomas and cervical adenocarcinomas.

Because of the demonstrated activity of Cis-platinum in squamous cell carcinoma of the cervix, a phase III study comparing three different regimens of Cis-platinum in advanced squamous cell carcinoma of the cervix was activated as GOG 43.

GOG 26 (continued)

Because of the demonstrated activity of Cis-platinum in epithelial ovarian carcinoma, protocol GOG 46 was activated comparing Adrimycin plus Cyclophosphamide plus Cis-platinum with Adriamycin plus Cyclophosphamide.

VP-16 - VP-16 appears to have minimal activity against ovarian adenocarcinoma and insignificant activity against squamous cell carcinoma of the cervix at the dose and schedule tested.

Galacticol - Complete and partial remissions in carcinoma of the cervix have been 20% which is encouraging enough for future studies, possibly in combination with other drugs. One complete remission continues at 22+ months.

Complete and partial remissions in carcinoma of the ovary were 15%. Almost all of these patients had received prior chemotherapy. Two complete remissions continue at 12+ and 14+ months.

Baker's Antifol - Although limited activity is noted, this drug is not as useful as more conventional drugs and probably will not add to current therapeutic regimens.

IRCF - IRCF appears to have moderate activity in squamous cell carcinoma of the cervix at the dose and schedule tested despite induction of significant myelosuppression. Results of this study will be used to determine the future role, if any, of IRCF-159 in the treatment of gynecologic cancer.

Maytansine - Maytansine has insignificant activity against squamous cell carcinoma of the cervix and epithelial tumors of the ovary. Two few cases have accrued in other categories to comment. Therefore, the study is closed to cervix and ovary but accrual continues in other categories.

AMSA and YOSHI - It is too early to evaluate the results. When these are obtained, they will be used to determine the future role, if any of AMSA and YOSHI in the treatment of gynecologic cancer either alone or in combination with other drugs.

Detail Summary Sheet

Date: 9 Feb 81		Proj No: GOG 28		Status: Completed	
TITLE: A Randomized Comparison of Melphalan, 5-FU and Megace vs Adriamycin, Cytosan, 5-FU and Megace in the Treatment of Patients with Primary Stage III, Primary Stage IV, Recurrent or Residual Endometrial Carcinoma, Phase III.					
Start Date: FY 79			Est Comp Date:		
Principal Investigator			Facility		
Milton H. Leman, M.D., COL, MC			Brooke Army Medical Center		
Dept/Sec:			Associate Investigators:		
Department of Obstetrics and Gynecology					
Key Words:					
Endometrial carcinoma					
Accumulative MEDCASE		Est Accumulative		Periodic	
Cost:		OMA Cost:		Review Results:	

Objective: To determine the efficacy of multi-drug preparations and to see if one or two programs previously shown to be effective by pilot studies is superior.

Technical Approach: All patients with primary Stage III, primary Stage IV, recurrent or residual endometrial adenocarcinoma, adenoacanthoma, or adeno-squamous cancer whose potential for cure by radiation therapy or surgery alone or in combination is very poor and who have received no prior chemotherapy other than progestins are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: The overall objective response rate is 36.8%, and the activity of Melphalan + 5-FU has been established for the first time in a collaborative study. The trend suggests a better response to combination chemotherapy in patients with poor prognostic features compared to response to single agents.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: GOG-29	Status: Terminated
TITLE: A Randomized Comparison of Pelvic and Abdominal Radiation Therapy vs Pelvic Radiation and Melphalan Alone in Stage II Carcinoma of the Ovary, Phase III.		
Start Date: FY 79	Est Comp Date:	
Principal Investigator	Facility	
Milton H. Leman, M.D., COL, MC	Brooke Army Medical Center	
Dept/Sec:	Associate Investigators:	
Department of Obstetrics and Gynecology		
Key Words:		
Carcinoma of ovary		
Pelvic radiation		
Abdominal radiation		
Melphalan		
Accumulative MEDCASE	Est Accumulative	Periodic
Cost:	OMA Cost:	Review Results:

Objectives: To determine the duration of relapse-free survival obtained by pelvic and abdominal radiation.

To determine the duration of relapse-free survival obtained by pelvic radiation and chemotherapy.

To determine the duration of relapse-free survival obtained by chemotherapy alone.

To study the influence of various forms of treatment, and of tumor differentiation upon patterns of relapse and recurrence; local, nodal, abdominal, diaphragmatic and distant disease.

Technical Approach: All patients must have had an adequate surgical staging to be eligible for this study. At the time of surgical staging (restaging), the disease stage must be Stage IIa, IIb, or IIc. Patients must have a histopathologic diagnosis of ovarian cancer of one of the following types: serous, mucinous, endometrioid, clear cell, or undifferentiated.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was terminated by the GOG.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: GOG 31	Status: Ongoing
TITLE: A Randomized Comparison of Local Excision vs Cryosurgery in Patients with Limited Grade 1, 2, or 3 Cervical Intraepithelial Neoplasia.		
Start Date: FY 79	Est Comp Date: Unknown	
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:	
Key Words: Cervical neoplasia Cryosurgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To evaluate and compare the immediate and long-term effectiveness of outpatient cryosurgery and outpatient local excision in the treatment of limited cervical intraepithelial neoplasia grade 1, 2 or 3, in a randomized prospective study.

Technical Approach: All eligible patients must have a tissue diagnosis of cervical intraepithelial neoplasia within six weeks prior to randomization in the study. All patients must have a lesion which can be completely delineated through the colposcope. Only patients with the following histologic diagnosis will be eligible: mild dysplasia, moderate dysplasia, severe dysplasia, and carcinoma in situ.

Therapy and randomization will follow the schema outlined in the study protocol.

Progress: Median follow-up for the evaluable patients on this study is only 9.0 months; consequently, it is still too early to perform a meaningful analysis.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: GOG 32	Status: Ongoing
TITLE: A Radomized Comparison of Surgical Conization vs Cryosurgery in Patients with Extensive Grade 3 Cervical Intraepithelial Neoplasia.		
Start Date: FY 79	Est Comp Date: Unknown	
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:	
Key Words: Cervical neoplasia Cryosurgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To evaluate and compare the immediate and long-term effectiveness of outpatient cryosurgery to the standard cold-knife conization in the treatment of extensive cervical intraepithelial neoplasia Grade 3 in a randomized prospective study.

Technical Approach: All eligible patients must have a diagnosis of cervical intraepithelial neoplasia within six weeks prior to randomization in the study. All patients must have a lesion which can be completely delineated through the colposcope. The lesion should involve at least two quadrants of the portio. Only patients with the following histologic diagnosis will be eligible: severe dysplasia and carcinoma in situ.

Therapy and randomization will follow the schema outlined in the study protocol.

Progress: Seventy-three patients have been entered on the study. It is too early to draw any conclusions from the 33 evaluable patients.

Detail Summary Sheet

Date: 9 Feb 81 Proj No: GOG 33 Status: Ongoing

TITLE:

A Clinical-Pathologic Study of Stage I and II Carcinoma of the Endometrium.

Start Date: FY 78	Est Comp Date: Unknown
Principal Investigator	Facility
Milton H. Leman, M.D., COL, MC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Obstetrics and Gynecology	
Key Words:	
Endometrial carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objective: To determine the incidence of pelvic and aortic lymph node metastases and the relationship of these node metastases to other important prognostic factors.

Technical Approach: All patients with histologically proven endometrial carcinoma clinical FIGO Stage I and II who are medically suitable for hysterectomy and lymphadenectomy are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: Analysis of survival and progress-free interval is too early at this time.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: GOG 34	Status: Ongoing
TITLE: A Randomized Study of Adriamycin as an Adjuvant After Surgery and Radiation Therapy in Patients with High Risk Endometrial Carcinoma, Stage I, and Occult Stage II.		
Start Date: FY 78	Est Comp Date: Unknown	
Principal Investigator	Facility	
Milton H. Leman, M.D., COL, MC	Brooke Army Medical Center	
Dept/Sec:	Associate Investigators:	
Department of Obstetrics and Gynecology		
Key Words:		
Endometrial carcinoma		
Radiation therapy		
Adriamycin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objective: To study differences in morbidity and patient survival as functions of various tumor growth patterns as well as treatments.		

Technical Approach: All patients with primary, previously untreated, histologically confirmed invasive carcinoma of the endometrium Stage I, and Stage II occult, all grade, with one or more of the following high risk criteria are eligible: (1) all lesions with equal to or greater than one-half myometrial involvement; (2) positive pelvic and/or para-aortic nodes; (3) microscopic evidence of cervical involvement but no gross clinical involvement of the cervix. The following types of histologically confirmed uterine carcinoma are eligible: adenocarcinoma, adenoacanthoma, adenosquamous carcinoma.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 9 Feb 81 Proj No: GOG 36 Status: Ongoing

TITLE:

Surgical-Pathologic Study of Women with Squamous Cell Carcinoma of the Vulva.

Start Date: FY 78	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Squamous cell carcinoma of vulva	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To determine the validity of current FIGO staging to the histopathologic prognostic factors of size of lesion, location of lesion, depth of invasion of tumor in millimeters, histologic grade, and site and number of positive lymph nodes in Stage I-IV carcinoma of the vulva.

To rapidly accumulate prospectively significant surgical pathologic data for development of further protocols for subsets of disease identified.

To determine morbidity of primary radical surgical therapy.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive squamous cell carcinoma of the vulva clinically determined to be Stage I through IV are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: GOG 37	Status: Ongoing
TITLE: Randomized Study of Radiation Therapy vs Pelvic Node Resection for Patients with Invasive Squamous Cell Carcinoma of the Vulva Having Positive Groin Nodes.		
Start Date: FY 78	Est Comp Date: Unknown	
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:	
Key Words: Squamous cell carcinoma of vulva		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the benefit and morbidity of adding adjunctive radiation therapy to pelvis and groin for patients with positive groin nodes at radical vulvectomy and bilateral groin dissection.

Technical Approach: All patients with primary, previously untreated, histologically confirmed squamous cell carcinoma of the vulva such that radical vulvectomy suffices to remove all of the local lesion and whose surgery revealed that there were nodes in the groin on one or both sides containing metastatic carcinoma are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 9 Feb 81 Proj No: GOG 40 Status: Ongoing

TITLE:

A Clinical-Pathologic Study of Stage I and II Uterine Sarcomas.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator	Facility
Milton H. Leman, M.D., COL, MC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Obstetrics and Gynecology	
Key Words:	
Uterine sarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objective: To determine the incidence of pelvic and aortic lymph node metastases associated with Stage I and II uterine sarcomas, the relationship of these node metastases to other important prognostic factors such as mitotic index of the tumor, and the complication rate of the procedures.

Technical Approach: All patients with histologically proven uterine sarcoma clinical Stage I and II who are medically suitable for hysterectomy and lymphadenectomy are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 9 Feb 81 Proj No: GOG 41 Status: Ongoing

TITLE:

Surgical Staging of Ovarian Carcinoma.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Ovarian carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results: Continue

Objectives: To determine the spread of ovarian carcinoma in intraperitoneal structures and retroperitoneal lymph nodes by direct examination, cytologic sampling, and biopsy.

To establish a surgical protocol for patients entered into GOG ovarian cancer treatment protocols.

To determine the complication rate of the procedures.

Technical Approach: Patients with all histologic types of primary ovarian cancer are eligible, including epithelial tumors, germ cell tumors, stromal tumors, and all others. Patients must be entered within two weeks of the last surgery.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: GOG 42	Status: Ongoing
TITLE: Treatment of Recurrent or Advanced Uterine Sarcoma. A Randomized Comparison of Adriamycin vs Adriamycin and Cyclophosphamide, Phase III.		
Start Date: FY 79	Est Comp Date: Unknown	
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:	
Key Words: Uterine sarcoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objectives: To determine if Adriamycin alone is more effective than Adriamycin and Cyclophosphamide in producing responses in advanced or recurrent uterine sarcoma.		

To determine the duration of response for each different treatment arm.

Technical Approach: Patients with primary Stage III, primary Stage IV or recurrent uterine sarcoma are eligible. Both patients with measurable and non-measurable disease are eligible, but they will be analyzed separately. Patients with all cell types of uterine sarcoma are eligible.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: The regimens are well tolerated. Patient accrual will be continued to reach a statistically valid conclusion with regard to progress-free interval and survival.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: GOG 43	Status: Ongoing
TITLE: A Randomized Comparison of Cis-platinum 50mg/m ² IV Every 3 weeks vs Cis-platinum 100mg/m ² IV Every 3 weeks vs Cis-platinum 20mg/m ² IV Daily x 5 Days in Treatment of Patients with Advanced Carcinoma of the Cervix, Phase III.		
Start Date: FY 79	Est Comp Date: Unknown	
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:	
Key Words: Carcinoma of cervix		

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To confirm the effectiveness of cis-diamminedichloroplatinum (DDP) in advanced and recurrent squamous cell carcinoma of the cervix no longer responding to radiation therapy or surgery.

To compare the frequency and duration of response and adverse effects of DDP therapy using three different doses and treatment schedules.

To evaluate the roles of serial determination of serum carcinoembryonic antigen (CEA) levels in determining extent of disease, response to treatment, and in predicting treatment failure.

Technical Approach: Eligible patients must have histologically confirmed, locally advanced, recurrent, persistent, or metastatic squamous cell carcinoma of the cervix which is resistant to curative treatment with surgery or radiotherapy. All patients must have lesions which are measurable or evaluable by physical examination. Patients will have recovered from effects of recent surgery or radiotherapy, and will be free of clinically significant infection.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: There is no significant difference in response when the three regimens are compared. Median time to response for regimens A, B and C is 2.3, 1.8 and 2.4 months, respectively. Survival by response category is significant at the .001 level.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: GOG 44	Status: Ongoing
TITLE: Evaluation of Adjuvant Vincristine, Dactinomycin, and Cyclophosphamide Therapy in Malignant Germ Cell Tumors of the Ovary After Resection of All Gross Tumor, Phase III.		
Start Date: FY 79	Est Comp Date: Unknown	
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:	
Key Words: Germ cell tumor of ovary		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To evaluate the effect of combined prophylactic vincristine, dactinomycin, and cyclophosphamide chemotherapy in patients with endodermal sinus tumor, embryonal carcinoma, immature teratoma (Grades 2 and 3), chorio-carcinoma, and malignant mixed germ cell tumors of the ovary, Stages I and II after total removal of all gross tumor.

To evaluate the role of serum markers, especially alpha-fetoprotein (AFP) and human chorionic gonadotropin (beta HCG), when these are present, in predicting response and relapse.

To determine the role of restaging laparotomy in determining response, predicting relapse and planning further therapy.

Technical Approach: Patients with histologically confirmed malignant germ cell tumors of the ovary, Stages I or II, if previously untreated and completely resected, excluding patients with pure dysgerminoma unless classified as anaplastic, are eligible. Patients with grade 2 or 3 immature teratoma are also eligible. Patients with early Stage III disease will be accepted if all gross tumor is resected.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 9 Feb 81 Proj No: GOG 45 Status: Ongoing
TITLE:

Evaluation of Vinblastine, Bleomycin, and Cis-platinum in Stage III and IV and Recurrent Malignant Germ Cell Tumors of the Ovary, Phase III.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Malignant germa cell tumor of ovary	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives: To evaluate the effect of four cycles of combined Vinblastine, Bleomycin and Cis-platinum (VBP) chemotherapy in the management of patients with endodermal sinus tumor, embryonal carcinoma, immature teratoma (all grades), choriocarcinoma, and malignant germ cell tumors of the ovary with advanced or recurrent disease, incompletely resected.

To evaluate the role of serum markers, especially alpha-fetoprotein (AFP) and human chorionic gondaotropin (beta JCG), when these are present, in predicting response and relapse.

To determine the role of restaging laparotomy in patients in clinical remission, in assessing completeness of response, and in planning further therapy.

To evaluate and compare the effect of Vincristine, Dactinomycin and Cyclophosphamide (VAC) chemotherapy in patients found to have persistent disease at the time of restaging laparotomy.

To determine the need for maintenance Vinblastine therapy in patients found free of disease at restaging laparotomy.

Technical Approach: Patients with histologically confirmed malignant germ cell tumors of the ovary with advanced (Stage III-IV) or recurrent disease, incompletely resected, excluding patients with pure dysgerminoma (mature or anaplastic) are eligible. Patients with incompletely resected Stage II disease and patients previously treated with Vincristine, Dactinomycin and Cyclophosphamide are also eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: As expected, toxicity is considerable but genreally manageable. Early results are encouraging.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: GOG 46	Status: Ongoing
TITLE: A Randomized Comparison of Melphalan vs Intraperitoneal Chromic Phosphate in the Treatment of Women with Stage I (exclusive of Stage IA(i) G1 and IB(i) G1) Epithelial Carcinoma of the Ovary, Phase III.		
Start Date: FY 79	Est Comp Date: Unknown	
Principal Investigator	Facility	
Milton H. Leman, M.D., COL, MC	Brooke Army Medical Center	
Dept/Sec:	Associate Investigators:	
Department of Obstetrics and Gynecology		
Key Words:		
Epithelial carcinoma of ovary		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objective: To evaluate the relative effectiveness of Melphalan vs intraperitoneal Chromic Phosphate as adjuvant therapy in Stage I exclusive of Stage IA (i) G1 and Stage IB(i) G1 epithelial cancers of the ovary in a randomized prospective study.		

Technical Approach: Patients with surgical Stage IA(i) Gs, G3; IA(ii); IB(i) G2, G3; IB(ii), and IC epithelial cancer of the ovary who have undergone optimal staging described in GOG 41 are eligible.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: GOG 47	Status: Ongoing
TITLE: A Randomized Study of Adriamycin + Cyclophosphamide vs Adriamycin + Cyclophosphamide + Cis-platinum in Patients with Advanced Ovarian Adenocarcinoma - Suboptimal Stage II, Stage IV and Recurrent, Phase III.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:	
Key Words: Ovarian adenocarcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine if the addition of Cis-platinum to Adriamycin plus Cyclophosphamide improves remission rate, remission duration or survival in Stage IV, suboptimal Stage III and recurrent ovarian adenocarcinoma.

To determine the frequency and duration of true complete remission using these regimens as judged at second-look laparotomy.

Technical Approach: Patients who have been diagnosed as Stage IV and suboptimal Stage III primary cases together with all recurrent cases are eligible. Both patients with measurable disease and patients without measurable disease, as a separate category, will be evaluated.

Therapy will follow the schema outlined in the study protocol.

Progress: There are no significant differences in either survival or progress-free interval. Presently, there are too few failures to perform detailed analysis.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: GOG 48	Status: Ongoing
TITLE: A Study of Progestin Therapy and A Randomized Comparison of Adriamycin vs Adriamycin + Cyclophosphamide in Patients with Advanced Endometrial Carcinoma After Hormonal Failure, Phase III.		
Start Date: FY 80	Est Comp Date: Unknown	
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:	
Key Words: Endometrial Carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To evaluate the response of advanced or recurrent endometrial carcinoma to oral progestins in patients who have received no prior hormonal therapy.

To compare a combination of adriamycin and cyclophosphamide to adriamycin alone as therapy for advanced or recurrent endometrial carcinoma which no longer responds to or has failed to respond to progestins in patients who have received no prior cytotoxic drugs.

Technical Approach: To be eligible for entry on this study, all patients must have documented primary Stage III, primary Stage IV, recurrent or residual endometrial adenocarcinoma, adenoacanthoma or adenosquamous carcinoma. Those patients with positive cytology as evidence of spread are eligible as non-measurable disease cases.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 9 Feb 81	Proj No: 7601	Status: Ongoing
TITLE: Ovarian Cancer Study Group Protocol for Selected Stage IA1 - IB1 Ovarian Cancer (Well and Moderately Differentiated).		
Start Date: FY 79	Est Comp Date: Unknown	
Principal Investigator Milton H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center	
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:	
Key Words: Ovarian cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
Objectives: To define the natural history (relapse rate, relapse site, relapse free survival) of patients treated by surgery alone.		

To determine whether prophylactic, adjuvant chemotherapy with melphalan alters the natural history.

To study the effect of various potential prognostic factors (stratification factors) on the natural history of patients treated by each form of therapy.

To determine the patterns of relapse for each form of therapy.

To establish the value of various staging parameters on the stage of disease and its natural history.

Technical Approach: All eligible patients must have a histopathologic diagnosis of common epithelial ovarian cancer of one of the following types: serous, mucinous, and those listed in Appendix I of the protocol. After definitive staging procedures, the patient is a selective Stage IA1 or IB1 (Stage I-C excluded), and whose histological grade is well or moderately differentiated.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available.

Detail Summary Sheet

Date: 9 Feb 81 Proj No: 7602 Status: Ongoing

TITLE:

Ovarian Cancer Study Group Protocol for All Stage IC and II (A,B,C) and Selected Stage IAii and IBii Ovarian Cancer.

Start Date: FY 79	Est Comp Date: Unknown
Principal Investigator Miltch H. Leman, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Ovarian cancer	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue
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Objectives; To define the natural history (relapse rate, relapse sites, relapse free survival, regression rate, duration of regression) of patients treated by surgery plus either chemotherapy or chemotherapy plus radiation therapy.

To study the effect of various potential prognostic factors (stratification factors) on the natural history of patients treated by each form of therapy.

To determine the patterns of relapse for each form of therapy.

To establish the value of various staging parameters on the stage of disease and its natural history.

Technical Approach: All eligible patients must have a histopathologic diagnosis of common epithelial ovarian cancer of one of the following types: serous, mucinous or one of the types identified in Appendix I of the study protocol. After a definitive staging procedure, if the patient is Stage II-A, II-B, II-C, I-Aii, I-Bii, or I-Ai or I-Bi with poorly differentiated tumors, she is eligible for this study. The patient must have had no previous treatment except surgical therapy.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

APPENDIX C

Polycythemia Vera Study Group

Detail Summary Sheet

Date: 6 Feb 81 Proj No: PVSG-5 Status: Ongoing

TITLE:

Treatment of Thrombosis in Patients with Polycythemia Vera.

Start Date: FY 79		Est Comp Date:
Principal Investigator		Facility
Ray O. Lundy, M.D., LTC, MC		Brooke Army Medical Center
Dept/Sec:		Associate Investigators:
Department of Medicine/Hematology		Glenn M. Mills, M.D., MAJ, MC
Key Words:		
Polycythemia Vera		
Thrombosis		
Accumulative MEDCASE	Est Accumulative	Periodic
Cost:	OMA Cost:	Review Results: Continue

Objective: To determine whether phlebotomy in conjunction with antiaggregating agents can decrease the frequency of thrombotic complications in patients with PV to the level in patients treated with 32P.

Technical Approach: Only those patients who have well-documented, active polycythemia vera, as demonstrated by rigorous diagnostic studies designed to eliminate spurious (stress) polycythemia, anoxic erythrocytosis, or erythrocytosis secondary to increased erythropoietin, or erythrocytosis without additional evidence of myeloproliferative disease either past or present, will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been slow; however, the study remains open.

Detail Summary Sheet

Date: 6 Feb 81 Proj No: PVSG-6 Status: Terminated
TITLE:

Treatment of Acute Leukemia Preceded by Polycythemia Vera.

Start Date: FY 79	Est Comp Date:
Principal Investigator	Facility
Ray O. Lundy, M.D., LTC, MC	Brooke Army Medical Center
Dept/Sec:	Associate Investigators:
Department of Medicine/Hematology	Glenn M. Mills, M.D., MAJ, MC
Key Words:	
Polycythemia vera	
Acute leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objectives: To determine the characteristics of the leukemic transformation in polycythemia vera.

To determine what fraction of patients with this disorder will respond to vincristine and prednisone chemotherapy.

To determine if chemotherapy, designed for patients with acute myeloblastic leukemia, is useful in the treatment of leukemic transformation.

Technical Approach: Only those patients who have well-documented polycythemia vera as demonstrated by rigorous diagnostic studies, as described in the protocol, will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: The study was terminated because of revisions of study.

Detail Summary Sheet

Date: 6 Feb 81 Proj No: PVSG-7 Status: Completed

TITLE:

Phase II Efficacy Trial Using POTABA in Treatment of Postpolycythemia and Agnogenic Myeloid Metaplasia.

Start Date: FY 79	Est Comp Date:
Principal Investigator Ray O. Lundy, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Agnogenic myeloid metaplasia Postpolycythemia myeloid metaplasia Potaba	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To determine by bone marrow section examination whether Potaba has any antifibrosing action in patients with PPMM and AMM.

Technical Approach: All asymptomatic patients with PPMM and AMM as defined in the study protocol are eligible. Patients with AMM or PPMM who have had previous chemotherapy or androgens or steroids will be eligible for the study providing (1) they have been off chemotherapy for a period of at least two months; (2) they have been off prednisone or androgens for a period of at least one month.

Therapy will follow the schema outlined in the study protocol.

Progress: POTABA did not influence marrow fibrosis.

Detail Summary Sheet

Date: 6 Feb 81 Proj No: PVSG-8 Status: Ongoing
 TITLE:

Efficacy Trial Using Hydroxyurea (HU) in Polycythemia Vera.

Start Date: FY 79	Est Comp Date:
Principal Investigator Ray O. Lundy, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Polycythemia vera Hydroxyurea	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To evaluate the efficacy of HU in patients of all ages with polycythemia vera who have active disease and to assess the influence of HU upon the symptoms and signs of active disease and upon the abnormal hematological and biochemical manifestations of the panmyelosis that characterize this condition.

Technical Approach: Only those patients who have well-documented, active polycythemia vera, as demonstrated by rigorous diagnostic studies designed to eliminate spurious (stress) polycythemia, anoxic erythrocytosis, or erythrocytosis secondary to increased erythropoietin, or erythrocytosis without additional evidence of myeloproliferative disease either past or present, will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been slow. No reportable data are available at this time.

Detail Summary Sheet

Date: 6 Feb 81 Proj No: PVSG 9 Status: Terminated

TITLE:

Complications of Splenomegaly in Myeloproliferative Disease.

Start Date: FY 79		Est Comp Date:
Principal Investigator		Facility
Ray O. Lundy, M.D., LTC, MC		Brooke Army Medical Center
Dept/Sec:		Associate Investigators:
Department of Medicine/Hematology		Glenn M. Mills, M.D., MAJ, MC
Key Words:		
Myeloproliferative disorder		
Splenomegaly		
Accumulative MEDCASE	Est Accumulative	Periodic
Cost:	OMA Cost:	Review Results:

Objectives: To determine the effects of a short course of high dose prednisone on the hemolytic process associated with splenomegaly in myeloproliferative disorders.

To determine, in those patients whose hemolytic anemia is refractory to prednisone therapy, in a prospective randomized trial, the value of splenectomy vs alkylating agents.

To study the effects of high dose prednisone on thrombocytopenia in patients with myeloproliferative disorders.

To determine, in those patients whose thrombocytopenia is refractory to prednisone therapy, in a prospective randomized trial, the value of splenectomy vs supportive care alone.

To study the effects of a short course of high dose prednisone on the pain and mechanical discomfort caused by an enlarged spleen.

To determine, in those patients whose pain and mechanical discomfort is refractory to prednisone therapy, in a prospective randomized trial, the results of splenectomy vs those of alkylating agents.

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

Progress: This study was terminated due to poor patient accrual.

Detail Summary Sheet

Date: 9 Feb 81 Proj No: PVSG-10 Status: Terminated

TITLE:

Thrombosis in Myeloproliferative Disease Other Than Polycythemia Vera.

Start Date: FY 79		Est Comp Date:
Principal Investigator Ray O. Lundy, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology		Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Myeloproliferative disease Thrombosis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To prevent and control the symptoms of bleeding and thrombosis associated with (1) the clinical entity, primary thrombocytopenia, (2) those patients with myelofibrosis-myeloid metaplasia with elevated platelet counts, and (3) those patients with classified myeloproliferative disease with elevated platelet counts.

Technical Approach: Those patients with the entity - primary thrombocytopenia, myelofibrosis, myelosclerosis and unclassifiable myeloproliferative disease shall be eligible for randomization between ³²P and Alkeran provided they meet the requirements outlined in the study protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: Therapy with Alkeran was to continue for one year only. Therefore, the study was terminated.

Detail Summary Sheet

Date: 9 Feb 81 Proj No: PVSG-11 Status: Terminated
 TITLE:

Anemias with or without Cytopenia in Myeloproliferative Disease.

Start Date: FY 79	Est Comp Date:
Principal Investigator Ray O. Lundy, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Myeloproliferative disease Cytopenia Anemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To evaluate the use of high dose androgens both orally and parenterally in a randomized clinical trial in patients with myeloproliferative disease whose primary problem is a resistant anemia, and in some instances, is associated with single or multiple cytopenia.

Technical Approach: All patients with a myeloproliferative disorder with anemia who are unresponsive to iron, B₁₂, folate and/or pyridoxine will be eligible for this study. All previously untreated patients will be eligible provided they are symptomatic and meet the criteria outlined in the study protocol.

All patients will be randomized between oral androgen and intramuscular androgen as outlined in the study protocol.

Progress: This study was terminated because of poor patient accrual.

Detail Summary Sheet

Date: 9 Feb 81 Proj No: PVSG-12 Status: Ongoing

TITLE:

Hydroxyurea in Thrombosis.

Start Date: FY 80	Est Comp Date:
Principal Investigator Ray O. Lundy, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Thrombocytopenia Myelofibrosis-myeloid metaplasia Myeloproliferative disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To evaluate the efficacy of hydroxyurea in preventing and controlling the symptoms of thrombosis and bleeding with 1) the clinical entity primary thrombocytopenia, 2) those patients with myelofibrosis-myeloid metaplasia with elevated platelet counts, and 3) those patients with unclassified myeloproliferative disease with elevated platelet counts.

Technical Approach: In order to be eligible for entry on this study, the patient must meet the following criteria: 1) Absence of Philadelphia chromosome, 2) Absence of an increased red cell mass, 3) bone marrow which shows marked megakaryocytic hyperplasia and abundant platelet clumps, 4) Thrombosis not secondary to some identifiable cause, i.e., infection, cancer etc., and 5) Patient must not have had a pre-existing cancer, other than skin cancer.

Therapy will follow the schema outlined in the study protocol.

Progress: Hydroxyurea continues to appear to be quite efficacious in reducing platelet counts in patients with myeloproliferative disease and thrombocytosis.

Detail Summary Sheet

Date: 9 Feb 81 Proj No: PVSG-13 Status: Ongoing
TITLE:

Study of the Clinical Features and Natural History of Asymptomatic Patients with Myeloproliferative Disorders.

Start Date: FY 79	Est Comp Date:
Principal Investigator Ray O. Lundy, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Myeloproliferative disorder	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:
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Objectives: To obtain a clinical and laboratory data base on patients with myeloproliferative disorders prior to the time they require treatment under other MPD protocols.

To define the natural course of the disease as to the development of:
a) splenomegaly, b) progressive fibrosis, c) leukemic conversion, d) thrombo-embolic complications, and e) other neoplasm.

To demonstrate the development of cytogenetic and pathologic abnormalities in bone marrow and peripheral blood.

To establish predictors of a more symptomatic stage of the disease.

Technical Approach: All newly diagnosed (less than one year), previously untreated patients (including patients transfused for a period of less than three months) considered to have one of the myeloproliferative disorders outlined in the protocol are eligible.

Progress: Data continues to be collected for analysis.

Detail Summary Sheet

Date: 9 Feb 81	Proj No: PVSG-14	Status: Terminated
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TITLE:

Efficacy Trial Using Cimetidine for Pruritus in Polycythemia Vera.

Start Date: FY 79	Est Comp Date:
Principal Investigator Ray O. Lundy, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Hematology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Polycythemia vera Pruritus Cimetidine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results:

Objective: To determine whether H₂ antagonists are efficacious in alleviating the pruritus of polycythemia vera.

Technical Approach: Only those patients who have well-documented, active polycythemia vera, as demonstrated by diagnostic studies designed to eliminate spurious (stress) polycythemia, anoxic erythrocytosis, or erythrocytosis secondary to increased erythropoietin, or erythrocytosis without additional evidence of myeloproliferative disease either past or present, will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was terminated because cimetidine alone has not significantly controlled the pruritus in polycythemia vera.

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