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BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON TX
J H ANDERSON 01 OCT 82

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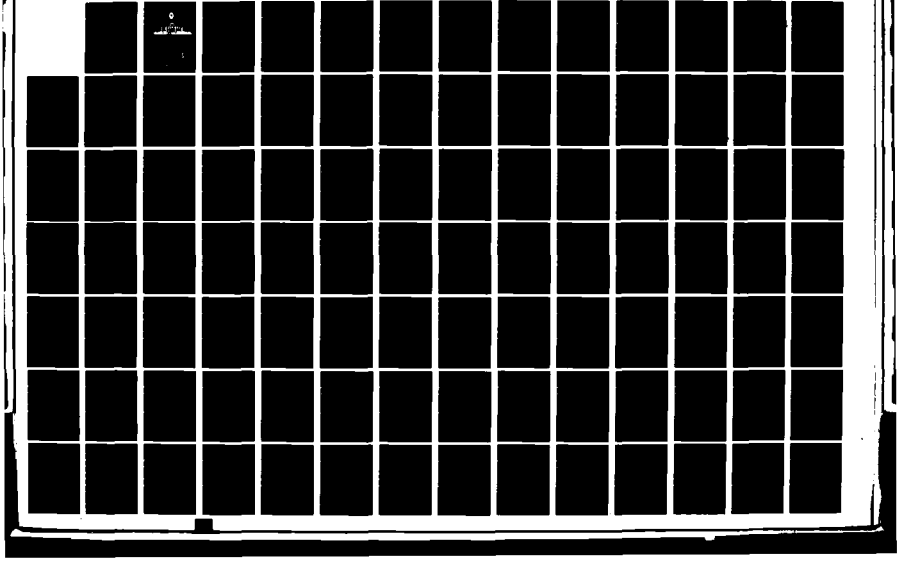

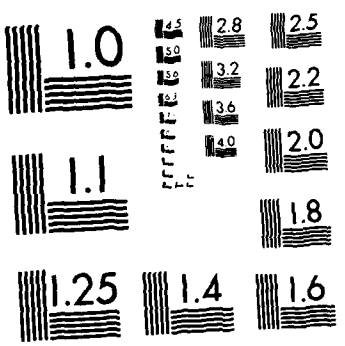

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ANNUAL RESEARCH PROGRESS REPORT

FISCAL YEAR 1982

BROOKE ARMY MEDICAL CENTER
FORT SAM HOUSTON, TEXAS 78234

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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. (Cont. on reverse side)		
20. ABSTRACT *(Continue on reverse side if necessary and identify by block number)* Subject report identified the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee, the Human Use Committee, and the Laboratory Animal Use Committee and registered with the Department of Clinical Investigations during Fiscal Year 1982. Report also includes known presentations and publications by the Brooke Army Medical Center staff. The research protocols described were conducted under the provisions of ar 40-38, as amended, Clinical (continued on reverse side)		

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Block 19. Key Words

Southwest Oncology Group
Gynecology Oncology Group
Polycythemia Vera Study Group
Pediatric Oncology Group

Block 20. Abstract

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

FOREWORD

> "Then you should say what you mean," the March Hare went on. "I do," Alice hastily replied; "at least - at least I mean what I say - that's the same thing, you know."
>
> "Not the same thing a bit!" said the Hatter. "Why, you might just as well say that 'I see what I eat' is the same thing as 'I eat what I see'!" (Carroll, L., Alice's Adventures in Wonderland, 1865)

The "meaning" of a word, a concept, or a discipline is not absolute but relative to the context (or environment) in which it is defined. Consider oxygen for example. Who discovered oxygen? While Boyle was given credit for formalizing in 1661 the Greek concept of elements, Joseph Priestley is generally given credit for the discovery of oxygen in 1774 by heating metal oxides. However, Priestley (in his context of understanding) thought he had discovered phlogiston free gas. A century later, Lavoisier named oxygen and proposed a role for it in respiration and combustion as an acid former. Neither of these scientists really discovered oxygen as defined by our present day context.

The value of Clinical Investigation as a department or a method must be judged by its relationship to the military medical community and the larger population which it serves. Isolated and minimally nurtured it might produce some scientific research, perhaps even good research. This product would be of little benefit except to the proverbial "bean counters".

Clinical Investigation must be involved throughout the medical center as part of the context in which the medical center defines it's missions and accomplishments. As a formalization of intellectual curiosity, clinical investigation must be a part of the medical staff to germinate, a part of the administrative staff to survive and a part of the patient population to blossom.

As we succeed in increasing patient education as a vital part of health care, we must impart to patients the value of clinical investigation as a guide for our common curiosity. To ignore this segment of the medical community fosters a trap characterized by Trevelyan,

> "Education. . . has produced a vast population able to read but unable to distinguish what is worth reading." (Trevelyan, G. M., Grey of Fallodon, 1937)

Brooke Army Medical Center has been fortunate in having a command leadership that is supportive of clinical investigations. There has been a continued growth in the number of active protocols (as well as their quality), the number of publications and presentations, and facilities, especially the new Laboratory Animal Research and Training Center. The real credit for the work presented in this volume belongs to the clinical investigators (from principal investigators to laboratory technicians) who have devoted their time and talents to increasing medical knowledge and quality of care. Equally important are the patient

volunteers who freely consented, sometimes without direct benefit to themselves to participate in gathering new knowledge and providing a base for improved patient care.

JAMES H. ANDERSON, JR., M.D.
Lieutenant Colonel, MC
Chief, Department of Clinical Investigation

UNIT SUMMARY - FISCAL YEAR 1982

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.

3. Staffing

Name	Rank	MOS	Title
Anderson, James H., Jr.	LTC	61C00	Chief, Endocrinologist
Pedersen, Carl E., Jr.*	LTC	68A9B	Laboratory Director/Virologist
Burleson, David G.**	MAJ	68C00	Laboratory Director/Biochemist
Lieberman, Michael M.	CPT	68A00	Microbiologist
Madonna, Gary S.**	CPT	68A00	Microbiologist
Merrill, Gerald A.***	CPT	68A00	Microbiologist
Quagliani, Joseph G.***	1LT	68J00	Biomedical Information Off.
Loyd, Charles M.	SFC	92B3R	Sr Med Lab Sp, NCOIC
Sinegal, John H.	SSG	92B2R	Med Lab Sp
Diaz, Noel	SSG	92B2R	Med Lab Sp
Kelly, Jack L.	SP5	92B1R	Med Lab Sp
Lipp, Gary	SP5	91T20	Animal Care Sp
Mead, Michael	SP4	92B1R	Med Lab Sp

* Assigned 15 Sep 82
** Reassigned 15 Oct 82
***REFRAD

C. Staffing (continued)

Name	Rank	MOS	Title
		91T10	Animal Care Sp
		92B1R	Med Lab Sp
	GS12	00401	Research Immunologist
	GS11	00334	Computer Sp
Ayala, Eleanor F.	GS9	00644	Medical Technologist
Peek, Michael W.	GS9	01320	Chemist
Vaughn, George K.	GS9	00404	Biological Technician
Chapa, Isidoro	GS7	00645	Medical Technician
Esposito, Margaret	GS7	00645	Medical Technician
Wolcott, Karen	GS7	00404	Biological Technician
Rios, Roberto	GS9	01020	Medical Scientific Illustrator
Bratten, Dodie	GS9	00301	Clin Research Protocol Coord
Smith, Helen K.	GS6	01087	Editorial Assistant

D. Funding

Type	Fiscal Year 81	Fiscal Year 82
Civilian personnel to include benefits	60,074.00	136,238.00
Consumable supplies	120,891.00	199,343.00
Civilian contracts to include consultants	14,408.70	16,381.00
TDY	13,265.00	12,452.00
Publications	4,665.00	3,511.00
Noninvestment equipment (Minor MEDCASE)	55,078.38	20,323.00
Other OMA		
OMA Total	268,382.08	388,248.00
MEDCASE	151,381.42	178,069.00
Other		
Military	279,317.00	311,217.00
TOTAL	699,080.50	877,534.00

E. Progress

Protocol Disposition FY 82

	Terminated	Transferred	Completed	Ongoing to FY 83
FY 74	-	-	1	0
FY 75	-	-	1	0
FY 77	-	-	2	1
FY 78*	-	-	1	2
FY 79	-	-	3	3
FY 80	3	-	4	5
FY 81*	13	-	11	28
FY 82	6		16	45
	22	-	39	84

*C-22-78 and C-16-81 were completed during FY 81.

Group Protocol Disposition FY 82

	Terminated	Completed	Ongoing to FY 83
SWOG	7	15	70
GOG	1	-	27
PVSG	-	-	3
POG	-	-	17
	8	15	117

F. Problems.

Again this year principal problem areas are concerned with personnel assets and adequate facilities for laboratory animal studies. While this Department currently has 28 recognized requirements and 22 validated authorizations, an average annual strength of only 17 were assigned to Clinical Investigation during the previous year. The critical shortage of enlisted Medical Laboratory Specialists (92B) has hampered support to many approved BAMC protocols and only one Animal Care Specialist (91T) has been assigned to provide support for approved protocols requiring laboratory animals. Only very recently has a Veterinary Officer been detailed to this Department to oversee animal support activities. This demonstrated shortfall comes at a time when a minor construction project for housing laboratory animals has been formulated and forwarded to the BAMC staff engineers for renovation of the laboratory animal facility. In order to meet the American Association for Accreditation of Laboratory Animal Care (AAALAC) standards, the facility unit must be upgraded as expeditiously as possible and appropriate staffing must beeffected.

The generic issue of in-house "critical mass" for support of BAMC Clinical Investigation will be addressed in the forthcoming manpower survey. In order to function with any real credibility, this Department must be staffed with an appropriate cross-section of qualified scientists and support personnel.

Military Allied Scientists should be at least field grade officers, with a PhD in their discipline, have demonstrated bench level experience and hold the 9B ASI. The assigned nucleus of expertise required includes Microbiology (one Bacteriologist and one Virologist), Biochemistry, Immunology (cellular and humoral aspects), and whole system Physiology. Without these skills, the Clinical Investigation staff cannot effectively interact with other BAMC resources in sophisticated technological subspecialties required for a comprehensive training and research program meeting JCAH standards.

TABLE OF CONTENTS

Appendix B
Gynecology Oncology Group

Code:

C - Completed
O - Ongoing
T - Terminated

P - Published
PR - Presentation

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

PUBLICATIONS

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DEPARTMENT OF PEDIATRICS

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DEPARTMENT OF THE ARMY
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DEPARTMENT OF CLINICAL INVESTIGATION

PRESENTATIONS

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Cardiology Service

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Kraus, E.W. Interesting case presentations from Brooke Army Medical Center Dermatology Service. James C. White Club Special Clinical Seminar, Harvard Medical School Department of Dermatology, Massachusetts General Hospital, Boston, MA, 30 Apr 1982.

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Endocrinology Service

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Gastroenterology Service

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Hematology-Oncology Service

Cowan, J.D. Predictive value of trypan blue exclusion cell viability measured on colony formation in a human tumor cloning assay. Third Conference on Human Tumor Cloning, Tucson, AZ, Jan 1982.

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Carpenter, J.L. Drug resistant Mycobacterium tuberculosis in Korean isolates. 21ths Meeting of the Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, IL, Nov 1981.

Internal Medicine

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Nephrology Service

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Neurology Service

McFarling, D.A. The management of intracerebral hematomas. Society of Clinical Neurology, Lake George, NY, Oct 1981.

Conomy, J.P., Hanson, M.R., McFarling, D.A. Does migraine increase the risk of cerebral ischemic events in persons with mitral valve prolapse? American Neurological Association, Washington, D.C., Sep 1982.

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Sullivan, J.P. Asthma. Physician Assistant Course, San Antonio, TX, 16 Nov 1981.

Richey, H.M. Pleurisy and atelectasis. Physician Assistant Course, San Antonio, TX, 25 Nov 1981.

Matthews, J.I. Chronic lung disease and RB. Physician Assistant Course, San Antonio, 1981.

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Fetters, L.J. Methacholine challenge testing in the diagnosis of asthma. Carl W. Tempel Symposium on Pulmonary Disease and Allergy, Fitzsimons Army Medical Center, 25 Jan 1982.

Bruno, P.P. Esophageal perforation presenting as a pleural effusion. Carl W. Tempel Symposium on Pulmonary Disease and Allergy, Fitzsimons Army Medical Center, 26 Jan 1982.

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DEPARTMENT OF PATHOLOGY

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Bell, J. Clinical laboratory support in Army field medical facilities. Seventh Annual Meeting of the Society of Armed Forces Medical Laboratory Scientists, Reno, NV, 22 Mar 1982.

Joyce, R.P. Arteriographic dye [illegible]: A highly reliable radiological indicator of carotid artery ulcerations associated with cerebrovascular embolization - pathologic correlation. Texas Medical Association Exhibit, San Antonio, TX, 5-7 May 1982.

Joyce, R.P. Esthesioneuroblastoma. San Antonio Society of Pathologists, San Antonio, TX, 14 Sep 1982.

Alexander, H.G., Jr. Pleomorphic renal oncocytoma. San Antonio Society of Pathologists, San Antonio, TX, 14 Sep 1982.

Poston, W.K., Jr. Leiomyomatosis peritonealis disseminata. San Antonio Society of Pathologists, San Antonio, TX, 14 Sep 1982.

Ortiz, R. Alveolar soft part sarcoma. San Antonio Society of Pathologists, San Antonio, TX, 14 Sep 1982.

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Broussard, I.D. Pancreatic islet cell tumor, Beta cell type. San Antonio Society of Pathologists, San Antonio, TX, 14 Sep 1982.

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DEPARTMENT OF PSYCHIATRY

Gaupp, P.A. Split brain learning theories. 1982 Dietetic Faculties Course, Dietetic Section, Beach Pavilion, Fort Sam Houston, TX, 10 Jun 1982.

Cohen, A. Attentional deficits in chronic schizophrenia. American Psychological Association, Washington, D.C., 25 Aug 1982.

DEPARTMENT OF RADIOLOGY

Bunker, S.R. Advantages of in vitro labeled Tc-99m red blood cells in the detection of gastrointestinal bleeding sites. Plenary Session, Western Regional Meeting, Society of Nuclear Medicine, San Francisco, CA, Oct 1981.

Bunker, S.R. The role of Fourier phase analysis in gated equilibrium blood pool studies. Medical Data Systems Users' Meeting, Western Regional Meeting, Society of Nuclear Medicine, San Francisco, CA, Oct 1982.

Bunker, S.R. Scintigraphic methods for the detection and localization of gastrointestinal hemorrhage: Advantages of in vitro labeled Tc-99m red blood cells. Southwestern Chapter Meeting, Society of Nuclear Medicine, Dallas, TX, Mar 1982.

Telepak, R.J. Computer edge displays for cardiac wall motion evaluation. Southwestern Chapter Meeting, Society of Nuclear Medicine, Dallas, TX, Mar 1982.

Hartshorne, M.F. Utility of non-cardiac Fourier phase analysis. Medical Data Systems Users' Meeting, Dallas, TX, Mar 1982.

Janaki, L.M. Carcinoma of pancreas. Southwest Oncology Group Meeting, Houston, TX, 3-5 Mar 1982.

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Bunker, S.R. Fourier phase analysis. Medical Data Systems Users' Annual Meeting, Miami Beach, FL, Jun 1982.

Blatt, E.S. Participant in the Aberdeen Area Indian Health Hospital System Radiology Symposium, Rapid City, SD, 23 and 25 Jul 1982.

McNeill, D.H., Jr. CT of sacroiliac arthritis. Exhibit at Rocky Mountain Radiological Society Meeting, Denver, CO, 19-21 Aug 1982.

Brown, C.W. Introduction to CT scanning. Val Verde County Medical Society, 17 Sep 1982.

Huggins, M.J. Seminar in uroradiology with emphasis on pathologic correlation. Armed Forces Institute of Pathology, Washington, D.C., 20-24 Sep 1982.

DEPARTMENT OF SURGERY

Anesthesia and Operative Service

Isenhower, N.N. Hespan. 88th Annual AMSUS, San Antonio, TX, 2-3 Nov 1981.

Isenhower, N.N. Hespan. Toronto, Ontario, Canada, 10-12 Feb 1982.

Middaugh, R.E. Arterial blood gas interpretation. Seminar for Intensive Care Nurses, Santa Rosa Hospital, San Antonio, TX, 23 Jul 1982.

Middaugh, R.C. Post CPR management. Texas Society of Anesthesiologists, El Paso, TX, 18-19 Sep 1982.

Cardiothoracic Surgery Service

Collins, G.J., Jr. Mycotic aneurysms. Ninth Annual Meeting of Military Vascular Surgeons, Bethesda, MD, Dec 1981.

Mueller, L.P., Peake, J.B. Update on coronary artery disease. 38th Parallel Medical Society, US Army, 8th MEDCOM (Prov) Medical Seminar, Seoul, Korea, 14-16 Apr 1982.

Peake, J.B. Long term follow-up in operated patients and a new case report. Army Cardiology Conference, Denver , CO, 21 May 1982.

Collins, G.L., Jr. Co-existent cardiac and cerebrovascular insufficiency. Army Cardiology Conference, Denver, CO, 21 May 1982.

Collins, G.L., Jr. Cerebrovascular insufficiency: Medical and Surgical Management, Triple Army Medical Center, Jul 1982.

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General Surgery Service

Spebar, M.J. Trauma, the surgeon and nuclear war. Grand Rounds, Department of Surgery, University of Texas Health Science Center at San Antonio, San Antonio, TX, 9 Oct 1982.

Spebar, M.J. Adjuvant hyperbaric oxygen in the management of fungal burn wound sepsis. Annual Meeting of Undersea Medical Society-Gulf of Mexico Chapter, New Orleans, LA, 19-20 Mar 1982.

Briggs, R.M. Cystosarcoma phylloides - The military experience. Gary P. Wratten Surgical Symposium, Washington, D.C., 27-30 Apr 1982.

Gomez, E.R. Gastric carcinoma in young adults. Southwestern Surgical Congress, Coronado, CA, 26-29 Apr 1982.

Spebar, M.J. Trauma, the surgeon and nuclear war. San Antonio Surgical Society, San Antonio, TX, 16 Mar 1982.

Spebar, M.J. Trauma, the surgeon and nuclear war. Trauma Seminar, Emergency Care Nurses and Technicians, Brooke Army Medical Center, 10 May 1982

Spebar, M.J. Improved survival with aggressive surgical management of non-candidal fungal investions of the turn wound. American Burn Association, Boston MA, 11-14 May 1982.

Walters, M.J. Occult breast carcinoma - its detection and treatment. Gary P. Wratten Surgical Symposium, Washington, D.C., 27-30 Apr 1982.

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Clary, R.M. Changing trends in colon carcinoma. Grand Rounds, Department of Surgery, University of Texas Health Science Center, San Antonio, TX, 21 May 1982

Rosenthal, D. Abdominal trauma - diagnosis and management. 38th Parallel Medical-Surgical Meeting, Seoul, Apr 1982.

Rosenthal, D. Common anorectal problems. 38th Parallel Medical Society, Seoul, Apr 1982.

Spebar, M.J. Trauma, the surgeon and nuclear war. Distinguished Visiting Professor Series, Uniformed Services University of the Health Sciences, Bethesda, MD, 27 Aug 1982.

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Neurological Surgery Service

Gendell, H.M. Brooke formula for management of head injuries. Southern Neurosurgical Society, Hot Springs, W VA, Apr 1982.

Gendell, H.M. Brooke formula for management of head injuries. International Craniocerebral Trauma Symposium, University of Edinburgh, Scotland, Sep 1982.

Harris, R.D. Craniocerebral trauma and the autonomic nervous system: an alternative approach to therapy. International Craniocerebral Trauma Symposium, University of Edinburgh, Scotland, Sep 1982.

Ophthalmology Service

Coronado, T. Retinitis pigmentosa sine pigmento. Ophthalmology Conference, University of Texas Health Science Center, San Antonio, TX, 26-27 Apr 1982.

Brennan, M.W. Pediatric proptosis. Ophthalmology Conference, University of Texas Health Science Center, San Antonio, TX, 26-27 Apr 1982.

Mauldin, W.M. Corneal lye injury. Ophthalmology Conference, University of Texas Health Science Center, San Antonio, TX, 26-27 Apr 1982.

Gearhart, J.R. Effects of nonionizing radiation on the eye. Ophthalmology Conference, University of Texas Health Science Center, San Antonio, TX, 26-27 Apr 1982.

Hollsten, D.A. The ICE syndrome. Ophthalmology Conference, University of Texas Health Science Center, San Antonio, TX, 26-27 Apr 1982.

San Martin, A.A. Ocular changes in myotonic dystrophy. Ophthalmology Conference, University of Texas Health Science Center, San Antonio, TX, 26-27 Apr 1982.

Board, R.J. Modern concepts of superior rectus surgery. Ophthalmology Conference, University of Texas Health Science Center, San Antonio, TX, 26 Apr 1982.

Board, R.J. Superior rectus surgery update. Walter Reed Biennial Ophthalmology Postgraduate Course, Washington, D.C., 27 Apr 1982.

Griffith, D.G. Spontaneous hyphema. Ophthalmology Conference, University of Texas Health Science Center, San Antonio, TX, 26 Apr 1982.

Griffith, D.G., Spontaneous hyphema. Walter Reed Biennial Ophthalmology Postgraduate Course, Washington, D.C., 27 Apr 1982.

Milne, H.L. Dysgerminoma of pituitary gland. Ophthalmology Conference, University of Texas Health Science Center, San Antonio, TX, 26-27 Apr 1982.

Davitt, W.F. Corneal ulcers--sometimes a diagnostic dilemma. Ophthalmology Conference, University of Texas Health Science Center, San Antonio, TX, 26-27 Apr 1982.

Zervas, J.P. Pseudoxanthoma elasticum with SRN. Ophthalmology Conference, University of Texas Health Science Center, San Antonio, TX, 26-27 Apr 1982.

Lloyd, W.C. Surgical considerations in the hemodialysis patient. Ophthalmology Conference, University of Texas Health Science Center, San Antonio, TX, 26-27 Apr 1982.

Orthopaedic Service

Thomas, S.R. Tara hip resurfacing experience at Brooke Army Medical Center. Western Orthopaedic Assoc., Portland, OR, 4-8 Oct 1981.

Dreher, G.F. Fracture of the talus - Experience at Brooke Army Medical Center. Southern Medical Assoc., New Orleans, LA, 15-18 Nov 81.

Thomas, S.R. Tomographic bone scans of the hip. Southern Medical Assoc., New Orleans, LA, 15-18 Nov 1981.

Dreher, G.F. Review of BAMC snake bite experience involving upper extremity, 1976-1980. Society of Military Orthopaedic Surgeons, Bethesda, MD, 6-10 Nov 1981.

Dreher, G.F. Fractures of the talus - experience at Brooke Army Medical Center. Society of Orthopaedic Military Surgeons, Bethesda, MD, 6-10 Nov 1981.

Nash, W.C. Review of surgical treatment of transchondral talar dome fractures. Society of Orthopaedic Military Surgeons, Bethesda, MD, 6-10 Nov 1981.

Faralli, V.J. The Brooke meniscectomy. Society of Orthopaedic Military Surgeons, Bethesda, MD, 6-10 Nov 1981.

Spires, T.D. Acute posterior cruciate ligament injuries. Society of Orthopaedic Military Surgeons, Bethesda, MD, 6-10 Nov 1981.

Baker, C.L. Acute posterolateral instability of the knee. Society of Orthopaedic Military Surgeons, bethesda, MD, 6-10 Nov 1981.

Peters, V.J. Sudeck atrophy. Biomechanics and Surgery of the Human Foot - 1981 Style, San Francisco, CA, 4-6 Dec 1981.

Baker, C.L. Knee problems in the female athlete. Annual Symposium on Sports Medicine, University of Texas Health Science Center, San Antonio, TX, 18-21 Jan 1982.

Thomas, S.R. Tomographic bone scans of the hip. American Academy of Orthopaedic Surgeons, New Orleans, LA, 21 Jan 1982.

Peters, V.J. Podiatry in general for the family practice physician. Texas Academy of Family Physicians, San Antonio, TX, 20 Feb 1982

Peters, V.J. The runner and biomechanics. Texas Academy of Family Physicians, San Antonio, TX, 20 Feb 1982.

Peters, V.J. Use of peripheral catheters in treatment of reflex sympathetic dystrophy of the lower extremity. Podiatry Seminar, Madigan Army Medical Center, Tacoma, WA, 22-26 Mar 1982.

Peters, V.J. CT scans and their application in the foot. Podiatry Seminar, Madigan Army Medical Center, Tacoma, WA, 22-26- Mar 1982.

Hawkes, T.A. Bone scanning in Legg-Perthes disease. Annual Michael Hoke-Hiran Kite Program, Scottish Rite Hospital, Atlanta, GA, 23-24 Apr 1982.

Thomas, S.R. Tomographic bone scans of the hip. Traveling Fellows, University of Texas Health Science Center, San Antonio, TX, 14 May 1982.

Urology Service

Bryant, K.R. Infantile retroperitoneal fibrosarcoma. James C. Kimbrough Urological Seminar, Fitzsimons Army Medical Center, 16-20 Nov 1981.

Mora, R. Vasectomy revisited: open-ended cutaneous vasostomy. James C. Kimbrough Urological Seminar, Fitzsimons Army Medical Center, 16-20 Nov 1981. (C)

Spence, C.R. Winter bladder neck suspension for stress urinary incontinence. James C. Kimbrough Urological Seminar, Fitzsimons Army Medical Center, 16-20 Nov 1981.

Wikert, G.A. Evaluation of the coagulation and fibrinolytic systems in patients undergoing TURP. James C. Kimbrough Urological Seminar, Fitzsimons Army Medical Center, 26-20 Nov 1981. Won second prize in resident competition. (C)

Mora, R.V. Vasectomy revisited: open-ended cutaneous vasostomy. 20th Annual Meeting of the Society of Urology Residents, St. Louis, MO, 12-15 May 1982. (C)

Wikert, G.A. Evaluation of coagulation and fibrinolytic systems in patients undergoing TURP. 20th Annual Meeting of the Society of University Urology Residents, St. Louis, MO, 12-15 May 1982. (C)

Gangai, M.P. Unusual incomplete triplication of the ureter. T. Leon Howard Hour, South Central Section AUA, 14 Sep 1982. Won 1st prize.

PHARMACY SERVICE

Rembold, J. Pharmacy discharge consultations. 88th Annual Meeting of the Association of Military Surgeons of the United States, San Antonio, TX, 3 Nov 1981.

Sikora, R.G. Planning and implementing a mobile decentralized unit dose system. 88th Annual Meeting of the Association of Military Surgeons of the United States, San Antonio, TX, 3 Nov 1981.

PHYSICAL AND REHABILITATION SERVICE

Riggan, J. Work-play skill development for learning disabled children. Texas Association for Children with Learning Disabilities, Lubbock, TX, 12-13 Nov 1982.

Riggan, J. Remediation for the learning disabled student/soldier. Exhibit at Association for Children with Learning Disabilities, Chicago, IL, 3-6 Mar 1982. (C)

Cunningham, D.D. Remediation for the learning disabled student/soldier. Exhibit at American Occupational Therapy Association, Philadelphia, PA, 10-14 May 1982. (C)

VETERINARY LABORATORY SERVICE

Keefe, T.J. Veterinary laboratory progress. 30th International Veterinary Medical Training Conference, Berchtesgaden, Germany, 2 Oct 1981.

Keefe, T.J. Leptospirosis. Eastern Regional Veterinary Conference, Augusta, GA, 27 Mar 1982.

Keefe, T.J. Veterinary laboratory support to Panama on leptospirosis. Walter Reed Institute of Research, Washington, D.C., May 1982.

Gray, M.R. Leptospirosis among military personnel training in Panama. American Leptospirosis Research Conference, University of MA, Amherst, MA, 16-17 Aug 1982.

BROOKE ARMY MEDICAL CENTER

DETAIL SUMMARY SHEETS

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-25-78	Status: Completed

TITLE:

Determination of Opsonizing Antibody in People Receiving Polyvalent Pneumococcal Vaccine

Start Date 30 May 78		Est Comp Date:
Principal Investigator Robert C. Allen, M.D., Ph.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Clinical Investigation		Associate Investigators:
Key Words: Pneumococcal vaccine Antibodies Opsonification Streptococcus species		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $1808	Periodic Review Results:

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® MSD). These sera are being tested for opsonic activity directed against a number of serotypes of Streptococcus pneumoniae as well as other streptococcal species. A highly sensitive chemiluminescent assay has been developed for quantification of neutrophil (PMNL) leukocyte O_2-redox metabolism, and this technique is being applied to the quantification of the rate of opsonification for these sera.

Progress: A method for quantification of antigen-specific antibody opsonic capacity has been developed. The experimental approach is based on chemiluminigenic probing of stimulated granulocyte oxygenation activity. This approach allows measurement of the rate of antigen opsonification, and thus provides kinetic data not obtainable by conventional techniques. The method is highly sensitive requiring microliter quantities of serum, and does not require radioisotopes.

Detail Summary Sheet

Date: 1 Oct 82	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:
Principal Investigator Robert C. Allen, M.D., Ph.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Clinical Investigation		Associate Investigators: Deborah J. Hunter, SP5 Jack Kelly, SP5 Michael Meed, PFC
Key Words: Complement Immunoglobulin Chemiluminigenic probes Redox Metabolism		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $47,524	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. Luminol, 5-amino-2,3-dihydro-1,4-phthalazinedione, various substituted luminol derivatives, and lucigenin, 10,10'-dimethly-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 chemiluminigenic probes.

Progress: The chemilumingenic probe approach to the study of complement-mediated opsonic activity has been expanded through use of several different cyclic hydrazide probes that allow differential measurement of stimulated granulocyte oxygenation response. A titration method has been developed for mathematically describing the functional activity of the recognition components of both the classical and alternative pathways of complement. Circulating immune complexes can also be measured by a modification of this approach.

Use of different probes in combination with immune and chemical stimuli allows differentiation of the type and location of stimulated granulocyte oxygenation activities.

Detail Summary Sheet

Date: 1 Oct 82	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 84
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: $10,927	Periodic Review Results:

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 lymphocytes are separated on density gradients and further purified by fluorescent activated cell sorting. Cultures from these purified populations are subjected to lectin stimulation and the cultures extracted by acid precipitation at various time periods. Extracts are neutralized, dried over night and reconstituted for purification of cyclic nucleotides by high pressure liquid chromatography (HPLC). Purified extracts are measured by radioimmunoassay. Levels of cyclic AMP and cyclic GMP in stimulated cultures will be compared to unstimulated controls.

Progress: The necessary equipment (HPLC and FACS 400) is now on board to complete this study. A HPLC procedure for purification of cyclic AMP and GMP was worked out by two reserve officers on active duty for training. The FACS 400 is now operational. As soon as technical assistance is available, this study can proceed.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-26-79	Status: Completed

TITLE:

Studies on the Opsonization and Phagocytosis of Invasive and Non-invasive Shigella Species by Polymorphonuclear Leukocytes (PMNL).

Start Date: 6 Nov 79	Est Comp Date:
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. MAJ, MC Michael M. Lieberman, Ph.D. CPT, MSC
Key Words: Shigella sonnei Polymorphonuclear leukocytes (PMNL) Chemiluminescence (CL)	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $7611	Periodic Review Results:

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

Technical Approach: Target bacteria, luminol and source of opsonin were added to sterile, siliconized vials and centrifuged at 2400 x G for 10 min at 4°C. PMNL (Percoll separated) were then added to the vials, followed by recentrifugation at 350 x G for 5 min at 4°C. Chemiluminescence (CL), a product of luminol oxygenation, was then measured intermittently at 24°C over a 2 hr interval by single photon counting. Specimens were then diluted in sterile water, agitated and aliquots plated on solid media. Following overnight incubation, colony counts were performed and an index of bactericidal killing for each mixture calculated.

Progress: Polymorphonuclear leukocytes (PMNL) function by phagocytosing and killing opsonified bacteria. This PMNL-mediated bactericidal action is dependent upon the generation of oxygenating agents. Chemiluminigenic reaction (CL) provides an ultrasensitive method for continuous measurement of PMNL oxygenation activity and is based upon the measurement of luminescence resulting from oxygenation of high quantum yield substrates such as luminol.

The above described technique provides a sensitive method for assessment of serum opsonic capacity and under the conditions of testing, PMNL-oxygenation activity was found to correlate with bacterial killing.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-38-79	Status: Ongoing

TITLE: The Effect of Prostaglandin Synthesis Inhibitors on in vitro Suppressor Cell Activity in Lymphocytes from Patients with Common Variable Agammaglobulinemia.

Start Date Sep 79	Est Comp Date: Oct 83
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
Key Words: Agammaglobulinemia T-cell Suppressor	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $9,658	Periodic Review Results: Continue

Objectives: 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, patients with common variable agammaglobulinemia, or HPBL subjected to a suppressor cell stimulant are incubated in the presence of pokeweed mitogen and selected cultures in the presence of immunomodulating drugs. After six days of culture, the cells are harvested and plated on slides in agar. Immunoglobulin cells are detected using the reverse hemolytic plaque assay. Increased numbers of plaques indicate decreased lymphocyte suppressor activity. Plaque counts of normal patient and suppressor-normal patient cultures are compared to determine the presence of suppressor cell activity. Suppressed cultures incubated with immunomodulating drugs are evaluated for release from suppressor activity. An assay for measuring numbers of suppressor cells and suppressor activity is being developed on the FACS.

Progress: Progress has slowed on this project due to loss of technical help. When technical assistance is restored, this project can continue.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-4-80	Status: Ongoing

TITLE:

The Development of a Pseudomonas aeruginosa 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: Eleanor Ayala, DAC
Key Words: Pseudomonas aeruginosa Vaccine		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $10,927	Periodic Review Results:

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

Technical Approach: Ribosomal vaccines will be chemically and physically characterized and analyzed for cross reactions with outer membrane proteins. Outer membranes will be prepared from P. aeruginosa by sucrose density step gradient fractionation as well as other methods. Isolated membrane fractions will be analyzed serologically for cross reaction with ribosomes and ribosomal subunits dissociated by magnesium depletion. Preparation of ribosomal vaccines will be done as previously described.

Progress: Outer membranes were prepared from P. aeruginosa by sucrose density step gradient fractionation. The membrane fractions were analyzed for protein and 2-keto-3-deoxyoctulosonic acid (KDO), a marker specific for outer membranes. Material with a high ratio of KDO to protein was analyzed for a serological cross reaction with ribosomal vaccines and found to react with antiserum to such vaccines. Previous studies have also demonstrated a reaction between antiserum to ribosomal vaccines and a protein antigen on the bacterial cell surface. Ribonucleic acid (RNA) was isolated from purified ribosomes by sodium dodecyl sulfate extraction. This material will be used to determine if antiserum to the ribosomal vaccine contain antibodies directed against the RNA component of the ribosomes.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-4-81	Status: Ongoing

TITLE:

Chemiluminescence (CL) in Populations of Immunocompetent Cells.

Start Date 4 Feb 81		Est Comp Date: Dec 82
Principal Investigator David G. Burleson, Ph.D., MAJ, MSC		Facility Brooke Army Medical Center
Dept/Sec Department of Clinical Investigation		Associate Investigators: Robert C. Allen, M.D., Ph.D., MAJ, MC John H. Sinegal, SSG Jack Kelly, SP5
Key Words: Chemiluminescence Immunocompetent cells		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $5303	Periodic Review Results:

Objectives: To quantitate the oxidative metabolic response of stimulated populations of immunocompetent cells isolated from mouse or guinea pig spleen, thymus, liver, and lymph nodes using chemilumigenic probes.

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

Technical Approach: Peritoneal cells from guinea pigs injected IP with sodium caseinate are harvested at 7 days. Macrophages (MP) and polymorphonuclear leukocytes (PMNL) are separated after the harvested cells are subjected to density gradient centrifugation on Percoll. The purified cells are incubated with various chemical, lectin and phagocytic stimulants as well as various metabolic inhibitors and scavenger enzymes. The resulting oxygenation activity is measured by chemiluminigenic probe (CLP) technique. Luminol and DBA are used as CLP and the resulting chemiluminescence (CL) is measured in Beckman scintillation counters modified to be single photon counters.

Progress: The project is nearing completion. Oxygenation activity has distinctive characteristics that are unique for each stimulant and cell type employed. The inhibition of oxygenation activity by superoxide dismutase, catalase, and azide give unique patterns depending on the stimulant and cell type used.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-13-81	Status: Ongoing

TITLE:

Therapeutic Manipulation of Metabolic Endocrine Controls During Infection

Start Date 11 Mar 81	Est Comp Date: Aug 85
Principal Investigator James H. Anderson, Jr., M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Clinical Investigation	Associate Investigators: Gerald A. Merrill, CPT, MSC
Key Words: Metabolic endocrine controls Infection	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $3,404	Periodic Review Results: Continue

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

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

Progress: Continuation of this study at BAMC awaits completion of the laboratory animal facility.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-14-81	Status: Ongoing

TITLE:

Investigation of the Involvement of Endogenous Opiates in the Development of the Metabolic Pathophysiology of Infection and Endotoxin Shock

Start Date 11 Mar 81		Est Comp Date: Sep 83
Principal Investigator James H. Anderson, Jr., M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Clinical Investigation		Associate Investigators: Gerald A. Merrill,
Key Words: Endogenous opiates Endotoxin shock Metabolic pathophysiology		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $14,073	Periodic Review Results:

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

Technical Approach: Plasma β endorphin (β-EP), methionine enkephalin (MET-ENK), immunoreactive insulin (IRI) and glucose responses were measured over a 6 hour period in fasted, anesthetized dogs divided into groups given either (1) an LD_{70} dose of E. coli endotoxin, (2) endotoxin and glucose, (3) endotoxin, glucose and naloxone (infused continuously at a rate of 500 µg/kg/hr), (4) glucose and naloxone, or (5) glucose alone.

Progress: Plasma β-EP response was rapid with a two fold increase within 5 minutes of endotoxin administration plateauing at 270 min at 126 ± 27 pM/L (n = 11). β-EP response in animals given glucose alone remained basal while β-EP in the naloxone animals were consistently higher than basal after 120 min (16 ± 6 vs 38 ± 14 pM/L at 360 min). Plasma MET-ENK responses paralleled β-EP but lagged approximately 90 min. Naloxone alone did not induce an increase in MET ENK over basal values. Plasma IRI in dogs given endotoxin and glucose was 1935 ± 1027 µU/ml at 360 min. Naloxone treated dogs given endotoxin and 360 min of 198 ± 58 µU/ml, although IRI did not suppress to values seen in dogs given only glucose (46 ± 11 µU/ml). Interestingly in dogs given naloxone and glucose, IRI was stimulated to levels equivalent to the IRI values in endotoxin dogs treated with naloxone. In conclusion,

C-14-81 (continued)

naloxone clearly inhibits the marked IRI response suggesting a definite role of endogenous opiates in glucose induced hyperinsulinism in endotoxin shock. Additionally, naloxone itself appears to stimulate IRI release either directly or by blocking a tonic inhibitory mechanism.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-15-81	Status: Ongoing

TITLE:

Diabetogenicity of Venezuelan Equine Encephalomyelitis Virus

Start Date 11 Mar 81		Est Comp Date: Jun 84
Principal Investigator James H. Anderson, Jr., M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Clinical Investigation		Associate Investigators: Gerald A. Merrill, CPT, MSC
Key Words: Diabetogenicity Venezuelan equine encephalomyelitis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $1,522	Periodic Review Results: Continue

Objective: To examine the hypothesis that Venezuelan equine encephalomyelitis (VEE) vaccine virus is diabetogenic in animals.

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

Progress: Continuation of this study at BAMC awaits completion of the laboratory animal facility.

Detail Summary Sheet

Date: 13 Oct 82	Proj No: C-28-81	Status: Ongoing

TITLE:

In vitro Synthesis of Immunoglobulins and Suppressor Cell Activity in Patients with Solid Tumors and Lymphomas on and off Therapy.

Start Date 1 Apr 81		Est Comp Date: Jun 83
Principal Investigator David G. Burleson, Ph.D., MAJ, MSC		Facility Brooke Army Medical Center
Dept/Sec Department of Clinical Investigation		Associate Investigators: James Boyd, M.D., LTC, MC Karen Wolcott, DAC, GS-7
Key Words: Suppressor cell activity Lymphoma Solid tumors Immunoglobulins		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $165	Periodic Review Results: Continue

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

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

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

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

The isolated lymphocytes will also be analyzed by the FACS using fluorescene labeled monoclonal antibody to detect surface markers. Cells will be analyzed for Leu 2a (suppressor) and Leu 3 (helper) antigens and surface Ig (Ig D, M, G). Cells cultured with PWM will be monitored for surface Ig in an attempt to detect shifts from one Ig class to another as on indicator of B cell stimulation. This may be a quicker and more sensitive assay of B cell activity than the plaque assay.

Progress: Forty-eight patients have been entered on the study. No progress was possible this year because of a lack of technical support. As soon as technical assistance is restored, the project will proceed.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-53-81	Status: Ongoing

TITLE:

The Use of Monoclonal Antibody to a Pseudomonas Ribosomal Protein Antigen for Passive Immunization Against P. aeruginosa.

Start Date 6 Aug 81		Est Comp Date: Aug 83
Principal Investigator Michael M. Lieberman, Ph.D., CPT, MSC		Facility Brooke Army Medical Center
Dept/Sec Department of Clinical Investigation		Associate Investigators: Eleanor Ayala, DAC
Key Words: Monoclonal antibody Pseudomonas Ribosomal protein antigen		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:$10,638	Periodic Review Results:

Objective: To determine whether monoclonal antibody to a Pseudomonas ribosomal protein antigen can protect mice by passive immunization against challenge with P. aeruginosa.

Technical Approach: Mice are immunized with the Pseudomonas ribosomal vaccine, spleens are excised and spleen cell suspensions prepared. Spleen cells and myeloma cells (obtained from another laboratory where they are maintained in culture) are mixed in the presence of polyethylene glycol, resulting in a fusion of the two cell types. The fused cells, called hybridomas, are then fluorescein labeled with conjugated antigen. Next, the hybridoma cells are processed by the fluorescence activated cell sorter and plated such that individual cells are deposited in separate wells of tissue culture plates and grown in culture for several weeks. The hybridoma clones produced are then tested for antibody production to a particular antigen. Antibody positive hybridomas are subcultured and injected into the peritoneal cavity of mice. The ascites fluid is then collected from the mice and should contain relatively large amounts of monoclonal antibody. All monoclonal antibody preparations will be tested for antibodies to both protein and LPS antigens and those preparations showing antibody activity to protein antigen only will be tested for passive mouse protection. Preparation of Pseudomonas ribosomal vaccines and passive mouse protection experiments will be performed as previously described (C-7-77).

Progress: Several fusions of mouse myeloma cells and spleen cells from immunized mice have been performed. Some of these fusion experiments have yielded stable hybridomas (fused cells) which have been grown in tissue culture and subcultured (cloned) manually by limiting dilution. (The fluorescence activated cell sorter was not ready to be used for cloning.)

C-53-81 (continued)

The hybridomas were screened for antibody production and while the presence of mouse immunoglobulin was detected in some of them, hybridoma culture supernatants, the presence of ribosomal antigen specific antibody could not be demonstrated until the most recent fusion experiment. From this experiment, one of the wells in the primary culture plate was shown to contain specific antibody. These cells were then cloned and are being grown at present.

Detail Summary Sheet

Date: 12 Oct 82	Proj No: C-16-82	Status: Ongoing

TITLE:

The Use of Biosynthetic Human Insulin in the Treatment of Insulin-Dependent Diabetes Mellitus in Patients Who Have Never Received Insulin.

Start Date 20 Oct 81		Est Comp Date: Unknown
Principal Investigator James H. Anderson, Jr., M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Clinical Investigation		Associate Investigators:
Key Words: Insulin-dependent diabetes mellitus Biosynthetic human insulin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the efficacy and safety of Biosynthetic Human Insulin (BHI) in the treatment of insulin-dependent diabetes.

To detect, if present, immunologic evidence of E. coli proteins in patients who have received BHI.

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

Progress: Two patients have been entered on the study. Both patients are doing well with no complication from the insulin or pump. No adverse effects have been detected.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-43-82	Status: Ongoing

TITLE:

Immunogenicity of Pseudomonas aeruginosa Ribosomal Vaccines in a Cystic Fibrosis Animal Model.

Start Date Jul 82		Est Comp Date: Jul 85
Principal Investigator Michael M. Lieberman, Ph.D., CPT, MSC		Facility Brooke Army Medical Center
Dept/Sec Department of Clinical Investigation		Associate Investigators:
Key Words: Pseudomonas aeruginosa Ribosomal vaccine Cystic fibrosis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the efficacy of a vaccine prepared from the ribosomal fraction of Pseudomonas aeruginosa in an animal mode for cystic fibrosis.

Technical Approach: a. Reproduce the chronically reserpinized rat model for cystic fibrosis as described in the literature.

b. Analyze the reserpinized and control rats biochemically for confirmation of the CF model.

c. Determine the virulence of mucoid and non-mucoid strains of P. aeruginosa in the CF animal model after exposure by direct instillation of aerosolized sultures. Virulence will be assessed by a determination of the lethality of the bacteria (if lethality is demonstrated) and by a measurement of pulmonary clearance of the bacteria.

d. Determine the effects of parenteral and local vaccination of the reserpinized rats with the Pseudomonas ribosomal vaccine. Vaccinated animals will be compared to control animals after exposure to P. aeruginosa as described above for lethality and pulmonary clearance. In addition, vaccinated animals will be analyzed for specific antibody in their serum and respiratory secretions using techniques previously developed such as complement fixation, passive hemagglutination, or agar gel diffusion.

e. Determine the effects of administration of pre-formed antibody to ribosomal vaccine (passive immunization) on reserpinized rats. Passively immunized animals will be compared to control animals after exposure to P. aeruginosa for lethality and pulmonary clearance.

Progress: This protocol will not be initiated until at least one full-time technican is assigned to the project.

Detail Summary Sheet

Date: 13 Oct 82	Proj No: C-64-82	Status: Ongoing

TITLE:

A Study of the Efficacy of a Pseudomonas aeruginosa Ribosomal Vaccine in the Burned Rat Model.

Start Date 24 Sep 82		Est Comp Date: Sep 84
Principal Investigator Michael M. Lieberman, Ph.D., CPT, MSC		Facility Brooke Army Medical Center
Dept/Sec Department of Clinical Investigation		Associate Investigators:
Key Words: Pseudomonas aeruginosa Ribosomal vaccine		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To assess the efficacy of a ribosomal vaccine prepared from Pseudomonas aeruginosa in the burned rat (20% total body surface) animal model.

To assess the ability of antiserum raised against the Pseudomonas ribosomal vaccine to protect burned rats by passive immunization against challenge with P. aeruginosa.

Technical Approach: Ribosomal vaccines will be prepared from specific strains of P. aeruginosa. The burned rat model employed consists of a ten-second scald (using boiling water) administered to anesthetized rats with 20% of their total body surface exposed. This reulsts in a full thickness burn on the exposed area with no lesions on the non-exposed area. The vaccines will be used for two purposes: (1) to vaccinate groups of rats either before or after burning as described above; (2) to vaccinate groups of rabbits for the production of specific antisera to the vaccines. The antisera will then be administered to burned rats either as prophylaxis ("passive protection") or specific therapy for established infections with P. aeruginosa.

Progress: This is a new study.

C-40-80 (continued)

decrease in PtO_2 seen in Group B which crossed baseline between the second and third surgical minute, but did not continue to rise significantly, indicates the least variation from baseline of the three experimental groups. Although the mean dose of diazepam for Group C was 2.45 mg less than Group B, the addition of only .05 mg of fentanyl resulted in a significant decrease in PtO_2 in Group C. The significant decrease in PtO_2 seen in Group C and the delayed return to baseline (ninth surgical minute), may indicate that this technique should be reserved for ASA I and II patients.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-40-80	Status: Completed

TITLE:

Evaluation of PO_2 Changes Associated with Intravenous Sedation for Outpatient Oral Surgery

Start Date 1 Nov 80		Est Comp Date: 1 Jan 82
Principal Investigator Richard A. Kraut, D.C., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Dentistry/Oral Surgery		Associate Investigators:
Key Words: PO_2 changes Intravenous sedation Oral Surgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the change from baseline PO_2 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: Twenty five patients were selected for each of the three study groups. Patients were selected from those patients who require removal of at least one maxillary and one mandibular impacted wisdom tooth. Patients were assigned to study groups based on their request for sedation or local anesthesia. Patients requesting sedation were alternately assigned to Group B and C.

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

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

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

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

4. A continuous cutaneous oxygen monitor.

Progress: The increased PtO_2 seen in the group receiving only local anesthesia can be attributed to the stimulation of the local anesthetic injections and the apprehension present at the start of surgery. It is interesting that, by the tenth surgical minute, PtO_2 approaches baseline and remains around baseline, perhaps indicating an acceptance of the srugery being performed. The minimal

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-62-81	Status: Ongoing

TITLE:

Effect of Supplemental Nasal Oxygen on the PO_2 of Patients Undergoing Outpatient Oral Surgery

Start Date 23 Sep 81		Est Comp Date: Mar 83
Principal Investigator Richard A. Kraut, D.D., LTC, DC		Facility Brooke Army Medical Center
Dept/Sec Department of Dentistry/Oral Surgery		Associate Investigators:
Key Words: Nasal oxygen PO_2		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the changes from baseline PO_2 in patients undergoing outpatient oral surgery with supplementsl nasal oxygen utilizing local anesthesia or local anesthesia plus intravenous Valium and Sublimaze.

Technical Approach: Nasal prongs and a nasal anesthetic mask are to be compared as delivery methods for supplemental O_2 for patients undergoing outpatient oral surgery.

Progress: Due to lack of staff within the Oral and Maxillofacial Surgery Service, this project has been postponed during FY 82. The staffing situation has been corrected, and it is anticipated that this study will be completed early in FY 83.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-63-81	Status: Completed

TITLE:

Evaluation of PO_2 Changes During Surgical Removal of Wisdom Teeth Utilizing General Anesthesia

Start Date 23 Sep 81		Est Comp Date:
Principal Investigator Richard A. Kraut, D.D., LTC, DC		Facility Brooke Army Medical Center
Dept/Sec Department of Dentistry/Oral Surgery		Associate Investigators:
Key Words: PO_2 changes Wisdom teeth		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

Technical Approach: The study group consisted of 15 males ranging in age from 18 to 34 and 11 females ranging in age from 18 to 25 who requested general anesthesia in association with the removal of their impacted wisdom teeth. The Roche Transcutaneous Oxygen Monitor utilized in this study provided a written graphic record of the PO_2 of the patient. This served as the data collection vehicle for collecting PO_2' in this study.

Progress: Initial inspection of the $PtcO_2$ indicated a marked rise in $PtcO_2$ during the pre-induction oxygenation period, as well as during the controlled ventilation period surrounding intubation. While breathing spontaneously, the patients arrived at a plateau $PtcO_2$ between 90 and 150 mm Hg. A segment of the patients showed a marked rise in $PtcO_2$ when enflurane and nitrous oxide were discontinued at the termination of surgery. A second group retained the level of $PtcO_2$ they had established during surgery, in spite of receiving 100% oxygen via the endotracheal tube, which was still in place.

Repeated measurements analysis of variance was performed, and two different group means emerged. The two groups did not behave the same way across

C-63-81 (continued)

time. The group time interaction of the two group means are significantly different, P less than .001. Group A consisted of 11 males and four females; group B consisted of three males and six females. Groups A and B differ starting with pre-induction oxygenation and remain different, though parallel, until the end of surgery when Group A showed a 150 mm rise in $PtcO_2$ while Group B failed to show an increase in $PtcO_2$, in the face of 100% oxygen administered via an endotracheal tube. A review of all criteria failed to separate Group A and B.

Upon completion of the 26 patients reported in this study, we have continued to use transcutaneous oxygen monitoring while administering general anesthesia. We continue to see two distinct patient groups; however, we are still unable to determine what it is that separates patients into these groups.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-5-82	Status: Ongoing

TITLE:
Evaluation of EKG Changes in Dentists Treating Awake Patients

Start Date21 Oct 81		Est Comp Date: Mar 83
Principal Investigator L. P. Bilodeau, D.D.S., MAJ, DC		Facility Brooke Army Medical Center
Dept/Sec Department of Dentistry/Oral Surgery		Associate Investigators: Richard A. Kraut, D.D.S., LTC, DC
Key Words: Holter monitors EKG changes		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To measure changes in cardiac rate and associated arrhythmias in dentists while treating patients.

Technical Approach: Holter monitors are being worn for 24 hour periods by dentists. A diarry is being kept to indicate the time period during which they are treating patients.

Progress: Numerous logistical obstacles have had to be overcome in completing the entry requirements for this study. It is anticipated that data collection will be completed in the near future and that instead of a total of 50 participants, approximately 30 will be all that can be accomplished.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-52-82	Status: Ongoing

TITLE:

A Comparison of Intravenous and Laryngotracheal Lidocaine before Endotracheal Intubation.

Start Date 13 Aug 82		Est Comp Date: Dec 82
Principal Investigator Richard A. Kraut, D.D.S., LTC, DC		Facility Brooke Army Medical Center
Dept/Sec Department of Dentistry/Oral Surgery		Associate Investigators:
Key Words: Laryngotracheal lidocaine Intravenous lidocaine Endotracheal intubation		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To describe the effect of intravenous lidocaine compared to laryngotracheal lidocaine in patients having wisdom teeth removed under general anesthesia.

To determine if there is a preferred route for administration of lidocaine before endotracheal intubation.

Technical Approach: Patients are being randomly assigned to LTA versus IV lidocaine study groups. Monitoring is progressing well with the Dinamap Recorder.

Progress: Thirty patients have been entered on the study. Preliminary results indicate that there is less physiologic change in patients receiving lidocaine via "LTA" kit compared to the group receiving lidocaine intravenously.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-54-82	Status: Ongoing

TITLE:

Evaluation of PO_2 Changes Associated with Intravenous Sedation for Outpatient Oral Surgery.

Start Date 13 Aug 82		Est Comp Date: May 83
Principal Investigator Richard A. Kraut, D.D.S., LTC, DC		Facility Brooke Army Medical Center
Dept/Sec Department of Dentistry/Oral Surgery		Associate Investigators:
Key Words: PO_2 changes Intravenous sedation Outpatient oral surgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the change from baseline $PtcO_2$ in patients undergoing outpatient oral surgery utilizing local anesthesia, intravenous diazepam, fentanyl and methohexital.

To determine the effect of 6 liters/min O_2 on the $PtcO_2$ of patients undergoing outpatient oral surgery utilizing local anesthesia and intravenous diazepam, fentanyl and methohexital.

Technical Approach: Study has not started.

Progress: Project has not been started due to a lack of staff and ongoing projects within the Oral Maxillofacial Surgery Service.

Detail Summary Sheet

Date: 5 Nov 82	Proj No: C-59-82	Status: Ongoing

TITLE:

The Relationships of Soft and Hard Tissue Changes in Combined Maxillary and Mandibular Surgical Procedure.

Start Date 8 Sep 82		Est Comp Date: Dec 85
Principal Investigator George D. Suchko, D.D.S., MAJ, DC		Facility Brooke Army Medical Center
Dept/Sec Department of Dentistry/Oral Surgery		Associate Investigators:
Key Words: Maxillary repositioning Mandibular repositioning		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To assess the effects of combined maxillary and mandibular surgery on soft and hard tissues and to compare our findings with prior studies done which evaluated changes noted after single jaw surgical procedures.

Technical Approach: Thirty patients will be selected who present to the Oral Surgery Clinic who require total maxillary and mandibular repositioning that can be accomplished simultaneously. There will be three groups of patients involved in the study with each group consisting of ten patients. They will be categorized as follows:

1. Maxillary superior repositioning via Le Fot I osteotomy with mandibular advancement.

2. Maxillary repositioning via total alveolar osteotomy with mandibular advancement.

3. Maxillary repositioning (A-P) via Le Fort I osteotomy with mandibular retrusion.

Progress: The study has not been started.

Detail Summary Sheet

Date: 29 Oct 82	Proj No: C-65-82	Status: Ongoing

TITLE:

Electrocardiographic Changes During Outpatient Oral Surgery.

Start Date 27 Sep 82		Est Comp Date: Sep 83
Principal Investigator Richard A. Kraut, D.D.S., LTC, DC		Facility Brooke Army Medical Center
Dept/Sec Department of Dentistry/Oral Surgery		Associate Investigators:
Key Words: Oral surgery Electrocardiographic changes Physiologic Monitor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

Technical Approach: Adult patients presenting to the Oral and Maxillofacial Surgery Service will serve as the study group. All patients assigned to the investigator for surgery utilizing either local anesthesia or local anesthesia plus sedation, will be included in the study. The patients will be attached to an Electronics for Medicine CM 140 Physiologic Monitor which contains an arrhythmia function block via standard chest electrodes. The patient's initial V-2 rhythm strip will be printed by the in-line AR 110 Recorder attached to the CM 140 Monitor. The patients will then be either sedated or anesthetized and the required surgery performed. All patients will be monitored until the completion of their surgery.

Progress: This is a new study.

Date: 14 Oct 82	Proj No: C-9-75	Status: Completed

TITLE:

Clinical Outpatient Algorithm Validation - A Pilot Study

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

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

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

Progress: All of the algorithms developed have been shown to be safe and effective in the hands of BAMC AMOSISTs. This acute care system can be used effectively within or without the Army Medical Department.

Detail Summary Sheet

Date: 14 Oct 82	Proj No: C-37-79	Status: Completed

TITLE:
Ankle Trauma Study.

Start Date Sep 79		Est Comp Date:
Principal Investigator Robert Slay, Jr., M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Emergency Medicine		Associate Investigators:
Key Words: Trauma Algorithm		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: 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 efficient ratios.

Technical Approach: Each patient with indirect ankle trauma was offered the opportunity to enter the study. A PGY-2 in Emergency Medicine followed a precise format for obtaining a history and for performing a physical exam which included both plain and stress x-rays. The x-rays were interpreted by the physician and assigned to a specific classifcation established by the protocol. The patient was treated according to the established classification of the ankle injury.

Progress: 693 patients were entered on the study prior to FY 82; none were entered during FY 82. The data has been forwarded to the University of Washington for analysis; therefore, no definite conclusions are available for this report. One determination which was reported previously was that approximately one-third of the ankle studies (x-rays) can be eliminated.

Detail Summary Sheet

Date: 29 Oct 82 Proj No: C-32-82 Status: Ongoing

TITLE:

Comparison of Speed and Complication Rate of Nasotracheal or Endotracheal Intubation by Standard Methods vs Fiber Optic Assisted Intubation

Start Date18 May 82	Est Comp Date: May 83
Principal Investigator Daniel J. Boyle II, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Emergency Medicine	Associate Investigators: William H. Dice, M.D., MAJ, MC Victor L. Burgos, M.D., LTC, MC Donald J. Gordon, M.D., LTC, MC
Key Words: Nasotracheal intubation Endotracheal intubation	

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

Objective: To determine the quickest and safest method of rapid intubation in the Emergency Room.

Technical Approach: The first fifty patients arriving in the Brooke Army Medical Center Emergency Room who require intubation will be included in the study. They will be randomized using a table for random numbers to determine whether intubation will be done with standard methods or with fiber optic assistance.

Progress: We have not been able to obtain the required equipment. American Optical has now offered to lend us the fiberoptic scope and we should be able to start the study soon after its arrival.

Detail Summary Sheet

Date: 19 Oct 82	Proj No: C-60-82	Status: Ongoing

TITLE:

The Effects of Pneumatic Trousers on Cardiovascular Hemodynamics.

Start Date 8 Sep 82		Est Comp Date: April 1983
Principal Investigator William H. Bickell, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Emergency Medicine/Medicine		Associate Investigators: Michael R. Geer, M.D., MAJ, MC William E. Craig, M.D., MAJ, MC William Dice, M.D., MAJ, MC Joseph P. Murgo, M.D., COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To study the effects of external counterpressure on the cardiovascular system through invasive monitoring.

Technical Approach: Volunteers previously selected for cardiac catheterization will be asked to consent to application of the pneumatic counterpressure device (MAST). Hemodynamic and metabolic parameters will be measured before and after inflation of the MAST. Each patient will serve as his own control and all data will be evaluated for significance using standard statistical methods.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 29 Oct 82	Proj No: C-61-82	Status: Ongoing

TITLE:

Ionizing Radiation Exposure of Emergency Room Personnel.

Start Date 8 Sep 82		Est Comp Date: Dec 82
Principal Investigator Robert L. Kinsman, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Emergency Medicine		Associate Investigators: Edward W. Ellenbec, M.D., CDR, USN, MC Robert J. Matthews, Ph.D., CPT, MSC William H. Dice, M.D., MAJ, MC Robert N. Cherry, Jr., Ph.D., CPT, MSC Phillip M. Berry, Ph.D., CPT, MC
Key Words: Radiation exposure		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To quantitate ionizing radiation exposure of medical personnel assigned to the Brooke Army Medical Center Emergency Room and to determine the need, if any, for routine personnel monitoring in accordance with AR 40-14.

Technical Approach: The ionizing radiation exposure of eight nurses, ten residents and twenty enlisted corpsmen permanently assigned to the ER will be monitored. The Student "T" test will be used to test the hypothesis that ionizing radiation levels in the ER do not (or do) exceed the minimum (250 millirem) standard for designating an occupation as "radiation exposed".

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 14 Oct 82	Proj No: C-6-77	Status: Completed

TITLE:
Mechanism of Modulation of Lymphocyte Responses by Complement.

Start Date 15 Sep 76		Est Comp Date:
Principal Investigator Michel N. Laham, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Allergy-Immunology		Associate Investigators: Isidoro Chapa, DAC, GS-7
Key Words: Complement Cell mediated immunity		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $5,892	Periodic Review Results:

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: Purified human C1, C4 and C2 were sequentially added to a suspension of peripheral blood lymphocytes in complement fixation buffer in a ratio of 1:5:.15. Aliquots of the supernatants were drawn at 10, 20, 40 and 60 minutes, and kept frozen at -70°c until they were assayed for residual C2 activity. At each time interval stated, the lymphocytes were sedimented, washed free of complement fixation buffer and resuspended in RPMI 1640 and assayed for the proliferative response to mitogens and the ability to suppress normal cells.

Progress: We were able to demonstrate fluid-phase consumption of C2 by C1 and C4 in complement fixation buffer but not in tissue culture medium. We also demonstrated a sequential increase in lymphocyte inhibition with progressively longer exposures to active C1, C4 and C2 prior to culture with mitogen.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-23-77	Status: Completed

TITLE:

Oral Methoxalen Followed by Longwave UV Light Effectiveness in the Treatment of Psoriasis.

Start Date: 19 Jan 77		Est Comp Date:
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:

Objective: To determine the efficacy of 8-methoxypsoralen (methoxalen) 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 beginning the study forty-five patients with extensive psoriasis and nine patients with parapsoriasis have been treated. Thirty-eight of the fifty-four patients have shown good to excellent response. The remaining sixteen patients had poor to no response.

The FDA has approved the use of PUVA in the treatment of psoriasis. It is our plan to use PUVA therapy for patients with extensive psoriasis that is resistant to other forms of therapy.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-5-80	Status: Completed

TITLE:

Lopressor Intervention Trial.

Start Date Jan 80		Est Comp Date:
Principal Investigator Francis R. D'Silva, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Cardiology		Associate Investigators: Joseph P. Murgo, M.D., COL, MC Joe Moody, M.D., MAJ, MC
Key Words: Lopressor Beta blocker		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: 22 Jul 82 Continue

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

Technical Approach: The efficacy of beta-blocade was evaluated by way of a double blind study. All patients were postinfarct.

Progress: Nineteen patients were studied and now are in the follow-up phase. No significant complications have been reported. No new patients will be entered on the study.

Detail Summary Sheet

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

TITLE:

Clotting Studies in Liver Disease.

Start Date: 24 Jan 80	Est Comp Date:
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:

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: Results of a similar study were recently published in the literature. Therefore, the study was terminated.

Detail Summary Sheet

Date: 20 Oct 82	Proj No: C-7-80	Status: Completed

TITLE:

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

Start Date 24 Jan 80		Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Hematology-Oncology		Associate Investigators: Gary Wikert, M.D., CPT, MC John J. Posch, Jr., DAC
Key Words: Prostatectomy Coagulation system Fibrinolytic system		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $6,950	Periodic Review Results:

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: A detailed, prospective study of the coagulation and fibrinolytic systems in fifty patients undergoing transurethral resection of the prostate under spinal anesthesia was conducted. Twenty controls consisting of patients undergoing urologic surgery not involving the prostate but with spinal anesthesia were evaluated in the same manner. The new and more accurate chromogenic assays for coagulation and fibrinolytic factors were used, as well as immunologic methods.

Progress: TURP patients had significant decreases postoperatively in fibrinogen, plasminogen and antithrombin III. When compared to controls, however, only the change in fibrinogen was statistically significant. Seven patients with adenocarcinoma of the prostate were included in the study and had no significant changes in any factors measured compared to controls and to the rest of the TURP group. Six patients with large glands had significant changes in antithrombin III and antiplasmins but the group was too small for comparison. Only two patients required transfusion, but twelve additional patients had changes in hemoglobin of more than two standard deviations from the mean.

C-7-80 (continued)

"bleeder" group had significant falls in antithrombin III, plasminogen, progressive antiplasmin and prekallikrein. Compared to nonbleeders, the only significant change was in the antithrombin III level. The absolute value of antithrombin III was low postoperatively in the "bleeder" group and compared to controls, this was significant. The preoperative antithrombin III level in the "bleeder" group was normal but consistently low normal.

Conclusions: In those who had statistically significant bleeding, the most active pathophysiologic mechanism was local fibrinolysis. Also, it was proposed that the preoperative antithrombin III level may be of predictive value for bleeding complications.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-17-80	Status: Terminated

TITLE:

Role of Digoxin in Preventing Myocardial Toxicity in Cancer Patients Receiving Adriamycin.

Start Date: 6 Jun 80		Est Comp Date:
Principal Investigator Walter H. Harvey, 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:

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: The study was terminated due to inability to obtain enough patients on the digoxin treated arm.

Detail Summary Sheet

Date: 27 OCT 82 | 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:
Principal Investigator Daniel A. Ramirez, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Allergy-Immunology	Associate Investigators:
Key Words: Local anesthetic skin testing Challenge Adverse reaction	

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

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

Technical Approach: Patients with histories of adverse reactions to local anesthetics are evaluated by a skin test progressive challenge protocol.

Progress: No adverse effects have been encountered in the 16 patients studied. Study is a multicenter study originally from FAMC. As many patients as possible will be enrolled.

Detail Summary Sheet

Date: 27 OCT 82	Proj No: C-24-80	Status: Terminated

TITLE:
Establishment of a Plasma Bank for Oncology Patients

Start Date 30 JUN 80		Est Comp Date:
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:

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: All specimens frozen to date were lost when the freezer in Clinical Investigation thawed. The protocol will be discontinued due to freezer failure.

Detail Summary Sheet

Date: 27 OCT 82 Proj No: C-36-80 Status: Completed

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:
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:

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: The patients applied either sulconazole nitrate 1% solution or placebo once daily for three weeks. Follow-up evaluations were conducted at two, three, and seven weeks in this double-blind study. If the patient was clear at the three week visit, medication was stopped and a follow-up visit scheduled one month later. If the patient was not clear at the three week visit, the study was stopped and effective medication started.

Progress: Approximately one-half of the patients cleared within three weeks of treatment. Of the original 23 patients, all on sulconazole nitrate cleared while those on placebo did not. No adverse reactions were noted during this study. The code for the last 35 patients has not been broken at this writing. These results probably will be published in Cutis as a multicenter study.

Detail Summary Sheet

Date: 28 OCT 82	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:
Principal Investigator Lucius F. 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., MAJ, MC
Key Words: Dialysis Polymorphonuclear leukocyte Redox metabolism Chemilumigenic probes		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	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: Eleven dialysis patients have had multiple samples of blood from both the arterial and venous limbs of the dialyzer circuit obtained and measured for the generation of Cl function in response to known stimuli such as DBA and Zymosan. Additionally, the serum from these determinations has been frozen and will be further analyzed. A new approach to the measurement of complements system activity has been devised and should be further perfected in the upcoming fiscal year.

Progress: A paper describing the basic concept and approach is in preparation. A paper describing the methods of the paper as well as assessment of granulocyte and opsonic capacity should be prepared during FY83.

Detail Summary Sheet

Date: 20 Oct 82	Proj No: C-2-81	Status: Ongoing

TITLE:

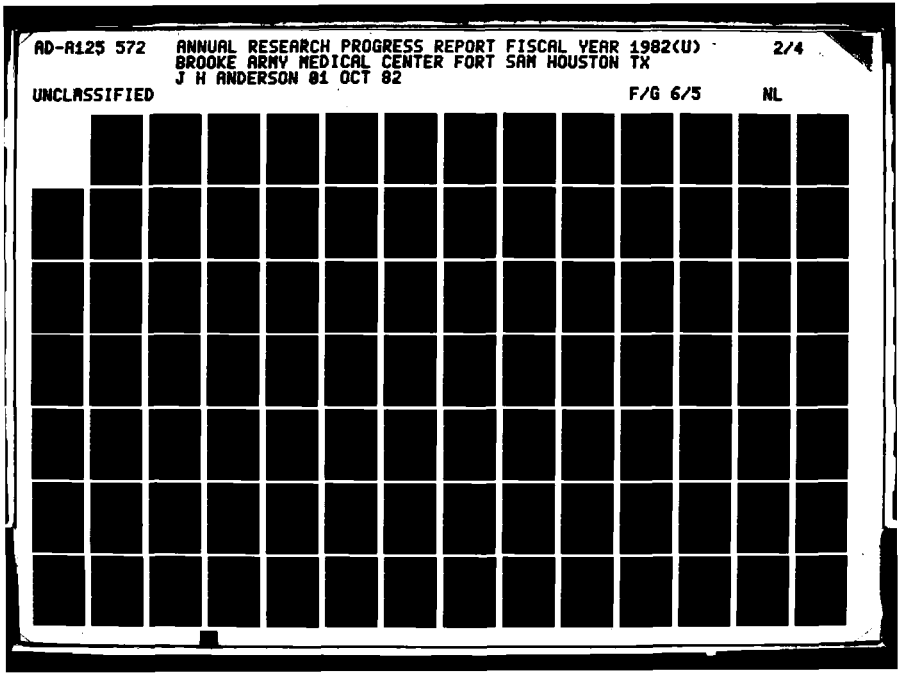
Evaluation of the Coagulation, Fibrinolytic, and Humoral Immune Abnormalities Induced by Crotalus Atrox (Western Diamondback Rattlesnake) Snakebite.

Start Date 10 Oct 80		Est Comp Date: Undetermined
Principal Investigator John J. Posch, Jr., DAC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Hematology-Oncology		Associate Investigators: Glenn M. Mills, M.D., MAJ, MC Barbara Reeb, DAC Thomas G. Glass, Jr., M.D.
Key Words: Snakebite Envenomate Rattlesnake		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $9,374	Periodic Review Results: Continue

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

Technical Approach: Coagulation tests have been performed on 112 individual specimens from 43 different snakebite patients received to date. Serum and plasma specimens have been stored for further evaluation using chemiluminescence techniques. Because of the small number of specimens, hoever, that could be obtained per patient, the future emphasis will be on serially collected specimens from future snakebite patients. An estimate of 15 to 20 more patients is desired. Differences in qualitative and quantitative coagulation changes induced in pooled plasma using crude venom from different size groups of C. Atrox has also been characterized. During the winter months when snakebite is rare, further isolation and characterization of venom enzymes will be resumed using isoelectric focusing purification techniques and chromogenic substrate assays.

Progress: Several patterns of coagulation abnormalities have been detected in snakebite patients. Additional tests will be necessary to further characterize these changes in present and future snakebite victims.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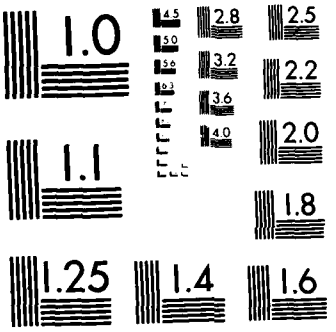

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Detail Summary Sheet

Date: 25 Oct 82	Proj No: C-3-81	Status: Ongoing

TITLE:

Study of Granulocyte Function in Leukemia Patients Receiving Granulocyte Transfusions

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

Objectives: Prospective evaluation of neutrophil function and humoral immunity in patients with leukemia.

Evaluation of changes induced in humoral immunity and neutrophil function by either radiation therapy or chemotherapy.

Evaluation of kinetics of transfused neutrophils in leukemia patients.

Correlation of improvement in neutrophil function and humoral immunity in recipients of granulocyte transfusions and clinical course.

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

Progress: Overall, one patient has been entered on the study. This past year we have been refining our capabilities to do multiple samples of whole blood for chemiluminescent studies.

Detail Summary Sheet

Date: 25 Oct 82	Proj No: C-5-81	Status: Ongoing

TITLE:

The Natural History of Patients with Large Local Reactions (LLR) Following a Hymenoptera Sting

Start Date 3 Feb 81		Est Comp Date: Sep 85
Principal Investigator Daniel A. Ramirez, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Allergy-Immunology		Associate Investigators:
Key Words: Hymenoptera sting Large local reactions (LLR)		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To study the natural history of patients who have experienced LLR following an insect sting. Several aspects of this problem will be studied:
a. What is the risk of systemic anaphylaxis in this group of patients? and
b. Can patients with histories of LLR and at risk of anaphylaxis be identified prospectively.

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

a. Venom skin testing - up to 1 ug/ml of concentration.

b. Obtain specific venom IgE and IgG.

c. Stay challenged under controlled conditions to assess current reactivity.

d. Obtain specific venom IgE and IgG's following sting challenge.

Progress: Fourteen patients have so far been identified for the study. None of these patients have consented to an in-hospital sting. Their blood is to be analyzed by ELISA for venom specific IgE/IgG. Patients with field stings will be followed.

Detail Summary Sheet

Date: 12 Oct 82	Proj No: C-8-81	Status: Completed

TITLE:

Comparative Evaluation of Methods of Surveillance for Nosocomial Infections.

Start Date 3 Feb 81		Est Comp Date:
Principal Investigator C. Kenneth McAllister, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Infectious Disease		Associate Investigators:
Key Words: Nosocomial infections Infection control		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

Technical Approach: Comparison was made between surveillance of key high risk areas (ICU, etc.) plus pertinent microbiologic data versus review of each hospital ward and chart (total surveillance).

Progress: The study revealed that "guided surveillance" (high risk areas, etc.) was equal to total surveillance. The former method has now been employed by our infection control serves at Brooke Army Medical Center.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-9-81	Status: Terminated

TITLE:

Thyroid Function in Cancer

Start Date Feb 81		Est Comp Date:
Principal Investigator Lawrence Pupa, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Internal Medicine		Associate Investigators:
Key Words: Thyroid Cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To define the state of thyroid function in seriously ill oncology patients.

Technical Approach: Ten patients will be studied. Blood will be drawn and T_3U, FTI, T_4, TSH, T_3RIA, and RT_3 will be measured. Patients on thyroid hormone or with a family history of thyroid disease will be excluded.

Progress: The study was terminated due to inability to obtain enough patients to have data that would be statistically significant.

Detail Summary Sheet

Date: 25 Oct 82	Proj No: C-10-81	Status: Ongoing

TITLE:

Evaluation of the Complement System and Humoral Immunity in Patients Undergoing Fibrinolytic Therapy.

Start Date 3 Feb 81		Est Comp Date: Jun 82
Principal Investigator Glenn M. Mills, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Hematology-Oncology		Associate Investigators: Robert C. Allen, M.D., Ph.D. MAJ, MC
Key Words: Complement System Humoral immunity Fibrinolytic therapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

Technical Approach: Patients receiving fibrinolytic therapy have blood drawn every 12 hours for complete coagulation screening as well as functional complement assays and WBC chemiluminescence.

Progress: A total of five patients have been entered on this study (two during FY 82). Accrual is proceeding slowly as only limited numbers of patients have been receiving streptokinase.

Detail Summary Sheet

Date: 25 Oct 82	Proj No: C-12-81	Status: Ongoing

TITLE:

Study of Granulocyte Function, Complement Activity and Coagulation in Patients with the Adult Respiratory Distress Syndrome (ARDS)

Start Date 4 Feb 81		Est Comp Date: Jun 83
Principal Investigator Glenn M. Mills, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Hematology-Oncology		Associate Investigators: Robert C. Allen, M.D., Ph.D., MAJ, MC
Key Words: ARDS Complement Granulocyte-induced endothelial damage		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $1115	Periodic Review Results: Continue

Objectives: Evaluation of neutrophil metabolism by chemiluminescence in patients with ARDS.

Measurement of complement activity via the classical and alternate pathways in patients with ARDS.

Study of the coagulation and fibrinolytic systems in patients with ARDS.

Correlation of steroid therapy with the above objectives in patients with ARDS.

Technical Approach: Adequate number of control patients have been collected. Primary limiting step is accrual of patients with ARDS without congestive heart failure. Technical problems with contamination by heparin from indwelling lines have been overcome by using Hepabsorb. Documentation has been completed that this will not alter coagulation parameters to be measured.

Progress: The principal investigator, CPT Nathan Erteschick, PCS'd in July 1982. The study will be continued under a new principal investigator, MAJ Mills. Patients with ARDS and congestive heart failure will continue to be studied.

Detail Summary Sheet

Date: 25 Oct 82	Proj No: C-17-81	Status: Terminated

TITLE:
Effect of DMSO on Human Squamous Cell Cultures

Start Date 11 Mar 81		Est Comp Date:
Principal Investigator Walter C. Anderson, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Dermatology		Associate Investigators:
Key Words: Human squamous cell sultures DMSO		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

Technical Approach: None.

Progress: The principal investigator was reassigned to Darnall Army Hospital and was unable to conduct study.

Detail Summary Sheet

Date: 25 Oct 82	Proj No: C-24-81	Status: Completed

TITLE:

Identification of Bacterial Receptors on the Intestinal Mucosa of Rabbits and Determination of Its Role in the Pathogenesis of Bacterial Diarrhea.

Start Date 1 Apr 81		Est Comp Date:
Principal Investigator Robert A. Berendson, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Gastroenterology		Associate Investigators:
Key Words: Bacterial receptors Bacterial diarrhea		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:$1231.00	Periodic Review Results:

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

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

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

Technical Approach: To investigate the development of intestinal surface properties, we examined the ability of a series of fluoresceinated lectins (known to bind to specific sugars at certain locations in typical oligosaccharides from the aminal acid linkage (L), to core (C) and peripheral (P) sites), to bind to ileum from rabbits aged 18, 21, 25, 28 days and adults. Lectins used (and sugar specificity) were Concanavalin A (Con A)-mannose (man); Ricinus Communis (RCA)-galactose (Gal); Wheat Germ Agglutinin (WGA)-Nacetylglucosamine (GlcNac); Soybean Agglutinin (SBA-Nacetylgalactosamine (GalNac); and Ulex Europaeus (UEA)-fucose. Each lectin was incubated with ileal thin sections for 30 min. The apical surfaces of cells from crypt (C) to villus tip (V) were examined for the presence (+) or absence (-) of linear fluorescence.

Progress: Results are tabulated below.

			18 day		21 day		25 day		28 day		Adult	
Lectin	Sugars	Site	C	V	C	V	C	V	C	V	C	V
RCA	Gal	L/P	+	-	+	-	+	-	+	+	+	+
SBA	GalNac	L/P	+	-	+	-	+	-	+	+	+	+
WGA	GlcNac	L/P	-	-	-	-	+	-	+	+	+	+
Con A	Man	C	-	-	-	-	-	+	+	+	+	+
UEA	Fuc	P	-	-	-	-	-	-	+	+	-	-

C-24-81 (continued)

These results are consistent with the interpretation that 1) tip cells minimally express reactive carbohydrates on their surface until weaning; 2) crypt cells seem to express only rudimentary structures involving the linkage sugars before weaning; 3) more complex carbohydrates are not found until day 28 on both cell populations.

Detail Summary Sheet

Date: 7 Oct 82	Proj No: C-25-81	Status: Completed

TITLE:
Single-dose Treatment of UTI in Women.

Start Date 1 Apr 81		Est Comp Date:
Principal Investigator C. Kenneth McAllister, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Infectious Disease		Associate Investigators:
Key Words: Urinary tract infection		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $52.30	Periodic Review Results:

Objectives: To investigate the efficacy and safety of treating women with uncomplicated UTIs of the lower urinary tract with a single dose antibiotic.

To demonstrate a cost savings to the U.S. Army by utilizing a single dose of antibiotic therapy for UTI vs 10-14 days of conventional therapy.

To provide a convenient means of treating UTI which optimizes patient compliance and follow-up.

Technical Approach: Women between ages 18-55 with clinical findings suggesting bladder infection were given 3.0 gm. of Amoxicillin as a single dose with urine culture taken initially and at follow-up times of 5-9 days and four weeks.

Progress: Eighty-five patients entered the study. Of the 85, only 25 were evaluable due to a variety of reasons which include lack of return for follow-up. Of those evaluable patients, 72% were cured with single dose treatment and 28% were not cured. There were no adverse reactions to the antibiotic. We found that in all of the failures, the organism was resistant to Amoxicillin. We concluded that caution should be taken in giving single dose therapy to women with UTI's due to the potential for resistant organisms and resultant treatment failure.

Detail Summary Sheet

Date: 19 Nov 82	Proj No: C-26-81	Status: Terminated

TITLE:

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

Start Date 1 Apr 81		Est Comp Date:
Principal Investigator Charles E. Davis, Jr., M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Infectious Disease		Associate Investigators: John L. Carpenter, M.D., COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

Technical Approach: None

Progress: After the change in principal investigators, it was decided to terminate the study.

Detail Summary Sheet

Date: 25 Oct 82	Proj No: C-27-81	Status: Terminated

TITLE:

Karyology of in vitro Cultured Human Basal Cell Epithelioma Tissue.

Start Date 1 Apr 81		Est Comp Date:
Principal Investigator Stuart J. Salasche, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Dermatology		Associate Investigators:
Key Words: Karyology Basal cell epithelioma Cell culture		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

Technical Approach: Study terminated due to inability to maintain cell culture lines.

Progress: None. Cell cultures continued to become infected, and we were never able to combat this problem.

Detail Summary Sheet

Date: 25 Oct 82 Proj No: C-29-81 Status: Ongoing

TITLE:

Treatment of Severe Erythema Multiforme with Systemic Steroids

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

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

Objective: To determine if Prednisone is effective in the treatment of severe erythema multiforme.

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

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

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C- '-81	Status: Ongoing

TITLE:

Profile of Aortic Impedance in Patients with Congestive Cardiomyopathy.

Start Date 15 Mar 81		Est Comp Date: Dec 82
Principal Investigator Joseph P. Murgo, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Cardiology		Associate Investigators: N. Westerhoff, Ph.D.
Key Words: Impedance Congestive cardiomyopathy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic 22 Jul 82 Review Results: Continue

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

Technical Approach: Simultaneous high fidelity aortic pressure and flow velocity signals obtained during routine cardiac catheterization were retrospectively evaluated to assess aortic impedance changes during exercise and after afterload reduction.

Progress: Seven patients have been entered on the study. Data have not been evaluated.

Detail Summary Sheet

Date: 26 Oct 82	Proj No: C-33-81	Status: Ongoing

TITLE:

Renal Function in Primary Hyperparathyroidism.

Start Date 12 May 81		Est Comp Date: May 83
Principal Investigator Lucius E. Wright, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Nephrology		Associate Investigators: Charles J. Foulks, M.D., MAJ, MC
Key Words: Hyperparathyroidism Renal function		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

Technical Approach: Patients are admitted to the hospital on a controlled calcium, protein and sodium diet and have determinations of maximum urinary osmolality after overnight fasting. Urinary dilution ability following water loading - acidification of the urine following ammonium chloride loading and bicarbonate titration curb determinations through the use of sodium bicarbonate.

Progress: Complete studies have been obtained on six of the fourteen patients. Additional studies have been completed including a determination of osmotic fragility in these patients which should be reported separately during FY 83.

Detail Summary Sheet

Date: 26 Oct 82	Proj No: C-34-81	Status: Ongoing

TITLE:

The Effect of Propranolol on Cardiac Ejection Fractions as Determined by Gated Scans in Thyrotoxic Patients.

Start Date 15 Jun 81		Est Comp Date: Jun 83
Principal Investigator Thomas J. Taylor, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Endocrinology		Associate Investigators: Robert J. Telepak, M.D., LTC, MC Steven Bunker, M.D., MAJ, MC
Key Words: Propranolol Thyrotoxic Cardiac ejection		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

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

Progress: In 10 previously untreated patients with Graves' disease and symptomatic thyrotoxicosis (8 women and 2 men ages 23-58), serum total T_3 by radioimmunoassay (341-702 ng/dl) and thyroidal I^{131} uptake (51-79%) were markedly elevated and were significantly correlated ($r=0.70$, $p < 0.02$).

Detail Summary Sheet

Date: 26 Oct 82	Proj No: C-35-81	Status: Ongoing

TITLE:

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

Start Date 15 Jun 81		Est Comp Date: Jun 83
Principal Investigator Walter H. Harvey, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: J. Dean McCracken, M.D., COL, MC
Key Words: Hepatic artery embolization Hepatic neoplasm		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

To evaluate the morbidity of hepatic embolization.

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

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

Progress: The procedure has had success in palliation of patients with hepatic metastases and there have been deaths associated with the procedure. The study will be kept open until [illegible] cases are entered.

Detail Summary Sheet

Date: 28 Oct 82	Proj No: C-36-81	Status: Ongoing
TITLE: Comparison of Gray-Scale Ultrasonography and Computed Tomography with Infusion Nephrotomogram in Early Diagnosis of Adult-type Polycystic Kidney Disease		
Start Date 15 Jun 81		Est Comp Date: Jun 83
Principal Investigator Lucius F. Wright, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Nephrology		Associate Investigators: Harold Cable, M.D., CPT, MC
Key Words: Polycystic kidney disease Gray-scale ultrasonography Computed tomography Nephrotomogram		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

Technical Approach: Offspring of patients identified with adult type polycystic kidney disease undergo Gray-Scale ultrasonography and abdominal computed tomography as well as infusion nephrotomography which are then read blindly and independently of each other. Total number of patients in study now is 18, all of whom were entered in FY 82.

Progress: This study has shown that ultrasonography is about twice as sensitive as the more traditional nephrotomogram and is less hazardous and less expensive. We therefore consider ultrasonography the diagnostic method of choice; CT scanning does not appear to add to the diagnostic yield, although it is nearly as sensitive. Thusfar the study has shown that clinical findings are often present in children with PCKD at a younger age than is generally appreciated.

Detail Summary Sheet

Date: 28 Oct 82	Proj No: C-37-81	Status: Completed

TITLE:

Evaluation of Curettage and Electrodesiccation in Treatment of Basal Cell Epitheliomas

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

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

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

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

Progress: We found that [illegible] of the lesions on the nose were positive for residual tumor versus [illegible] of the lesions located on the face and [illegible]

Detail Summary Sheet

Date: 28 Oct 82	Proj No: C-38-81	Status: Terminated

TITLE:
The Use of Mannitol and Lasix in Intractable Ascites

Start Date 15 Jun 81		Est Comp Date:
Principal Investigator Willie R. Whitaker, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Internal Medicine		Associate Investigators: Lucius F. Wright, M.D., MAJ, MC
Key Words: Intractable ascites Mannitol Lasix		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

Technical Approach: None

Progress: The study was terminated because of the inability to identify suitable patients able and willing to give informed consent.

Detail Summary Sheet

Date: 1 Oct 81 Proj No: C-39-81 Status: Terminated

TITLE:

Program on the Surgical Control of the Hyperlipidemias

Start Date: 15 Jun 81	Est Comp Date:
Principal Investigator Ronald R. Blanck, COL, MC	Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine	Associate Investigators:
Key Words: Hyperlipidemias Myocardial infarcion	

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

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

Technical Approach: Data was to have been collected from clinical records, cover sheets and patients contacted for possible inclusion in the study.

Progress: The study was terminated due to transfer of principal investigator and the lack of interest of others to continue the study.

Detail Summary Sheet

Date: 28 Oct 82	Proj No: C-42-81	Status: Ongoing

TITLE: Effects of Dietary Sodium and Potassium Intake upon the Response of the Conscious Dog to Acute Hyperkalemia: The Quantitative Role of the Liver

Start Date 15 Jun 81		Est Comp Date: 84
Principal Investigator Charles J. Foulks, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Nephrology		Associate Investigators: Lucius F. Wright, M.D., MAJ, MC
Key Words: Hyperkalemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To study the quantitative role of the liver in the homeostasis response of a conscious dog to acute hyperkalemia.

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

Progress: This project will be initiated once the clinical investigation animal facility is available.

Detail Summary Sheet

Date: 28 Oct 82	Proj No: C-52-81	Status: Ongoing

TITLE:
Effect of Aspirin (ASA) on Airway Responses

Start Date 7 Jul 81		Est Comp Date: Jul 85
Principal Investigator Daniel A. Ramirez, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Allergy-Immunology		Associate Investigators:
Key Words: Nonallergic rhinitis Aspirin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

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

... the necessary equipment to perform nasal airway resistan... ... recently arrived. Most of the equipment has been rec... ... started.

Detail Summary Sheet

Date: 28 Oct 82	Proj No: C-54-81	Status: Ongoing

TITLE:
Phosphate Homeostasis in the Normal and Renal Failure Dogs

Start Date 6 Aug 81		Est Comp Date: Unknown
Principal Investigator Lucius F. Wright, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Nephrology		Associate Investigators: Charles J. Foulks, M.D., MAJ, MC
Key Words: Homeostasis Renal failure		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $5258	Periodic Review Results:

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

Technical Approach: Phosphate loads are given intravenously to awake dogs suspended in a sling while determinations of glomerular filtration rate are made. Variations include administration of glucose with the phosphorus and analysis of the rise in serum phosphorus, fall in serum calcium and increase in urinary phosphate excretion.

Progress: Equipment ordered during FY 82 has been slow to arrive and is now in place. Estimate initiation of the studies at the beginning of FY 83.

Detail Summary Sheet

Date: 28 Oct 82	Proj No: C-56-81	Status: Terminated

TITLE:

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

Start Date 17 Aug 81		Est Comp Date:
Principal Investigator Robert A. Berendson, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Gastroenterology		Associate Investigators: John F. Schultheiss, M.D., LTC, MC Gary West, M.D., COL, USAF, MC John R. Sharp, M.D., LTC, USAF, MC
Key Words: Esophagitis Rediation therapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

Technical Approach: Patients receiving radiation therapy for different gastrointestinal tumors in a port that will include radiation to the esophagus will be randomized blindly into four groups - one group of controlled subjects and three groups which will receive three different dose levels of Indomethacin, an agent that has been demonstrated in animal studies to be protective in radiation-induced esophagitis. The patients will undergo, prior to radiation therapy, esophagoscopy with photographs, with biopsies and brushing being taken at this time. At the completion of radiotherapy, each patient will undergo a second endoscopy with biopsy, photography, and collection of specimens. The patients will be asked to report any difficulty with esophagitis or dysphagia at weekly intervals. The treatment group will be compared with the control group and with each other using Student's t-test and two-way fixed effect model analysis of variance.

Progress: The principal investigators are no longer in the Army. Efforts to obtain any information regarding the outcome of this study

Detail Summary Sheet

Date: 28 Oct 82	Proj No: C-58-81	Status: Ongoing

TITLE:

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

Start Date 20 Aug 81		Est Comp Date: Aug 83
Principal Investigator Daniel A. Ramirez, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Allergy-Immunology		Associate Investigators:
Key Words: Allergen Nasal mucous membranes		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

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

Progress: The equipment necessary to perform nasal airway resistance measurements is finally arriving. When all the equipment has been received, the project will be started.

Detail Summary Sheet

Date: 12 Oct 82	Proj No: C-59-81	Status: Terminated

TITLE:

Utility of Urological Investigation of Females with Invasive Urinary Tract Infections.

Start Date 20 Aug 81		Est Comp Date:
Principal Investigator John L. Carpenter, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Infectious Disease		Associate Investigators:
Key Words: Urinary tract infection		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

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

Technical Approach: None.

Progress: The study was not started because of other commitments of the principal investigator.

Detail Summary Sheet

Date: 28 Oct 82	Proj No: C-61-81	Status: Terminated

TITLE:

A Phase IV Surveillance Study of Sucralfate in the Treatment of Duodenal Ulcer Disease - An Open Label Study

Start Date 1 Sep 81		Est Comp Date:
Principal Investigator John F. Schultheiss, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Gastroenterology		Associate Investigators: Robert A. Berendson, M.D., MAJ, MC Leonard Duran, M.D., CPT, MC Joseph W. Jackson, M.D., MAJ, MC USAF
Key Words: Duodenal ulcer disease Sucralfate		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To observe the use of Sucralfate in a population of duodenal ulcer patients for effectiveness and to detect possible adverse reactions.

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

Progress: Completed forms on patients entered into the study were forwarded to Marion Laboratories, Inc. The principal investigators are no longer in the Army and, as such, we were unable to obtain the final results of the study.

Detail Summary Sheet

Date: 28 Oct 82	Proj No: C-66-81	Status: Terminated

TITLE:

Double-Blind Parallel Comparison of Sulconazole Nitrate 1% Solution and Clotrimazole 1% Solution in the Treatment of Acute Symptomatic Tinea Pedis

Start Date 24 Sep 81		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., LTC, MC
Key Words: Tinea Pedis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

Technical Approach: None.

[illegible] terminated due to inability to obtain volunteers

Detail Summary Sheet

Date: 28 Oct 82 Proj No: C-67-81 Status: Completed

TITLE: Double-Blind Parallel Comparison of Sulconazole Nitrate 1% Cream and Miconazole Nitrate 2% Cream in the Treatment of Symptomatic Tinea Pedis

Start Date 24 Sep 81	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., LTC, MC
Key Words: Tinea Pedis	

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

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

Technical Approach: Patients were treated once a day for four weeks with either sulconazole or miconazole nitrate cream. The two drugs were randomly assigned. Patients were examined on initiation of therapy, at two weeks, and on completion of four weeks of therapy.

Progress: Twelve patients were entered on the study. Both medications were equally effective in treating tinea pedis. No adverse reactions occurred while on the medication. No further studies will be done as the study was terminated by the drug company.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-1-82	Status: Ongoing

TITLE:

Chronic Cardiopulmonary Adaptations in Pentathlon Athletes.

Start Date 21 Oct 81	Est Comp Date: Dec 82
Principal Investigator Bernard J. Rubal, Ph.D., DAC	Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Cardiology	Associate Investigators: Joe M. Moody, M.D., MAJ, MC S. Damore, M.D., MAJ, MC
Key Words: Endurance conditioning Pentathletes	

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

Objectives: To identify the risk and/or benefits of long-term, intense endurance training.

To examine the cardiovascular adaptations associated with athletic training.

Technical Approach: Ten pentathletes underwent echocardiography, MUGA, thallium stress test, and electrocardiography.

[illegible] Pentathletes exhibit a significantly greater left ventricular mass [illegible] volume and LVI than [illegible] and both [illegible] matched control subjects. [illegible] reaction during exercise were within normal limits.

Detail Summary Sheet

Date: 28 Oct 82	Proj No: C-3-82	Status: Ongoing

TITLE:
Assessment of Sunscreen Substantivity

Start Date 21 Oct 81		Est Comp Date: Unknown
Principal Investigator Eric W. Kraus, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Dermatology		Associate Investigators: Martha McCollough, M.D. James Keeling, M.D., MAJ, MC
Key Words: Sunscreen Substantivity		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

Technical Approach: Apply measured amount of sunscreen to one side of the back. Place a template over the site and expose to 40 minutes of swimming. Apply same sunscreen to the other side of the back (not water exposed) after 4-5 hours of sun exposure. Compare both sides immediately and after 24 hours.

Progress: Thirty seven volunteers entered the study. Sunscreens with substantivity (protection after water exposure) in decreasing order of effectiveness are as follows: (1) Sundown - 15; (2) Sundown - 8; (3) 3M15; (4) Supershade 15; (5) Pre Sun Creamy; (6) 3M8; and (7) Eclipse 15.

Detail Summary Sheet

Date: 28 Oct 82	Proj No: C-4-82	Status: Terminated

TITLE:

Pseudohypoxemia Due to Extreme Leukocytosis or Thrombocytosis.

Start Date 21 Oct 81		Est Comp Date:
Principal Investigator Ray O. Lundy, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Hematology-Oncology		Associate Investigators:
Key Words: Pseudohypoxemia Leukocytosis Thrombocytosis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To evaluate the effect of leukocytosis or thrombocytosis on the measurement of partial pressure of oxygen in arterial blood (PO_2).

Technical Approach: None.

[redacted] the principal investigator [redacted] [redacted] [redacted] [redacted]

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-7-82	Status: Terminated

TITLE:

Antibodies Directed to Streptococcus Bovis as an Indicator of GI Malignancy.

Start Date: 26 Oct 81		Est Comp Date:
Principal Investigator Peter C. Lafon, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Medicine/Internal Medicine		Associate Investigators:
Key Words: Streptococcus Bovis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine if antibodies to streptococcus bovis exist in patients with GI malignancies and can be used as an indicator of the presence of malignant disease in the GI tract.

Technical Approach: Study not done.

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

Detail Summary Sheet

Date: 28 Oct 82 Proj No: C-8-82 Status: Ongoing

TITLE:

The Effect of Cimetidine on Acetaminophen (Tylenol).

Start Date 21 Oct 81	Est Comp Date: Sep 83
Principal Investigator Rolando R. Longoria, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Gastroenterology	Associate Investigators:
Key Words: Cimetidine Acetaminophen	
Accumulative MEDCASE Cost:	Est Accumulat OMA Cost: $100

Objective: To investigate the effect [illegible] cimetidine and acetaminophen [illegible] subjects.

Research Approach: Subjects will be given acetaminophen at a dosage of 7[illegible] gm x 48 hours. Blood will be drawn at 0, 30 minutes, 1, 2, 4, and 8 hours after the first dose. Blood levels will then be drawn at the end of 48 hours. Subjects will then be off medication for 7 days and start cimetidine at 300 mg qid for 7 days. At the end of the 7 days subjects will be given acetaminophen (Tylenol), [illegible] mg, qid x 2 doses. Blood will be drawn at 0, 30 min, 1, 2, 4, and 8 hours after the [illegible] dose. Blood levels will also be drawn at the end of the 48 hour period.

[illegible] are available from [illegible] plans are to do [illegible] Surgery Department [illegible] Medical Investigators [illegible] been obtained. [illegible]

Detail Summary Sheet

Date: 29 Oct 82	Proj No: C-10-82	Status: Ongoing

TITLE:

Effects of Asynchronous and Nonhomogeneous Regional Function in Global Parameters of Ventricular Performance.

Start Date 18 Nov 81		Est Comp Date: Dec 82
Principal Investigator William E. Craig, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Cardiology		Associate Investigators: Ares D. Pasipoularides, M.D., Ph.D. Massimo Pagani, M.D., Universita de Milano, Milan, Italy
Key Words: Ventricular performance		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $214	Periodic Review Results:

Objectives: To establish in the chronically instrumented animal model: (1) how hyperdynamic (or hypodynamic) segmental function is embodied in global ventricular performance parameters, specifically pressure and pressure derived parameters; (2) how diastolic-systolic segmental functional abnormalities are related reciprocally; (3) how neurohumorally mediated cardiovascular reflexes could be complicated in inappropriate, nonhomogeneous myocardial performance patterns.

Technical Approach: This is a collaborative study which will consist of two parts. Part I will consist of experiments on conscious, chronically instrumented dogs. The experiments will be conducted at the Institute for Cardiovascular Research, University of Milan, Milan, Italy.

Part II will consist of a computer assisted analysis of the experimental results. This analysis will be conducted in the Cardiology Service, Brooke Army Medical Center.

Progress: Phase I of the study is almost complete. Phase II will start in the very near future. No progress can be reported until Phase II has started.

Detail Summary Sheet

Date: 29 Oct 82	Proj No: C-11-82	Status: Ongoing

TITLE: Open, Single-Dose Evaluation of Resting Hemodynamic Effects of Oral Nifedipine in Patients with Hypertrophic Cardiomyopathy and Acquired Left Ventricular Hypertrophy.

Start Date 4 Dec 81	Est Comp Date: Dec 82
Principal Investigator William E. Craig, 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: Cardiomyopathy Ventricular hypertrophy.	

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

Objective: To evaluate the effects of Nifedipine on resting hemodynamics in patients with hypertrophic cardiomyopathy and acquired left ventricular hypertrophy.

Technical Approach: This will be an open single-dose study of the hemodynamic effects of oral Nifedipine in ten patients with hypertrophic cardiomyopathy and [illegible] ten patients with left ventricular hypertrophy secondary to chronic pressure overload. The control group will consist of 10 patients with a clinical ind[illegible] [illegible] undergo catheterization but who are subsequently found [illegible] [illegible] of heart disease. All patients will initially be stu[illegible] [illegible] state. The hemodynamic response to sodium nitroprusside will then be [illegible] and the patient allowed to return to basal state. Nifedipine [illegible] will then be administered and hemodynamic measurements repeated [illegible]. All patients will [illegible] premedication with [illegible] one hour before the procedure. [illegible] heart catheteri[illegible] [illegible] performed with multi[illegible] [illegible] our laboratory.

[illegible]

Detail Summary Sheet

Date: 7 Oct 82	Proj No: C-12-82	Status: Completed

TITLE:

Evaluation of Nifedipine in Coronary Spasm and Refractory Angina.

Start Date 15 Dec 81		Est Comp Date:
Principal Investigator Richard A. Schatz, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Cardiology		Associate Investigators:
Key Words: Calcium channel blockers		
Accumulative MEDCASE [illegible]	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To evaluate the efficacy of Nifedipine in the management of angina pectoris: (a) where coronary artery spasm may be a pathogenetic element or (b) where fixed obstructive disease is unresponsive to conventional therapy.

Technical Approach: Patients not responsive to conventional antianginal drug were given Nifedipine and followed for clinical improvement.

Progress: Sixteen patients were entered on the study. Nifedipine has proven extremely effective in the management of angina pectoris.

The Food and Drug Administration (FDA) has approved the drug for widespread use; therefore the study has been completed.

Detail Summary Sheet

Date: 5 Oct 82 Proj No: C-13-82 Status: Ongoing

TITLE:

Intracardiac Pressure and Flow Changes Following Amyl Nitrite Inhalation.

Start Date: 8 Jan 82	Est Comp Date: 1 Jun 83
Principal Investigator [illegible] Moody, M.D., MAJ, MC	Facility Brooke Army Medical Center
[illegible] Department of Medicine/Cardiology	Associate Investigators: B. J. Rubal, Ph.D., DAC
[illegible] Amyl Nitrite [illegible] Blood Pressure	
[illegible] Cost Accumulative OMA Cost:	Periodic Review Results:

[illegible] understand the hemodynamic events responsible for the [illegible] following amyl nitrite inhalation in normal man.

[illegible] hemodynamic changes induced by the inhalation of [illegible] collected during cardiac catheterization. Simultaneous [illegible] pressures were evaluated.

[illegible] study is limited, only two patients [illegible] have been reported by these patients [illegible] applied as of this date.

Detail Summary Sheet

Date: 7 Oct 82	Proj No: C-15-82	Status: Ongoing

TITLE:

Percutaneous Transluminal Coronary Angioplasty, a Prospective Study on Its Indications, Use, and Efficacy.

Start Date 19 Jan 82		Est Comp Date: 30 Dec 83
Principal Investigator Richard A. Schatz, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Cardiology		Associate Investigators: S. Zumbrun, M.D., MAJ, MC
Key Words: Angioplasty Coronary artery disease		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate coronary angioplasty in selected patients with coronary artery disease as an alternative to surgical revascularization.

Technical Approach: Coronary angioplasty is a procedure that involves dilating a coronary artery that has been partially occluded by atheromatous lesion(s). This procedure is performed during cardiac catheterization.

Progress: Physicians and technicians are presently in training and angioplasty kits are on order. It is expected that this project will commence in the very near future.

Detail Summary Sheet

Proj No: C-23-82 Status: Terminated

...ariation of Lipid Levels in Asthmatic Patients on Chronic Medication

	Est Comp Date:
	Facility
MC	Brooke Army Medical Center
	Associat. Investigators:
st Accomplishments	Periodi
	Review Results:

...ciency is ...in ... stimulants chronically, with patients ... factors. ... groups will be compared with age ... chronic beta stimulant therapy affects

Detail Summary Sheet

Date: 19 Nov 82	Proj No: C-24-82	Status: Ongoing

TITLE:

Duration of Nosocomial Oropharyngeal Colonization Following Hospitalization

Start Date 9 Mar 82		Est Comp Date: Jun 83
Principal Investigator Charles E. Davis, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Infectious Disease		Associate Investigators: John L. Carpenter, M.D., COL, MC C. Kenneth McAllister, M.D., LTC, MC
Key Words: Pharyngeal flora		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the duration of the changed pharyngeal flora (gram negative rods and Staph aureus) acquired by hospitalized patients.

Technical Approach: Throat cultures will be obtained at the time of admission to CCU, ICU, General Medicine, Cardiology and Oncology Wards.

Progress: No patients have been entered on the study.

Detail Summary Sheet

Date: 12 Oct 82	Proj No: C-25-82	Status: Terminated

TITLE:

The Prophylactic Use of Intravenous Immune Globulin in Adult Neutropenic Patients with Acute Hematologic Malignancy.

Start Date 7 Apr 82		Est Comp Date:
Principal Investigator John L. Carpenter, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Infectious Disease		Associate Investigators:
Key Words: Immune globulin Neutropenic patients		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To compare the incidence of hospital acquired infections in neutropenic patients who receive immune globulin with incidence in neutropenic patients who receive albumin.

The study will provide information about the severity, frequency, and duration of adverse reactions that occur in patients with acute hematologic malignancy and neutropenia who receive immune globulin.

Technical Approach: None.

Progress: The study was not initiated due to other commitments by the principal investigators.

Detail Summary Sheet

Date: 29 Oct 82	Proj No: C-27-82	Status: Ongoing

TITLE:

The Role of Patient Education in Diabetes Care Utilizing Video Disc and Computer Technology

Start Date 5 Mar 82		Est Comp Date: Sep 83
Principal Investigator Thomas J. Taylor, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Endocrinology		Associate Investigators: William J. Georgitis, M.D., MAJ, MC James H. Anderson, Jr., M.D., LTC, MC
Key Words: Diabetes Computer technology		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: A video disc program is available that provides comprehensive diabetes education. We intend to evaluate the role of this teaching program in improving patient compliance and patient understanding of diabetes.

Technical Approach: Statisticially significant patient knowledge exams will be given to patients utilizing various methods of education including video disc programs.

Progress: The video disc machine has been ordered. The study will begin as soon as the machine is delivered.

Detail Summary Sheet

Date: 29 Oct 82	Proj No: C-28-82	Status: Ongoing

TITLE:

The Dose of Venom in Polistes Hypersensitivity

Start Date 5 May 82		Est Comp Date: Unknown
Principal Investigator Daniel A. Ramirez, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Allergy-Immunology		Associate Investigators:
Key Words: Polistes venom Immunotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $225	Periodic Review Results:

Objective: To determine whether the current recommended dose of venom (100 mcg) is appropriate for polistes sensitive patients.

Technical Approach: Patients who currently receive recommended dose of polistes venom immunotherapy (100 mcg) are candidates for this study. They will be evaluated by drawing venom specific IgE/IgG and by a controlled sting challenge in the hospital.

Progress: In cooperation with the Allergy-Immunology Service at Wilford Hall Air Force Medical Center, an assay for venom specific IgE/IgG has been set up utilizing the ELISA technique. Candidates for the study are currently having their blood drawn for antibody titer determinations prior to formally being enrolled into the study and proceeding with the sting challenges.

Detail Summary Sheet

Date: 7 Oct 82	Proj No: C-29-82	Status: Ongoing

TITLE:

A Comparison of the Accuracy of the Sphygmomanometric and Oscillometric Blood Pressure Measuring Techniques.

Start Date6 May 82		Est Comp Date: MAR 83
Principal Investigator William R. Cox, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Cardiology		Associate Investigators: Bernard J. Rubal, Ph.D., DAC Southwest Research Institute
Key Words: Blood pressure Pulse wave velocity Oscillometry		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: This study will compare the systolic, diastolic and mean blood pressure obtained by sphygmomanometry and oscillometry with an intravascular measurement of blood pressure obtained by high fidelity micromanometry during cardiac catheterization.

The study will evaluate the effect of occlusion cuff length on the accuracy of the noninvasive measurement of blood pressure.

Technical Approach: The accuracy of sphygmomanometry and oscillometry was compared using high fidelity brachial artery blood pressure measurements obtained during cardiac catheterization as the gold standard.

Progress: Two patients have been enrolled in this study. Sufficient data have not been collected for statistical analysis.

Detail Summary Sheet

Date: 12 Oct 82	Proj No: C-31-82	Status: Ongoing

TITLE:

Evaluation of a Non-Invasive Strategy for the Diagnosis of Coronary Artery Disease.

Start Date 18 May 82		Est Comp Date: May 1983
Principal Investigator David L. Brown, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Cardiology		Associate Investigators: William E. Craig, M.D., MAJ, MC
Key Words: Coronary artery disease		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the predictive value of a specific sequence of non-invasive tests to determine the probability of coronary artery disease in patients prior to selective coronary angiography.

Technical Approach: We will compare the results of multiple non-invasive tests to evidence of anatomical lesions obtained by coronary arteriography.

Progress: Twelve patients have been entered on the study. Significant progress has been made in data collection and evaluation; however, the patient number is too small to support statistical comparisons. No complications have been reported in the study.

Detail Summary Sheet

Date: 12 Oct 82	Proj No: C-35-82	Status: Ongoing

TITLE:
Pneumococcal Meningitis.

Start Date 18 May 82		Est Comp Date: May 83
Principal Investigator C. Kenneth McAllister, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Infectious Disease		Associate Investigators:
Key Words: Pneumococcal meningitis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To retrospectively review the U.S. Army experience in the management of pneumococcal meningitis.

To analyze the potential morbidity and mortality among active duty U.S. Army personnel with pneumococcal meningitis.

To determine whether or not the pneumococcal vaccine would be of potential benefit to active duty personnel.

Technical Approach: To seek record review of all cases of pneumococcal meningitis at all Army medical centers--utilizing Infectious Disease specialists for the review.

Progress: Project has not begun due to inability of principal investigator to obtain collaboration.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-37-82	Status: Ongoing

TITLE:

Evaluation of Sodium Ipodate as an Adjunctive Therapy to Radioactive Iodine for Graves' Hyperthyroidism.

Start Date 7 Jul 82	Est Comp Date:
Principal Investigator Thomas J. Taylor, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Endocrinology	Associate Investigators: William J. Georgitis, M.D., MAJ, MC
Key Words: Graves' hyperthyroidism Sodium ipodate Radioactive iodine	

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

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

Technical Approach: The study as originally designed was to consist of two groups. Group I would receive radioactive iodine alone and Group II would receive radioactive iodine followed by sodium ipodate. After a pilot study of five patients, it became clear that a double blinded, placebo control design would be necessary for this study. This means that a capsule identical to sodium ipodate must be prepared. One group of patients will receive the placebo and the other group will receive the drug. Neither the patients nor the physicians will know which capsule is being taken.

Progress: The principal investigators are now in the process of applying for an IND. The study will continue when the IND is received.

Detail Summary Sheet

Date: 29 Oct 82	Proj No: C-38-82	Status: Ongoing

TITLE:
Autologous Bone Marrow Transplantation in Resistant Neoplasms: A Phase I Study

Start Date 7 Jul 82		Est Comp Date: Jul 87
Principal Investigator Walter H. Harvey, D.O, MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Hematology-Oncology		Associate Investigators: Glenn M. Mills, M.D., MAJ, MC James F. Boyd, M.D., LTC MC Catherine Craven, M.D., CPT, MC
Key Words: Bone marrow transplantation		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To develop a bone marrow transplantation program at Brooke Army Medical Center.

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

To establish a competent transplantation service for all eligible DOD patients for present clinical indications and future indications.

Technical Approach: Bone marrow will be aspirated from the pelvis of patients who will undergo autologous bone marrow transplantation. The bone marrow will be frozen and stored in liquid nitrogen storage containers. High dose cytotoxic therapy will be given in an attempt to reduce the tumor burden and the frozen marrow will be thawed and transfused to the patient in order to reconstitute the bone marrow.

Progress: Phase I of the development of bone marrow transplantation unit is almost completed. Necessary equipment for freezing and storage of bone marrow has been ordered, and we are awaiting the arrival of this equipment. Contact has been made with the bone marrow transplant unit at the VA hospital in San Antonio and arrangements have been made to send our technicians there for a period of time in order to train in the processing of bone marrow samples for transplant. Once equipment has been procured and technicians have been trained, then we can develop protocols for actual use of autologous bone marrow transplants.

Detail Summary Sheet

Date: 29 Oct 82	Proj No: C-62-82	Status: Ongoing

TITLE:

The Effect of Calcium Channel Blockers on Sickling and Blood Viscosity in Hgb SS Disease

Start Date 27 Sep 82		Est Comp Date: Mar 83
Principal Investigator James F. Boyd, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Hematology-Oncology		Associate Investigators: Glenn M. Mills, M.D., MAJ, MC John J. Posch, Jr., DAC Barbara Reeb
Key Words: Hgb SS disease Calcium channel blockers Sickling Blood viscosity		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To study the in vitro effect of calcium channel blockers on sickling and on blood viscosity in Hgb SS disease.

Technical Approach: Venous blood will be collected in heparin from nontransfused patients with sickle cell anemia. Plasma will be separated and centrifuged to remove white cells and then used to resuspend the red cells to a hematocrit of approximately 30%. Glucose will then be added to the suspension to provide a final concentration of 10 millimolar. Samples of 6-8 ml with appropriate additives (verapamil or nifedipine) will be preincubated for 30 minutes in 12 ml glass flasks submerged in a 37°C water bath and shaken at 60 oscillations per minute. Hydrated warm gas will be passed over the cell suspensions and the pH stability maintained at 7.5 ± 0.1 by the presence of 5% carbon dioxide solution in all gas mixtures. The concentrations of verapamil to be investigated are 50, 150 and 300 ng/ml. The concentrations of nifedipine are 25, 50, and 150 ng/ml.

Progress. This is a new study.

Detail Summary Sheet

Date: 29 Oct 82	Proj No: C-63-82	Status: Ongoing

TITLE:

Evaluation of Catheter-Mounted Micromanometers vs External Fluid Transducers for Continuous Pressure Monitoring in the Coronary Care Unit

Start Date27 Sep 82		Est Comp Date: Sep 83
Principal Investigator William E. Craig, 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: Continuous pressure monitoring Catheter-mounter micromanometers		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To evaluate the use of high fidelity cather-mounted micromanometer transducers on flow-directed balloon-tipped right heart catheters in the Coronary Care Unit.

To determine whether the more accurate pressures obtained from the micromanometers are significantly different than those obtained from conventional fluid-filled transducer systems and whether or not these differences would change or improve the clinical management of patients requiring hemodynamic monitoring.

Technical Approach: Six patients in the Coronary Care Unit who require continuous pulmonary artery pressure monitoring will be included in this study. Patients selected will be those with acute myocardial infarctions complicated by Killip Class III or IV failure or patients with unstable angina that requires intravenous pharmacologic intervention.

The balloon-tipped flow-directed catheter containing the micromanometer will be inserted either at the bedside in the Coronary Care Unit or under fluoroscopic visualization in the cardiac catheterization laboratory. The techniques of insertion will be identical to those routinely used for placement of Swan-Ganz catheteris. Following insertion, hemodynamic monitoring and clinical management of the patient will proceed as usual.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 29 Oct 82	Proj No: C-66-82	Status: Ongoing

TITLE:

Detection of Immune Complexes in Serum and Synovial Fluid of Patients with Rheumatic Diseases and Other Diseases Characterized by Circulating Immune Complexes

Start Date 27 Sep 82		Est Comp Date: Sep 84
Principal Investigator Charles S. Via, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Rheumatology		Associate Investigators: Robert C. Allen, M.D., Ph.D., MAJ, MC
Key Words: Immune Complexes Rheumatic diseases		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: Study the effects of sera and synovial fluids containing immune complexes (IC's) on normal granulocyte function.

Develop an assay for quantifying serum or synovial fluid IC activity based upon direct stimulation of granulocyte oxygenation activity, or inhibition of oxygenation response to a second stimulus. Correlate these findings with currently used clinical laboratory techniques for IC detection such as C1q binding.

Develop techniques for quantifying the autoantibody activities of serum or synovial fluid for antigens such as DNA, ribonucleoprotein, mitochrondria, et cetera.

Measure the pre- and post-stimulation oxygenation activity of granulocytes (using microliter quantities of whole blood or synovial fluid aspirates) from patients with immune complex associated diseases.

Technical Approach: Cells obtained from blood or synovial fluid will be studied on the same day or discarded. When tested the cells will be differentially counted and specific oxygenation activity will be measured by chemiluminigenic probing by methods previously published (Allen & Pruitt, 1982; Allen, 1982). Resting background oxygenation activity and the responses to a battery of stimuli, such as C3b labeled zymosan, synthetic IC's, lectins and phorbol myristate acetate, will be recorded by single photon counting.

Progress: This is a new study

Detail Summary Sheet

Date: 27 Oct 82	Proj No: C-67-82	Status: Ongoing

TITLE:
Pathogenesis of Tissue Injury in Porphyria.

Start Date 27 Sep 82		Est Comp Date: Sep 85
Principal Investigator Charles W. Lewis, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Dermatology		Associate Investigators: Deborah A. Spiva, M.D.
Key Words: Prophyria Erythropoietin Porphyrins		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To investigate the pathophysiology by which circulating porphyrins produce hyperviscosity states and to determine the extent of tissue injury produced.

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

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

To examine immunologic parameters caused by fixed porphyrins, i.e., IgG deposition and complement activation by porphyrins.

Technical Approach: Plasma/neocytopheresis will be performed to lower circulating porphyrin levels in order to accumulate data concerning the development of hyperviscosity and tissue damage due to elevated levels of free porphyrins.

To investigate the mechanism of skin damage due to porphyrin deposition, two biopsy protocols will be followed.

Immunologic and coagulation factor participation in the development of skin damage will be examined.

The reasons for the development of hyperviscosity states and the effects of such states on erythropoietin levels and salt and water balance will be studied.

Progress: This is a new study.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-18-82	Status: Completed

TITLE:

The Effects of Patient Education on the Need for OB-GYN Care of the Active Duty Female.

Start Date 16 Feb 82		Est Comp Date:
Principal Investigator Patricia Cefaly, R.N., CPT, ANC		Facility Brooke Army Medical Center
Dept/Sec Department of Nursing		Associate Investigators:
Key Words: Feminine hygiene Venereal disease Birth control		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine if patient education in the areas of feminine hygiene, venereal disease and birth control affects the need for OB-GYN care of the active duty female.

Technical Approach: The study consisted of two control groups (299 students) and two test groups (295 students). Subjects were female students from four separate companies attending the 91B course at the Academy of Health Sciences, Fort Sam Houston, Texas. The test groups received a one hour class on feminine hygiene, venereal disease, and birth control. The control groups did not. The number of clinic visits for OB-GYN related problems were recorded and comparisons were made between the two groups.

Progress: The control groups made a total of 86 visits, or 29% of the control population were seen by the OB-GYN Nurse Practitioner. In contrast, the test groups made 121 visits, or 41% of the population was seen. To aid in assessing the effectiveness of the class, a post test was given to all test subjects who were seen in the clinic. About half (49%) of the test subjects thought the class made them more aware of their complaints.

We found that patient education in the areas of feminine hygiene, birth control and venereal disease resulted in a significant increase (12) in clinic visits. In addition there was a significant difference in the number of subjects seen for the purpose of obtaining birth control counselling. In this category 14% more test subjects than control subjects were seen.

C-18-8. (continued)

In applying the findings of this study, patient education in the above three areas should be made available as early as possible in the training of female soldiers.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-30-82	Status: Ongoing

TITLE:

Systematic Relaxation Training Group

Start Date 11 May 82		Est Comp Date: 30 Jun 83
Principal Investigator Elizabeth A. Bell, R.N., MAJ, ANC		Facility Brooke Army Medical Center
Dept/Sec Department of Nursing		Associate Investigators: Harley G. Klein, R.N., MAJ, ANC
Key Words: Relaxation training Oncology patients		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To provide an alternative or adjunctive intervention to oncology patients to deal with their responses to their illness and side effects concomitant with radiation, chemotherapy and/or surgery.

Technical Approach: Oncology patients are being provided training in systematic relaxation and visualization in a group format. Pre- and post-evaluation is done to determine the patients' current response to illness and other stressors.

Progress: A pilot study of six patients was completed in August 1982. The first study group of four patients is now in progress. It is anticipated that the project will be completed in approximately nine months.

Detail Summary Sheet

Date: 19 Nov 82	Proj No: C-12-79	Status: Completed

TITLE:

Clinicopathologic Study of Uterine Vascular Changes with and without Hormonal Influence

Start Date Mar 79		Est Comp Date:
Principal Investigator Charles V. Wilson, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics and Gynecology		Associate Investigators: Roby Joyce, M.D., LTC, MC
Key Words: Uterine vascular changes Oral contraceptives		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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: Seventy patients were entered on the study. All patients undergoing hysterectomy by an abdominal or vaginal route were eligible for the study. The operative specimen was taken to the pathologist for both electron microscopic and light microscopic fixation and preparation. Sections were made of both uterine and myometrial vessels and examined for intimal thickening and other abnormal vascular changes.

Progress: The results of this study are not available due to transfer of the principal investigator from this installation. A manuscript has been prepared and submitted for publication.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-2-82	Status: Completed

TITLE:

A Comparison of the Supine Pressor Test, vs the Short Supine Pressor Test, for the Prediction of Pregnancy Induced Hypertension.

Start Date: 21 Oct 81		Est Comp Date:
Principal Investigator Jerome N. Kopelman, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Supine pressor test Short supine pressor test Hypertension, pregnancy induced		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: 1. To study the relative merits of two different methods for the prediction of pregnancy induced hypertension.

2. To determine which test is a better predictor of pregnancy induced hypertension.

Technical Approach: Fifty-three primigravid patients between 28 and 32 weeks gestation, without prior history of renal disease or hypertension, were selected from the routine prenatal clinic at Brooke Army Medical Center. Of this initial group 43 remained evaluable. For the purposes of this study, pregnancy-induced hypertension was defined as a blood pressure of either 140/90 or an increase of 30 mm Hg in systolic or 15 mm Hg in diastolic blood pressure. The supine pressor test (SPT) technique was identical with that of Gant, and the technique for the short supine pressor test (SSPT) was identical to that of Peck.

Progress: The SPT was positive in 19/43 and the SSPT in 17/43. Results were negative for the SPT in 24/43 and for the SSPT in 26/43. Of the 43 subjects for which follow-up was available, 21/43 developed pregnancy-induced hypertension and 22/43 remained normotensive.

The results indicate that these pressor tests should be abandoned. The positional changes in blood pressure that occur in pregnancy do not allow the clinician to delineate a population at risk for pregnancy-induced hypertension. Careful prenatal evaluation of weight gain, blood pressure, proteinuria, etc. remains the best means for early diagnosis and management of pregnancy-induced hypertension.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-9-82	Status: Completed

TITLE:

Retrospective Analysis of Experience with Tubo-Ovarian Abscesses at Brooke Army Medical Center from 1976 to 1981.

Start Date: 21 Oct 81		Est Comp Date:
Principal Investigator Dale Wolford, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Tubo-ovarian abscesses		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objedtives: To evaluate surgically proven tubo-ovarian abscesses for: a) incidence and age of patients, b) relation to contraception, c) presenting signs and symptoms, d) bacteriology and antibiotic use, e) management, f) surgery performed and complications of surgery, g) days hospitalized, and h) outcome of patients treated with conservative surgery.

Technical Approach: This review encompassed five years - 1976 to 1981 - of all gynecological admissions to Brooke Army Medical Center. There were 7966 gynecological admissions during this period, and 50 cases were recorded as tubo-ovarian abscesses. Five charts were deleted because of insufficient evidence to substantiate the diagnosis of tubo-ovarian abscess. Of the 45 cases recorded as abscesses, 71% were surgically proven and 29% were diagnosed on clinical findings.

Each chart was reviewed with regard to: age and parity, contraception, presenting signs and symptoms, admitting diagnosis, significant medical and surgical histories, pertinent laboratory values, antibiotic use, fever, type of surgery and complications associated with management.

From [illegible] of the [illegible] reviewed, the majority of tubo-ovarian abscesses occurred in the child bearing years with 54% under the age of thirty. No [illegible] contraception could be discriminated as predisposing to the etiology of tubo-ovarian abscesses. The most consistent presenting symptom was lower abdominal pain. The average hospital stay was 10.5 days. The majority of patients in this series were managed conservatively with a trial of 48 hours of intravenous antibiotic therapy. If there was no response or [illegible] clinical status, they were then treated surgically. Of the 45 patients, 11 were managed conservatively without surgical intervention; the remainder had [illegible] surgical procedures performed for either diagnosis or treatment. Five patients underwent conservative surgery. One patient developed septic pelvic [illegible] phlebitis, and the other four patients had a relatively benign postoperative course.

Detail Summary Sheet

Date: 29 Oct 82	Proj No: C-36-82	Status: Ongoing

TITLE:

Intraoperative Intrauterine Irrigation with Cefamandole Nafate Solution at Cesarean Section vs Intravenous Prophylaxis with Cefoxitin.

Start Date 26 May 82		Est Comp Date: Sep 83
Principal Investigator Charles A. Jeffreys, Jr., M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics-Gynecology		Associate Investigators: Roger W. Wallace, D.O, MAJ, MC C. Neil Herrick, M.D., COL, MC
Key Words: Cefamandole nafate Cefoxitin Prophylaxis Intrauterine irrigation		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: By use of an irrigation solution containing a cephalosporin, the confirmation of its usefulness in decreasing postoperative infections will be assessed.

The study will compare the relative effectiveness of intravenous prophylaxis.

The study may also aid in determining if one of the two methods is more appropriate in certain clinical situations.

Technical Approach: Patients were randomized into two groups (1) receiving cefamandole irrigation (intrauterine) and (2) receiving intravenous prophylaxis with cefoxitin. Patients are placed on study if (1) primary C-section, labored, with ruptured membranes/without ruptured membranes; (2) repeat C-sections with failed trial of labor.

Progress: Twenty-nine patients have been entered on the study. Information is collected on data sheets concerning preoperative, intraoperative and postoperative course. This is an ongoing double blind study, and the code thusfar has not been broken. There have been no major complications sustained by anyone participating in the study. One patient was discontinued from the study for temperature elevation on day of surgery to 102^{o}. She was placed on appropriate double antibiotic therapy and had a benign postoperative course.

Detail Summary Sheet

Date: 29 Oct 82	Proj No: C-55-82	Status: Ongoing

TITLE:

The Reliability of the Beta Specific Urine Pregnancy Test vs the Radioimmunoassay for Beta-HCG in Serum in the Diagnosis of Ectopic Pregnancy.

Start Date 13 Aug 82		Est Comp Date: May 83
Principal Investigator Andrew W. Robertson, J.D., CP, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics-Gynecology		Associate Investigators: Charles V. Capen, M.D., LTC, MC Edward J. Shunski, M.D.
Key Words: Beta-HCG Beta specific urine pregnancy test Radioimmunoassay		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To compare the usefulness and reliability of a beta specific urine pregnancy test in the clinical diagnosis of ectopic pregnancy.

Technical Approach: All women admitted to the Gynecology Service with the diagnosis of "rule out ectopic pregnancy" will be included in the study. It is the policy to obtain certain laboratory tests on the patient to include urinalysis. This study will use the already collected urine to run a Beta-specific urine pregnancy test and compare these results with the serum pregnancy test. These results will be correlated with the final diagnosis of the patient. The study will compare the reliability and accuracy of the Beta-specific urine pregnancy test in the diagnosis of ectopic pregnancy.

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

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-58-82	Status: Ongoing

TITLE:
The Study of Hormonin[R] in the Management of Postmenopausal Symptoms.

Start Date 23 Aug 82		Est Comp Date: Unknown
Principal Investigator C. Neil Herrick, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics and Gynecology		Associate Investigators: Charles S. Foreman, Jr., M.D., CPT, MC Andrew W. Robertson, M.D., CPT, MC
Key Words: Postmenopausal symptoms Hormonin[R]		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the comparative short-term efficacy and safety of different Hormonin[R] dosages for the treatment of postmenopausal symptoms in both naturally and surgically menopausal women.

Technical Approach: The study group will be made up of females, age 30-65, who are naturally or surgically menopausal. They will be assigned to one of three groups of patients and will be given one of three dose levels of Hormonin or Premarin or a placebo. The medication will be taken daily for three weeks each month for three months. Endometrial biopsy will be obtained at the first and last visit.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-21-80	Status: Ongoing

TITLE:

In vitro Demyelination and Remyelination of Cultured Mammalian Central Nervous Tissue.

Start Date 7 May 80		Est Comp Date: Jan 83
Principal Investigator Roby P. Joyce, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pathology		Associate Investigators:
Key Words: Demeylination Remyelination Central nervous tissue		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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% CO_2 incubator. Twice weekly the cultures are washed and fed. Using an inverted tissue culture microscope and 35 mm camera attachment, the growth and eventual decline of the colonies is documented.

Progress: This study has been at a standstill for the past year due to lack of technical assistance. It is anticipated that work on the study will be started in the near future as a technician has now been assigned to assist [illegible] time basis.

Detail Summary Sheet

Date: 5 Oct 82	Proj No: C-64-81	Status: Completed

TITLE:

Detection of Rotavirus in Selected Pediatric Patients Utilizing Rotazyme Rotavirus Diagnostic Kit.

Start Date 23 Sep 81		Est Comp Date:
Principal Investigator Thomas R. Perez, DAC		Facility Brooke Army Medical Center
Dept/Sec Department of Pathology/Virology		Associate Investigators: S. Vern Juchau, Ph.D., LTC, MSC Paula Mosman, DAC
Key Words: Rotavirus Rotazyme, Rotavirus Diagnostic Kit		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

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

Technical Approach: Fresh stool from 58 Pediatric patients (6 months to 2 years) were submitted. If a stool sample proved to be impractical, rectal swabs were submitted using a "Virocult" for Rotavirus and other viral agents and a bacterial "culturette" for bacterial studies.

Progress: The number of specimens received were less than anticipated. This seemed to indicate a possible unawareness to the availability of a new methodology for detection of Rotavirus. Some specimens were not properly labeled "Rotavirus Study" which resulted in partial performance of procedures required. Age requirements were not always met resulting in older patients being included in the study. A total of 58 specimens were received. Of these, only 43 had complete testing for Rotavirus, other viral and bacterial agents.

This procedure has become a standard laboratory procedure.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-22-82	Status: Ongoing

TITLE:

Production of Leptospira hyperimmune sera in rabbits.

Start Date 4 Mar 82		Est Comp Date: Unknown
Principal Investigator Michael Gray, M.S., DAC		Facility Brooke Army Medical Center
Dept/Sec Department of Pathology/Veterinary Lab		Associate Investigators:
Key Words: leptospirosis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To produce diagnostic reagents for Leptospira.

Technical Approach: Urine and blood specimens from patients suspected of having leptospirosis were cultured. Leptospira isolates were purified, grown to heavy density, inoculated into rabbits by IV for production of antisera. Rabbit sera was collected 7-9 days post last injection (series of 4) and titered against homologous and heterologous antigens. The isolates with antisera were sent to CEC, Atlanta, GA for serologic identification.

Total Number of Patients on Study: 6

Number of Patients entered FY 82: 20

Progress: Antisera was produced against 6 leptospira isolates.

Isolates submitted to the Leptospirosis Reference Lab, CDC, Atlanta, GA, were serologically identified, and [illegible] leptospira were identical to those isolates [illegible] from animals and water in Panama.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-17-82	Status: Ongoing

TITLE:

Beta-Thromboglobulin Levels and Platelet Function in the Newborn.

Start Date 20 Jan 82		Est Comp Date: Jun 83
Principal Investigator Virginia Hallinan, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators: Lawrence K. Wickham, M.D., MAJ, MC Terry E. Pick, M.D., LTC, MC
Key Words: Beta-thromboglobulin Platelet Newborn		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $2543	Periodic Review Results:

Objectives: To determine the level of Beta-thromboglobulin in the healthy, full term and preterm gestation neonate.

To measure platelet aggregation in this same population.

To determine if a correlation exists between Beta-thromboglobulin levels and platelet aggregation in the term and preterm gestation neonate.

Technical Approach: Twenty cc of whole blood will be obtained from the umbilical cord of 50 healthy, term infants and 25 preterm infants. Beta-thromboglobulin determinations will be performed as well as a determination of platelet function.

Progress: Much difficulty has been encountered in making the Beta-thromboglobulin determinations. The problems seem to have been solved and the study will start in the near future.

Detail Summary Sheet

Date: 29 Oct 82 | Proj No: C-19-82 | Status: Completed

TITLE:

Comparison of Efficacy of Theophylline Administered by Continuous Infusion versus Bolus for Status Asthmaticus.

Start Date 14 Feb 82		Est Comp Date:
Principal Investigator Bradford R. Miller, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Status Asthmaticus Theophylline		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine which of two methods of IV Theophylline administration is more effective in reversing status asthmaticus.

Technical Approach: Twenty consecutive admissions to the Pediatric Intensive Care Unit (PICU) who satisfied the definition of status asthmaticus were entered into the study after informed consent was obtained. Upon admission to the PICU, the random assignment of each subject to a treatment protocol was made in a double-blind fashion. Equivalent 24-hour doses of intravenous theophylline were administered and responses measured by respiratory scores.

Progress: There was no significant difference discovered between theophylline levels or respiratory scores of the two populations.

Detail Summary Sheet

Date: 2 Nov 82 Proj No: C-26-82 Status: Completed

TITLE:

The Effect of Tylenol Therapy on Subsequent Chloramphenicol Serum Levels.

Start Date 20 Apr 82	Est Comp Date:
Principal Investigator Thomas G. Hardway, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics	Associate Investigators:
Key Words: Tylenol Chloramphenicol	

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

Objective: To confirm an observation suggesting an interaction between chloramphenicol and tylenol.

Technical Approach: Retrospective analysis of patient records at Bexar County Hospital using Microbiology log of chloramphenicol assays done in past three years was accomplished noting use of or lack of use of tylenol.

Progress: Approximately 50 records were reviewed. However, the results are not available due to reassignment of principal investigator.

Detail Summary Sheet

Date: 2 Nov 82 Proj No: C-35-74 Status: Completed

TITLE:
Clinical Evaluation of Cisternography Utilizing ^{111}Indium DTPA.

Start Date 25 Jan 74	Est Comp Date:
Principal Investigator Steven Bunker, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Radiology/Nuclear Medicine	Associate Investigators:
Key Words: Cisternography Hydrocephalus	

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

Objective: To evaluate the safety and efficacy of ^{111}Indium DTPA for cisternography.

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

Progress: ^{111}Indium DTPA has been approved by the FDA for unrestricted use [illegible], requirements as an investigational drug no longer apply.

Detail Summary Sheet

Date: 2 Nov 82	Proj No: C-12-77	Status: Ongoing

TITLE:
Intravenous Administration of I^{131} for Adrenal Evaluation of Imaging.

Start Date 15 Nov 76		Est Comp Date: Unknown
Principal Investigator Steven Bunker, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Radiology/Nuclear Medicine		Associate Investigators:
Key Words: Adrenal Scan I^{131} (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 IV 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. Bisual image interpretation as well as computer enhanced processing of the images is used to evaluate them. In selected patients, two repeat studies employing dexamethasone suppression may also be performed.

Progress: During the period 1980 to the present, there has been no usage of this product. The protocol is being maintained in an active status should a diagnostic need arise.

Detail Summary Sheet

Date: 2 Nov 82	Proj No: C-20-81	Status: Completed

TITLE:

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

Start Date 18 Mar 81		Est Comp Date:
Principal Investigator Steven Bunker, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Radiology/Nuclear Medicine		Associate Investigators:
Key Words: Hepatobiliary Scan		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

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

Progress: One hundred and seventy patients were studied. The results have been reproducible. DPA has recently released Di-isopropyliminodiacetic acid (Prolatect) which is superior to 99mTc-EHIDA. Therefore, no patients will be [illegible] 99mTc-EHIDA

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-21-81	Status: Terminated

TITLE:

Evaluation of Young Amateur Boxers by Computed Tomography

Start Date 26 Mar 81		Est Comp Date:
Principal Investigator Luis Canales, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Radiology		Associate Investigators:
Key Words: Computed tomography		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

Technical Approach: CT scanning of the head of the amateur boxer will be done after a boxing bout.

Progress: Fifteen cases were studied and no abnormalities were found. However, the study was terminated due to inability to obtain volunteers.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-65-81	Status: Completed

TITLE:

Odontodysplasia and the Trico-Dento-Osseous Syndrome, Type II.

Start Date: 23 Sep 81		Est Comp Date:
Principal Investigator Frank Quattromani, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec: Department of Radiology		Associate Investigators:
Key Words: Odontodysplasia Trico-Dento-Osseous Syndrome		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:$1290.00	Periodic Review Results:

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

Technical Approach: Radiographs of the immediate family of the proband as well as twelve other members of the kindred were performed. Blood was obtained for genetic association and linkage studies. Additional family members were asked to complete a questionnaire and through this the kindred members were identified according to generation to form the pedigree.

Progress: The earliest reported affected kindred member was the great grandfather of the proband. All marriages in the kindred were nonconsanguinous although there was a common name in several generations.There was no instance where an affected child was born to two unaffected parents, nor was there a marriage between two affected individuals. Each affected individual had an affected parent and male to male transmission was noted several times. Nearly equal numbers of males and females (21 males/26 females) were affected. Thus, the pedigree indicated an autosomal dominant pattern. Affected family members were invariably edentulous by the fourth decade of life, but frequently before age 30. All 47 affected individuals reported loss of maxillary teeth prior to loss of mandibular

teeth. Twenty-two of forty-seven individuals with enamel dysplasia had at one time tightly coiled (fuzzy) hair, while 165 of 179 with normal teeth had straight hair.

Interestingly enough, in 1972, Lichtenstein et al. investigated a kindred of 169 members from Washington County, Virginia, with an autosomal dominant syndrome of curly hair since birth, dysplastic enamel and a generalized skeletal dysplasia involving long bones. The present kindred of 226 members live along the Holston River Valley of Tennessee and demonstrate a similar disorder of hair and teeth but in which the skeletal findings include a markedly sclerotic and sometimes thickened calvarium with long bones that are slightly undertubulated without sclerosis. In spite of radiologic differences between the two kinships, it is likely that they have a common ancestor given the similar geographic origins. However, after an extensive genealogic survey, no such ancestor was identified.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-21-78	Status: Ongoing

TITLE:

Clinical Study of Intraocular Lenses.

Start Date Feb 78		Est Comp Date: Unknown
Principal Investigator John Gearhart, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/Ophthalmology		Associate Investigators: Donald Griffith, M.D., COL, MC Charles Aronson, M.D., LTC, MC
Key Words: Intraocular lens Cataract extraction		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To establish the safety and effectiveness of this device for use in human subjects according to guidelines recommended by the Food and Drug Administration ophthalmic advisory panel.

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

Progress: Overall, 300 patients have been entered on the study (160 during FY 82). Since last year enough data has been accumulated nationally to start removing some lens styles from the investigational requirement, and many more are planned for release. The data is showing the devices to be safe and effective.

Detail Summary Sheet

Date: 3 Nov 82 Proj No: C-14-80 Status: Ongoing

TITLE:

Abdominal Wound Closure

Start Date Mar 80	Est Comp Date: Indefinite
Principal Investigator Michael J. Walters, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/General Surgery	Associate Investigators: General Surgery Residents
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: Wound closure techniques are evaluated for: (a) time of closure at operation and (b) immediate and long-term postoperative wound complications.

Progress: The hospital has been out of nylon suture for continuous closure for many months. As such, the study has been at a standstill but will be activated as soon as the suture material is available.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-7-81	Status: Ongoing

TITLE:
Open-ended Cutaneous Vasostomy

Start Date 3 Feb 81		Est Comp Date: Undetermined
Principal Investigator Mauro P. Gangai, M.D.		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/Urology		Associate Investigators: C. Ritchie Spence, M.D., COL, MC
Key Words: Spermatic granuloma Open-ended cutaneous vasostomy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

Technical Approach: Open-ended vasostomy is performed by isolating the vas deferens in a standard fashion and using vaso-clips on the distal end of the vas. The proximal vas is spatulated and sutured in an open fashion to the scrotal skin.

Progress: This study was designed to include 200 patients--100 in the study and 100 as controls. To date 138 patients have been entered into the study, of which 63 were entered in FY 82.

It appears that an equal number of complications are occurring in both the study and control group. No unexpected adverse effects have been noted from either group. The study is incomplete at present until the total number of patients are registered.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-22-81	Status: Ongoing

TITLE:

The Effect of Prophylactic Antibiotics on Wound Sepsis Following Elective Cholecystectomy

Start Date 26 Mar 81	Est Comp Date: Jun 83
Principal Investigator Cheryl A. Wesen, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/General Surgery	Associate Investigators: Michael J. Walters, M.D., LTC, MC
Key Words: Prophylactic antibiotics Cholecystectomy	

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

Objective: To determine if the use of prophylactic, broad-spectrum antibiotics will significantly decrease the incidence of wound sepsis following elective cholecystectomy for chronic cholecystitis and/or cholelithiasis.

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

Progress: Twenty seven patients have been enrolled in the study, six during FY 82. There have been no wound infections in any of the patients studied thus far and no instances of adverse effects attributable to the administration of Cefamandol. Progress was limited earlier this year secondary to departure of the principal investigator and assignment of a new principal investigator.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-23-81	Status: Completed

TITLE:
Comparative Efficacy of Serum Albumin Products

Start Date 31 Mar 81		Est Comp Date:
Principal Investigator Nelson E. Isenhower, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/Anesthesiology		Associate Investigators: Chester E. Pruett, M.D., MAJ, MC
Key Words: Albumin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:$35,280	Periodic Review Results:

Objective: To determine if there is a difference in the therapeutic effectiveness of the Federal Standard 25% Normal Serum Albumin U.S.P. (which requires refrigeration with 10 year shelf life) and the commercially available 25% Normal Serum Albumin U.S.P. (which requires no refrigeration with 3 year shelf life).

Technical Approach: Clinical comparison of patients needing colloid volume expander comparing Depot albumin and commonly available albumin.

Progress: No significant clinical difference has been noted between the two. Therefore the study is considered to be completed.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-30-81	Status: Ongoing

TITLE:

Renal Sequelae of Vasectomy

Start Date 10 Apr 81		Est Comp Date: Apr 83
Principal Investigator Ian M. Thompson, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/Urology		Associate Investigators: Mauro P. Gangai, M.D. C. Ritchie Spence, M.D., COL, MC
Key Words: Vasectomy Renal sequelae		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

Technical Approach: We will compare patients with history of vasectomy to age matched controls using 24 hour creatinine/protein clearances as a measure of renal function.

Progress: As the principal investigation has been at Fort Hood for the past six months, the study has not yet started.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-32-81	Status: Ongoing

TITLE:
The Role of Continuous Peritoneal Lavage in the Treatment of Severe Acute Pancreatitis

Start Date 12 May 81		Est Comp Date: Jun 83
Principal Investigator James M. Kunkel, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/General Surgery		Associate Investigators:
Key Words: Pancreatitis Peritoneal lavage		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

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

Progress: One patient has been enrolled and was treated with peritoneal lavage. The patient survived and ultimately did well.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-40-81	Status: Terminated

TITLE:

Anterior Vitrectomy for Aphakic Cystoid Macular Edema - Collaborative Study

Start Date 15 Jun 81		Est Comp Date:
Principal Investigator Donald G. Griffith, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/Ophthalmology		Associate Investigators:
Key Words: Vitrectomy Aphakic cystoic macular edema		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

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

[illegible] few patients eligible to be randomized have declined to enter the study. With new cataract techniques, fewer and fewer patients are [illegible] problem this study was designed to study. Therefore, the [illegible] terminated.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-41-81	Status: Ongoing

TITLE:

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

Start Date 15 Jun 81		Est Comp Date: Mar 83
Principal Investigator Leonard Brown, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/Otolaryngology		Associate Investigators:
Key Words: Ultrasound		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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

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

Progress: Due to the lack of patient response to numerous letters sent out during FY 82 (only two patients tested), our plan is to take another approach in cooperation with the Department of OB-GYN.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-57-81	Status: Ongoing

TITLE:

Cardiac Surgery Prospective Follow-up Project

Start Date 20 Aug 81		Est Comp Date: Aug 84
Principal Investigator George F. Schuchmann, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/Cardiothoracic		Associate Investigators: James B. Peake, M.D., COL, MC
Key Words: Cardiac surgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To follow-up patients who have had cardiac surgical procedures to assess: a. short-term outcome; b. long-term outcome; c. prognostic factors and relate above to work status and military service.

Technical Approach: After informed consent, patients were asked to fill out baseline data sheets including information to allow contact for follow-up. Further construction of data base was accomplished by physician review of cardiac cath data and angiographic studies and historical data which were recorded on a standard format and the data base was expanded with a form filled out intraoperatively. Follow-up letters have been sent, initially at six months but were recently only at one year to determine the effect of cardiac surgery upon 1) survival, 2) preoperative symtpoms, 3) quality of life, 4) employment status.

Seven hundred and forty two patients have been registered, 427 during FY 82

Progress: The success of this project was predicted upon availability of automatic data processing capability. Because of funding, automated processing has not yet been instituted, and these files have been hand maintained. A word processing system with data processing capability has been available for several months but has been limited by turn-over in clerical staff necessitating retraining, and by limited availability because of other commitments of the ADP section. Because of these clerical problems, we are somewhat behind in our follow-up letters. We hope to correct this over the next two months.

Detail Summary Sheet

Date: 2 Nov 82	Proj No: C-60-81	Status: Terminated

TITLE:

Post-cholecystectomy Analgesia and Respiratory Function in Patients Treated with Epidurally Administered Morphine, Bupivicaine or Sterile Saline.

Start Date26 Aug 81		Est Comp Date:
Principal Investigator Chester E. Pruett, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/Anesthesiology		Associate Investigators: Wallace H. Good, Jr., M.D. CPT, MC
Key Words: Epidural morphine Analgesia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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

Technical Approach: To randomly epidurally administer morphine, Bupivicaine or saline to patients undergoing cholecystectomy in right subcostal approach by the investigators and compare preop and postoperative respriatory functions.

Progress: Principal resident investigator PCSd and principal staff investigator not interested in doing the study by himself. Other residents likewise not interested in the study, therefore it was terminated before significant number of patients were entered.

Detail Summary Sheet

Date: 3 Nov 82 Proj No: C-6-82 Status: Ongoing

TITLE:

Antibiotic Prophylaxis for Transurethral Resection of the Prostate TURP.

Start Date 21 Oct 81		Est Comp Date: Oct 83
Principal Investigator Ian M. Thompson, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/Urology		Associate Investigators: C. Kenneth McAllister, M.D., LTC, MC
Key Words: Transurethral resection of prostate (TURP) Prophylaxis Antibiotics		Vern Juchau, Ph.D., LTC, MSC Mauro Gangai, M.D. C. Ritchie Spence, M.D., COL, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine if a rationale exists for the prophylactic use of antibiotics prior to and during transurethral resection of the prostate (TURP).

Technical Approach: This is a randomized, double blinded placebo controlled study of Septra (2 doses preop/2 doses postop) for TURP in low-risk patients.

Progress: Because of exclusions, many patients cannot be entered, however, it is progressing well with eleven patients having been enrolled.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-14-82	Status: Ongoing

TITLE:

Association of Geniourinary Tract Abnormalities with Inguinal Hernia and Prognosis of Inguinal Hernia Repair

Start Date Jan 82		Est Comp Date: Unknown
Principal Investigator John K. Hamelink, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/General Surgery		Associate Investigators: Ian Thompson, M.D., CPT, MC, Urology Service Cheryl Wesen, M.D., CPT, MC General Surgery
Key Words: Inguinal Hernia Prostatism		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the degree of association of genitourinary tract abnormalities and inguinal hernia.

To attempt to identify any association that may exist between genitourinary tract abnormalities and prognosis of inguinal hernia repair.

Technical Approach: Part I: Male patients over age 40 with inguinal hernia, (without previous hernia surgery or transurethral surgery) are evaluated in the General Surgery Clinic for repair. Following consent, patients are sent to the Urology Clinic for examination and urine flow rates with recommended treatment.

Part II: Follow-up schedule of postoperative herniorrhaphy patients on protocol from Part I. Complications, hernia recurrence, and progression of urologic disease are recorded.

Progress: The study has been dormant until recently because the principal investigators were off their respective services or on TDY. Five patients have been entered on the study and significant progress is anticipated in the coming year.

Detail Summary Sheet

Date: 2 Nov 82	Proj No: C-20-82	Status: Ongoing

TITLE:

Long-Term Effect of Orthoptics on the Fusional Vergeances.

Start Date 16 Feb 82		Est Comp Date: Dec 84
Principal Investigator John C. Kotulak, O.D., CPT, MSC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/Optometry		Associate Investigators: William B. Knapp, O.D., Ph.D. Mark D. Cooney, O.D.
Key Words: Orthoptics Fusional Vergeances		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the long-range efficacy or permanency of orthoptics as a treatment modality for strabismus.

Technical Approach: Only patients who have been successfully treated with orthoptics are eligible for inclusion in this study. After being admitted to the study, patients are given regular post-orthoptic follow-up care at regular time intervals. At each follow-up visit, the amplitude of the particular fusional vergeance that has been enhanced orthoptically is measured and recorded. The major thrust of this study is to observe the effect of time on this amplitude and to gain the ability to quantitatively predict the end-stage or ultimate amplitude many years after therapy has been terminated.

Fifteen patients have been studied thusfar.

Progress: This study is in its earliest stages, during which time the initial patients are being incorporated. After allowance for attrition, approximately 30 new patients are expected to be added to the study each year.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-34-82	Status: Ongoing

TITLE:

Preoperative Detection of Gram Negative Pathogens in Intraocular Surgery Candidates.

Start Date 18 May 82		Est Comp Date: Sep 83
Principal Investigator Don G. Griffith, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/Opthalmology		Associate Investigators: Vern Juchau, Ph.D., LTC, MSC
Key Words: Limulus lysate Conjunctiva		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To utilize Limulus Lysate screening to detect the presence of gram negative organisms in and around the eye in patients scheduled for ocular surgery. Patients will have simultaneous cultures performed to correlate caterio-logic growth and potential pathogenicity with positive Limulus Lysate Test results.

Technical Approach: Fourteen patients have been entered on the study. Limulus Lysate is inoculated with swabs from subject's conjunctiva.

Progress: Currently all types of swabs tried have resultedin false positive tests. A search is underway to find a new type of swab or a new collection method that does not result in a false positive test.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-40-82	Status: Terminated

TITLE: A Comparative Study of Two Peripheral IV Site Dressing Methods: The Present Sterile Gauze and Antibiotic Ointment Method vs a Transparent Polyurethane Dressing and Antibiotic Ointment.

Start Date 7 Jul 82		Est Comp Date:
Principal Investigator Alan Rastrelli, M.D., CPT, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/Anesthesiology		Associate Investigators: Nelson Isenhower, M.D., LTC, MC Paul E. Casinelli, M.D., CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To observe and compare in a prospective study using a random sample, the incidence of phlebitis using two methods of IV site dressing.

Technical Approach: Study terminated before doing patients.

Progress: Terminated; necessity for study no longer present.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-41-82	Status: Ongoing

TITLE:
Color Defects in Glaucoma.

Start Date 7 Jul 82		Est Comp Date: Sep 83
Principal Investigator John R. Gearhart, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Surgery/Ophthalmology		Associate Investigators:
Key Words: Color vision Glaucoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: Assess the relationship between glaucoma and color vision defects. Primary emphasis will be on the correlation of early color vision defects with other signs of glaucoma, such as visual field changes and optic disc changes. The prognostic significance of color vision defects in the early glaucoma and ocular hypertensive groups will also be evaluated.

Technical Approach: We plan to administer the Farnsworth 100 Hue Color Vision Test to about 100 glaucoma patients and 100 patients with elevated intraocular pressure without optic nerve damage. We will follow these patients in the traditional manner as well as with the Farnsworth 100 Hue Test. We will attempt to correlate any changes in color vision with other demonstrated defects.

Progress: None. Awaiting equipment.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-21-82	Status: Ongoing

TITLE:

A Predictive Model for Estimating the Response to the Army Physical Fitness and Weight Control Program.

Start Date 16 Feb 82		Est Comp Date: Dec 82
Principal Investigator Kenneth D. James, MAJ, AMSC		Facility Brooke Army Medical Center
Dept/Sec Food Service Division/Clinical Dietetics		Associate Investigators:
Key Words: Weight control Army Physical Fitness Program		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine if overweight but generally healthy soldiers participating in a mandatory weight reduction program lose weight at the same rate and degree as matched general clinic patients desiring weight loss for cosmetic and/or health reasons.

To identify and evaluate factors which will predict compliance with and results of the weight control program as applied to individual soldiers.

To identify and evaluate factors within the administration of the program which may be indicative to successful compliance with and completion of the program by individual soldiers.

Methodical Approach: Patients were selected, questionnaires administered and monthly follow-up questionnaires are currently being administered.

Progress: Preliminary results of the study are being tabulated. No data available at this time.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-33-82	Status: Ongoing

TITLE:

Evaluation of Radiation Exposure to Personnel During Cardiac Catheterization.

Start Date 18 May 82		Est Comp Date: Dec 82
Principal Investigator Robert J. Matthews, Ph.D., CPT, MSC		Facility Brooke Army Medical Center
Dept/Sec Medical Physics Service		Associate Investigators:
Key Words: Radiation exposure Cardiac catheterization		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $4000	Periodic Review Results:

Objective: This project will assess x-ray exposure levels of personnel during cardiac catheterizations, particularly exposures to the lens of the eye and the thyroid which are the radiosensitive organs of interest.

Technical Approach: The mensuration of the x-ray exposure levels is accomplished by placing small solid state detectors (LIF) on the foreheads and at the sternal notch of physicians and technicians performing the cardiac catheterizations. Additional data is obtained from film badge exposures and mechanical timers placed in the laboratory.

Progress: The necessary laboratory equipment is operational. Several trial runs to test methodology were accomplished. With the opening of a second cardiac catheterization lab, the study was modified in order to distinguish data taken from the two labs. This will allow the assessment of exposures due to different laboratory equipment.

Detail Summary Sheet

Date: 3 Nov 82	Proj No: C-11-81	Status: Completed

TITLE:
Teaching the Language and Learning Disabled Soldier.

Start Date 4 Feb 81		Est Comp Date:
Principal Investigator Judith Riggan, MAJ, AMSC		Facility Brooke Army Medical Center
Dept/Sec Physical Medicine & Rehabilitation Service		Associate Investigators:
Key Words: Learning disabled soldier		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine ifAcademy of Health Science students documented as "language and learning disabled adults" (LLD) can be helped to succed in their advanced individual training program thus reducing attrition and/or failure rates at the Academy of Health Sciences.

Technical Approach: The 91E Basic Dental Specialist Course was chosen as the course for initial inclusion in this stud . A questionnaire was given to each student on orientation day which covere uch areas as: previous educational history; participation in special education services during high school; reading and/or writing problems. If any of these areas were noted, the staff would immediately consult with the student regarding special needs during the 91E Course. Based on the faculty screening process, some of the students were referred to the occupational therapist for more definitive testing. If a "language and learning disability" was suspected, the student was referred to Psychology Service for thorough psychometric evaluation.

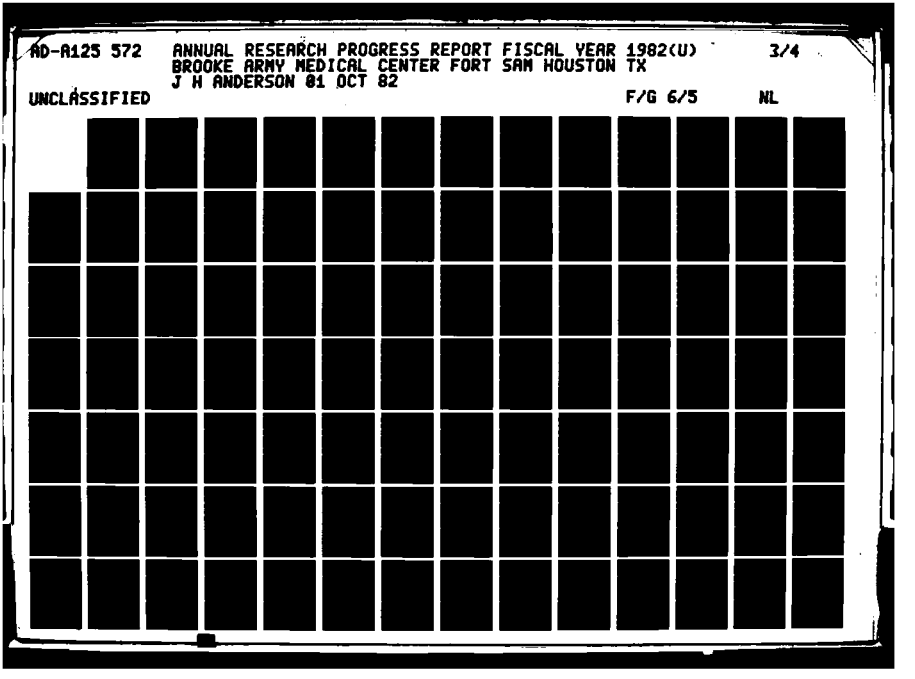
If sensory integration (the ability of an individual to receive and process a variety of stimuli so that they can react to the evironment in an integrated, organized manner) or learning disability was noted, the student was asked to participate in the Occupational Therapy Learning Abilities Program (OTLAP) to enhance sensory integration skills and develop compensatory work/study skills.

Progress: A total of 93 students were evaluated during this study. A total of 27 (29%) were documented as having significant sensory integrative dysfunction; 21 (22.5%) were documented as having significant integrative dysfunction; 6 (6%) were assisted in a series of appointments dealing with only study; 39 (42%) had no significant problems noted.

Occupational Therapy formally intervened with 47 sensory integrative or learning disabled students with the following results: 91% of the soldiers

3-11-81 (continued)

that received training/skill development from the Occupational Therapy Learning Abilities Program are currently productive soldiers satisfactorily fulfilling their initial or subsequent enlistment commitments.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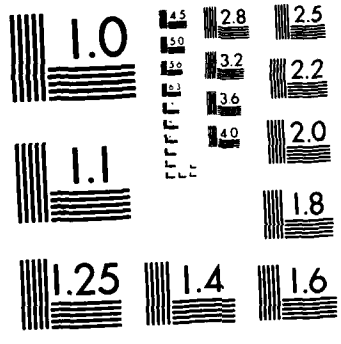

Detail Summary Sheet

Date: 1 Dec 82	Proj No: C-44-82	Status: Completed

TITLE:

Torque Production by the Quadriceps Muscle Group on the Cybex II Dynamometer as Related to Changes in Lever Arm Length

Start Date 7 Jul 82		Est Comp Date:
Principal Investigator 2LT James Casey/2LT Rogan Taylor		Facility Academy of Health Sciences
Dept/Sec Physical Therapy Section		Associate Investigators:
Key Words: Cybex II Dynamometer Torque		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine if change in lever arm length will affect torque output when using an isokinetic exerciser.

Technical Approach: Active knee extension by 32 active duty Army men and women was measured on the Cybex II Dynamometer. Each subject randomly selected three of four predetermined levels for resistance pad placement and delivered four maximal knee extensions at each of the three levels chosen.

Progress: As the lever arm was shortened, the subjects' ability to produce torque was decreased. It was concluded that when using this piece of equipment, torque production is significantly affected by changes in lever arm length. Therefore, for the most accurate use of this equipment in the clinic and for research, a standard lever arm length should be extablished for each subject tested.

Detail Summary Sheet

Date: 1 Dec 82	Proj No: C-45-82	Status: Completed

TITLE:

Shoulder Mobilization, Ice, Ultrasound, and Pendulum Exercises: A Treatment for Adhesive Capsulitis

Start Date 7 Jul 82	Est Comp Date:
Principal Investigator 2LT Suzanne Groff/2LT Jeremy P. Hutton	Facility Academy of Health Sciences
Dept/Sec Physical Therapy Section	Associate Investigators:
Key Words: Adhesive capsulitis	

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

Objective: To evaluate shoulder mobilization for increasing range of motion in patients with adhesive capsulitis.

Technical Approach: Shoulder mobilization techniques were used in conjunction with ice, ultrasound, and pendulum exercises to treat 5 patients with adhesive capsulitis. Four patients in the control group were treated with ice, ultrasound, and exercises, but did not receive mobilization. Passive shoulder motions were measured with a standard 180 degree long-arm goniometer before and after a two-week treatment period.

Progress: A one-tailed t-test showed significantly greater gains ($p < .05$) in the passive abduction of patients in the mobilized group, but their [illegible] external rotation, and external rotation did not increase signifi[illegible] more than the control group. It was concluded that mobilization [illegible]tive for increasing passive abduction, but that further study is [illegible] evaluate its overall effectiveness to treat adhesive capsulitis

Detail Summary Sheet

Date: 1 Dec 82	Proj No: C-46-82	Status: Completed

TITLE:
Effect of Plantar Flexor Strengthening on Vertical Jump Ability

Start Date 7 Jul 82		Est Comp Date:
Principal Investigator 2LT Kathleen F. McCoy		Facility Academy of Health Sciences
Dept/Sec Physical Therapy Section		Associate Investigators:
Key Words: Plantar flexor strength Vertical jump		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate BAMC's method of assessing its plantar flexor strengthening program.

Technical Approach: The Cybex II Dynamometer was used to measure plantar flexor strength at speeds of 10 rpm and 30 rpm in 19 active duty military personnel. The subjects were also measured as to vertical jump ability in an effort to determine if a relationship existed between plantar flexor strength and vertical jump ability. The subjects were divided into an experimental and a control group. The experimental group was given a three-week exercise program consisting of 100 toe raises done twice daily. Both groups were then retested as to strength and jump height.

Progress: The data was analyzed using t-tests and simple regression tests. No significant strength increases were produced by the exercise program, and no correlation was found to exist between plantar flexor strength and vertical jump ability. Thus, plantar flexor strengthening may not be an effective means of improving vertical jump height.

Detail Summary Sheet

Date: 5 Nov 82 | Proj No: C-47-82 | Status: Terminated

TITLE:

Cardio-pulmonary Responses to Bicycle Ergometry with Toe Clips.

Start Date 8 Jul 82	Est Comp Date:
Principal Investigator 2LT Charles Lauer	Facility Academy of Health Sciences
Dept/Sec Physical Therapy Section	Associate Investigators:
Key Words: Ergometry	

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

Objective: To assess the effects of toe-clips on the heart rate and respiratory exchange efficiency of normal male subjects.

Technical Approach: None

Progress: Project terminated due to breakdown of essential pieces of equipment with no feasible replacement or repair possible within the time constraints of the school curriculum.

Detail Summary Sheet

Date: 1 Dec 82	Proj No: C-48-52	Status: Completed

TITLE:

Comparison of Oxygen Consumption Levels in Adult Males Running in Combat Boots and Running Shoes

Start Date 7 Jul 82		Est Comp Date:
Principal Investigator 2LT James M. McKivigan		Facility Academy of Health Sciences
Dept/Sec Physical Therapy Section		Associate Investigators:
Key Words: Oxygen consumption		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To provide a data base for administrative policy with regards to running.

Technical Approach: Six, male, armed forces officers whose age ranged from 24 to 33 years ran on a treadmill on two separate occasions, once in combat boots and once in running shoes. Two gas samples were taken after 5 and 10 minutes of running in each type of footwear and used to calculate each subject's oxygen consumption level.

Progress: A t-test was utilized to determine any statistical difference in these oxygen levels, and none was found at the .05 level. In this study, there was no difference in oxygen consumption levels between running in combat boots and running shoes.

Detail Summary Sheet

Date: 1 Dec 82	Proj No: C-49-82	Status: Completed

TITLE:

Footprint Sequencing in the Analysis of the Angle of Gait in 75 Normal Children

Start Date 7 Jul 82		Est Comp Date:
Principal Investigator 2LT Christina Barnett/2LT Vicki Belcher		Facility Academy of Health Sciences
Dept/Sec Physical Therapy Section		Associate Investigators:
Key Words: Angle of gait		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To provide a data base for standardized evaluation of the angle of gait in children.

Technical Approach: Footprint sequencing was used to measure the angle of gait in 75 normal children. This study was undertaken to generate normative data in children between the ages of 12 and 72 months.

Progress: Statistical analysis revealed the mean angle of gait to be independent of chronological age.

Detail Summary Sheet

Date: 1 Dec 82	Proj No: C-50-82	Status: Completed

TITLE:
Relationship between Isokinetic Torque and Body Weight

Start Date 7 Jul 82		Est Comp Date:
Principal Investigator 2LT Leo H. Mahony, Jr.		Facility Academy of Health Sciences
Dept/Sec Physical Therapy Section		Associate Investigators:
Key Words: Isokinetic torque		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To add to the existing body of knowledge on isokinetic dynamometry through the establishment of normative data for use by clinicians and researchers.

Technical Approach: Thirty active duty U.S. Army personnel ranging in age from 19 to 29 were studied. There were 12 females and 18 males. None of the subjects had a history of serious knee pathology. The peak torque of each subject's knee extensors was measured using a Cybex II isokinetic dynamometer. Following two minutes of rest, the subject performed three maximal effort contractions in both directions of possible rotation. The left knee was initially tested in all subjects, with the right knee tested in the same manner.

Progress: The study indicated that body weight was the best determinant of maximum isokinetic torque generating capabilities ($r = .85$). The mean values of maximum torque divided by body weight resulted in 100.23% for males and 78.63% for females. Also proposed were minimal values of 77.42% and 66.23% for the same populations.

Detail Summary Sheet

Date: 1 Dec 82	Proj No: C-51-82	Status: Completed

TITLE:

Reliability of Goniometric Measurements: The Lower Member

Start Date 7 Jul 82		Est Comp Date:
Principal Investigator 2LT Randal J. Halter		Facility Academy of Health Sciences
Dept/Sec Physical Therapy Section		Associate Investigators:
Key Words: Goniometric measurements		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To evaluate the intratester and intertester reliability of measurements taken with the universal goniometer. More specifically, the reliability of range of motion measurements for the lower member will be investigated.

2. The manner in which reliability relates to the tester's years of clinical experience will also be examined.

Technical Approach: Both intratester and intertester reliability of selected goniometric measurements were studied. These motions included flexion, extension, abduction, adduction, internal and external rotation of the hip, extension and felxion of the knee, dorsi and plantar flexion of the ankle and supination and pronation of the foot. Fifteen subjects, including graduate students in physical therapy and practicing therapists, took five series of these 12 measurements. The two-way analysis of variance was used to determine the significance of the differences between (intertester) and within (intratester) subjects.

Progress: Although the intratester variation was found to be significant for only hip abduction and foot supination/pronation, all of the motions were significant for intertester variation (at the .05 level). The means and standard deviations of intertester measurements indicate that the reliability of these measurements varies from joint to joint. Therefore, a blanket statement of goniometric reliability being a certain number of degrees would be invalid.

Detail Summary Sheet

Date: 1 Dec 82	Proj No: C-53-82	Status: Completed

TITLE:
Effect of Stretching on Ankle Range of Motion While Running

Start Date 13 Aug 82		Est Comp Date:
Principal Investigator 2LT Mary Dillon/2LT Jane Freund		Facility Academy of Health Sciences
Dept/Sec Physical Therapy Section		Associate Investigators:
Key Words: Stretch exercise Jogging		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To compare the effects of stretching immediately before running, stretching after five minutes of slow jogging, and no stretching at all before running two miles.

Technical Approach: Ankle dorsiflexion measurements before and after a two-mile run were used to compare the effects of different Achilles' tendon stretching procedures on ankle range of motion. Testing procedures were: (1) Achilles' tendon stretching prior to running; (2) Achilles' tendon stretching after a five-minute warm-up jog, and (3) no stretching. All three procedures were followed by a two mile run. Eight male and five female subjects participated in the study. Each subject performed each of the three run/jog/stretch sequences on three separate test dates.

Progress: Analysis of the data comparing pretest and posttest dorsiflexion measurements demonstrated no significant difference among the three procedures.

Detail Summary Sheet

Date: 1 Dec 82	Proj No: C-56-82	Status: Completed

TITLE:

Analysis of a method for Estimating Percent Body Fat

Start Date 13 Aug 82		Est Comp Date:
Principal Investigator 2LT Keith R. Kolakowski		Facility Academy of Health Sciences
Dept/Sec Physical Therapy Section		Associate Investigators:
Key Words: Fat-O-Meter (FOM)		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the effectiveness of a skinfold caliper by comparing it to a standard method for determining percent body fat.

Technical Approach: Two methods for estimating body fat percentages were compared on 46 healthy male volunteers ages 20-38. Skinfold measurements were taken according to the FOM Manual. Only one caliper was used in the study. Sites were specific for age groupings and three readings were taken of each site.

Potassium-40 counting was performed in a low level whole body counter. The counting procedure consisted of the volunteer lying prone in the canvas sling of the motorized trolley and riding into the counting cylinder. This procedure was supervised by personnel at Brooks AFB. Background readings were taken for five minutes between each group of three subjects.

Progress: The standard method of potassium-40 counting showed a higher fat percentage in 27 of the 46 subjects when compared to the Fat-O-Meter. A t-test found no significant difference between the two methods (P = N.S.). Simple regression showed a correlation factor of 0.64, although a coefficient of variation indicated that the values presented by the FOM were twice as disperse (relative to the mean) than the standard method.

Detail Summary Sheet

Date: 1 Dec 82	Proj No: C-57-82	Status: Completed

TITLE:
Reliability of Trunk Strength Measurements

Start Date 13 Aug 82		Est Comp Date:
Principal Investigator 2LT Nancy L. Seaver		Facility Academy of Health Sciences
Dept/Sec Physical Therapy Section		Associate Investigators:
Key Words: Cybex II dynamometer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To estimate the reliability of measurements of trunk strength using the Prototype Cybex II Isokinetic Dynamometer Trunk Apparatus.

Technical Approach: Eight normal male and four normal female soldiers were studied to estimate the reliability of measurements of trunk strength using the Prototype Cybex II Isokinetic Dynamometer Trunk Apparatus. The four trunk strength parameters studied were: isometric flexion, isokinetic flexion, isometric extension, and isokinetic extension. The subjects performed three maximal contractions or trials for each of the four trunk strength parameters on day one and three more trials on a second day. Trunk strength was determined by measuring the highest point on the torque curve produced throughout the range of trunk motion.

Progress: No difference in trunk strength measurements was found between the three trials or between day one and day two for the trunk strength parameters studied. Resultant findings are that trunk strength measurements of isometric flexion, isokinetic flexion, isometric extension, and isokinetic extension using the Prototype Cybex II Isokinetic Dynamometer Trunk Apparatus and experimental procedures appear to give reliable and verifiable results.

Detail Summary Sheet

Date: 29 Oct 82	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 83
Principal Investigator William W. Burgin, M.D., COL, MC		Facility Darnall Army Hospital
Dept/Sec		Associate Investigators:
Key Words: Fluorescence Tetracycline Fiberoptic bronchoscope		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To establish whether in vivo tetracycline labeling can be used to aid the endoscopist in locating pathologic pulmonary tissues when viewed through a fiberoptic bronchoscope incorporating an ultraviolet light source.

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

Progress: This study has been transferred to the original proponent of the study, COL William W. Burgin, and will be conducted at Darnall Army Hospital.

Detail Summary Sheet

Date: 7 Oct 82	Proj No: C-39-82	Status: Ongoing

TITLE:

Comparison of Electrosurgery and Surgical Blade Loops in the Removal of Inflammatory Papillary Hyperplasia.

Start Date 7 Jul 82		Est Comp Date: Jul 83
Principal Investigator Furmon M. Gardner, D.D.S., LTC, DC		Facility Cowan Dental Clinic, Fort Sill, OK
Dept/Sec Department of Dentistry		Associate Investigators: Steven A. Rathofer, D.D.S., LTC, DC
Key Words: Inflammatory papillary hyperplasia Electrosurgery Surgical blade loops		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To compare clinical healing time and subjective relative patient discomfort between the two methods of inflammatory papillary hyperplasia removal.

Technical Approach: Two accepted surgical techniques using reports of patient comfort as the criterion were compared. One method was used on the right side of the palate and the other on the left.

Progress: Six patients have been treated. Data are inadequate for specific conclusions. Since all techniques used are accepted therapeutics, no adverse responses attributable to the project have been noted.

Detail Summary Sheet

Date: 1 Oct 82	Proj No: C-42-82	Status: Completed

TITLE:

Clinical Evaluation of New Strep-ID Plate.

Start Date 7 Jul 82		Est Comp Date:
Principal Investigator William F. Nauschuetz, CPT, MSC		Facility Reynolds Army Hospital
Dept/Sec Department of Pathology/Microbiology		Associate Investigators:
Key Words: Strep ID plate		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the efficacy of the Strep-ID Plate (Carr Microbiologicals, Wichita, KS) using parallel studies. Streptococci from clinical specimens will be identified by existing standard methods and by the Strep-ID Plate to determine efficacy.

Technical Approach: The Strep-ID Plate is divided into thirds: tryptic soy agar with 5% washed sheep blood, bile-esculin agar, and pyroglutamyl-B-naphthylamide (PYR) agar. The blood agar section is used for detection of hemolysis and for the CAMP test. The CAMP test is simplified by using staphylococcal beta-lysin impregnated disks. The bile-esculin agar is used to differentiate the group D streptococci and non-group D streptococci. The PYR agar differentiates group D enterococci from group D non-enterococci, as well as group A streptococci from non-group A beta hemolytic streptococci.

Streptococci were obtained from clinical specimens and stock cultures. Specimens were streaked onto 5% sheep blood agar to obtain isolated colonies. Inocula of isolated streptococci were streaked onto the bile-esculin section of the tri-plate and then onto the PRY section. A single straight line streak of the organism was made on the SBA section, and a CAMP disk was placed approximately 5 mm from the streak line.

Progress: The Strep-ID Plate not only offers a uniformity not present in existing methods of strep work-ups, but also corresponds very well to standard methodology in identification capabilities. Overall, the Strep-ID Plate had a 99%+ agreement with conventional presumptive methods.

APPENDIX A

SOUTHWEST ONCOLOGY GROUP

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7703	Status: Completed

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: 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 nervous tumors of the following histologic types are eligible: Astrocytoma, grades 3 and 4 (gliobastoma multiforme).

Therapy will follow the schema outlined in the study protocol.

Progress: The response rate to radiation therapy plus Procarbazine is statistically inferior to the other two arms. The two most important prognostic factors are age of the patient and extent of surgery. Radiation therapy plus BCNU appears to be superior to the other arms in duration of survival for a small group of patients.

Detail Summary Sheet

Date: 15 Nov 82	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: John D. Cowan, M.D., MAJ, MC
Key Words: Chemoimmunotherapy Non-Hodgkin's Lymphoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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: No data are available at this time.

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7727	Status: Ongoing

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

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

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

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

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

Therapy will follow the schema outlined in the study protocol.

Progress: There has been no change in response data, toxicity, prognostic factors or survival. Median survival for DTIC + Actinomycin-D patients is 33 weeks; 27 weeks for BHD patients and 19 weeks for Levamisole patients.

A total of eight patients from BAMC have been entered on this study, all prior to FY 82. Four have expired, two have been withdrawn from the study, and two remain on study.

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7765	Status: Completed

TITLE:
Adriamycin and Single Dose DTIC in Soft Tissue Sarcomas, Phase I/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: John D. Cowan, M.D., MAJ, MC
Key Words: 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: The overall response rate was 31.3%, with a complete remission rate of 12%.

Detail Summary Sheet

Date: 15 Nov 82	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 J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Gastric adenocarcinoma Chemotherapy Disease-free interval		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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: Groupwide, 86 patients have been registered on this study (two from BAMC). No difference has been seen in survival rate or disease free interval. The median survival after relapse has been three months for the control arm and one month for FAM.

Detail Summary Sheet

Date: 15 Nov 82	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: John D. Cowan, M.D., MAJ, MC
Key Words: Hodgkin's disease		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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: Eligibile 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: Groupwide, 222 patients (5 from BAMC) have been entered and 145 are currently evaluable. The very preliminary complete remission rate is 55%. Early information on administration of radiation therapy to patients achieving a partial response indicates a high likelihood of converting partial responses to complete responses.

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7811	Status: Completed

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: John D. Cowan, M.D., MAJ, MC
Key Words: Brain metastases		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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 int the study protocol.

Progress: Seven patients from BAMC were entered on this study. All have expired. Metronidazole does not appear to alter response rates, duration of response or survival. The study was closed due to poor patient accrual.

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7813	Status: Completed

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: John D. Cowan, M.D., MAJ, MC
Key Words: Disseminated malignant melanoma Ifosfamide		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate and survival of Ifosfamide in patients with disseminated malignant melanoma who are either ineligible for higher priority studies or who have become resistant to standard therapy of a higher priority program.

To determine the qualitative and quantitative toxicity of Ifosfamide in patients with disseminated melanoma.

Technical Approach: All patients with histologically confirmed diagnosis of disseminated malignant melanoma who are not eligible for higher priority protocols or who have failed on standard regimens or higher priority programs are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: A total of 53 patients were entered on this study (one from BAMC). Of 36 evaluable patients, one had a complete remission and three had a partial response.

Detail Summary Sheet

Date: 15 Nov 82 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: 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: Groupwide patient accrual has been excellent (13 from BAMC). The complete response rate is approximately 60%. In SWOG 7826, the relapse rate among patients receiving Levamisole remains high compared to the group not receiving the drug.

Detail Summary Sheet

Date: 15 Nov 82	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: John D. Cowan, M.D., MAJ, MC
Key Words: Receptor positive (ER+) Chemotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy.

To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using combination chemotherapy plus tamoxifen versus tamoxifen alone versus combination chemotherapy alone.

To compare the disease-free interval and recurrence rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy.

To compare the effect of these various adjunctive therapy programs upon the survival patterns of such patients.

To correlate the ER status with disease-free interval and survival.

Technical Approach: All patients must have had a radical or modified radical mastectomy with histologically proven breast cancer and with one or more pathologically proven axillary nodes. Primary neoplasm and clinically apparent axillary disease must be completely removed. Pretherapy studies must reveal no evidence of metastatic disease or involvement of the other breast. Patients with postoperative radiation therapy are eligible but will be randomized and evaluated separately. Therapy will follow the schema outlined in the protocol.

Progress: Twenty nine patients from BAMC have been registered on this study, nine during FY 82. The study remains open in order to accrue sufficient numbers in the critical subsets to draw firm conclusions. It is too early to draw any conclusions with regard to the various treatment arms.

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7830	Status: Completed

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:
Key Words: Carcinoembryonic antigen Duke's B and C colorectal cancer	

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

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: This study was closed due to inadequate patient registration. No patients from BAMC were entered on the study.

Detail Summary Sheet

Date: 15 Nov 82	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: John D. Cowan, M.D., MAJ, MC
Key Words: Chemotherapy Gastric adenocarcinoma Chlorozotocin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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 adenocarinoma, Stage IV in extent, to be eligible for this study. They must not have received prior chemotherapy nor should they have received radiotherapy within four weeks of entry. Patients must have a minimum life expectancy of 6 weeks and a performance status of 0-3 in order to be eligible.

The protocol has been amended and arms being used are FAM vs DHAD.

Progress: There has been no difference in long-term survival, but a slight advantage for FAM with short-term survival. The study remains open until 25 patients have been accrued on the DHAD arm. No patients from BAMC have been entered on this study.

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7860	Status: Completed

TITLE:

Evaluation of MGBG in Solid Tumors and Refractory Hematologic Malignancies

Start Date 11 May 81		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: John D. Cowan, M.D., MAJ, MC
Key Words: Solid tumor MGBG Hematologic malignancy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine response rate and remission duration with primary weekly intravenous therapy using MBGB in patients with advanced esophageal, breast, pancreatic, colorectal, and head and neck carcinomas and lymphoma.

To define the qualitative and quantitative toxicity of this regimen.

Technical Approach: Patients must have pathologically verified histologic diagnosis of cancer. MBGB is intended as initial chemotherapy for patients with inoperable or disseminated renal, esophageal, and pancreatic carcinoma. It is intended for use in patients with other forms of advanced malignancy (breast, head and neck, colorectal, lymphoma and multiple myeloma) if their disease has become progressive after initial chemotherapy and who are not candidates for SWOG studies of higher priority.

Therapy will follow the schema outlinedin the study protocol.

Progress: Forty-five patients have been evaluated with approximately a 20% response rate. Only a small number of patients with Hodgkin's disease have been entered. No patients from BAMC have been entered on this study.

The study confirms that MGBG has clear cut activity in refractory lymphoma.

Detail Summary Sheet

Date: 15 Nov 82	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: 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: No patients from BAMC have been entered on this study. Patient accrual has been poor. No data are available at this time.

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7904	Status: Completed

TITLE:

Hexamethylmelamine vs FAC in Advanced Transitional Cell Bladder Carcinoma in Patients with Impaired Renal Function, Phase II-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: John D. Cowan, M.D., MAJ, MC
Key Words: Transitional cell bladder carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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 T_4 transitional cell bladder carcinoma, if there is a contraindication to radical surgery or radiotherapy, and recurrent or residual cases after surgery, radiotherapy or both; and M_1 cases with liver, osseous, pulmonary or other metastases are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirty-two patients have been entered into this study (none from BAMC). Response rates have been poor. Therefore, the study was closed.

Detail Summary Sheet

Date: 15 Nov 82	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: 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 not 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: This study is now open to bladder cancer patients only. Nine patients have been entered with seven being evaluable. One complete response and two partial responses have been seen. Gallium nitrate appears to be an active drug in bladder cancer.

No patients from BAMC have been entered on this study.

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7920	Status: Terminated

TITLE:

m-AMSA in Hepatocellular Carcinoma, Gallbladder Carcinoma and Bile Duct Carcinomas, Phase II.

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: 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:

Objective: To determine the efficacy of m-AMSA at a dose of 120 mg/M2 IV every three weeks in producing regressions or remissions in patients with hepatocellular, bile duct, and gallbladder carcinoma.

Technical Approach: All patients who have histologically confirmed hepatocellular carcinoma, gallbladder carcinoma or bile duct carcinoma beyond hope of surgical cure are eligible. There must be histologic proof of residual, recurrent or metastatic carcinoma. Patients must have measurable disease and a life expectancy of at least 4 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: The study was terminated due to poor patient accrual.

Detail Summary Sheet

Date: 15 Nov 82	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: John D. Cowan, M.D., MAJ, MC
Key Words: Transitional cell bladder cancer	

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

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: The response rates reported have been 8/13 patients in the CAP arm versus 2/12 in the m-AMSA arm. No difference has been noted in the response rates, duration, survival or between response versus non-response in the two arms. It appears that survival has not been prolonged with chemotherapy.

The one patient from BAMC entered on this study expired a year ago, and no new patients have been enrolled.

Detail Summary Sheet

Date: 15 Nov 82	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: 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 multiagent 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: To date, 339 patients have been registered on this study (six from BAMC with two being registered during FY 82). The median response rate was 35-38% and the median survival was over 1 year which is comparable to earlier studies. Patients who achieved a CR status from chemotherapy alone were randomized to Group A (x-ray therapy) and Group B (no x-ray therapy). Thirty-five patients were in Group A and 24 in Group B. Eight of 18 Group A patients had chest relapse while 14/15 patients in Group B had chest relapse. Therefore, it appeared that radiation therapy benefited the disease free interval in CR patients over that of no radiation therapy.

Detail Summary Sheet

Date: 15 Nov 82	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: John D. Cowan, M.D., MAJ, MC
Key Words: Ovarian carcinoma Chemoimmunotherapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To compare the effectiveness of A-C + BCG vs A-C + Cis-Platinum for remission and induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma.

To compare the effectiveness of A-C + Cis-Platinum vs A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival in patients with Stage III and IV ovarian carcinoma.

To compare the effectiveness of A-C + BCG vs A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma.

To compare the toxicities of the A-C + BCG, A-C + Cis-Platinum and A-C + Cis-Platinum + BCG regimens.

Technical Approach: Only patients with epithelial type neoplasms will be eligible for this study. The patient must have histologically confirmed diagnosis of ovarian carcinoma.

Therapy will follow the schema outlined in the study protocol.

Progress: Fewer patients have been entered on the A-C + Cis-Platinum treatment arm. Thus, it is difficult to draw conclusions concerning the preliminary data with respect to differences in response rates between the three treatment arms. Nevertheless, there is at this point, a statistical difference (P=.012) in complete plus partial response rates between the three groups with the A-C + BCG treated patients having the lowest CR + PR rate (36%). When patients with an "improved status" are included, there are no statistical differences between the three treatment arms.

Detail Summary Sheet

Date: 15 Nov 82	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: 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 jave objective evidence of and be symptomatic from complications due to myeloma.

Therapy will follow the schema outlined in the study protocol.

Progress: Over 300 patients have been registered on the induction phase of the study (10 from BAMC, 2 during FY 82). All three induction arms seem to be active, but the response rates are preliminary. Currently the VMCP-VBAP + Levamisole arm has the highest response rate, but both Levamisole induction arms have had a slightly higher frequency of early deaths although not a significant number.

Detail Summary Sheet

Date: 15 Nov 82	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 J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology	Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: 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 outlinedin the study protocol.

Progress: The protocol has been amended to discontinue the Cis-platinum alone arm. Six fully evaluable patients have been entered on MOB plus Cis-platinum with one (17%) showing a partial response. Two of 7 patients (29%) treated with Mitomycin-C plus Cis-platinum have shown partial responses and 2 of 8 patients (25%) treated with Cis-platinum as a single agent have responded. There are too few patients evaluable at this point to draw any firm conclusions concerning the benefits of combination chemotherapy.

Detail Summary Sheet

Date: 15 Nov 82	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: 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 prtocols.

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: m-AMSA appears to have no activity in cancer of the bladder or urethra. In prostate, 25 patients are evaluable with 1 PR seen. The study was closed to bladder patients and remains open to prostate, urethra and testicular. All patients from BAMC who have been entered into the study are now off study.

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7940	Status: Completed

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:
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Metastatic adenocarcinoma of large bowel MGBG Gallium Nitrate DHAD		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the relative activity of a phase II drug (MGBG SWOG 7941, Gallium Nitrate SWOG 7943, DHAD SWOG 7944) in previously untreated patients with disseminated colon and rectal cancer.

To compare the survival of patients with disseminated colon cancer receiving a Phase II agent (MGBG/Gallium Nitrate/DHAD) as first therapy to the survival of patients receiving fluorinated pyrimidine 5-Fluorouracil (5-FU) therapy first.

To determine the effect of a previously administered Phase II drug on the response rate seen with 5-FU in patients with disseminated colon and rectal cancer.

Technical Approach: Eligible patients must have biopsy proven adenocarcinoma arising from the colon or rectum. Patients must have clinically measurable recurrent or disseminated disease to qualify for the study. Obstructive lesions in the colon and rectum must have been bypassed or adequately 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: The 5-FU arm appears to be no better or worse than any other phase II agent.

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7942	Status: Completed

TITLE:
Appendix VI SWOG 7940, Evaluation of Indicine-N-Oxide in Metastatic Adenocarcinoma of the Large Bowel, Phase II

Start Date 11 May 81		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: John D. Cowan, M.D., MAJ, MC
Key Words: Indicine-N-Oxide Metastatic adenocarcinoma Large bowel		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the efficacy of indicine-N-oxide administered in a single dose schedule in patients with advanced adenocarcinoma of the colon and rectum by evaluation of response rates.

To determine more completely the nature and degree of toxicities of indicine-N-oxide in an expanded Phase II study.

Technical Approach: Eligibility is as outlined in SWOG 7940.

Therapy will follow the schema outlined in the study protocol.

Progress: The 5-FU arm appears to be no better or worse than any other phase II agent.

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7944	Status: Completed

TITLE:

Appendix VI SWOG 7940, Evaluation of DHAD in Metastatic Adenocarcinoma of the Large Bowel, Phase II

Start Date 11 May		Est Comp Date:
Principal Investigator J. Dean McCracken		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: DHAD Metastatic adenocarcinoma Large bowel		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response-rate and remission duration in patients with colorectal carcinoma treated with dihydroxyanthracenedione in a single-dose, every 3-weeks.

To define the qualitative and quantitative toxicities of dihydroxy-anthracenedione.

Technical Approach: Patient eligibility is as outlined in SWOG 7940.

Therapy will follow the schema outlined in the study protocol.

Progress: The 5-FU arm appears to be no better or worse than any other phase II agent.

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7945	Status: Completed

TITLE:

Appendix VI SWOG 7940, Evaluation of AZQ in Metastatic Adenocarcinoma of the Large Bowel, Phase II Portion

Start Date 25 Sep 81		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: John D. Cowan, M.D., MAJ, MC
Key Words: Adenocarcinoma large bowel		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the antitumor activity of AZQ in colorectal carcinoma by determination of response-rate and remission duration.

To further determine the nature and extent of AZQ toxicity in a Phase II study.

Technical Approach: Patient eligibility is as outlined in SWOG 7940.

Therapy will follow the schema outlined in the study protocol.

Progress: Survival of patients receiving a phase II agent followed by 5-FU vs survival of patients receiving 5-FU followed by a phase II agent is not significantly different.

Detail Summary Sheet

Date: 15 Nov 82	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 J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Metastatic renal cell carcinoma Postinfarction nephrectomy Depo-Provera		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic 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 post-infarction 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 study has recently been amended to administer the Depo-Provera immediately following infarction prior to a nephrectomy and only 1-2 patients have been entered since then. Six patients entered from BAMC are now off study.

Detail Summary Sheet

Date: 15 Nov 82	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/Oncoloty		Associate Investigators: 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: Patients with epithelial carcinoma of the ovary who failed primary chemotherapy are not sensitive to subsequent treatment with m-AMSA. No patients from BAMC have been entered on this study. The study was closed to ovarian carcinomas.

Detail Summary Sheet

Date: 15 Nov 82	Proj No: SWOG 7963	Status: Completed

TITLE:

m-AMSA in Melanoma, Myeloma, Lymphoma, Oat Cell Lung and Breast Carcinomas

Start Date 11 May 81		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: John D. Cowan, M.D., MAJ, MC
Key Words: m-AMSA		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the efficacy of m-AMSA at a dose of 120 mg/M^2 IV every 3 weeks in producing regressions or remission in metastatic melanoma, lymphoma, myeloma, metastatic oat cell lung carcinoma, and metastatic breast cancer, which are resistant to standard chemotherapies.

To determine the effect of m-AMSA on survival of patients with metastatic melanoma, lymphoma, myeloma, metastatic oat cell carcinoma of the lung, and metastatic breast cancer, which are resistant to standard chemotherapies.

To correlate in vitro m-AMSA sensitivities in the tumor stem cell colony drug system and in vivo m-AMSA activity in patients with metastatic melanoma, lymphoma, myeloma, metastatic oat cell carcinoma of the lung and metastatic breast cancer, all of which are resistant to standard chemotherapies.

Technical Approach: Patients must have histologically confirmed melanoma, myeloma, breast carcinoma, lymphoma or oat cell carcinoma of the lung, refractory to standard therapies. Patients must have measurable disease and a life expectancy of six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-seven melanoma patients were entered on the study. One partial response was noted.

There have been 50 patients with myeloma registered on this study, 32 which were evaluable. Two patients had an improved prognosis. No partial responses have been reported. Overall, m-AMS does not appear to be a major induction drug for the next Phase III study.

Detail Summary Sheet

Date: 16 Nov 82	Proj No: SWOG 7965	Status: Terminated

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:
Principal Investigator J. Dean McCracken	Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncolog	Associate Investigators: 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:

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 clincally disease free by s 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: The study was terminated due to slow patient accrual. Some reasons for the slow accrual were (1) lack of a 50% response-rate with methotrexate, (2) Patient's wishes, and (3) maintenance arm (no treatment).

Detail Summary Sheet

Date: 16 Nov 82	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: 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: Seven patients have been registered to date (none from BAMC). No reportable data are available at this time.

Detail Summary Sheet

Date: 16 Nov 82	Proj No: SWOG 7980	Status: Terminated

TITLE:
Study of Cis-Platinum for Recurrent Gliomas.

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: John D. Cowan, M.D., MAJ, MC
Key Words: Gliomas, recurrent Cis-Platinum		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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 protoco.

Progress: There has been a 10% response rate seen with cis-platinum. The study was terminated due to poor patient accrual.

Detail Summary Sheet

Date: 16 Nov 82	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: 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: Two patients from BAMC have been entered on this study. Groupwide a total of 29 patients have been entered thus far. No reportable data are available at this time.

Detail Summary Sheet

Date: 16 Nov 82	Proj No: SWOG 7984	Status: Ongoing

TITLE:

Treatment of Chronic Stage CML with Pulse, Intermittent Busulfan Therapy with or without Oral Vitamin-A, Phase III

Start Date Nov 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Leukemia Busulfan Vitamin A		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the efficacy of standard pulse, intermittent busulfan therapy plus oral vitamin A in prolonging the chronic phase of CML, and hence in prolonging survival.

Technical Approach: *All patients with newly diagnosed chronic stage CML will* be eligible for entry onto protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been slow. The protocol will be amended to include the analysis of cell surface markers at diagnosis and at blast crisis.

Detail Summary Sheet

Date: 16 Nov 82	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 J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Breast cancer Estrogen receptor negative (Er-)		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic 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: Patient accrual continues to be slow. No data are available at this time.

Detail Summary Sheet

Date: 16 Nov 82	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: 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: One patient from BAMC has been entered on thisstudy. Preliminary follow-up has shown 12 patients who were in treatment relapsed later.

Detail Summary Sheet

Date: 17 Nov 82	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: 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: Of 32 fully evaluable plus the partially evaluable patients, there have been 27 complete responses with a complete response rate of 84%. One patient from BAMC remains on the study; two others entered on the study were removed from the study prior to FY 82.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8004	Status: Terminated

TITLE:

Evaluation of DHAD in Soft Tissue and Bone Sarcomas, Phase II.

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: 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:

Objectives: To determine the efficacy, by response rate, of Dihydroxyantracenedione (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: The study was terminated due to poor patient accrual.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8005	Status: Ongoing

TITLE:
Evaluation of DHAD in Refractory Malignant Lymphomas, Phase II - Pilot.

Start Date 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: DHAD Malignant lymphoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine response rate and response duration of patients with refractory malignant lymphomas, both Hodgkin's disease and non-Hodgkin's lymphoma treated with anthracenedione used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of anthracenedione in a Phase II study.

Technical Approach: All patients with malignant lymphoma who are not eligible for higher priority SWOG protocols are eligible. There are no age restrictions and patients must have a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Forty-nine patients have been entered including 11 patients with Hodgkin's disease and 38 with non-Hodgkin's disease (none from BAMC). Two of 8 evaluable patients with Hodgkin's disease have shown partial responses. In non-Hodgkin's lymphoma there is a 26% partial and complete response rate, with one patient achieving a complete response.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8006	Status: Ongoing

TITLE: Postoperative Reductive Chemotherapy for Stage III or IV Operable Epidermoid Carcinoma of the Oral Cavity, Oropharynx, Hypopharynx, or Larynx, Phase III.

Start Date Nov 80	Est Comp Date: 0 Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology	Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Epidermoid carcinoma	

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

Objective: To determine the length of remission, recurrence rates, survival rates, and pattern of recurrence for patients receiving therapy utilizing surgery and postoperative radiation vs combined therapy utilizing preoperative chemotherapy, surgery and postoperative radiation therapy in operable Stage III or IV epidermoid carcinoma of the head and neck.

Technical Approach: Patients with operable lesions will be randomized between two therapeutic programs: Arm I - combined therapy including surgery and post-operative radiation therapy; or Arm 2 - combination chemotherapy followed by surgery and radiation therapy. Patients randomized to the chemotherapy limb will receive three courses of chemotherapy consisting of cis-platinum, methotrexate, vincristine and bleomycin.

Therapy will follow the schema outlined in the study protocol.

Progress: Nineteen patients from BAMC have been entered on this study. Ten remain on the study and the remaining nine have either expired or placed on other therapy. Groupwide, it is too early to evaluate the data.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8008	Status: Ongoing

TITLE:
Evaluation of Dihydroxyantracenedione (DHAD) in Refractory Breast Cancer, Phase II.

Start Date FY 80		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: 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 antracenedione used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: Eligible patients must have pathologically verified histologic diagnosis of breast cancer. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: The preliminary conclusion at this time is that DHAD has limited activity in heavily treated patients with advanced breast cancer. The study has been closed to patients with previous Adriamycin therapy. One patient from BAMC entered on this protocol is now off study.

Detail Summary Sheet

Date: 17 Nov 82	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: 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: The study has been closed to patients who have had Adriamycin therapy. Patient accrual has been slow; no patients from BAMC have been entered on this study.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8010	Status: Completed

TITLE:
Evaluation of DHAD in Advanced Prostate Cancer, Phase II.

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: John D. Cowan, M.D., MAJ, MC
Key Words: Prostate cancer DAHD		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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: One patient from BAMC remains on this study; however, the study has been closed. DHAD appears to have a low level of activity in advanced prostatic cancer.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8011	Status: Terminated

TITLE:

Evaluation of DHAD in Patients with Advanced Renal Cell Carcinoma, Phase II.

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: John D. Cowan, M.D., MAJ, MC
Key Words: Renal cell carcinoma DHAD		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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: No patients from BAMC were entered on this study. Therefore, the study was terminated when SWOG closed the protocol.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8012	Status: Ongoing

TITLE:

Treatment for Advanced Adenocarcinoma and Large Cell Carcinoma of the Lung: FOMi vs CAP vs FOMi/CAP, Phase III.

Start Date Jan 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Adenocarcinoma Large cell carcinoma Lung		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To evaluate by pairwise comparison the response rate, duration of response, and survival of 3 regimens FOMi, CAP, and FOMi/CAP in patients with advanced (TMN Stage III M_1) adenocarcinoma and large cell undifferentiated carcinoma of the lung.

To evaluate the degree of non-cross resistance of FOMi in CAP failures and of CAP on FOMi failures.

To compare the toxicities and side effects of FOMi and CAP.

Technical Approach: Patients are eligible who have a histologically confirmed diagnosis of adenocarcinoma of the lung or large cell undifferentiated carcinoma of the lung. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: A total of 20 patients from BAMC have been entered into this study (10 during FY 82). Ten remain on the study. Groupwide, there has been a median survival advantage (28 weeks) with the FOMi/CAP arm which is significantly superior to the other two arms. This may represent the first regimen shown in a cooperative group to prolon survival benefit in patients with this regimen as the best arm for comparison in future protocols.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8014	Status: Completed

TITLE:

Colchicine in Refractory Chronic Lymphocytic Leukemia, Phase I-II.

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: John D. Cowan, M.D., MAJ, MC
Key Words: Chronic lymphocytic leukemia Colchicine		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

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: No patients from BAMC were entered on this study. Groupwide, seven evaluable patients showed no response.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8015	Status: Ongoing

TITLE: Evaluation of Two Combination Chemotherapy Programs, Adriamycin and Cis-Platinum (AP) vs Adriamycin, Cis-platinum plus VP-16 (VAP), in the Treatment of Extensive Squamous Cell Carcinoma of the Lung, Phase III

Start Date Jan 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Lung Squamous cell carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the activity, in terms of response-rate, remission duration, and survival in patients with extensive squamous cell (epidermoid) carcinoma of the lung, for two combination chemotherapy programs: Adriamycin and Cis-platinum vs VP-16, Adriamycin and Cis-platinum.

To evaluate the relative toxicities of these respective regimens.

To assess the feasibility and reliance of applying "measurable versus evaluable" criteria of tumor regression in determining therapeutical response.

To correlate tumor grade with response and survival.

Technical Approach: Eligible patients are those with "extensive" squamous cell (epidermoid) lung carcinoma defined as "spread beyond the hemithorax and ipsilateral scalene, supraclavicular and mediastinal lymph nodes", equivalent with TNM system Stage III class M_1 with any T or N other than mediastinal, supraclavicular scalene nodes involved. Relapsing or recurrent TNM Stage I or II patients, failing after radiation therapy alone to the primary site of involvement are also eligible for study.

Therapy will follow the schema outlined in the study protocol.

Progress: Four patients from BAMC have been entered on this study. One entered during FY 82 remains on study. Groupwide, the response rates have been low. There appears to be no apparent advantage with the addition of VP-16 to the AP combination.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8017	Status: Ongoing

TITLE:

5-FU, Adriamycin, Streptozotocin and Cyclophosphamide (FAC-S) in the Treatment of Metastatic Carcinoid Tumors, Phase II

Start Date Nov 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: John D. Cowan, M.D., MAJ, MC
Key Words: Carcinoid		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine whether combination chemotherapy employing 5-FU, Cyclophosphamide, Adriamycin and Streptozotocin is effective in the management of metastatic carcinoid.

To study the duration of survival of patients with metastatic carcinoid tumor treated with combination chemotherapy regimens.

To provide further information concerning the response and/or survival of patients with metastatic carcinoid originating in different sites and having different metastatic patterns.

Technical Approach: All patients must have biopsy-proven carcinoid tumor not amenable to further surgical therapy with no prior chemotherapy. A minimum life expectancy of 6 weeks and a performance status of 3 or better per Southwest Oncology Group criteria is necessary. All patients must have objectively measurable disease either as a measurable lesion or significant biochemical abnormality specific for their tumor.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, six partial responses have been noted in seventeen evaluable patients. No patients from BAMC have been entered on this study.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8020	Status: Ongoing

TITLE:

Adriamycin + VP-16 vs Adriamycin Alone in Advanced Adenocarcinoma of the Breast, Phase II

Start Date Jan 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Adenocarcinoma Breast		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the efficacy of the Adriamycin and VP-16 combination in the treatment of previously treated patients with disseminated breast cancer, as determined by response-rate compared with Adriamycin alone.

To determine the length of the remission on VP-16 maintenance after an Adriamycin/VP-16 regimen.

Technical Approach: Patients must have histological proof of breast cancer currently Stage IV with measurable lesions. ER+, ER-, and ER unknown patients are eligible. Patient must have adequate cardiac function and no clinical evidence of congestive heart failure.

Therapy will follow the schema outlined in the study protocol.

Progress: Thus far, there is no difference in response rates between the two treatment arms. No patients from BAMC are enrolled on this study.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8024	Status: Ongoing

TITLE:
Combined Modality Therapy for Disseminated Soft Tissue Sarcomas, Phase III

Start Date May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Sarcoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To compare the effectiveness of bolus administration of Adriamycin and DTIC, to continuous infusion administration of Adriamycin and DTIC, in remission induction of patients with disseminated soft tissue sarcomas.

To compare the toxicities of these two drug schedules.

To determine the feasibility on a group-wide basis of surgical excision of accessible lesions in partially responding patients.

To compare the histology of the diagnostic lesion with the histology of tumor removed from the partial responder.

Technical Approach: Patients with a biopsy confirmed diagnosis of a soft tissue sarcoma with convincing clinical or biopsy-documented evidence of metastatic disease are eligible for this study. Patients must not have received any prior chemotherapy with the agents used in this study. Patients must have a life expectancy of 10 weeks, and all patients mut have lesion(s) which is measurable and can be followed for tumor response.

Therapy will follow the schema outlined in the study protocol.

Progress: Only one of six patients from BAMC remains on this study. Group-wide, there have been three responses and only two patients have undergone surgical resection.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8025	Status: Ongoing

TITLE:
Combination Chemotherapy for Chronic Lymphocytic Leukemia

Start Date 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Chronic lymphocytic leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and duration of remission in patients with CLL treated with combination chemotherapy consisting of Prednisone, Vincristine, Cytosine Arabinoside, Cytoxan, and Adriamycin.

To correlate parameters obtained in the clinical, pathological, and immunological staging with response to treatment.

To determine the effect of stopping chemotherapy after patients have achieved a complete remission plus two consolidation courses, in order to define a cured or stabilized fraction of patients.

Technical Approach: All patients who fulfill the criteria for diagnosis of chronic lymphocytic leukemia according to the Rai Classification will be eligible for registration.

Therapy will follow the schema outlined in the study protocol.

Progress: Forty-seven patients have been entered thus far (5 from BAMC; 2 during FY 82). Groupwide, 64% of the patients treated with chemotherapy achieved complete + partial responses.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8026	Status: Ongoing

TITLE:

Cis-Platinum in the Treatment of Refractory Epidermoid Carcinoma of the Penis, Phase II

Start Date Jan 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Epidermoid carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine response-rate and survival in patients with advanced epidermoid carcinoma of the penis treated with Cis-platinum.

Technical Approach: *Patients must have epidermoid carcinoma of the penis* confirmed by biopsy, Stage III or IV, refractory to surgery and radiotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 4 patients have been entered on this study (none from BAMC). Two cases have achieved a partial response. The drug appears to be active in the preliminary analysis.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8027	Status: Ongoing

TITLE:

The Natural History of Pathological Stage T_{1-2} N_0 M_0 ER+ Breast Cancer, Phase III

Start Date 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Breast cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To document recurrence-rates, patterns of recurrence, and survival among patients with Stage I or Stage II node negative (T_{1-2} N_0 M_0) breast cancer whose tumors are determined to be estrogen receptor positive at the time of surgery.

Technical Approach: All female patients having had a radical, modified radical, or adequate local excision, with axillary node dissection for histologically proven breast carcinoma, whose axillary nodes are negative for tumor, and whose estrogen receptor assay on the primary tumor is positive are eligible for this study.

Progress: No reportable data are available.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8028	Status: Completed

TITLE:
Evaluation of DHAD in Gynecologic Cancers, Stage II

Start Date 11 May		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: John D. Cowan, M.D., MAJ, MC
Key Words: Gynecologic cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response-rate and remission duration in patients with gynecologic tumors treated with DHAD used in a single dose every-three-week schedule.

To define the qualitative and quantitative toxicities of DHAD as administered in this Phase II Study.

Technical Approach: To be eligible for this study, patients must have a pstho logically verified histologic diagnosis of ovarian (epithelial type), endometrial, or cervical (squamous cell type) carcinoma. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: DHAD proved to be ineffective treatment for epithelial carcinoma of the ovary in patients who have had prior chemotherapy. No patients from BAMC were entered on this study.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8030	Status: Ongoing

TITLE:

Evaluation of DHAD in Advanced Squamous Cell Carcinoma of the Head and Neck, Phase II

Start Date 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Squamous cell carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and remission duration in patients with advanced squamous cell carcinoma of the head and neck treated with DHAD used in a single dose every-three-week schedule.

To define further the qualitative and quantitative toxicities of DHAD.

Technical Approach: To be eligible for this study, patients must have a verified histologic diagnosis of squamous cell carcinoma of the head and neck region. All patients must have a life expectancy of at least three months.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been slow. No patients from BAMC have been entered on this study.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8031	Status: Ongoing

TITLE:

Evaluation of DHAD in Refractory Multiple Myeloma, Phase II

Start Date 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Multiple myeloma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and response duration of patients with refractory multiple myeloma treated with dihydroxyanthracenedione (DHAD) used in a single dose every-three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: All patients with multiple myeloma who are not eligible for higher priority Southwest Oncology Group protocols are eligible. Patients must have clearly measurable myeloma protein levels and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirteen patients have been entered on this study (none from BAMC). Eleven of those patients are evaluable with one partial response and two improved.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8032	Status: Ongoing

TITLE:
Evaluation of DHAD in Acute Leukemia, Phase II

Start Date 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Acute leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the efficacy of dihydroxyanthracenedione (DHAD) in patients with adult acute leukemia, who have failed on higher priority treatment protocols, as determined by response-rate and remission duration.

To determine the nature and degree of toxicity of this drug used in a single-dose, every-three-week schedule.

Technical Approach: Eligible patients must have a bone marrow diagnosis of acute leukemia.

Therapy will follow the schema outlined in the study protocol.

Progress: Forty-two patients have been enrolled on this study (none from BAMC). On the new dose schedule of 4 mg/M^2 daily x 5, of 8 patients there has been one complete response.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8033	Status: Terminated

TITLE:
Trial of m-AMSA in Sarcomas of the Bone and Cartilage, Phase II

Start Date 11 May 81		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: John D. Cowan, M.D., MAJ, MC
Key Words: Bone sarcoma Cartilage sarcoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the efficacy of m-AMSA in producing regression or remission in refractory sarcomas arising within the bone or cartilage.

Technical Approach: All patients having histologically proven disease with bony and cartilagenous sarcomas who failed accepted standard intervention with surgery, chemotherapy, and/or radiotherapy are eligible. Patients must have measurable disease and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: The study was terminated because of poor patient accrual.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8037	Status: Ongoing

TITLE:
Combined Therapies for Squamous Cell Carcinoma of the Esophagus, Phase II

Start Date 22 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Squamous cell carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the feasibility and toxicity of combined radiotherapy and chemotherapy with 5-fluorouracil and cis-platinum followed by surgery in patients with epidermoid carcinoma of the middle or distal esophagus.

To determine the time to local or distant progression in patients treated by these three combined modalities.

To determine the survival of patients treated by these three combined modalities.

To determine the response-rate by clinical and pathological staging at the time of surgery.

Technical Approach: Previously untreated patients with biopsy-proven squamous cell carcinoma of the middle or distal esophagus are eligible. Patients must be judged medically to be a surgical candidate for laparotomy and thoracotomy. Patients must have a life expectancy of 6 weeks or greater.

Therapy will follow the schema outlined in the study protocol.

Progress: It is too early for data analysis. One patient from BAMC has been entered on this study.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8038	Status: Ongoing

TITLE:
Vinblastine in Advanced Ovarian Cancer, Phase II

Start Date 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Ovarian cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and remission duration with intravenous therapy using Velban as a continuous infusion in patients with advanced ovarian cancer.

To define further the qualitative and quantitative toxicity of the continuous infusion of Velban.

Technical Approach: To be eligible, patients must have histologically confirmed, advanced, incurable ovarian cancer who are refractory to or ineligible for treatment on Southwest Oncology Group protocols of higher priority. Patients must have measurable disease and a life expectancy of six weeks or more.

Therapy will follow the schema outlined in the study protocol.

Progress: Twelve patients have been entered on this study (none from BAMC). It is too early to evaluate.

Detail Summary Sheet

Date: 19 Nov 82	Proj No: SWOG 8040	Status: Ongoing

TITLE:

Evaluation of Combination Chemotherapy (FAM-S) vs a Phase II Drug in Pancreatic Adenocarcinoma, Phase II

Start Date 22 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Pancreatic adenocarcioma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and survival in patients with advanced pancreatic adenocarcinoma treated with 5-FU, Adriamycin, Mitomycin-C and Streptozotocin (FAM-S).

To determine further the toxicity of the FAM-S regimen.

To determine the activity of a Phase II drug in previously untreated patients with advanced adenocarcinoma of the pancreas by determination of response-rate and duration of response and survival.

To determine further the toxicity of each Phase II agent.

Technical Approach: Patients with histologic confirmation of adenocarcinoma of the exocrine pancreas with distant metastases and/or those with localized disease not amenable to curative surgery or radiotherapy are eligible. All patients must have objectively measurable disease and a life expectancy of at least 10 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. Groupwide, it is too early to know survival data or to interpret the statistics meaningfully.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8042	Status: Ongoing

TITLE:
Evaluation of MGBG in Pancreatic Adenocarcinoma, Phase II

Start Date 22 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John A. Cowan, M.D., MAJ, MC
Key Words: Pancreatic adenocarcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the response-rate and its duration in patients with advanced adenocarcinoma of the pancreas treated with MGBG.

To determine the qualitative and quantitative toxicities of MGBG when given on this schedule.

Technical Approach: Patient eligibility is as stated in SWOG 8040.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. No reportable data are available.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8043	Status: Terminated

TITLE:
Evaluation of DHAD in Pancreatic Adenocarcinoma

Start Date 22 May 81		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: John D. Cowan, M.D., MAJ, MC
Key Words: Pancreatic adenocarcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the antitumor activity of DHAD, as determined by response-rate and duration of response, used in a single dose schedule every three weeks in patients with advanced adenocarcinoma of the pancreas.

To determine additional information concerning the nature and degree of toxicity of this drug.

Technical Approach: Patient eligibility is as outlined in SWOG 8040. In those patients treated initially on the FAM-S arm, patients must have received no mitomycin-C for 6 weeks; no Adriamycin, 5-FU or streptozotocin for 3 weeks; and must show evidence of hematologic recovery prior to beginning treatment with DHAD.

Therapy will follow the schema outlined in the study protocol.

Progress: The study was terminated because of poor patient accrual.

Detail Summary Sheet

Date: 19 Nov 82	Proj No: SWOG 8049	Status: Ongoing

TITLE:

The Treatment of Resected, Poor Risk Prognosis Malignant Melanoma: Stage I: Surgical Excision vs Surgical Excision + Vitamin A, Phase III.

Start Date 9 Oct 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Malignant melanoma Vitamin A		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the efficacy of surgical excision or surgical excision plus vitamin A in preventing the recurrence of high-risk, Stage I malignant melanoma by determination of remission or disease-free interval.

To determine the immunocompetence of patients with malignant melanoma and to determine the influence of vitamin A upon that immunocompetence.

Technical Approach: All patients with a histologically-confirmed diagnosis of high-risk Stage I malignant melanoma who have not been previously treated with chemotherapy, radiation therapy, or immunotherapy are eligible. All patients must have had a wide local excision of the primary lesion.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirty patients have been accrued at this time (none from BAMC). It is too early to report any data.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8051	Status: Ongoing

TITLE:
Evaluation of L-Alanosine in Acute Leukemia, Phase II

Start Date 25 Sep 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Acute leukemia L-Alanosine		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the antitumor activity of L-alanosine as determined by response-rate and duration of response in patients with acute leukemia who are not eligible for higher priority studies.

To determine the nature and degree of toxicity of this drug.

Technical Approach: Patients with acute leukemia, either lymphocytic or non-lymphocytic, not eligible for higher priority Southwest Oncology Group studies are eligible. Patients must have at least a 30% cellular marrow and 30% leukemic cells.

Therapy will follow the schema outlined in the study protocol.

Progress: No responses have been seen in the eight evaluable patients. No patients from BAMC have been entered on this study.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8066	Status: Ongoing

TITLE: Adjuvant Intrahepatic Chemotherapy with Mitomycin-C and 5-FU Combined with Hepatic Radiation in High Risk Patients with Carcinoma of the Colon, Phase II-Pilot

Start Date Jan 81	Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology	Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Carcinoma of colon	

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

Objective: To determine the toxicities of combined intra-arterial chemotherapy with hepatic radiotherapy in patients after total clinical resection of cancer of the colon who have a high risk of recurrence, for potential use in an adjuvant Group-wide protocol.

Technical Approach: To be eligible, the patient must have adenocarcinoma of the large bowel with involvement of the adjacent regional lymph nodes. There must be no evidence of any residual tumor.

Therapy will follow the schema outlined in the study protocol.

Progress: Ten patients have been entered on this study (six from BAMC). No significant toxicity has been observed.

Detail Summary Sheet

Date: 19 Nov 82	Proj No: SWOG 8077	Status: Ongoing

TITLE:

Combined Chemotherapy and Hormonal Therapy for Recurrent or Disseminated ER+ Breast Cancer, PACT vs ACT, Phase II

Start Date 9 Oct 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: John D. Cowan, M.D., MAJ, MC
Key Words: ER+ Hormone Therapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate of a combined chemo-hormonal program in ER+ patients with metastatic breast cancer.

To determine if the addition of Prednisone will greatly increase the response rate.

Technical Approach: Patients who have histologic evidence of metastatic breast carcinoma are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. Groupwide, it is too early to report any meaningful data.

Detail Summary Sheet

Date: 19 Nov 82	Proj No: SWOG 8092	Status: Ongoing

TITLE:

Use of Human Tumor Cloning System to Select Chemotherapy for Patients with Ovarian Cancer Refractory to Primary Therapy, Ancillary Study

Start Date 11 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Human tumor cloning system		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To utilize the human tumor cloning assay to select single agent chemotherapy for patients with epithelial-type ovarian cancer, refractory to standard therapy.

To determine if the human tumor cloning system can be utilized to select individual patient's therapy in a cooperative group setting.

Technical Approach: Eligible patients must have a pathological diagnosis of epithelial-type ovarian cancer in pleural or peritoneal fluid. Patients should have measurable disease and a life expectancy of at least three months.

Progress: Forty samples have been evaluated for growth. Thirty-one of the samples were in the form of malignant serous, and nine were solid tumors. Of the 40 samples, 14 have shown adequate growth (greater than 30 colonies per dish). Only two of the tumor samples showed less than 30% survival in response to exposure to an anti-cancer drug (DHAD in one sample and m-AMSA in another). There have been too few "sensitive" assays to allow conclusions concerning clinical correlations.

Detail Summary Sheet

Date: 17 Nov 82	Proj No: SWOG 8093	Status: Ongoing
TITLE: Treatment of Metastatic Malignant Mesothelioma: A Comparison of Cyclophosphamide (Cytoxan), DTIC and Adriamycin (CIA) vs Cyclophosphamide and Adriamycin (CA), Phase III		
Start Date 9 Oct 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: John D. Cowan, M.D., MAJ, MC
Key Words: Mesothelioma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the effect of the drug combination, Cyclophosphamide, DTIC, and Adriamycin vs Cyclophosphamide and Adriamycin (CA) on response-rate, remission duration, and survival of patients with metastatic malignant mesothelioma in a prospective, randomized Phase III clinical trial.

To determine the qualitative and quantitative toxicities of these two drug combinations.

To conduct an epidemiologic survey on all patients designed to identify important environmental factors which may place an individual at risk for the development of malignant mesothelioma.

Technical Approach: All patients must have histologically proven malignant mesothelioma of pleural or peritoneal origin with evidence of distant metastases or documented failure to previous radiation therapy. There must be an expected survival of at least 8 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. Groupwide, it is too early to report any meaningful data.

Detail Summary Sheet

Date: 19 Nov 82	Proj No: SWOG 8094	Status: Ongoing

TITLE:

Radiotherapy with and without Chemotherapy for Malignant Mesothelioma Localized to One Hemithorax, Phase III

Start Date 22 May 81		Est Comp Date: Unknown
Principal Investigator J. Dean McCracken, M.D., COL, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Oncology		Associate Investigators: John D. Cowan, M.D., MAJ, MC
Key Words: Mesothelioma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To evaluate in a randomized prospective manner, the efficacy of Adriamycin in improving the disease-free interval in patients who will receive hemithoracic radiotherapy for Stage I pleural mesothelioma.

To further define prospectively the efficacy of radiotherapy to the involved hemithorax in patients with pleural mesothelioma.

Technical Approach: Eligible patients will have histologically confirmed malignant mesothelioma of the pleural cavity. Patients with measurable disease or evaluable disease as well as those in whom all gross disease has been resected will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been slow (no patients from BAMC). No data are available at this time.

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8101	Status: Ongoing

TITLE:
VM-26 in Advanced GU Cancer, Phase II

Start Date 9 Oct 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: John D. Cowan, M.D., MAJ, MC
Key Words: GU cancer VM-26		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response-rate and duration of response of VM-26 in locally advanced or metastatic transitional cell carcinoma of the bladder, ureter, renal pelvis, and renal cell carcinoma.

To determine further the quantitative and qualitative toxicity in patients treated with VM-26.

Technical Approach: All patients not eligible for higher priority Southwest Oncology Group protocols, with histologically proven, incurable, advanced or metastatic, transitional cell carcinoma of the bladder, ureter or renal pelvis and renal cell carcinoma are eligible. There are no age restrictions. Patients must have a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirty patients have been registered (one from BAMC), 19 of whom had renal cancer and 3 with transitional cell cancer. Two of the 19 renal patients have had a response.

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8102	Status: Ongoing

TITLE:

Whole Brain Irradiation and Intrathecal Methotrexate in the Treatment of Solid Tumors Leptomeningeal Metastases, Phase II

Start Date 12 Feb 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Leptomeningeal metastases Solid tumor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the response-rate (CR + PR) of intrathecal methotrexate and whole brain irradiation in the control of solid tumor leptomeningeal metastases.

Technical Approach: All patients must have cerebrospinal fluid which is cytologically positive for malignant cells.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been enrolled at this time.

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8104	Status: Ongoing

TITLE:

Treatment of Advanced Seminoma (Stage cII (N_4) + cIII) with Combined Chemotherapy and Radiation Therapy, Phase II.

Start Date May 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Seminoma Chemotherapy Radiation Therapy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the response-rate and survival patterns in patients with advanced seminoma (Stage CII (N_4) + cIII) treated with combined chemotherapy and radiation therapy.

Technical Approach: All patients with histologically proven, Stage cII(N_4) and cIII, advanced, pure or anaplastic testicular seminoma who have had no prior chemotherapy or radiation therapy are eligibile. Patients must have no other evidence of malignant disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. It is too early to make any preliminary conclusions.

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8106	Status: Ongoing

TITLE:

Evaluation of AZQ (Carbamic Acid) in Central Nervous System Tumors, Phase II

Start Date 12 Feb 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Carbamic Acid (AZQ) Central Nervous System Tumors		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the efficacy of AZQ given by intermittent bolus schedule in malignant gliomas by evaluation of response-rate, duration and survival.

To determine the qualitative and quantitative toxicities of AZQ given by this schedule in a Phase II setting.

Technical Approach: To be eligible patients must have a histologically-confirmed diagnosis of astrocytoma, Grades III and IV; ependymoblastoma; medulloblastoma; or oligodendroglioma. Patients must have failed primary surgical and/or radiation therapies and not be eligible for higher priority protocols. All patients should have received adequate prior radiotherapy. Patients must have a life expectancy of six weeks or more.

Therapy will follow the schema outlined in the study protocol.

Progress: Three patients from BAMC entered on this study in FY 82 are now off study. The study is too early to evaluate.

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8107	Status: Ongoing

TITLE:
Management of Disseminated Melanoma, Master Protocol, Phase II-III

Start Date 9 Jul 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Melanoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the effectiveness of cranial irradiation given electively in disseminated melanoma patients with lung and/or liver metastases to prevent or delay the clinical appearance of brain metastases.

Technical Approach: Patients should have histologic proof of melanoma and a negative radiographic study of the brain. Patients must have established disseminated melanoma with lung and/or liver metastases.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8108	Status: Ongoing

TITLE:

Evaluation of Bisantrene Hydrochloride in Refractory Multiple Myeloma, Phase II

Start Date 14 May 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Multiple myeloma Bisantrene hydrochloride		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate and response duration of refractory multiple myeloma treated with biasntrene hydrochloride used in a single dose, every three-week schedule.

To define the qualitative and quantitative tocities of bisantrene administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of multiple myeloma. Bisantrene hydrochloride is intended for therapy of patients with multiple myeloma who have had prior exposure to, and progression of disease on, protocols of higher priority.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8110	Status: Ongoing

TITLE:

Treatment of Advanced Germ Cell Neoplasms of the Testis: A Comparison of Remission Induction...vs Observation, Phase III

Start Date11 Jun 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Germ cell neoplasm		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To compare in a randomized fashion the effectiveness of the drug combination Vinblastine, Cis-platinum, and VP 16-213 vs Vinblastine, Bleomycin and Cis-platinum in the remission induction of patients with disseminated germ cell neoplasms of testicular origin.

To determine the role of six months maintenance chemotherapy vs observation for those patients who achieve a complete response during induction, or have a totally resected mature teratoma, in terms of relapse-free survival and overall survival.

To determine the role of six months of maintenance chemotherapy vs observation for those patients with residual carcinoma having no evidence of disease following surgery, in terms of relapse-free survival and overall survival.

To document the nature and extent of the hematologic and non-hematologic side effects of the treatment modalities.

Technical Approach: Patients should have a histologically confirmed diagnosis of disseminated germ cell neoplasms of testicular origin. All patients with bulky abdominal disease (Stage cII(N_4) or Stage cIII) will be eligible for the study. Patients should have an expected survival of at least eight weeks.

Progress: This is a new study.

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8112	Status: Ongoing

TITLE:
Combination Chemotherapy of Unfavorable Histology Non-Hodgkin's Lymphoma with CHOP and CVB, Phase II.

Start Date 13 Mar 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Non-Hodgkin's lymphoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To gain experience with a treatment program utilizing a combination of two non-cross resistant drug regimens in the treatment of "poor prognosis" lymphomas.

To determine an approximate complete remission rate to the Cyclophosphamide, Adriamycin, Vincristine, and Prednisone (CHOP)/Cis-platinum, Vinblastine, and Bleomycin (CVB) treatment program prior to initiating a group-wide Phase III study utilizing this program.

Technical Approach: Biopsy proven previously untreated patients with Stage II-IV non-Hodgkin's lymphoma, "poor prognosis" histology will be eligible for treatment with this regimen. No prior chemotherapy with a single agent or combined chemotherapy is allowed.

Progress: This is a new study. Two of three patients from BAMC remain on the study. No meaningful data are available at this time.

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8116	Status: Ongoing

TITLE:
Evaluation of Bisantrene Hydrochloride in Refractory Lymphoma, Phase II

Start Date 9 Apr 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Lymphoma, refractory Bisantrene hydrochloride		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate and response duration of malignant lymphoma treated with bisantrene hydrochloride used in a single dose, every three-week shcedule.

To define the qualitative and quantitative toxicities of bisantrene hydrochloride administered in a Phase II study.

Technical Approach: All patients must ha[illegible] a pathologically verified histologic diagnosis of malignant lymphoma. Bisantrene is intended for therapy of patients with refractory lymphomas who have had prior exposure to, and progression of disease on, protocols of higher priority. Patients must have evaluable disease.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8117	Status: Ongoing

TITLE:

Evaluation of Bisantrene Hydrochloride in Refractory Ovarian Cancer, Phase II

Start Date 9 Apr 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Ovarian cancer Bisantrene hydrochloride		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine response rate and response duration of refractory ovarian cancer treated wtih bisantrene hydrochloride used in a single dose, every three-week schedule.

To define the qualitative and quantitative toxicities of bisantrene administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of ovarian cancer. Bisantrene is intended to therapy of patients with ovarian cancer who have had prior exposure to, and progression of disease on, protocols of higher priority. Patients must have evaluable disease. Patients must not be receiving concomitant radiation therapy, hormonal therapy, or other chemotherapy while on this protocol.

Therapy will follow the schema outlined in the study protocol

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

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BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON TX
J H ANDERSON 01 OCT 82

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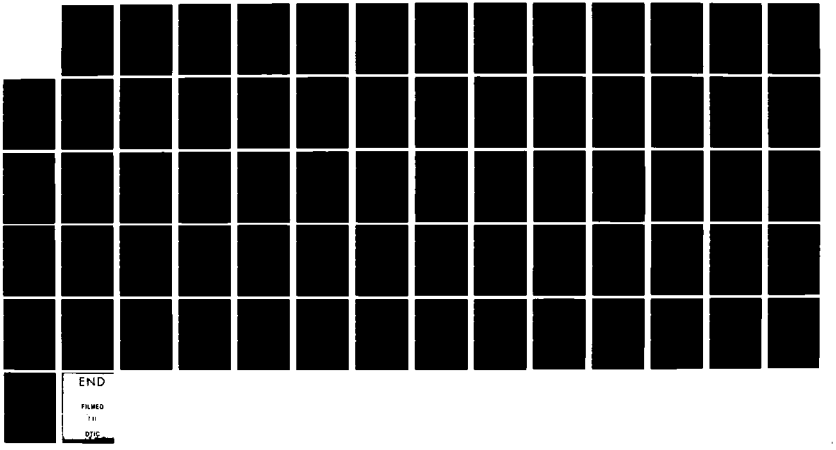

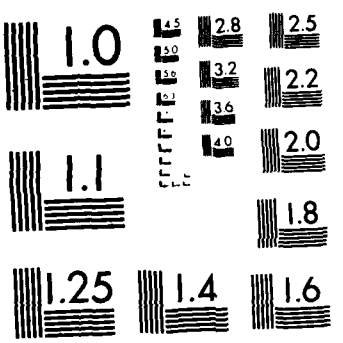

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8118	Status: Ongoing

TITLE:

Evaluation of Bisantrene Hydrochloride in Refractory Malignant Melanoma, Phase II

Start Date 9 Apr 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Malignant melanoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate and response duration of malignant melanoma treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

To define the qualitative and quantitative toxicities of bisantrene administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of melanoma. Bisantrene is intended for therapy of patients who have had prior exposure to, and progression of disease on, protocols of higher priority. Patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8119	Status: Ongoing

TITLE:
Evaluation of Bisantrene Hydrochloride in Hepatoma

Start Date 9 Apr 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Hepatoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate and response duration of hepatomas treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

To define the qualitative and quantitative toxicities of bisantrene administered in a Phase II Study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of hepatoma. Bisantrene is intended to therapy of patients with extensive disease or those patients not eligible or relapsing on protocols of higher priority. Patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8120	Status: Ongoing

TITLE:

Evaluation of Bisantrene Hydrochloride in Gastric Carcinoma, Phase II

Start Date 9 Apr 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Gastric carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate, response duration, and duration of survival of gastric carcinoma patients treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

To define the qualitative and quantitative toxicities of bisantrene hydrochloride administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of adenocarcinoma of the stomach with gross unresectable residual disease. Bisantrene is intended for therapy of patients with gastric carcinoma not eligible for protocols of higher priority and patients relapsing on protocols of higher priority. Patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. One patient from BAMC has been enrolled into the study but it is too early to evaluate.

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8122	Status: Ongoing

TITLE:
Combined Modality Treatment of Extensive Small Cell Lung Cancer, Phase III

Start Date 14 May 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Small cell lung cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To compare the response rate and duration of a new induction program (multiple alkylating agents plus Vincristine), with emphasis on complete response, to the combination of Vincristine, Adriamycin and Cyclophosphamide in the treatment of extensive small cell lung cancer.

To examine the effect of radiation consolidation on relapse in the chest and liver in patients without widespread skeletal disease.

To assess qualitative and quantitative toxicity of this combined modality approach.

To perform a prospective analysis, by electron microscopy, of the available material for clinicopathologic correlation.

To evaluate the effectiveness of a more aggressive radiation therapy approach to clinically evident brain metastases.

To evaluate the impact of chest radiation therapy following relapse as to the duration of response and survival.

To improve survival and the quality of life in patients with extensive small cell lung cancer.

Technical Approach: All patients with extensive small cell carcinoma of the lung (spread of disease beyond the ipsilateral hemithorax and its regional nodal drainage) are eligible for entry onto this study. Patients must not have had prior treatment with chemotherapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient from BAMC has been entered on this study. It is too early to evaluate.

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8161	Status: Ongoing

TITLE:

Evaluation of Bisantrene Hydrochloride in Adult Acute Leukemia, Phase II - Pilot

Start Date 9 Apr 82		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: John D. Cowan, M.D., MAJ, MC Glenn M. Mills, M.D., MAJ, MC
Key Words: Acute Leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate and response duration of adult acute leukemia treated with bisantrene hydrochloride.

To define the qualitative and quantitative toxicities of bisantrene when administered daily for five days every three weeks.

Technical Approach: All patients must have pathologically verified histologic diagnosis of adult acute leukemia. The diagnosis of adult acute leukemia will be made by bone marrow smear and an absolute infiltrate of 50% leukemic cells or greater. Bisantrene is intended for therapy of patients with adult acute leukemia in relapse who have had prior exposure to, and progression of disease, on protocols of higher priority. Patients must not be receiving concomitant chemotherapy while on this protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: Two of five patients entered on this study at BAMC did not respond to therapy and were removed from the study. It is too early to evaluate the three remaining on the study.

Detail Summary Sheet

Date: 18 Nov 82	Proj No:	Status: Ongoing

TITLE:

Aclacinomycin - Phase II Evaluation in Lung Cancer. Pilot Study

Start Date 9 Apr 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Lung cancer Aclacinomycin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the activity of aclacinomycin against carcinoma of the lung in minimally pretreated patients.

Technical Approach: Patients must have histologically proven advanced lung cancer. Patients who have previously received more than one prior chemotherapeutic regimen will be eligible only with approval of the principal investigator. Preferably, patients with non oat cell lung cancer or extensive small cell cancer will have received no prior therapy. Patients with small cell cancer failing first line SWOG protocols are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No data are available at this time.

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8200	Status: Ongoing

TITLE:

Evaluation of Vinblastine by Continuous Infusion for Advanced, Recurrent Endometrial Carcinoma, Phase II

Start Date 14 May 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Endometrial carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To evaluate the efficacy of a five day vinblastine infusion with respect to remission induction, remission duration, and survival duration in patients with advanced, recurrent, or Stages III and IV endometrial carcinoma refractory to prior chemotherapy.

Technical Approach: Patients with pathologically proven adenocarcinoma or adenosquamous carcinoma of the endometrium who have recurrent disease, or Stage III or IV disease no longer treatable with radiation therapy or surgery, are eligible. Patients must not have received prior chemotherapy with vinca alkaloids. Patients may have had previous chemotherapy of other types. Patients must have clinically measurable disease either by radiologic techniques or physical examination.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8206	Status: Ongoing

TITLE:
Evaluation of Aclacinomycin-A in Colorectal Carcinoma, Phase II

Start Date 9 Jul 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Colorectal carcinoma Aclacinomycin-A		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the antitumor activity of Aclacinomycin A in previously untreated patients with colorectal carcinoma by determination of the response-rate and remission duration of two dosage schedules; a single dose, every three-week schedule and a weekly dosage schedule for four weeks out of six.

To further define the qualitative and quantitative toxicities of this drug for each of the two dosage schedules in a Phase II study.

Technical Approach: Patients must have biopsy proven adenocarcinoma arising from the colon or rectum. They must have clinically measurable recurrent or disseminated disease to qualify for the study. Patients must be equal to or less than 65 years old, have a life expectancy of at least ten weeks and a performance status of at worst Grade 2 by Southwest Oncology Group criteria.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8207	Status: Ongoing

TITLE:

AZQ in Advanced Renal Cell Carcinoma, Phase II

Start Date 10 Sep 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Renal cell carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate and duration of response in patients with advanced renal cell carcinoma treated with AZQ used in a single dose, every three-week schedule.

To define the qualitative and quantitative toxicities of AZQ administered in a Phase II study.

Technical Approach: All patients with a diagnosis of histologically proven, advanced renal cell carcinoma not eligible for higher priority Southwest Oncology Group protocols 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: This is a new study. No data are available.

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8213	Status: Ongoing

TITLE:

Evaluation of Aclacinomycin-A in Refractory Multiple Myeloma, Phase II

Start Date 10 Sep 82		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: John D. Cowan, M.D., MAJ, MC
Key Words: Multiple myeloma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objective: To determine the response rate and duration of remission of Aclacinomycin A used in a weekly schedule (followed by two weeks rest) for patients with refractory multiple myeloma.

Technical Approach: All patients with histologically confirmed multiple myeloma, refractory to initial therapy, who are not eligible for higher priority Southwest Oncology Group protocols are eligible. Patients must have a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

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

Detail Summary Sheet

Date: 18 Nov 82	Proj No: SWOG 8218	Status: Ongoing

TITLE:

Evaluation of Spirogermanium (NSC-192965) in Renal Cell Carcinoma, Phase II

Start Date10 Sep 82		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: John D. Cowan, M.D., MAU, MC
Key Words: Renal cell carcinoma Spirogermanium		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine the response rate and remission duration of renal cell carcinoma when treated with Spirogermanium, used as a 60 minute infusion in a three times weekly schedule.

To define the qualitative and quantitative toxicities of Spirogermaium administered as a Phase II study.

Technical Approach: All patients must have a histologically proven diagnosis of renal cell carcinoma, and not be eligible for Southwest Oncology Group protocols of higher priority. Patients must have a clearly measurable disease. Patients should have a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

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

APPENDIX B

GYNECOLOGY ONCOLOGY GROUP

Detail Summary Sheet

Date: 4 Nov 82	Proj No: GOG 20	Status: Ongoing

TITLE: A Randomized Comparison of Adriamycin vs No Further Therapy in Patients with Uterine Sarcomas, Stage I and II, Phase III

Start Date FY 81	Est Comp Date: Unknown
Principal Investigator Charles Capen, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Uterine Sarcoma Adriamycin	

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

Objective: To determine if adjuvant chemotherapy will improve the cure rate in uterine sarcomas, Stage I and II.

Technical Approach: Patients with histologically proven sarcomas of the uterine corpus will be considered if they have Stage I or Stage II disease clinically, and if they have no known gross residual disease following surgery. Preoperative or postoperative pelvic radiotherapy may be given at the discretion of the principal investigator, but a decision about this mode of therapy must be made prior to the chemotherapy randomization.

Therapy will follow the schema outlined in the study protocol.

Progress: Three patients have been registered on this study. Groupwide, there has been no significant difference between survival and progression-free interval. Moreover, Mantel-Haentzel techniques adjusting for such parameters as stage, histology, prior radiotherapy and various combinations of these three have been employed, revealing no treatment difference.

Detail Summary Sheet

Date: 4 Nov 82	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 Charles Capen, M.D., LTC, 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 concommitantly with radiation in patients with advanced carcinoma of the uterine cervix.

Technical approach: Patients with histologically confirmed, previously untreated carcinoma of the uterine cervix (adenocarcinoma or squamous carcinoma) are eligible.

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

Progress: No patients have been entered on the study.

Preliminary analysis of data by GOG suggests that C-parvum does not add any therapeutic effect as an adjuvant to radiotherapy.

Detail Summary Sheet

Date: 4 Nov 82	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 Charles Capen, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics and Gynecology	Associate Investigators:
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 surgey will be included in the study.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered on the study and is responding well to therapy.

Analysis of data by GOG indicates that there is no significant difference when the duration of progression-free interval (PFI) and survival are compared by therapy. However, when compared by size of residual tumor at surgery, both are highly statistically significant.

Detail Summary Sheet

Date: 9 Nov 82	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 Charles Capen, M.D., LTC, 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

Objective: This protocol constitutes a Phase II design outlining the procedures that will be performed to screen for activity of new agents or drug combinations in patients with advanced recurrent pelvic malignancies. Its intent is to determine the efficacy of chemotherapeutic agents in patients whose advanced malignancies have been resistant to high priority methods of treatment.

Technical Approach: This is a study of multiple chemotherapeutic agents. Therapy will follow the schema outlined in the study protocol. Agents to be used in this study include: Piperazinedione, Cis-platinum, VP-16, Galacticol, Baker's Antifol, ICRF-159, Maytansine, m-AMSA and Yoshi 864.

Progress: No patients have been registered on this study. Groupwide progress is as follows.

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 adenocarcinoma and mixed mesodermal sarcoma of the uterus at the dose and schedule tested. The drug appears to be inactive against endometrial carcinoma and leiomyosarcoma but may have limited activity in the therapy of cervical adenocarcinomas.

VP-16 - VP-16 appears to have minimal activity against ovarian adenocarcinoma and insignificant activity against squamous cell carcinoma of the cervix and endometrial adenocarcinoma at the dose and schedule tested. Insufficient numbers of cases have been entered into other tumor categories and the study continues.

GOG 26 (continued)

Galacticol - Complete and partial remissions in carcinoma of the cervix have been 19% which is encouraging enough for further studies, possibly in combination with other drugs. One complete remission continues at 33+ months.

Complete and partial remissions in carcinoma of the ovary were 15%. Almost all of these patients had received prior chemotherapy. One complete remission continues at 24+ months.

One partial remission in 17 patients with endometrial adenocarcinoma was observed. Activity appears negligible at the dose and schedule tested.

Bakers Antifol - Although limited activity is noted, this drug is not as useful as more conventional drugs and probably will not add to our current therapeutic regimens.

ICRF - ICRF appears to have moderate activity in squamous cell carcinoma of the cervix and no significant activity in epithelial tumors of the ovary at the dose and schedule tested.

Maytansine - Maytansine has insignificant activity against squamous cell carcinoma of the cervix and epithelial tumors of the ovary. The study is closed to these two types of tumors.

AMSA - Patient accrual has been slow. It is too early to report any significant findings.

Yoshi 864 - Too early to report any significant findings.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: GOG 31	Status: Terminated

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:
Principal Investigator Charles Capen, M.D., LTC, 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:

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: No patients have been entered on this study. Groupwide the study was terminated because of an inability to obtain adequate follow-up.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: GOG 32	Status: Terminated

TITLE:

A Radomized Comparison of Srugical Conization vs Cryosurgery in Patients with Extensive Grade 3 Cervical Intraepithelial Neoplasia.

Start Date FY 79		Est Comp Date:
Principal Investigator Charles Capen, M.D., LTC, 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:

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: No patients have been entered on this study. The study was terminated due to an inability to obtain adequate follow-up.

Detail Summary Sheet

Date: 9 Nov 82	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 Charles Capen, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics and Gynecology	Associate Investigators:
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 grades, with one or more of the following high risk criteria are eligible: (1) all lesions with equal to or greater than one-half myometrial involvement; (2) positive pelvic and/or para-aortic nodes; (3) microscopic evidence of cervical involvement but no gross clinical involvement of the cervix. The following types of histologically confirmed uterine carcinoma are eligible: adenocarcinoma, adenoacanthoma, adenosquamous carcinoma.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient remains in the study and one patient was dropped when it was discovered that she was not eligible for this protocol. It is too early to draw any meaningful conclusions from the data available.

Detail Summary Sheet

Date: 9 Nov 82	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 Charles Capen, M.D., LTC, 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

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 patients have been entered on this study. Groupwide, it is too early to draw any meaningful conclusions from available data.

Detail Summary Sheet

Date: 9 Nov 82	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 Charles Capen, M.D., LTC, 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 patients have been registered on this study. Groupwide, no o reportable data are available at this time.

Detail Summary Sheet

Date: 9 Nov 82	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 Charles Capen, M.D., LTC, 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

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 patients have been registered on this study. Groupwide, it is too early to draw any conclusions.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: GOG 41	Status: Ongoing

TITLE:

Surgical Staging of Ovarian Carcinoma.

Start Date FY 79		Est Comp Date: Unknown
Principal Investigator Charles Capen, M.D., LTC, 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: One patient has been entered on this study. Groupwide it is too early to report any conclusions.

Detail Summary Sheet

Date: 9 Nov 82	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 Charles Capen, M.D., LTC, 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 Cyclphosphamide 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: No patients have been entered on the study. Groupwide, the regimens are well tolerated.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: GOG 43	Status: Ongoing

TITLE: A Randomized Comparison of Cis-platinum 50mg/m2 IV Every 3 weeks vs Cis-platinum 100mg/m2 IV Every 3 weeks vs Cis-platinum 20mg/m2 IV Daily x 5 Days in Treatment of Patients with Advanced Carcinoma of the Cervix, Phase III.

Start Date FY 79	Est Comp Date: Unknown
Principal Investigator Charles Capen, M.D., LTC, 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

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 resistent 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: One patient has been registered on this protocol. Groupwide evaluations have shown that there is no difference in the efficacy of the three regimens; however, there is less toxicity with the lower dose.

Detail Summary Sheet

Date: 9 Nov 82	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 Charles Capen, M.D., LTC, 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), choriocarcinoma, and malignant mixed germ cell tumors of the ovary, Stages I and II after total removal of all gross tumor.

To evaluate the role of serum markers, especially alpha-fetoprotein (AFP) and human chorionic gonadotropin (beta HCG), when these are present, in predicting response and relapse.

To determine the role of restaging laparotomy in determining response, predicting relapse and planning further therapy.

Technical Approach: Patients with histologically confirmed malignant germ cell tumors of the ovary, Stages I or II, if previously untreated and completely resected, excluding patients with pure dysgerminoma unless classified as anaplastic, are eligible. Patients with grade 2 or 3 immature teratoma are also eligible. Patients with early Stage III disease will be accepted if all gross tumor is resected.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this protocol. As far as GOG results are concerned, it is too early to report any meaningful results.

Detail Summary Sheet

Date: 9 Nov 82	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 Charles Capen, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Malignant germ cell tumor of ovary		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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: No patients have been registered on this study. Groupwide, there continues to be considerable toxicity; however, early results are encouraging.

Detail Summary Sheet

Date: 9 Nov 82	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 Charles Capen, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics and Gynecology		Associate Investigators:
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 patients have been registered on this study. Groupwide, it is too early to draw any conclusions.

Detail Summary Sheet

Date: 9 Nov 82	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 Charles Capen, M.D., LTC, 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: One patient has been entered on the Study. Groupwide, there is no survival difference. The addition of cis-platinum appears to significantly influence response and progression-free interval.

Detail Summary Sheet

Date: 9 Nov 82	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 Charles Capen, M.D., LTC, 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: No patients have been registered on this study. Groupwide, there is no significant difference when survival and progression-free interval are compared by treatment.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: GOG 49	Status: Ongoing

TITLE: A Surgical-Pathologic Study of Women with Invasive Carcinoma of the Cervix Stage IB and Randomly Assigned Radiation Therapy versus no Further Therapy in Selected Patients.

Start Date FY 81	Est Comp Date: Unknown
Principal Investigator Charles Capen, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Invasive carcinoma Cervix	

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

Objectives: To determine by observations of the 5-year survival and disease-free interval, the validity of current FIGO staging to the histopathologic prognostic factors of size of lesion, location of lesion, depth of invasion of tumor, in millimeters, histology and grade, growth pattern, and site and number of positive lymph nodes in Stage IB carcinoma of the cervix.

To rapidly accumulate prospectively significant surgical pathologic data which would expedite development of further protocols.

To determine morbidity of primary radical surgical therapy.

To determine if radiation therapy will improve survival in selected patients with positive nodes.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive carcinoma of the cervix (squamous cell, adenocarcinoma or adenosquamous) are eligible. Patients must have had a pelvic and para-aortic lymphadenectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study. Groupwide, it is too early to evaluate.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: GOG 50	Status: Ongoing

TITLE:

A Study of Adriamycin as Postoperative Therapy for Ovarian Sarcoma, Primary or Recurrent, with No Prior Chemotherapy, Phase III.

Start Date FY 81		Est Comp Date: Unknown
Principal Investigator Charles Capen, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Ovarian sarcoma Adriamycin		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To evaluate the efficacy of Adriamycin in the treatment of ovarian sarcomas, primary or recurrent, through historic controls.

To accumulate additional srugical-pathological data relative to ovarian sarcomas.

Technical approach: All patients must have histologically confirmed primary Stage I-IV or recurrent ovarian sarcoma. Optimal reductive surgery is required for cases with advanced disease, whether primary or recurrent. Patients may have measurable disease, non-measurable disease or no residual disease postoperatively. The endometrium must be examined to exclude an endometrial origin of tumor.

Patients with primary Stage I-IV disease must be entered and protocol therapy begun within six weeks of surgery. Patients with recurrent disease must be entered and protocol therapy begun within six weeks of documented recurrence.

Progress: No patients have been registered on this study. Groupwide, it is too early to report any meaningful data.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: GOG 51	Status: Ongoing

TITLE: A Randomized Comparison of Droperidol versus THC in the Treatment of Nausea and Vomiting Produced by Cis-platinum Chemotherapy for Gynecologic Malignancies.

Start Date FY 81	Est Comp Date: Unknown
Principal Investigator Charles Capen, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: THC (Delta-9-Tetrahydrocannabinol) Droperidol (Dehydrobenzperidol) Cis-platinum	

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

Objective: To evaluate the effectiveness of Droperidol and THC as anti-emetic agents in chemotherapy of gynecologic malignancies treated with Cis-platinum.

Technical Approach: Patients with gynecologic malignancies who receive Cis-platinum as a single agent are eligible. Patients will be randomized to one of two treatment groups. Group 1 will receive THC by mouth during two courses of chemotherapy, and then take droperidol by injection for two chemotherapy courses. Group 2 will receive droperidol by injection for two chemotherapy courses and then THC by mouth during two courses of chemotherapy.

Progress: No patients have been enrolled in this study. Groupwide, no reportable data are available at this time.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: GOG 52	Status: Ongoing

TITLE: A Phase III Randomized Study of Cyclophosphamide plus Adriamycin plus Platinol (Cis-platinum) vs Cyclophosphamide plus Platinol in Patients with Optimal Stage III Ovarian Adenocarcinoma.

Start Date Oct 81		Est Comp Date: Unknown
Principal Investigator Charles Capen, M.D., LTC, 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 in "optimal" Stage III ovarian adenocarcinoma, if the addition of adriamycin to cyclophosphamide plus cis-platinum (platinol) improves progression-free interval, frequency of negative second-look laparotomy and survival.

Technical Approach: Patients with proven primary Stage III ovarian adenocarcinoma (serous, mucinous, endometrioid, undifferentiated carcinoma, mixed epithelial carcinoma or clear cell) confined to the abdominal cavity and its peritoneal surfaces with residual tumor masses after surgery no larger than 1 cm in diameter are eligible. Entry must be no more than six weeks postoperative.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been registered on this study. Groupwide, it is too early to report any meaningful data.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: GOG 56	Status: Ongoing

TITLE: A Randomized Comparison of Hydroxyurea vs Misonidazole as an Adjunct to Radiation Therapy in Patients with Stages IIB, III and IVA Carcinoma of the Cervix and Negative Para-Aortic Nodes.

Start Date Nov 81		Est Comp Date: Unknown
Principal Investigator Charles Capen, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics and Gynecology		Associate Investigators:
Key Words: Carcinoma of cervix Para-aortic nodes		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results:

Objectives: To determine whether hydroxyurea or misonidazole is superior as a potentiation of radiation therapy in advanced cervical cancer.

To compare the toxicity of hydroxyurea vs misonidazole when given concurrently with radiotherapy.

Technical Approach: All patients with primary, previously untreated, histologically confirmed invasive squamous cell carcinoma of the uterine cervix, clinical stages IIB through IVA confined to the pelvis will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled in the study. No reportable data are available from GOG.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: GOG 59	Status: Ongoing

TITLE: A Randomized Comparison of Extended Field Radiation Therapy and Hydroxyurea Followed by Cisplatin or No Further Therapy in Patients with Cervical Squamous Cell Carcinoma Metastatic to High Common Iliac...Lymph Nodes--III.

Start Date Nov 81	Est Comp Date: Unknown
Principal Investigator Charles Capen, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Sec Department of Obstetrics and Gynecology	Associate Investigators:
Key Words: Cervical squamous cell carcinoma Metastatic Common iliac lymph nodes	

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

Objectives: To determine if cis-diamminedichloroplatinum, cisplatin, given in an adjuvant setting will decrease the risk of geographic failure or improve the survival rate or progression-free interval in patients with squamous carcinoma of the cervix with metastases to high common iliac and/or para-aortic lymph nodes, proven by either histologic or cytologic means.

To evaluate the role of scalene fat pad biopsy in this group of patients before initiation of extended field irradiation therapy.

To accumulate clinical/surgical/pathologic data on this high-risk group of patients to expedite development of further protocols.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive squamous cell carcinoma of the uterine cervix, all clinical stages, with metastasis to high common iliac or para-aortic lymph nodes proven by cytologic or histologic means are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study. It is too early for reportable data from GOG.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: GOG 60	Status: Ongoing

TITLE: A Randomized Study of Doxorubicin plus Cyclophosphamide plus Cisplatin vs Doxorubicin plus Cyclophosphamide plus Cisplatin plus BCG in Patients with Advanced Suboptimal Ovarian Adenocarcinoma, Stage III and IV.

Start Date Nov 81		Est Comp Date: Unknown
Principal Investigator Charles Capen, M.D., LTC, 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:

Objectives: To determine if the addition of BCG to doxorubin (adriamycin) plus cyclophosphamide plus cisplatin improves remission rate, remission duration, or survival in suboptimal Stage III and IV ovarian adenocarcinoma.

To determine the frequency and duration of true complete remission using these regimens as judged at second-look laparotomy.

Technical Approach: Patients wih estabilished suboptimal Stage III and IV ovarian epithelial cancer are eligible. All patients must have optimal surgery and appropriate tissue for histologic evaluation, as detailed in protocol GOG 41.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled in this study. No reportable data are available from GOG.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: GOG 61	Status: Ongoing

TITLE: Randomized Study of Cis-platinum + Cyclophosphamide vs Hexamethylmelamin after Second-Look Surgery in Nonmeasurable Stage III Ovarian Adenocarcinoma Partially Responsive to...Cis-platinum and Cyclophosphamide.

Start Date Nov 81		Est Comp Date: Unknown
Principal Investigator Charles Capen, M.D., LTC, 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, in nonmeasurable but residual Stage III ovarian adenocarcinoma partially responsive after treatment with regimens containing cis-platinum and cyclophosphamide, if the progression-free interval and survival are improved by continuing cyclophosphamide plus cis-platinum or by changing treatment to hexamethylmelamine.

Technical Approach: Patients who have been diagnosed as Stage III ovarian cancer and who have had residual disease found at second-look laparotomy may be eligible. A patient who began with measurable disease and achieved a clinical complete response, but then at second look was found to have residual disease after treatment with regimens containing cis-platinum plus cytoxan would be eligible. A patient who originally had nonmeasurable disease and who at the time of second look has less volume of disease than was described at the time of the original surgery or in whom there has been no change in the volume of disease would be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study. No reportable data are available from GOG.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: 7601	Status: Ongoing

TITLE:

Ovarian Cancer Study Group Protocol for Selected Stage IAi - IBi Ovarian Cancer (Well and Moderately Differentiated).

Start Date FY 79		Est Comp Date: Unknown
Principal Investigator Charles Capen, M.D., LTC, 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 procedure, if the patient is a selective Stage IAi, or IBi, and the histologic grade is well or moderately differentiated, the patient is eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been registered on this study. No reportable data are available from GOG.

Detail Summary Sheet

Date: 9 Nov 82	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 Charles Capen, M.D., LTC, 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 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 patients have been entered on this study. Groupwide, patient accrual has been slow. No reportable data are available.

APPENDIX C

POLYCYTHEMIA VERA STUDY GROUP

Detail Summary Sheet

Date: 9 Nov 82	Proj No: PVSG-12	Status: Ongoing

TITLE:
Hydroxyurea in Thrombosis.

Start Date FY 80		Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Hematology-Oncology		Associate Investigators:
Key Words: Thrombocytopenia Myelofibrosis-myeloid metaplasia Myeloproliferative disease		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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: Eight patients have been entered into this study. No significant data are available at this time.

Detail Summary Sheet

Date: 9 Nov 82	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 Glenn M. Mills, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Hematology-Oncology		Associate Investigators:
Key Words: Myeloproliferative disorder		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

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) thromboembolic 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: No patients have been entered on this study.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: PVSG-15	Status: Ongoing

TITLE:

Efficacy Trial Using Cyproheptadine and Cimetidine for Pruritus in Polycythemia Vera

Start Date 10 Oct 81		Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Medicine/Hematology-Oncology		Associate Investigators:
Key Words: Pruritus Polycythemia Vera		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine whether H_1 and H_2 blocking agents used concomitantly are efficacious in alleviating the pruritus of polycythemia vera.

Technical Approach: Any patient with polycythemia vera in remission, i.e., Hct. of 40-45%, following treatment who suffers from persistent pruritus which worsens with bathing or showering and which does not antedate the onset of symptoms of polycythemia vera is eligible for this protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

APPENDIX D

PEDIATRIC ONCOLOGY GROUP

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 7376	Status: Ongoing

TITLE:
Evaluation of Natural History of Histiocytosis X in Childhood

Start Date Feb 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Histiocytosis X		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To obtain information about the natural history of all forms of histiocytosis X and histiocytic medullary reticulosis.

Technical Approach: All new patients with a biopsy-proven diagnosis of histiocytosis X should be registered for the study.

This study involves reporting on the results of examinations, tests, and treatment during the course of the disease. The examinations and tests are as outlined in the study protocol.

Progress. No patients have been registered on the study.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 7612	Status: Ongoing

TITLE:
MOPP + Bleo vs A-COPP with IF RT in Stage III Hodgkin's Disease in Children

Start Date 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Hodgkin's disease		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To compare the effectiveness of IF radiotherapy plus MOPP + Bleo with IF radiotherapy plus A-COPP chemotherapy in treating Stage III Hodgkin's disease in children.

To determine the patient tolerance of the two chemotherapy regimens in terms of immediate toxicity including the incidence of infection.

Technical Approach: All children, 18 years or younger, with Stage III Hodgkin's disease including extranodal presentations + constitutional symptoms, regardless of specific with no prior therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered into the study. It is too early to report any significant results of therapy in this patient.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 7621	Status: Ongoing

TITLE:

MOPP vs OPP in the Treatment of Children with Recurrent Brain Tumors

Start Date Feb 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Brain tumor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine and compare response to MOPP or OPP in children with recurrent brain tumors.

Technical Approach: All patients who have been diagnosed to have a central nervous system tumor, and who have previously received maximally allowable dose of radiotherapy will be eligible for randomization which will require no prior therapy with either nitrogen mustard or BCNU. Patients must be 18 years of age or under at the time of diagnosis.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 7712	Status: Ongoing

TITLE:
Comparison of Treatment Regimens for the First CNS Relapse in Children with Acute Lymphocytic Leukemia - CNS #6

Start Date 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Acute lymphocytic leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To compare two therapies for CNS leukemia with respect to length of CNS remission and CNS toxicity.

Technical Approach: Patients less than 21 years of age at time of initial diagnosis with first CNS relapse who have not had more than one marrow relapse are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 7799	Status: Ongoing

TITLE:
Rare Tumor Registry for Childhood Solid Tumor Malignancies

Start Date 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Solid tumor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To collect natural history data on malignancies which occur so rarely that large series of patients cannot be accumulated at any single institution.

To evaluate therapies in those groups of rare tumors in which fair numbers of cases can be accrued.

Technical Approach: Any child under the age of 18 years at diagnosis with a rare solid tumor is eligible for the study.

Progress: No patients have been registered on this protocol.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 7812	Status: Ongoing

TITLE:
Anguidine in Central Nervous System Tumors

Start Date 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Central nervous system tumors		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the anti-tumor activity of anguidine in the treatment of malignant brain tumors in children and adolescents relative to clinical response and survival.

Technical Approach: Patients with histologically confirmed primary CNS tumors as follows are eligible: Astrocytoma, Grades III and IV; ependymoma, oligodendroglioma; medulloblastoma and patients under 21 years of age with clinical diagnosis of recurrent brain stem glioma following radiation therapy are eligible. Patients must not be eligible for protocols of higher priority or treatment of proven or likely higher efficacy.

Progress: No patients have been registered on this protocol.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 7818	Status: Ongoing

TITLE:

Rubidazone in Children with ALL and AML in Relapse

Start Date 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Acute lymphocytic leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the clinical efficacy and toxicity of rubidazone when used for the induction of remission in children with acute leukemia.

Technical Approach: Patients 21 years of age or under with acute leukemia in relapse, not eligible for protocols of higher priority, are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this protocol.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 7829	Status: Ongoing

TITLE:

Comparison of Two Dose Regimens of Intrathecal Methotrexate for CNS Leukemia, Phase II

Start Date 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: CNS leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To compare the toxicity, response rates and duration of response obtained by using a two dose regimen of intrathecal methotrexate.

Technical Approach: Patients under the age of 21 with CNS leukemia in relapse who are not known to be resistant to intrathecal methotrexate are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this protocol.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 7834	Status: Ongoing

TITLE:
Second Induction Maintenance in Acute Lymphocytic Leukemia, Phase III

Start Date 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Acute lymphocytic leukemia		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine in children in the first relapse of ALL in remission duration which can be achieved following an ingensive and aggressive induction regimen and maintenance.

Technical Approach: Patients under the age of 21 years in their first CNS and/or extramedullary and/or bone marrow relapse with acute lymphocytic leukemia are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered into this study. It is too early to make any positive or negative statement regarding response to therapy.

Detail Summary Sheet

Date: 9 Nov 8[illegible]	Proj No: POG 7837	Status: Ongoing

TITLE:
Evaluation of Systemic Therapy for Children with T Cell Acute Lymphatic Leukemia, Phase III

Start Date 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Acute lymphatic leukemia T-cell		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To evaluate the effectiveness of a program of sequential systemic chemotherapy plus CNS treatment for children with untreated T-cell leukemia.

Technical Approach: Patients under the age of 21 with a diagnosis of T-cell leukemia as defined by SWOG 7865 including all patients who have 20% or greater E-rosetting leukemia cells are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been registered on this study. No reportable data of significance are available at this time.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 7843	Status: Ongoing

TITLE:

Evaluation of Rubidazone in the Treatment of Children with Solid Tumors, Phase II

Start Date 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Solid tumor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the clinical efficacy of rubidazone in the treatment of malignant tumors in children with and without previous anthracycline therapy and to determine the toxicity of this drug in children with solid tumors.

Technical Approach: All patients under the age of 21 with a measurable tumor lesion, resistant to conventioanl chemotherapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 7895	Status: Ongoing

TITLE:

Multimodal Therapy for Management of Primary Non-Metastatic Ewing's Sarcoma of Pelvic and Sacral Bones.

Start Date 25 Sep 81		Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Ewing's sarcoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To determine the effectiveness of high dose intermittent chemotherapy to prevent local recurrence and/or metastases with surgical resection and a uniform radiation therapy regimen to control local disease.

Technical Approach: Patients with biopsy-proven localized Ewing's sarcoma with no prior chemotherapy and/or radiation therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 7909	Status: Ongoing

TITLE:

Evaluation of MOPP Adjuvant Chemotherapy in the Treatment of Localized Medulloblastoma and Ependymoma

Start Date May 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Medulloblastoma Ependymoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objective: To evaluate the efficacy and toxicity of the MOPP adjuvant chemotherapy in the prevention of local recurrence of distant metastasis in children with localized medulloblastoma and ependymoma.

Technical Approach: Patients between 1 and 21 years (inclusive) with histologically proven medulloblastoma and ependymoma are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered into this study. It is too early to evaluate the results.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 7919	Status: Ongoing

TITLE:

Evaluation of m-AMSA in Children with Acute Leukemia and Non-Hodgkins in Relapse

Start Date Nov 80		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Acute leukemia Non-Hodgkin's lymphoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the clinical efficacy of m-AMSA, as indicated by the induction of partial or complete remission, in pediatric patients with acute leukemia or non-Hodgkin's lymphoma in relapse.

To further assess the toxicity of m-AMSA in children.

Technical Approach: All patients with acute leukemia (lymphocytic and non-lymphocytic) or non-Hodgkin's lymphoma in relapse who are 18 years of age or under at the time of diagnosis, who are not eligible for protocols of higher priority and who are resistant to standard forms of therapy, will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 8000	Status: Ongoing

TITLE:
National Wilms' Tumor Study, III

Start Date 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Wilms' tumor		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To gain better understanding of Wilms' tumor by gathering detailed information regarding gross and histologic morphology.

To refine methods of treatment according to staging.

To test treatment hypotheses by randomized, prospective clinical trials according to stage and histologic grade of disease.

To gather information about family cancer in an attempt to identify children and families at high risk.

To study the late consequences of successful treatment given for Wilms' tumor.

Technical Approach: Patients under the age of 15 with Wilms' tumor are eligible.

Progress: Two patients have been entered on this study. No results from the National Study have been received.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 8002	Status: Ongoing

TITLE:

Combination Chemotherapy with Adriamycin, Cis-Platinum, Vincristine, and Cytoxan in Children with Metastatic Neuroblastoma (Stage IV)

Start Date 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Neuroblastoma, metastatic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To delineate the toxicity of the combination of cytoxan, vincristine, adriamycin and cis-platinum in children with metastatic neuroblastoma.

To do a preliminary analysis of the therapeutic efficacy prior to consideration of this four-drug combination as front-line therapy for children with Stage IV neuroblastoma.

Technical Approach: Children from 1 to 18 years of age with biopsy-proven metastatic neuroblastoma (Stage IV) who have not had prior exposure to cis-platinum are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

Detail Summary Sheet

Date: 9 Nov 82	Proj No: POG 8075	Status: Ongoing

TITLE:
Circulating Immune Complexes in Pediatric Malignancies

Start Date 25 Sep 81		Est Comp Date: Unknown
Principal Investigator Terry E. Pick, M.D., LTC, MC		Facility Brooke Army Medical Center
Dept/Sec Department of Pediatrics		Associate Investigators:
Key Words: Immune complex		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Continue

Objectives: To determine the incidence of elevated levels of circulating immune complexes at diagnosis in children with neuroblastoma, osteogenic sarcoma, ALL and AML.

To correlate serial levels of circulating immune complexes with disease activity should significant quantities be initially detected.

Technical Approach: Newly diagnosed and staged patients under 21 years of age with neuroblastoma, osteogenic sarcoma, acute lymphocytic leukemia or acute myelogenous leukemia are eligible. Patients should not have had excisional surgery, chemotherapy or radiotherapy prior to initial serum sample.

Progress: No patients have been registered on this protocol.

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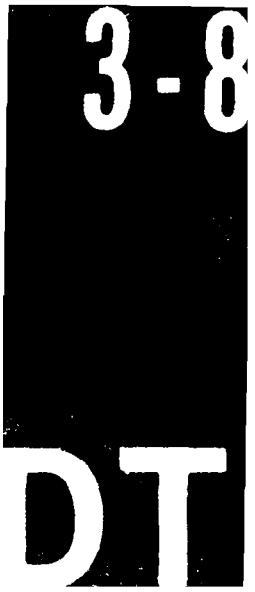
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