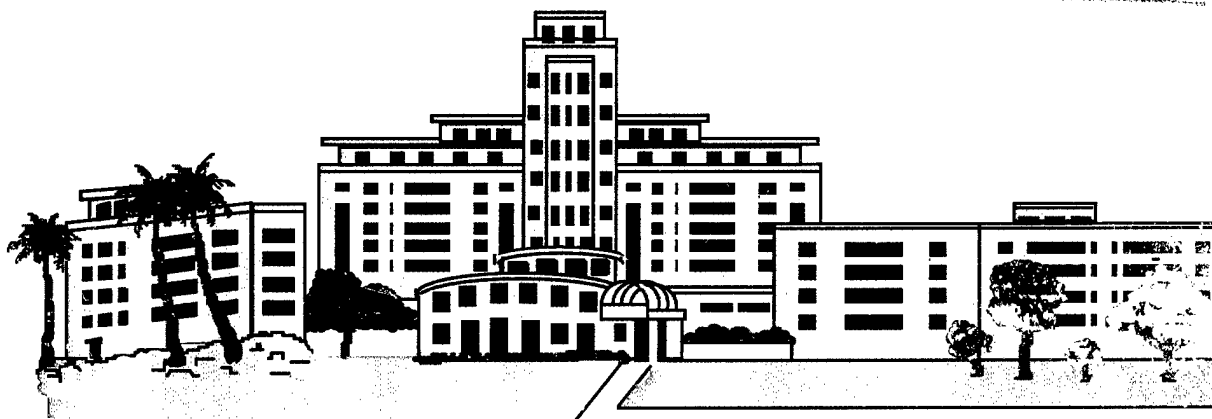


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CLINICAL INVESTIGATION PROGRAM

REPORTS CONTROL SYMBOL MED-300 (R1)

FISCAL YEAR 1996

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13. ABSTRACT (Maximum 200 words) Subject report identifies the research activities conducted by Tripler Army Medical Center investigators through protocols approved by the Clinical Investigation/Human Use Committees, the Institutional Animal Care and Use Committee, and the Institutional Review Board. The research protocols described were conducted under the provisions of AR 40-38 (Clinical Investigation Program); AR 40-7 (Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances; AR 70-25 (Use of Volunteers as Subjects of Research); HSC Reg 40-23 (Management of Clinical Investigations Protocols and Reports); and AR 70-18 (The Use of Animals in DOD Programs).				
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ANNUAL PROGRESS REPORT

DEPARTMENT OF CLINICAL INVESTIGATION
Reports Control Symbol MED-300(R-1)

FISCAL YEAR 1996
15 November 1996

DEPARTMENT OF CLINICAL INVESTIGATION
TRIPLER ARMY MEDICAL CENTER
Tripler AMC, Hawaii 96859-5000

DEPARTMENT OF CLINICAL INVESTIGATION HISTORY REPORT

Mission:

While we made no changes in Department of Clinical Investigation's mission, we modified strategies for accomplishing our mission. Utilizing the newest mechanism for extramural funding of research, TAMC saw an increase in Collaborative Research and Development Agreements (CRDAs) to 16 for 1996. The CRDAs had a potential for contributing approximately \$616,000 for research conducted at TAMC.

In the past, grant and CRDA monies were largely managed by outside organizations (either the Henry M. Jackson Foundation or the Facilitators of Applied Clinical Trials). Clinical Investigation established a separate APC for managing research dollars rather than paying a significant fee to other organizations to do so. Investigators assigned to DCI received a total of \$310,682 in grant monies from external sources, and the Physiology Section received \$48,936 in a Medical Research and Materiel Command (MRMC) award this FY96.

An active research consultation service was established in DCI. Individuals interested in doing research or publishing research results were invited to consult with DCI personnel who helped them with design, methodology, power analysis, and data analysis for their studies.

Success stories:

DCI developed and published new guidelines for an "Application for Clinical Investigation Project Involving Human Subjects." The guidelines, which conform to the required U.S. Public Health format, greatly facilitate proposal submittals which satisfy both our local Institutional Review Board (IRB) and grant awarding agencies. The format includes a budget section, allowing a more accurate estimation of the cost of doing research at TAMC. Informed consent guidelines were also modified to assist investigators in meeting required criteria in a timely manner.

We completed and published "TAMC Pamphlet No. 40-31: Clearance Procedures for Publication or Presentation of Scientific Abstracts and Manuscripts." The Pamphlet identifies responsibilities of key personnel, includes checklists and sample forms for submitting publications and presentations, and delineates the clearance process for our investigators.

We purchased and installed a FAX Back machine, enabling immediate instruction with forms retrieval for our investigators. The FAX forms will continuously be expanded as changes or additions occur.

Issues:

Issues are much the same as in FY95. DCI and the Animal Care Facility (ACF) occupy aging buildings. Little has been done to remodel or update DCI and the Animal Care Facility since their construction in 1948. Building #40 has no hot water in most areas, and the electrical/power supply is inadequate to run air conditioning or provide adequate lighting. The separation of the ACF from DCI degrades our current performance, increases our workload, and jeopardizes both our animals and the studies using these animals. Animals must be transported from the ACF to Building #40. This exposes them to contaminants in the environment (a problem for many studies), and increases chances of accidents for both animals and the personnel transporting them. The security and safety of the animals in their remote location is an issue. In fact, the separation of the two buildings is an AAALAC accreditation issue.

DCI saw significant budget decrements. Our supply budget for FY96 was cut almost 50% from that of FY95. Civilian salaries continue to increase along with the annual cost of living; at the same time, we are losing a significant portion of our annual budget.

Trends:

As our budgets continue to shrink and resources become increasingly scarce, we need to cultivate our skills in developing external funding sources, such as research grants and CRDAs. In order to do this, we will need to concentrate on teaching grant writing and grant management skills for investigators.

DEPARTMENT OF CLINICAL INVESTIGATION
TRIPLER ARMY MEDICAL CENTER

UNIT SUMMARY

A. **OBJECTIVES:** To sponsor clinical investigation, in compliance with applicable laws, regulations and policies, to increase the academic professional stature of the MEDCEN.

B. **TECHNICAL APPROACH:** 1) Renew research documentation and advise the Commander and his institutional committees on matters pertaining to clinical investigation, and 2) Provide consultative and collaborative support to approved investigations.

C. **STAFFING:**

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Hassell, L. Harrison	COL	61A9B	Chief
DeRuvo, Sharon S. ¹	LTC	66H9B	Assistant Chief
Hill, Elizabeth E. ²	MAJ	66H8A	Assistant Chief
Parlett Jr, William R. ³	MAJ	75C9B	Chief, Animal Research Section
Rebert, Nelson W. ⁴	MAJ	71B67	Chief, Biochemistry Section
Whippo, Paul E. ⁵	MAJ	75C64	Chief, Animal Research Section
Moussa-Obermeyer, Susan	SSG	91K30	NCOIC
Young, Raquel J.	SSG	91T30	Senior Animal Care Specialist
Simons, Robert T. ⁶	SGT	91K10	Medical Laboratory Specialist
Truss, Stephanie L. ⁷	SGT	91K20	Medical Laboratory Specialist
Barker, Charles T.	SPC	91T10	Animal Care Specialist
Egerstaffer, William D. ⁸	SPC	91K10	Medical Laboratory Specialist
Bush, Tiffanie ⁹	SPC	91K10	Medical Laboratory Specialist
Claybaugh, John R.	GM15	00413	Chief, Physiology Section
Uyehara, Catherine F.T.	GS13	00405	Chief, Research Pharmacology
Ichimura, Wayne M.	GS11	00802	Biomedical Engineer
Sato, Aileen K.	GS11	00644	Medical Technologist
Hashiro, Glenn M.	GS11	00644	Medical Technologist
Leighnor, Agatha M.	GS09	00301	Research Protocol Specialist
Alexander, James	GS06	00318	Secretary
Burghardt, Claudia	GS05	00404	Biomedical Science Lab Tech
Freitas, Brian C.	WG05	05048	Animal Caretaker
Miyake, Jean T.	GS04	00326	Office Automation Clerk

¹PCS'd Jul 96; ²Assigned Mar 96; ³Assigned Sep 96; ⁴PCS'd Aug 96; ⁵PCS'd Jul 96;
⁶PCS'd Apr 96; ⁷Assigned Jun 96; ⁸PCS'd Dec 95; ⁹Reassigned May 96

Officers: 4 authorized; 4 required; 4 assigned

Civilians: 8 authorized; 18 required; 10 assigned

Enlisted: 5 authorized; 8 required; 5 assigned

Number of personnel funded by grants and not included in TDA: 7

D. FUNDS:

Funding Type	1996	CRADA	Other Federal Grants	Other Nonfederal Grants
Civilian Payroll (including benefits)	510,240.29			
Contracts	64,001.39		15,000	
Consumable supplies	165,157.55		8,862.45	
Travel	37,492.47		1,739.90	
Printing/Publica tion	1,306.00			
OMA Total	778,197.70			
CEEP	40,296.02		23,333.75	
Equipment				
MEDCASE	0			
Military Pay	538,625.00			
TOTAL	1,357,118.72	0.00	48,936.10	0.00

E. PROGRESS:

Number of residency and fellowship training programs that use Clinical Investigation: 16
17 Residents held approved protocols in 1996 with the total number of 17 protocols held by this group in 1996.

4 Fellows held approved protocols in 1996 with the total number of 4 protocols held by this group in 1996.

83 Hospital staff members held approved protocols in 1996 with the total number of 275 protocols held by this group in 1996.

F. PROBLEMS:

(refer to Foreword)

Tripler Army Medical Center Research History

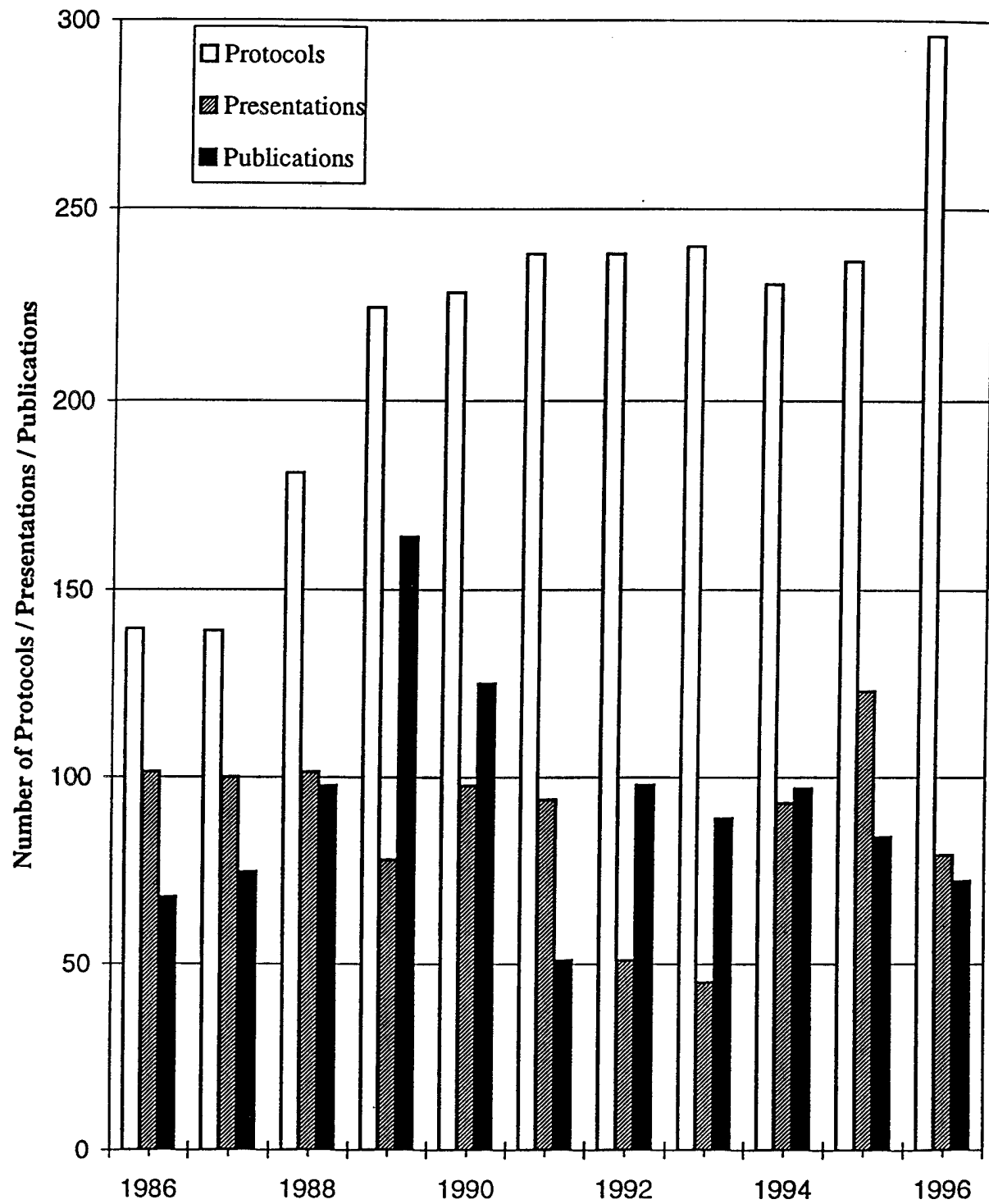


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Leatherman K; Tamanaha D; Staeger C; Delaney A; Nauschuetz W: Emerging Pathogens. Society of Clinical Laboratory Science, Honolulu HI, May 96.

Nauschuetz W: Clinical Gene Amplification: Closing in on Goof-Proof. Teleconference Network of Texas, San Antonio TX, Oct 96.

Nauschuetz W: Everything You Wanted to Know About Flesh-Eating Bacteria, but the National Enquirer Wouldn't Tell You. Teleconference Network of Texas, San Antonio TX, Feb 96.

Nauschuetz W: Laboratory Diagnosis of Sexually Transmitted Diseases. Teleconference Network of Texas, San Antonio TX, Jun 96.

Nauschuetz W: STDs: Still a Catchy Subject. Society of Clinical Laboratory Science, Honolulu HI, May 96.

Nauschuetz W: Update and New Technology. Teleconference Network of Texas, San Antonio TX, May 96.

Sprague TH: Telemedicine Efforts at Tripler Army Medical Center. Society of Armed Forces Medical Laboratory Sciences, Washington DC, Mar 96 & Asia-Pacific Military Medicine Conference, Sydney Australia, Apr 96.

DEPARTMENT OF PEDIATRICS

Imai WK; Stafford EM: Implementation of AMA Guidelines for Adolescent Preventive Services. Uniformed Services Pediatric Seminar, McLean VA, Mar 96.

Stafford EM; Holm PF; Anderson SW: Adolescent Medicine Practice in the Military: Being All You Can Be. Society for Adolescent Medicine, Crystal City VA, Mar 96.

DEPARTMENT OF PSYCHIATRY

Batzer WB: (1) Issues of Development and Comorbidity in Adolescent Substance Abuse. (2) Helping the Difficult Adolescent Enter Treatment. (3) The Use of Medication to Aid the Recovery Process. (4) Talking with Patients about Drugs and Alcohol. Far East Addictions Conference; Camp Zama Japan, Aug 96.

Batzer WB; Lee BJ: Multidisciplinary Evaluation of Preschool Children, A 10 Year Comparison and a Brief Followup Study. U.S. Army Behavioral Science Postgraduate Short Course, San Diego CA, Mar 96.

Childers AM: Girls At Risk: The Rosemont Project. APA's Institute on Psychiatric Services, Boston MA, Oct 95.

James LC: An Inpatient Weight Management Program: The TAMC LEAN Program. 18th MEDCOM Conference, Seoul KOREA, Oct 95. (C)

PSYCHOLOGY SERVICE

Bolte ME; Elmore RT: MMPI Profiles of Combat Veterans: Differences in Levels of Functional Impairment. Convention of the Hawaii Psychological Association, Honolulu HI, Jan 96.

DEPARTMENT OF RADIOLOGY

Allen AW: Computed Radiographic Examinations Through Cast Material. European Society of Musculoskeletal Radiology, Salzburg Austria, Nov 96.

Nicklay JM; Syms MJ; Burton BS: Kawasaki Disease Presenting as Retropharyngeal Cellulitis. The Western Neuroradiologic Society Meeting, San Diego CA, Oct 96.

SOCIAL WORK SERVICE

Gearhart B; Hamlin E: Maternal and Child Health Throughout the Army: Survey Responses. Social Work Professional Postgraduate Short Course, San Antonio TX, Aug 96.

Leighnor HD: CHCS as a Management Tool. Social Work Post Graduate Short Course Force XXI: Adjusting to Rapid C, San Antonio TX, Aug 96.

DEPARTMENT OF SURGERY

Plastic Surgery Service

Suthun: Laser and Cleft Palate Surgery. Pediatric Surgeons Children's Hospital, Bangkok Thailand, Mar 96.

Neurosurgery Service

Bergman W; Schultz R; Geil G; Shatsky S; Collins J: Holographically Guided Stereotactic Surgery. American Association of Neurological Surgeons, Minneapolis MN, Apr 96.

Collins JJ; Burton BS; Geil GG; Schultz R: The Use of Holograms Generated from very Thin Slice Contrast Helical CT and MR Angiograms for Planning Cranial Base Tumor Surgery: A Report of Five Cases. Congress of Neurological Surgeons, Montreal Quebec Canada, Oct 96.

Collins JJ; Burton BS; Geil GE; Schulz R; Felber J: The Intra-Operative Use of MR and CT Holography; Demonstration of Utility in Resection of an Acoustic Neuroma and An Intradural Cervical Tumor in a Patient with Neurofibromatosis Type II. American Society of Neuroradiology, Seattle WA, Jun 96.

Collins J; Lane J; Geil GG; Schultz R; Wood K; Felber J: Preoperative SSEP Brain Mapping at the Scalp Surface in Combination with MRI and Three Dimensional Holographic MR Imagery. Congress of Neurological Surgeons, Montreal Quebec Canada, Oct 96.

Potter PS; Keating RF; Collins JJ; Linskey ME: Autologous Fibrin-Platelet Gel: A Useful Tool for Neurosurgery with Distinct Advantages Compared with Fibrin Glue. Congress of Neurological Surgeons Annual Meeting, San Diego CA, Oct 95.

Orthopedic Service

Bottoni CR: Cervical Spine Injuries in Infants - An Indicator of Child Abuse. POSNA, May 96.

Bottoni CR: The Use of Telos Radiographic Evaluation Device in the Quantitative Evaluation of Pre-operative and Postoperative Posterior Cruciate Ligament Deficient Knees. Society of Military Orthopaedic Surgeons, Vail CO, Dec 95 & Western Orthopaedic Association, Aug 96.

DeJong ES: Carpal Tunnel Release With vs Without Release of the Antibrachial Fascia: A Prospective Randomized Study. Society of Military Orthopaedic Surgeons, Vail CO, Dec 95. (C)

Griffiths G: Open Reduction Internal Fixation of Acute Cravicular Fractures Using Heggs Pin Fixation: A Case Report. Hawaii Orthopaedic Association, Honolulu, Honolulu HI, Apr 96.

Hall JA: Avascular Necrosis of the Adolescent Femoral Head After Intramedullary Nailing of Femoral Shaft Fractures. Hawaii Orthopaedic Association, Honolulu HI, Apr 96 & Society of Military Orthopaedic Surgeons, Vail CO, Dec 95.

Harpstrite JK; et al: Correction of Severe Pediatric Forearm Deformities Using the Ilizarov Device. Western Orthopedic Association, Aug 96 & Society of Military Orthopaedic Surgeons, Vail CO, Dec 95.

Harpstrite JK; et al: Core Decompression and Autogenous Fibula Bone Grafting for Atraumatic Avascular Necrosis of the Femoral Head. Society of Military Orthopaedic Surgeons, Vail CO, Dec 95.

Harry P: The Effects of Femoral Shortening with Varus Derotational Osteotomies in Cerebral Palsy. Hawaii Orthopaedic Association, Honolulu, Honolulu HI, Apr 96.

Kesling K; et al: The Medical Experience in Sri Lanka. Hawaii Orthopaedic Association, Honolulu HI, Apr 96.

Klemme WR: Spinal Instrumentation without Fusion for Progressive Scoliosis in Young Children. Society of Military Orthopaedic Surgeons, Vail CO, Dec 95 & American Academy of Orthopaedic Surgeons, Atlanta GA, Feb 96.

Klemme WR: The Results of Hip Arthrodesis in Adolescents Employing the Cobra-head Plate for Internal Fixation. Pediatric Orthopaedic Society of North America, May 96.

Martin R: Impingement and Rotator Cuff Pathophysiology. New England Sports Medicine Society, Boxborough MA, Nov 95.

Martin R: Patellefemoral Pain after ACL Reconstruction: Bone Grafting the Patellar Defect. American Academy of Orthopedic Surgeons, Atlanta GA, Feb 96.

Masterson JP: False Negative Bone Scan in Children (poster). Hawaii Orthopaedic Association, Honolulu, Honolulu HI, Apr 96 & American Academy of Orthopaedic Surgeons, Atlanta GA, Feb 96.

Miller CK: Focal Myositis as a Cause of Acute Compartment Syndrome. Hawaii Orthopaedic Association, Honolulu, Honolulu HI, Apr 96.

Providence B: Bipolar Shoulder Hemiarthroplasty Review of Literature and Report on Two Cases. Hawaii Orthopaedic Association, Honolulu HI, Apr 96.

Rodriguez J: ACL Reconstruction Morbidities from the Donor Graft Areas. Hawaii Orthopaedic Association, Honolulu HI, Apr 96.

Santangelo J: Radiographic Results of Treated Clubfoot. Hawaii Orthopaedic Association, Honolulu HI, Apr 96.

Santangelo J; et al: The Gamekeeper's Thumb: Diagnosis Using MRI and MR-Arthrography. The Thirty-Seventh Annual SOMOS Meeting, Vail CO, Dec 95. (C)

Smith TN: Peroneal Tendon Repair. Society of Armed Forces Podiatrists Seminar, Colorado Springs CO, May 96.

Taylor GW; et al: Mongolian Medicine Experience. Hawaii Orthopaedic Association, Honolulu HI, Apr 96.

Wilckens JH; et al: Compartment Syndrome of the Thigh 2° to Focal Myositis. Hawaii Orthopaedic Association, Honolulu HI, Apr 96.

Wilckens JH; et al: Complications of the Extensor Mechanism Following ACL Reconstruction. Hawaii Orthopaedic Association, Honolulu HI, Apr 96.

Otolaryngology Service

Hull JJ. Epiglottic Anomalies (poster). American Academy of Otolaryngology-Head and Neck Surgery, Washington DC, Sep 96.

Johnson RE. The Radial Forearm Free Flap: Workhorse Flap of the 1990's. Academy of Otolaryngology-Head and Neck Surgery, Washington DC, Sep 96.

Stec E. Ectopic Nasal Dentition Presenting as Osteomeatal Complex Obstruction in a Pediatric Patient (poster). American Academy of Otolaryngology-Head and Neck Surgery, New Orleans LA, Sep 95.

Sheridan MF. Intracranial Hypotension Syndrome: An Unusual Complication of Cerebrospinal Fluid Leak. Western Section of the Triological Society, Los Angeles CA, Jan 96

Suk SA. Transfacial Approaches to Anterior Skull Base Tumors (poster). American Academy of Otolaryngology-Head and Neck Surgery, Washington DC, Sep 96.

Suk SA. Adult Lymphangioma: A Case Report. 38th Parallel Medical/Nursing Societies, Seoul, South Korea, Oct 95.

Tomaski SM. Avoiding Perils & Pitfalls in Pediatric Bronchoscopy. American Academy of Otolaryngology-Head and Neck Surgery, New Orleans LA, Sep 95.

Tomaski SM. Diagnosis and Treatment of Stridor in the Pediatric Patient. University of Texas San Antonio/Wilford Hall, San Antonio TX, Feb 96.

Tomaski SM. Sodium Iodate (Oragrafin) in the Preoperative Preparation of Grave's Hyperthyroidism. Western Section of the Triological Society, Los Angeles CA, Jan 96.

Urology Service

Deshon GE: Benign Prostatic Hypertrophy Database. Uniformed Services Urology Research Group, Denver CO, Mar 96.

Deshon GE: One Dose Lomafloxacin as Prophylaxis for Transrectal Ultrasound Guided Prostate Needle Biopsy. Western Section American Urological Association, Scottsdale AZ, Nov 95.

Deshon GE: Prognostic Value of Serum Beta Human Chronic Gonadotropin Levels in Stage I Seminoma. Western Section American Urological Association, Scottsdale AZ, Nov 95.

Kennon WG: Manpower & Bonus Update 1995. Kimbrough Urologic Seminar, Washington DC, Nov 95.

Kennon WG: Telemedicine: The Future of Military Medicine or a Billion Dollar Boondoggle. Kimbrough Urologic Seminar, Washington DC, Nov 95.

Lee SCK: Hereditary Renal Adysplasia and Multicystic Kidney Disease. Western Section American Urological Association, San Diego CA, Jul 96.

Lee SCK: Multicystic Dysplastic Kidney and Familial Inheritance. Kimbrough Urologic Seminar, Washington DC, Nov 95.

Shandera KC: The Necessity of VCUG in the Pretransplant Urologic Evaluation. Kimbrough Urologic Seminar, Washington DC, Nov 95.

Sutherland RS: Adult Penile Length the Effect of Pre-Pubertal Androgen Exposure. Kimbrough Urologic Seminar, Washington DC, Nov 95.

Sutherland RS: Clean Intermittent Catheterization With the LoFric Catheter in Boys. Western Section American Urological Association, Phoenix AZ, Nov 95.

Sutherland RS: Growth Factors and Receptors in Bladder Development and Obstruction. American Academy of Pediatrics Section on Urology, Oct 95.

Sutherland RS: Induction of Bladder Smooth Muscle in Acellular Tissue Matrix. American Academy of Pediatrics Section on Urology, Oct 95 (Basic Science Research Finalist).

Sutherland RS: Intermittent Catheterization: History and How We Do It! Pediatric Urology Seminar, University of California, San Francisco CA, Feb 96.

Sutherland RS: Pre-Pubertal Androgen Exposure and Adult Phallic Length (Poster). Western Section American Urological Association, Phoenix AZ, Nov 95.

Sutherland RS: The Effect of Pre-Pubertal Androgen Exposure on Adult Penile Length, American Academy of Pediatrics Section on Urology, Oct 95 (2nd Prize, Clinical Research).

Sutherland RS: Use of the LoFric Catheter in Boys on Intermittent Catheterization. Kimbrough Urologic Seminar, Washington DC, Nov 95.

Thibault GP: Open Surgery for Pediatric Nephrolithiasis. Kimbrough Urologic Seminar, Washington DC, Nov 95.

Thibault GP: Proximal Rupture of the Corpus Cavernosum: A Unique Location of a Well Known Injury. Western Section American Urological Association, San Diego CA, Jul 96.

General Surgery Service

Cordts PR: Remote Telepresence Surgery: Is the Future Now? Association for Academic Surgery, Dearborn MI, Nov 95.

Euhus DM: The Breast Lump. 38th Parallel Medical Meeting, Seoul Korea, Nov 95.

Euhus DM: Influence of Parenteral Progestones on the Prevalence and Severity of Mastodynia in Premenopausal Women: a Multi-Institutional Cross-Sectional Study. Gary P. Wratten Surgical Symposium, Breckenridge CO, Apr 96. (C)

Matsumoto C; Sawyer MAJ: Low Carbohydrate Enteral Feedings and Carbon Dioxide Production in the Intensive Care Unit. 38th Parallel Medical Meeting, Seoul Korea, Nov 95.

Nichols DD; Gott PE; Sawyer MAJ: Intraoperative Diverticulography in Acute Duodenal Diverticulitis With Hemorrhage (poster). American College of Gastroenterology, New York NY, Oct 95.

Zagorski SM; Sawyer MAJ: Delivery and Complications of Nutrition Support in the Surgical Intensive Care Unit. 38th Parallel Medical Meeting, Seoul Korea, Nov 95.

Code: SP - Submitted for Publications; C - Result of Approved CI Protocol

Detail Summary Sheet

Prot No: TAMC 1A93

Status: Completed

TITLE: Effects of Vasopressin on Cardio-pulmonary Responses in Newborn Piglets

Start date: Oct 92

Est Comp Date: Indef

Principal Investigator: John R. Claybaugh, PhD

Department/Section: Clinical Investigation/Physiology
Facility: TAMC

Associate Investigator: Catherine F.T. Uyehara, PhD; CPT Steven C. VanScoy, MC; Kenneth T. Nakamura, MD; Aileen K. Sato

Key Words: dopamine; dobutamine; vasopressin receptor; pulmonary circulation

Funding: FY 95:

FY 96:

Periodic Review Date: 10/31/96

Gifts: NIH appl

Decision: Completed

OBJECTIVES: 1) To identify the vasopressin receptor responsible for the improvement in oxygenation that occurs with vasopressin infusion in the new born piglet. 2) To compare the dobutamine, dopamine, and phenylephrine responses to the vasopressin responses to determine specificity or relative effectiveness of the vasopressin. 3) To compare the new born response to vasopressin to the response in a more mature pig. 4) To determine the effect of vasopressin on the regional blood flow distribution throughout the body and within the lungs of the new born piglet.

TECHNICAL APPROACH: Neonatal piglets (5 to 10 days old) and more mature pigs (approximately 100 lbs in weight) will be anesthetized and a Swan-Ganz catheter and femoral arterial and venous catheters will be placed. The critical measurements attained will be the systemic and pulmonary vascular resistances, the pulmonary arterial and systemic arterial blood pressures, cardiac output, blood gases and oxygen content of arterial and central venous. The responses of these measurements to hypoxia (15% FIO₂) with and without the infusions of vasopressin agonists and antagonists and dopamine and dobutamine and phenylephrine will be studied in the neonatal piglet, while only vasopressin agonists will be studied in the more mature pig. Different colored microspheres will be injected into the right side and into the left side of the heart prior to and after vasopressin infusion and hypoxia. The distribution of the different colored microspheres as an effect of treatment is dependent on blood flow to that organ or area of tissue.

ADDENDUM #1 (May 93): Added vasoconstrictor.

ADDENDUM #2 (Sep 93): Added mature piglets remaining from other approved protocols.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

All studies have been completed.

Presentations:

Uyehara CFT, Claybaugh JR, Matsuda LS, Sato AK, VanScoy SC. Vasopressin (VP) improves blood gas exchange in the neonatal piglets via V1-receptor stimulation. FASEB J 7: A434 (Abstract 2512), 1993.

Claybaugh JR, Uyehara CFT, Sato AK, Matsuda LS. Increased Plasma Aldosterone Concentration by exogenous infusion of lysine vasopressin in the neonatal piglet. FASEB J 7: A434 (Abstract 2513), 1993.

VanScoy SC, Sato AK, Claybaugh JR, Uyehara CFT, Nakamura KT. Vasopressin V1-agonist has beneficial effects on hemodynamics and gas exchange not seen with dopamine or dobutamine in neonatal piglets. Conference on Military Perinatal Research at Aspen (COMPRA), Aspen CO, September 11-14, 1993.

VanScoy SC, Uyehara CFT, Sato AK, Claybaugh JR, Nakamura KT. Improved gas exchange with vasopressin V1-agonist (V1) in newborn piglets is not seen with other vasoactive agents. Experimental Biology FASEB J 8: A824 (Abstract 4780), 1994.

VanScoy SC, Claybaugh JR, Uyehara CFT, Sato AK, Nakamura KT. Improved gas exchange with vasopressin V1-Agonist is not seen with other vasoactive agents in hypoxic neonatal piglets. American Pediatric Society, 1994.

VanScoy SC, Uyehara CFT, Sato AK, Claybaugh JR, Nakamura KT. Improved gas exchange with vasopressin V1-agonist (V1) in newborn piglets is not seen with other vasoactive agents. Biomedical Sciences Symposium, John A. Burns School of Medicine, University of Hawaii, February 19, 1994. (Award)

VanScoy SC, Claybaugh JR, Uyehara CFT, Sato AK, Nakamura KT, Jarrett RV. Improved gas exchange with vasopressin V1-agonist is not seen with other vasoactive agents in hypoxic neonatal piglets. Conference on Military Perinatal Research at Aspen (COMPRA), Aspen CO, September 11-13, 1994.

Detail Summary Sheet

Prot No: TAMC 25A95

Status: Ongoing

TITLE: The Identification of Vasopressin, and Vasopressin mRNA in the Blood Vessels of Rats

Start date: Aug 95

Est Comp Date: Oct 99

Principal Investigator: John R. Claybaugh, PhD

Department/Section: Clinical Investigation/Physiology
Facility: TAMC

Associate Investigator: Baozhi Yuan; Aileen K. Sato; Catherine F.T. Uyehara, PhD; Wen Qun Lee; Glenn M. Hashiro

Key Words: blood vessel vasopre; vasopressin mRNA; hypoxia; dehydration; hemorrhage; hypothalamus; spontaneously hypertensive rat

Funding: FY 95:

FY 96:

Periodic Review Date: 10/16/96

Gifts:

Decision: Continue

OBJECTIVE: (1) To determine whether vasopressin, shown previously to exist in blood vessels, is synthesized or stored in the blood vessels; (2) to also investigate the AVP and AVP mRNA responses in the blood vessels to factors known to stimulate AVP release from the posterior pituitary gland.

TECHNICAL APPROACH: The content of vasopressin and its mRNA will be assessed in blood vessels. Comparisons will be made for both measurements to determine the effects of sex, hypertension (by comparing hypertensive SHR to normotensive WKY rats), hypoxia, dehydration, and hemorrhage - all of these factors have been shown to affect normal circulating levels of vasopressin. The basic question to be answered: what causes a consistent change in the content of blood vessel vasopressin or its mRNA.

ADDENDUM (Jan96): Additional objective and animals.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

We have determined that there is more vasopressin in the aorta of the SHR (Spontaneously Hypertensive Rat) than in the vena cava. Also, there is more vasopressin in the aorta of the SHR than the aorta of the WKY (Wistar-Kyoto) normotensive control, and the WKY aorta and vena cava have similar levels. Thus, vasopressin on the arterial side of the vascular tree

is elevated approximately 2 fold in this model of hypertension. These findings have been presented. We have successfully developed techniques of measuring vasopressin mRNA, which we can identify in the hypothalamus, but even with PCR, we have been unable to measure it in the blood vessels of any rats.

Presentation:

Yuan B; Claybaugh JR; Uyehara CFT; SatoAK. Blood vessel vasopressin content is increased in the spontaneously hypertensive rat aorta. 10th International Congress of Endocrinology, 12-15 Jun 96 (abstract).

Detail Summary Sheet

Prot No: TAMC 41A93

Status: Completed

TITLE: Cardiovascular Control of and Responses to Vasoconstrictor Hormones During Hypoxia

Start date: Jul 93

Est Comp Date: Indef

Principal Investigator: John R. Claybaugh, PhD

Department/Section: Clinical Investigation/Physiology
Facility: TAMC

Associate Investigator: COL Richard A. Banks, MC; Catherine F.T. Uyehara, PhD; Aileen K. Sato

Key Words: pulmonary circulation; vasopressin; renin-angiotensin-aldosterone; hyperoxia; hypoxia; conscious goat

Funding: FY 95:
Gifts: MRDC appl

FY 96:

Periodic Review Date: 10/16/96
Decision: Completed

OBJECTIVE: This protocol had to be re-evaluated this year, and we took the opportunity to add a new objective which will be incorporated in the thesis work of Kevin Urada. The objectives that have not been completed from the original protocol are: 1) To assess the central vasopressinergic mechanisms in the hypoxia-induced attenuation of the baroreceptor reflex and 2) To assess the central angiotensinergic mechanisms in the hypoxia-induced attenuation of the baroreceptor reflex. The new aim is 3) To develop an antisense to the vasopressin V1a receptor in the goat, and determine its effectiveness in altering vasopressin-dependent cardiovascular responses to hemorrhage. Also, to compare the responses to the more conventional competitive inhibitors to vasopressin used in aim #1.

TECHNICAL APPROACH: Adult female goats will be prepared by the surgical placement of a carotid arterial loop prior to any experiments. Prior to experiments addressing objectives 4 and 5, a 3rd cerebroventricular catheter will be stereotactically placed. On the morning of the experiment, an "introducer" will be placed in the left jugular vein, and a Swan-Ganz catheter and a carotid arterial catheter will be positioned to allow for assessment of cardiac output, wedge pressure, pulmonary and carotid arterial pressures, and central venous pressure, and sampling of arterial and central venous blood for blood gases and oxygen content, and hormones.

ADDENDUM (Apr94): Add involvement of spleen in hemorrhage response.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

We have determined that angiotensin-stimulated vasopressin release is increased by hypoxia. These findings have been presented, but are not yet in manuscript form. We have determined that, hypoxia does not change the whole body clearance of vasopressin (as we saw in the piglet), but vasopressin does have a small but significant effect in improving arterial oxygenation in the goat exposed to hypoxia. These data have also been presented, but are not yet in manuscript form. We have determined that administration of 100% oxygen helps to maintain blood pressure during hemorrhage by improving systemic vascular resistance. These data have been presented and the manuscript is in preparation. Lastly, we have completed experiments assessing the role of the spleen in the hormonal and cardiovascular responses of the conscious goat to hemorrhage. These data will be presented at the Experimental Biology '97 meetings.

Claybaugh, J.R., A.K. Sato, and M.R. Eichinger. Blood pressure, AVP, ACTH, and PRA responses to iv and ivt angiotensin II during hypoxia. 8th International Hypoxia Symposium, Lake Louise, Canada. (Abstract). 1993.

Claybaugh JR, Sato AK, Uyehara CFT. Effects of vasopressin (VP) on the cardiopulmonary responses to hypoxia in the conscious, spontaneously breathing, goat. Experimental Biology 94. Abstract #4778, FASEB J 8: A824, 1994.

Claybaugh, JR, Sato, AK, Van Scoy, SC. Effects of Hyperoxia and hypoxia on cardiopulmonary and hormonal responses to hemorrhage. Experimental Biology '95, (Abstract # 1535), FASEB J. 9: A265,1995.

Detail Summary Sheet

Prot No: TAMC 58H94

Status: Ongoing

TITLE: Effects of Time of Day, Age and Gender on the Ability to Conserve a Water Load

Start date: Jul 94

Est Comp Date: Mar 96

Principal Investigator: John R. Claybaugh, PhD

Department/Section: Clinical Investigation/Physiology
Facility: TAMC

Associate Investigator: LTC David F. Crudo, MC; Linda Crosswhite; Aileen K. Sato

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 5/28/96

Gifts: MRDC DWHRP \$

Decision: Continue

OBJECTIVE: (1) To determine if the responses of plasma osmolality and plasma ADH to a water load given to adults differ depending on the time of day; (2) To determine if there are gender differences in this response and if the female responses are affected by the phase (follicular or luteal) of the menstrual cycle; and (3) To determine if this adult diurnal difference in urine formation is absent in children with enuresis and whether this absence is associated with a lack of an adult pattern of cortisol circadian rhythm and/or diurnal levels of cortisol.

TECHNICAL APPROACH: Adult men and women will be administered a water load based on % lean body mass, and will be a volume of about 900 ml. Prior to and after the water load, blood samples and urine will be collected every 30 minutes for 3 hours. We expect to see differences in the urinary response to the water load that will be dependent upon nighttime vs daytime, gender and, in women, the phase of the menstrual cycle. The mechanism explaining the differences will be investigated by assessing the temporal relationship between changes in plasma osmolality and plasma vasopressin concentrations with the changes in urine flow rate and urine osmolality. We further hypothesize, that the normal circadian rhythm that we see in adults will be absent in children that are bedwetters, and that these children will not have the normal circadian rhythms of cortisol or vasopressin (in urine samples). Since only bed wetting children can derive obvious benefit, we will study frequent bedwetters and nonfrequent bedwetters, with the hypothesis that the nonfrequent bedwetters have a more adult like pattern.

ADDENDUM (Oct95): Expand subject population.

PROGRESS: No. of Subjects Enrolled - To Date: 12
During FY96: 1

To Date we have enrolled 12 subjects, 6 males and 6 females. Due to incomplete data sets for various reasons, we will need 2 more females to enroll (assuming no failures) and 2 more males with no failures. No children have been enrolled to date, so that part has not been done. Data collection is continuing.

Briefly, the findings indicate that 1) There is a greater diuretic response to a water load during the daytime than the nighttime. 2) The difference is very likely due to a lesser suppression of vasopressin despite similar levels of plasma osmolality 3) Tentative data strongly suggest that women void a greater portion of the water load during the daytime than men (but they are similar at night).

Published abstract: Claybaugh, J.R., A.K. Sato, L.K. Crosswhite, and L.H. Hassell. Reduced diuretic response to water intake at night is accompanied by increased vasopressin in humans. FASEB J. 10:A15, 1996 (Abstract #85).

Detail Summary Sheet

Prot No: TAMC 9H94

Status: Ongoing

TITLE: Factors Influencing On-line Nursing Activities: Assessing the Change from a Character-based to Graphical User Interface

Start date: Jan 94

Est Comp Date: May 96

Principal Investigator: LTC Sharon S. DeRuvo, AN

Department/Section: Clinical Investigation/
Facility: TAMC

Associate Investigator: COL Nancy Staggers, AN

Key Words: computer; Composite Health Care System (CHCS); Graphical User Interface (GUI)

Funding: FY 95:

FY 96:

Periodic Review Date: 9/24/96

Gifts:

Decision: Continue

OBJECTIVE: The primary goal of this study is to better understand how nurses interact with computers in the performance of nursing activities. The focus of this study is to examine the relationship of nurses' demographic and cognitive information processing by comparing two different interfaces when entering nursing orders. Specific aims of this study are to:

(1) determine the differences between the two interfaces on the speed, accuracy, and subjective satisfaction of the nurses; (2) describe the relationship between the cognitive and demographic nurse characteristics and the type of user interface on speed, accuracy, and subjective satisfaction; and (3) determine the representative of a sample of nurses from TAMC to the population of nurses in the Army Nurse Corps.

TECHNICAL APPROACH: This study will examine speed, accuracy, and subjective satisfaction between the two different interfaces. The nurse characteristics to be investigated are spatial visualization and spatial memory, age, gender, and computer experience. To test the difference in interactions with CHCS and GUI interfaces, the study will use a one-group counterbalanced repeated measures design. The data will be analyzed using a two-factor within subjects repeated measures analysis.

Since nurses are primary information processors in hospitals, the findings of this study will demonstrate whether the present character based or CHCS system versus the graphical user system or GUI system is significantly better on performance measures. Given the tremendous frequency of use of the CHCS system by nurses, the application of these results will significantly enhance military health care delivery for nurses.

PROGRESS: No. of Subjects Enrolled - To Date: 20
FY96: 0

We have used focus groups to build the schema on how to structure the GUI order sets. This has been accomplished and is now with the computer engineers to design the GUI interface. Pending completion of this work, we will then test the difference on speed, accuracy, and subjective satisfaction between the two systems.

MAJ Elizabeth E. Hill, AN will be the new PI upon PCS of LTC Sharon S. DeRuvo.

Detail Summary Sheet

Prot No: TAMC 42H96

Status: Ongoing

TITLE: Designing a Satisfaction Tool for Telemedicine Services

Start date: Jul 96

Est Comp Date:

Principal Investigator: LTC Sharon S. DeRuvo, AN

Department/Section: Clinical Investigation/
Facility: TAMC

Associate Investigator: LTC Elizabeth E. Hill, AN

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: To evaluate the human impact on providers of performing consultations using advanced telecommunications technology.

TECHNICAL APPROACH: (1) Perform a concept analysis of patient and provider satisfaction to identify key factors of patient and provider satisfaction with telemedicine; (2) Design an instrument to measure patient and provider satisfaction with telemedicine using qualitative methods; (3) Test the instrument with patients and providers experiencing telemedicine.

PROGRESS: No. of Subjects Enrolled - To Date:
 During FY96:

Detail Summary Sheet

Prot No: TAMC 46H92

Status: Completed

TITLE: Differentiated Group Professional Practice

Start date: Sep 92

Est Comp Date: May 95

Principal Investigator: LTC Sharon S. DeRuvo, AN

Department/Section: Clinical Investigation/
Facility: TAMC

Associate Investigator: Patricia Nishimoto, DNS

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 3/26/96

Gifts:

Decision: Completed

OBJECTIVES: Nurses are exploring ways to restructure nursing practice to meet the changing needs of health care management today. The Differentiated Group Professional Practice (DGPP) Model is one of the ways these needs are being studied in a health care setting. The purpose of this study is to implement and evaluate Differentiated Group Professional Practice (DGPP) in nursing. DGPP is an integrated model with three major components: group governance, differentiated care delivery, and shared values in a culture of excellence.

TECHNICAL APPROACH: Implementing this literature-based professional practice model is expected to strengthen the professional environment (as indexed by commitment, autonomy, control over practice, and cohesion). This model is further expected to increase nurse satisfaction with practice (as measured by job satisfaction). Increased nurse satisfaction is hypothesized to increase nurse resources (operationalized by retention). In turn, this is hypothesized to increase quality of care while decreasing or maintaining the level of fiscal resources needed to care for patients. Quality of care measures are: nursing documentation, complications, medication delivery, patient satisfaction, and length of stay. Fiscal resource measures are personnel costs, costs of using agency personnel, absenteeism costs, and operating costs. We will replicate the DGPP model in a military setting (original study jointly funded by the National Institutes of Health, National Center for Nursing Research and the Division of Nursing to demonstrate the DGPP model in hospital nurses practicing in Arizona). We have gathered pre-implementation data on: professional practice, nurse satisfaction, nurse resources, quality outcomes, fiscal outcomes; implemented the DGPP Model on selected medical-surgical, psychiatric, maternal/child health, and critical care inpatient units; and

maintained the DGPP Model with appropriate growth modifications on the selected demonstration units. The final step will be to collect post- implementation data on professional practice, nurse satisfaction, nurse resources, quality outcomes, and fiscal outcomes on the selected demonstration and comparison units.

PROGRESS: No. of Subjects Enrolled - To Date: 156
During FY96: 0

Presentations: Queens Medical Center, National Nursing Administration Conference, "Almost Paradise: Managing in the 21st Century," October 1993, in Honolulu, Hawaii; and American Association of Military Surgeons (AMSUS) National Conference, Sixth Annual Karen A. Reider Nursing Research Poster Session, November 1993, in San Antonio, Texas.

Results: The second year of the DGPP Model was spent introducing new nursing personnel to the model given the turnover of greater than 50% of the original nursing staff. Additionally, most of the nursing staff had not encountered the notion of shared governance because of their limited nursing experience. For example, over half of the registered nurses had less than one year of nursing experience. Those nurses with greater than 2 years of nursing experience were typically civil service registered nurses. Four hypotheses were tested during this past year of data analysis. The first hypothesis tested: Unit commitment ($t=.93$, $p=.35$), autonomy ($t=.41$, $p=.67$), and control over practice ($t=.11$, $p=.90$) will significantly increase after implementation of the DGPP model (time two) when compare to time one. The second hypothesis was unit job satisfaction ($t=.47$, $p=.63$) will significantly increase after implementation of the DGPP model (time two) when compared to baseline (time one). A between subjects design comparing the demonstration subjects to the comparison subjects also demonstrated no significant differences on the variables of commitment, autonomy, control over practice, and job satisfaction. These findings are consistent with the Arizona Project which demonstrated significant differences only after two years of implementing the project. There were two data collection periods during FY95 to determine if there was a long term effect of this model on practice delivery.

Detail Summary Sheet

Prot No: TAMC 6A94

Status: Ongoing

TITLE: Interaction of Inhaled Nitric Oxide with Epinephrine in the Treatment of Endotoxin-induced Systemic Hypotension in Neonatal Piglets

Start date: Oct 93

Est Comp Date: Sep 96

Principal Investigator: David Easa, MD

Department/Section: Clinical Investigation/KMCWC

Facility: TAMC

Associate Investigator: Catherine F.T. Uyehara, PhD; Sneha Sood, MD; Lei Cornette-Finn, PhD; Venkataraman Balaraman, MD

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 10/31/96

Gifts: EQ loan

Decision: Continue

OBJECTIVE: To determine whether the use of inhaled Nitric Oxide (NO) in the treatment of Escherichia coli endotoxin-induced pulmonary hypertension affects the ability of epinephrine to reverse the endotoxin-mediated systemic hypotension.

TECHNICAL APPROACH: See protocol.

PROGRESS: No. of Animals Studied - To Date: 12
During FY96: 0

Preliminary studies were done and further experiments will be continued. A manuscript utilizing experimental information has been submitted for publication---Easa D, Murai DT, Oka B, Dressel M, Vanderfor P, Pelke S, Balaraman V: Early Experience With Inhaled Nitric Oxide for the Treatment of Infants and Children With Pulmonary Hypertension. Hawaii Medical Journal.

Detail Summary Sheet

Prot No: TAMC 7A94

Status: Ongoing

TITLE: The Effects of Exogenous Surfactant on the Pulmonary and Hemodynamic Status of the Piglet Treated with Endotoxin: Part II

Start date: Oct 93

Est Comp Date: Sep 96

Principal Investigator: David Easa, MD

Department/Section: Clinical Investigation/KMCWC
Facility: TAMC

Associate Investigator: Catherine F.T. Uyehara, PhD; Lei Cornette-Finn, PhD; Sneha Sood, MD; Venkataraman Balaraman, MD; COL Stephen Y. Wilkerson, MC

Key Words:

Funding: FY 95:
Gifts: EQ loan

FY 96:

Periodic Review Date: 10/31/96
Decision: Continue

OBJECTIVE: (1) To modify the endotoxin model in order to create a more severe pattern of lung injury, while lengthening the period of experimental observation; (2) To compare the effects of the protein-containing exogenous surfactants, Survanta and KL4, with those of Exosurf on pulmonary function in endotoxin-treated piglets.

TECHNICAL APPROACH: See protocol.

ADDENDUM (Sep94): Add colored microspheres.

PROGRESS: No. of Animals Studied - To Date: 64
During FY96: 0

Publications:

Sood S, Balaraman V, Finn KC, Wilkerson S, Mundie TG, Easa D: Exogenous Surfactant Decreases Oxygenation in Escherichia Coli Endotoxin Treated Neonatal Piglets. Submitted to Pediatr Pulmonol (In press).

Detail Summary Sheet

Prot No: TAMC 12A96

Status: Ongoing

TITLE: Efficacy of Surfactant Administration by Lavage in Neonatal Piglets with Acute Lung Injury

Start date: Jan 96

Est Comp Date: Dec 98

Principal Investigator: David Easa, MD

Department/Section: Clinical Investigation/KMCWC
Facility: TAMC

Associate Investigator: Joan Meister, MD; Venkataraman Balaraman, MD; Lei Cornette-Finn, PhD; Sneha Sood, MD; Mary Elaine Patrinos, MD; Jeffrey L. Killeen, MD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/25/96
Decision: Continue

OBJECTIVE: To compare the effects of lavage administration of various exogenous surfactant preparation on non-homogeneous lung injury, as induced initially by saline lung lavage (surfactant-deplete, a homogeneous injury), then a second injury by one of the following: (a) intratracheal HCL instillation (chemical injury), (b) intratracheal meconium instillation (chemical and obstructive), (c) intratracheal endotoxin instillation (inflammatory).

TECHNICAL APPROACH: See protocol

PROGRESS: No. of Animal Studied - To Date: 39
During FY96: 39

Nothing to report at this time.

Detail Summary Sheet

Prot No: TAMC 19A93

Status: Completed

TITLE: Effects Of Lung Strategies On Hemodynamic, Pulmonary Function And Lung Pathology Of The Piglet With Normal Lungs: Part II

Start date: Mar 93

Est Comp Date: Indef

Principal Investigator: David Easa, MD

Department/Section: Clinical Investigation/KMCWC
Facility: TAMC

Associate Investigator: MAJ Thomas G. Mundie, MS; Sneha Sood, MD; COL Stephen Y. Wilkerson, MC; Lei Cornette-Finn, PhD; Venkataraman Balaraman, MD

Key Words:

Funding: FY 95:
Gifts: EQ loan

FY 96:

Periodic Review Date: 10/31/96
Decision: Completed

OBJECTIVES: To determine the effects of various lung inflation strategies or bronchodilator therapy on cardiopulmonary function, ventilator settings and pulmonary pathology in the normal piglet during and after prolonged ventilation: (a) using positive end-expiratory pressure (PEEP) to continuously inflate the lung at 6 cmH₂O, (b) using PEEP to 12 cmH₂O to periodically inflate the lung for 15 min of every 60 after pre-treatment with indomethacin (PEEP will be set at 2 cmH₂O during the alternated 45 min), (c) administering aerosolized salbutamol, ipratropium bromide, or furosemide every hour to bronchodilate the lung with PEEP set at 2 cmH₂O.

TECHNICAL APPROACH: Neonatal piglets are sedated, intubated and instrumented with femoral artery and vein, pulmonary artery and right atrial catheters. After stabilization, animals are divided into three groups (varied lung inflation strategies or bronchodilator therapy), and hemodynamic and pulmonary function measurements are taken.

PROGRESS: No. of Animals Studied - To Date: 8
During FY96: 0

Publication --

Easa D, Finn KC, Balaraman V, Sood S, Wilkerson S, Takenaka W, Mundie TG.
Preservation of pulmonary function in the ventilated neonatal piglet with normal lungs.
Pediatr Pulmonol 19:174-181, 1995.

Detail Summary Sheet

Prot No: TAMC 24A95

Status: Ongoing

TITLE: The Amelioration of Lung Injury With Natural and Artificial Surfactants in an ARDS Model Induced by Saline Lung Lavage in the Neonatal Pig

Start date: Jun 95

Est Comp Date: Indef

Principal Investigator: David Easa, MD

Department/Section: Clinical Investigation/KMCWC
Facility: TAMC

Associate Investigator: Joan Meister, MD; Sneha Sood, MD; Lei Cornette-Finn, PhD; Venkataraman Balaraman, MD; Mary Elaine Patrinos, MD; Jeffrey L. Killeen, MD; Catherine F.T. Uyehara, PhD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/25/96
Decision: Continue

OBJECTIVE: To compare the effects of a natural whole lung surfactant (WLS), and a protein-containing artificial surfactant (KL4-Surfactant), with an untreated Control group, on the ability to improve oxygenation and pulmonary function, and to attenuate the degree of lung injury induced by two series of sequential saline lung lavage in neonatal piglets.

TECHNICAL APPROACH: See protocol.

ADDENDUM (Dec95): Added animals & surfactants; title revision.

PROGRESS: No. of Animals Studied - To Date: 23
During FY96: 23

Preliminary studies have been done and the following manuscript has been submitted for publication --

Balaraman V, Meister J, Ku T, Sood S, Uyehara C, Easa D. Lavage Administration of Dilute Surfactants after Acute Lung Injury in Neonatal Piglets.

Publication:

Balaraman V, Sood SL, Finn K, Hashiro G, Uyehara C, Easa D. Physiologic response and lung distribution of lavage versus bolus Exosurf in piglets with acute lung injury. AJRCCM, 1996;153:1838-43

Detail Summary Sheet

Prot No: TAMC 39A94

Status: Ongoing

TITLE: Promoting Clearance of Meconium from the Lungs of the Neonatal Piglet With Asymmetric High-frequency Oscillation

Start date: Apr 94

Est Comp Date: Mar 97

Principal Investigator: David Easa, MD

Department/Section: Clinical Investigation/KMCWC
Facility: TAMC

Associate Investigator: MAJ Rebecca C. Bent, MC; Mary Elaine Patrinos, MD; Lei Cornette-Finn, PhD; Sneha Sood, MD; Venkataraman Balaraman, MD; Catherine F.T. Uyehara, PhD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/31/96
Decision: Continue

OBJECTIVE: To investigate the role of asymmetric high frequency oscillatory ventilation (AHFOV) in enhancing clearance of previously instilled human meconium from the lungs of the neonatal piglet.

TECHNICAL APPROACH: See protocol.

PROGRESS: No. of Animals Studied - To Date: 18
During FY96: 4

Presentations:

Patrinos M, Balaraman V, Meister JC, Ku T, Stenzler A, Easa D. The effect of Asymmetric High Frequency Oscillation (AHFO) on the clearance of meconium from the lungs of the neonatal piglet. *Pediatr Res*, 1996;39:237A.

Meister JC, Patrinos ME, Rubin BK, Balaraman V, Sood SL, Finn KC, Ku T, Easa D. Alteration of physical and transport properties of meconium by Exosurf®. *Pediatr Res*, 1996;39:230A.

Publication:

Patrinos ME, Balaraman V, Ku T, Meister J, Rubin B, Stenzler A, Easa D: Promoting meconium clearance from the lungs of the Neonatal piglet with the Asymmetric High Frequency Oscillation (AHFO).

Detail Summary Sheet

Prot No: TAMC 40A94

Status: Ongoing

TITLE: Comparison of Effects of Various Exogenous Surfactants on the Pulmonary and Hemodynamic Status of the Neonatal Piglet After Saline Lung-lavage

Start date: Apr 94

Est Comp Date: Indef

Principal Investigator: David Easa, MD

Department/Section: Clinical Investigation/KMCWC
Facility: TAMC

Associate Investigator: Sneha Sood, MD; Lei Cornette-Finn, PhD; Venkataraman Balaraman, MD; Catherine F.T. Uyehara, PhD; COL Stephen Y. Wilkerson, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/31/96
Decision: Continue

OBJECTIVE: To compare the effects of protein and non-protein-containing clinical surfactant on pulmonary function in neonatal piglets after progressive lung injury induced by two sequences of saline lung lavage.

TECHNICAL APPROACH: See protocol.

ADDENDUM #1 (Sep94): Add colored microspheres.

ADDENDUM #2 (Nov94): Added animals & dosing group.

PROGRESS: No. of Animals Studied - To Date: 100
During FY96: 25

Presentation:

V Balaraman, J Meister, SL Sood, KC Finn, D Easa. Lavage Administration of KL4-Surfactant and Exosurf in Neonatal Piglets with acute lung injury. AJRCCM, 1996;153:A587

Publication:

SL Sood, V Balaraman, KC Finn, B Britton, CFT Uyehara, D Easa. Efficacy of Exogenous Surfactants in a Neonatal Piglet Model of Acute Respiratory Distress Syndrome. AJRCCM 1996;153:820-828.

Detail Summary Sheet

Prot No: TAMC 10H96

Status: Ongoing

TITLE: The Influence of Cycle Phase on Heat Acclimatization Time Course in Young Women

Start date: Jan 96

Est Comp Date:

Principal Investigator: COL L. Harrison Hassell, MC

Department/Section: Clinical Investigation/
Facility: TAMC

Associate Investigator: Victoria Garshnek, PhD; David A. Lally, PhD; John R. Claybaugh, PhD; G. Harley Hartung, PhD; John E. Greenleaf, PhD; Wayne M. Ichimura

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: To determine: (1) whether heat acclimation time course in normally menstruating women is influenced by the phase at which prolonged heat stress is introduced (ovulatory, midluteal, or menses phases); (2) whether heat acclimation time course in women taking oral triphasic contraceptives is influenced by the phase at which prolonged heat stress is introduced (midluteal or menses phases); (3) if differences in heat acclimation time course exist between normally menstruating women and women taking oral contraceptives when similar phases are compared (midluteal and menses phases); (4) if differences in that acclimation time course exist between men and two groups of women (normally menstruating and those taking oral contraceptives).

TECHNICAL APPROACH: Three groups will be studied and compared: women not taking hormonal agents (NH group), women taking oral contraceptive for birth control (C group), and men. In NH group women, hormone levels at three distinct points in their hormone cycle will be measured. Hormone measurements from two base-line cycles will be used to time the heat acclimation tests that coincide with ovulation, the luteal elevation in progesterone, and menstrual flow. In C group women, the heat acclimation process during menses and mid-luteal phases will be studied. Men will be heat acclimated once.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: TAMC 17T95

Status: Ongoing

TITLE: Battlefield Casualty Care Surgical Skills Training for the Navy SEAL Corpsman
Using Sus Scrofa

Start date: Jul 95

Est Comp Date: May 98

Principal Investigator: COL L. Harrison Hassell, MC

Department/Section: Clinical Investigation/
Facility: TAMC

Associate Investigator: LCDR Lachlan D. Noyes, MC

Key Words: ATLS; pig; training

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/31/96
Decision: Continue

OBJECTIVE: To train Navy SEAL and other Special Operations corpsmen & medics in advanced surgical skills necessary to provide emergency medical care to casualties on the battlefield.

TECHNICAL APPROACH: Training lab.

PROGRESS: No. of Subjects Enrolled - To Date: 26
During FY96: 13

Another thirteen personnel have undergone training through the lab held in May 96.

Detail Summary Sheet

Prot No: TAMC 19H95

Status: Completed

TITLE: A Prospective Open Label, Randomized Comparison of Two Treatment Regimens: Losartan Potassium or Losartan/Hydrochlorothiazide Versus Usual Care in Patients Being Treated for Mild to Moderate Hypertension Who Need to Switch Drug Therapy

Start date: Jun 95

Est Comp Date:

Principal Investigator: COL L. Harrison Hassell, MC

Department/Section: Clinical Investigation/
Facility: TAMC

Associate Investigator: LTC Sharon S. DeRuvo, AN; Sandy S.G. Popham, MD; Catherine F.T. Uyehara, PhD

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 5/28/96

Gifts: HMJFAMM & \$/pt

Decision: Completed

OBJECTIVE: To compare efficacy, tolerability and safety of antihypertensive regimens of losartan-losartan/HCTZ versus replacement usual care.

TECHNICAL APPROACH: Randomized comparison of two treatment regimens.

ADDENDUM (Sep95): Recruitment advertisement

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 1

No publications or presentations. Study closed to enrollment 2/27/96.

Detail Summary Sheet

Prot No: TAMC 22H96

Status: Ongoing

TITLE: A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Phase III Clinical Trial to Evaluate the Safety and Efficacy of Auriculin Anaritide in the Treatment of Oliguric Acute Tubular Necrosis

Start date: Jul 96

Est Comp Date:

Principal Investigator: COL L. Harrison Hassell, MC

Department/Section: Clinical Investigation/
Facility: TAMC

Associate Investigator: Sandy S.G. Popham, MD; LTC Benjamin W. Berg, MC;
LTC Kathleen M. Sheehan, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 2/27/96

Gifts:

Decision: Continue

OBJECTIVE: To assess the safety and efficacy of Auriculin anaritide, compared to placebo, in treating patients diagnosed with oliguric acute tubular necrosis.

TECHNICAL APPROACH: A randomized, double-blind, placebo controlled study. Subject will receive a 24 hour intravenous infusion of either the study drug or placebo. Tests (urine and blood samples) will be performed prior to receiving the drug and over the next 21 days.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: TAMC 26H96

Status: Ongoing

TITLE: The Association of Abnormalities of the Renin-Angiotensin System With Fluid Noncompliance Among Adult ESRD Patients on Hemodialysis

Start date: Oct 96

Est Comp Date:

Principal Investigator: COL L. Harrison Hassell, MC

Department/Section: Clinical Investigation/
Facility: TAMC

Associate Investigator: Victoria Garshnek, PhD; John R. Claybaugh, PhD; John E. Greenleaf, PhD; Aileen K. Sato

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Continue

OBJECTIVE: (1) To measure the variation of pre-hemodialysis levels of A-II, PRA, ALDO, ADH, and ANP over three consecutive Mondays in adult ESRD patients on chronic outpatient hemodialysis; (2) To investigate the association between changes in levels of PRA, A-II, ALDO, ADH, and ANP and fluid gain during a single interhemodialytic interval in adult ESRD patients on chronic outpatient hemodialysis; (3) To investigate the association between changes in levels of PRA, A-II, ALDO, ADH, and ANP and plasma volume during a single interhemodialytic interval in adult ESRD patients on chronic outpatient hemodialysis; (4) To investigate the profile of interhemodialytic weight gain over a six-month period in adult ESRD patients on hemodialysis.

TECHNICAL APPROACH: (1) Review the medical records of the subject's hemodialysis treatments over the previous six months to evaluate the pattern of fluid gain between dialysis treatments during this time period; (2) Blood will be drawn to see how much the hormone levels vary when measured before dialysis over three consecutive Mondays; (3) Obtain blood tests and measure blood volume to see if there is a relationship between the hormone levels and fluid gain over a weekend between two consecutive dialysis treatments.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: TAMC 41H96

Status: Ongoing

TITLE: The Effect of Telemedicine Implementation on Clinical Outcomes in a Limited Military Setting

Start date: Jul 96

Est Comp Date:

Principal Investigator: COL L. Harrison Hassell, MC

Department/Section: Clinical Investigation/
Facility: TAMC

Associate Investigator: Victoria Garshnek, PhD; MAJ Brian J. Goldsmith, MC; MAJ Robert D. Rakov, MC; LTC Sharon S. DeRuvo, AN; LTC Elizabeth E. Hill, AN; Deborah P. Birkmire, PhD; Leslie A. Whitaker, PhD; Robert Doktor, PhD; David C. Bangert, PhD; Eric L. Mais, PhD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: To provide a scientific evaluation of clinical outcomes resulting from insertion of telemedicine into a primary care clinic that routinely refers patients to a tertiary medical care center.

TECHNICAL APPROACH: The study employs a randomized design to determine whether consultation to a tertiary care medical center by telemedicine technology from a primary care setting offers any advantage over usual care; the study has two groups.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: TAMC 44H96

Status: Ongoing

TITLE: Assessing Organizational Impact of the Implementation of a Telemedicine System

Start date: Aug 96

Est Comp Date:

Principal Investigator: COL L. Harrison Hassell, MC

**Department/Section: Clinical Investigation/
Facility: TAMC**

Associate Investigator: David C. Bangert, PhD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 7/23/96

Decision: Continue

OBJECTIVE: To measure the organization impact of telemedicine (into a natural, yet limited clinical setting) on a healthcare system.

TECHNICAL APPROACH: Analysis of one pretest and three follow-up post tests on participant physicians and medical staff.

PROGRESS:

No. of Subjects Enrolled - To Date:	
During FY96:	

Detail Summary Sheet

Prot No: TAMC 45H96

Status: Ongoing

TITLE: Assessing Cost-effectiveness in a Telemedicine System

Start date: Aug 96

Est Comp Date:

Principal Investigator: COL L. Harrison Hassell, MC

Department/Section: Clinical Investigation/
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 7/23/96
Decision: Continue

OBJECTIVE: To examine whether the application of telemedicine is cost-effective compared to the standard approach to health care delivery.

TECHNICAL APPROACH: Economic analysis of this project.

PROGRESS: No. of Subjects Enrolled - To Date:
 During FY96:

Detail Summary Sheet

Prot No: TAMC 32H95

Status: Terminated

TITLE: A New Concept in Physiological Monitoring for Military Nursing

Start date: Sep 95

Est Comp Date: Indef

Principal Investigator: LTC Elizabeth E. Hill, AN

Department/Section: Clinical Investigation/
Facility: TAMC

Associate Investigator: COL L. Harrison Hassell, MC; Victoria Garshnek, PhD; Patrick K. Sullivan, PhD; Christopher J. Sullivan, PhD; LTC Sharon S. DeRuvo, AN; Wayne M. Ichimura

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 7/23/96
Decision: Terminated

OBJECTIVE: To develop a monitor to non-invasively monitor heart rate, respiration, and blood pressure inside a MEDEVAC helicopter.

TECHNICAL APPROACH: A prototype of a passive monitor will be developed. Patients and health care providers will independently assess acceptability and ease of use.

MODIFICATION (Sep95): Consent revisions.

MODIFICATION (Apr96): PI change (formerly LHHassell).

NOTE (Jul96): Rewritten to new protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Funding was not received to initiate the study, so no subjects were enrolled and no data was collected. The PI was changed and the study was submitted for funding through the Tri-Service Nursing Research Program. Because of changes to this study, this study will be terminated and a new proposal written to replace it.

Detail Summary Sheet

Prot No: TAMC 39H96

Status: Ongoing

TITLE: A New Concept in the Physiological Monitoring for Military Nursing

Start date: Jul 96

Est Comp Date:

Principal Investigator: LTC Elizabeth E. Hill, AN

Department/Section: Clinical Investigation/

Facility: TAMC

Associate Investigator: COL L. Harrison Hassell, MC; Victoria Garshnek, PhD; Patrick K. Sullivan, PhD; Christopher J. Sullivan, PhD; LTC Sharon S. DeRuvo, AN; Wayne M. Ichimura

Key Words:

Funding: FY 95: FY 96:

Periodic Review Date: 6/25/96

Gifts: Tri-Svc Grant--271K/3yr

Decision: Continue

OBJECTIVE: To develop a monitor to non-invasively monitor heart rate, respiration, and blood pressure inside a MEDEVAC helicopter.

TECHNICAL APPROACH: A prototype of a passive monitor will be developed. Patients and health care providers will independently assess acceptability and ease of use.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

This new IRB-approved study has not been implemented.

Detail Summary Sheet

Prot No: TAMC 6A96

Status: Ongoing

TITLE: The Influence of Nitric Oxide on Newborn Lung Function

Start date: Dec 95

Est Comp Date: Nov 97

Principal Investigator: Kenneth T. Nakamura, MD

Department/Section: Clinical Investigation/KMCWC

Facility: TAMC

Associate Investigator: David Easa, MD; Lynn M. Iwamoto, MD; LTC Marshall V.C. Dressel, MC; CPT Sarah L. Lavalley, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 10/31/96

Gifts:

Decision: Continue

OBJECTIVE: To study the possible pulmonary toxicity of inhaled nitric oxide (NO).

TECHNICAL APPROACH: See protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 0

During FY96: 0

Presently designing exposure chamber and determining environmental safety of NO.

Detail Summary Sheet

Prot No: TAMC 7A96

Status: Ongoing

TITLE: Recovery of Cocaine and Metabolites from Meconium, Urine and Amniotic Fluid of Guinea Pigs

Start date: Dec 95

Est Comp Date: Nov 98

Principal Investigator: Kenneth T. Nakamura, MD

Department/Section: Clinical Investigation/KMCWC

Facility: TAMC

Associate Investigator: Lynn M. Iwamoto, MD; CPT Sarah L. Lavallee, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 10/31/96

Gifts:

Decision: Continue

OBJECTIVE: To determine elimination pharmacokinetics of cocaine and metabolites from meconium, urine and amniotic fluid during the perinatal period in guinea pigs.

TECHNICAL APPROACH:

PROGRESS: No. of Subjects Enrolled - To Date: N/A

During FY96: N/A

(12A92 rewritten)

Abstract:

Iwamoto LM, Moore CM, Nakamura KT: Meta-hydroxybenzoylecgonine recovery in fetal guinea pigs. J Invest Med (In Press).

Detail Summary Sheet

Prot No: TAMC 14A93

Status: Terminated

TITLE: Direct Effects of Bacterial Toxins on Vascular and Airway Smooth Muscle Contractility

Start date: Mar 93

Est Comp Date: Indef

Principal Investigator: Kenneth T. Nakamura, MD

Department/Section: Clinical Investigation/KMCWC
Facility: TAMC

Associate Investigator: John R. Claybaugh, PhD; Lynn M. Iwamoto, MD

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 10/31/96

Gifts: EQ loan

Decision: Terminated

OBJECTIVES: To study direct effects of toxins on vascular and airway smooth muscle in newborn guinea pigs, and to compare different toxins.

TECHNICAL APPROACH: Airway and vascular smooth muscle segments are incubated with LPS endotoxin in vitro and ex vivo effects of systemic LPS administration are being studied.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

New Abstract:

Iwamoto LM, Wilson VL, Ayau EL, Nakamura KT. Role of nitric oxide in endotoxin-exposed guinea pig airways. *Pediatr Res* 35:393A, 1994.

Presentation:

Role of nitric oxide in endotoxin-exposed guinea pig airways. Annual meeting of the American Pediatric Society and the Society for Pediatric Research, Seattle, Washington, May 2, 1994.

Project terminated due to lack of funds.

Detail Summary Sheet

Prot No: TAMC 18A96

Status: Ongoing

TITLE: Preliminary Studies to Determine Smooth Muscle Function in Transgenic Mice with Elastin Mutations

Start date: Mar 96

Est Comp Date: Feb 99

Principal Investigator: Kenneth T. Nakamura, MD

Department/Section: Clinical Investigation/KMCWC

Facility: TAMC

Associate Investigator: Lynn M. Iwamoto, MD; Charles Boyd, PhD; CPT Michael J. Christ, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 10/31/96

Gifts:

Decision: Continue

OBJECTIVE: To determine if and how transgenic mice with elastin mutations alter airway smooth muscle contractile properties.

TECHNICAL APPROACH: Isometric force measurements of airway and vascular smooth muscle segments.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

Preliminary experiments performed on 7 newborn mice. There does not appear to be a difference in airway contractility between transgenic mice with elastin gene mutations specific to the lung when compared to non-transgenic phenotypes.

Detail Summary Sheet

Prot No: TAMC 21H95

Status: Ongoing

TITLE: Pilot Project to Determine the Feasibility of Studying the Physiology and Pharmacology of Human Fetal Airway

Start date: Jun 95

Est Comp Date: Indef

Principal Investigator: Kenneth T. Nakamura, MD

Department/Section: Clinical Investigation/KMCWC
Facility: TAMC

Associate Investigator: Santosh Sharma, MD; Nancy L. McDaniel, MD; Herbert Uemura, MD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To compare physiology and pharmacology of human fetal airway at various gestational ages to published human newborn data and to data derived from fetal & newborn guinea pig studies.

TECHNICAL APPROACH: In vitro isometric tension recordings of tracheal segments.

PROGRESS: No. of Subjects Enrolled - To Date: 12
During FY96: 11

We have studied 12 human fetal trachea from 76 to 137 gestation obtained from the laboratory of human embryology, University of Washington, Seattle WA. The majority of the airways contract in an expected manner to generate a sigmoidal shaped concentration response curve. Thus, these preliminary results indicate the feasibility of employing this tissue for further study. During the course of generating the amiloride dose response, human fetal airway begins to lose tension until contractile effects are observed starting at 30uM amiloride suggesting that the sustained phase of contraction is not sufficient in human fetal airway.

Detail Summary Sheet

Prot No: TAMC 63A94

Status: Ongoing

TITLE: Ontogeny of Airway Smooth Muscle Function in Guinea Pigs and Mice

Start date: Aug 94

Est Comp Date: Jul 97

Principal Investigator: Kenneth T. Nakamura, MD

Department/Section: Clinical Investigation/KMCWC
Facility: TAMC

Associate Investigator: John R. Claybaugh, PhD; Lynn M. Iwamoto, MD; LTC Marshall V.C. Dressel, MC; Jonathan R. Wispe, MD; Nancy L. McDaniel, MD

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 10/31/96

Gifts: Grant appl by KMC

Decision: Continue

OBJECTIVE: (1) Determine if normal ontogeny of airway smooth muscle function to physiologic (hormones), pharmacologic (drugs) and environmental stimuli (hypoxia) are altered after exposure to passive cigarette smoking during the newborn period; (2) Determine if the normal ontogeny of airway smooth muscle function to physiologic, pharmacologic and environmental stimuli are altered after exposure to hyperoxia during the newborn period; (3) Determine if gestational age at birth influences specific airway smooth muscle function after exposure to hyperoxia and cigarette smoke.

TECHNICAL APPROACH: We will examine contractile and relaxation responses of isolated newborn guinea pig and mice airway rings using standard isometric techniques and a perfused-pressurized system. The effect of hyperoxic and cigarette smoke exposure will be examined. Mice will be of genetic strains that are known to have hyper- and hypo-responsive airway reactivity and an additional strain will be transgenic for the Mn SOD gene.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

Preliminary data have been obtained demonstrating that hyperresponsive strains of mice exhibit these airway characteristics early in the newborn period.

Abstract:

Christ MJ, Iwamoto LM, Lavalley SL, Nakamura KT: Amilorie Differentially Affects Inflammation- and Neural-Induced Airway Tone. J Invest Med (In Press).

Detail Summary Sheet

Prot No: TAMC 68A94

Status: Terminated

TITLE: Role of Neonatal Diet on Vascular Responses in Normotensive and Hypertensive Rats

Start date: Oct 94

Est Comp Date:

Principal Investigator: Kenneth T. Nakamura, MD

Department/Section: Clinical Investigation/KMCWC
Facility: TAMC

Associate Investigator: Catherine F.T. Uyehara, PhD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/31/96
Decision: Terminated

OBJECTIVE: To determine if dietary alterations by artificial rearing during the early postnatal period affects vascular responses and the development of hypertension in normotensive and genetically hypertensive rats.

TECHNICAL APPROACH: Artificial rearing by gastrostomy and dietary alterations.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

Experiments demonstrating the feasibility of artificial rearing to study vascular reactivity have been completed. Manuscript is in preparation.

Project is terminated due to lack of funds.

Detail Summary Sheet

Prot No: TAMC 5A94

Status: Completed

TITLE: Characterizing the Role of Nitric Oxide as the Mediator of Vasopressin Improvement of Blood Gas Exchange in a Neonatal Piglet Model of Hypoxic Pulmonary Hypertension

Start date: Oct 93

Est Comp Date: Sep 96

Principal Investigator: Catherine F.T. Uyehara, PhD

Department/Section: Clinical Investigation/Pharmacology

Facility: TAMC

Associate Investigator: Kenneth T. Nakamura, MD

Key Words: nitric oxide; pulmonary hemodynamics

Funding: FY 95:

FY 96:

Periodic Review Date: 10/31/96

Gifts:

Decision: Completed

OBJECTIVE: To determine whether vasopressin improvement of blood oxygenation during hypoxia-induced pulmonary hypertension in the neonate is mediated by nitric oxide.

TECHNICAL APPROACH: Nitric oxide involvement in mediation of beneficial effects of vasopressin in hypoxia will be analyzed by administration of 3 different nitric oxide synthase inhibitors before vasopressin administration in hypoxic neonatal piglets. The effects of these nitric oxide synthase inhibitors will be compared in piglets catheterized for assessment of pulmonary and systemic hemodynamics and blood gas exchange analysis.

ADDENDUM (Nov94): Added animals for additional arm.

PROGRESS: No. of Subjects Enrolled - To Date: N/A

During FY96: N/A

Experiments comparing the in vivo effects of aminoguanidine and N-w-nitro-L-arginine during normoxia and hypoxia have been completed.

Presentations this year:

COMPRA 1995; Society for Pediatric Research, May 1996; 1996 University of Hawaii Biosymposium

Awards: Wyeth-Lederle Vaccines and Pediatrics Neonatology Awards Program, 1996
University of Hawaii Biosymposium First Place Postdoctoral Division

Published abstracts this year:

Luchetti, J. M., Lee, W., and Uyehara, C.F.T. Acute hypoxia increases pulmonary artery inducible nitric oxide synthase in neonatal piglets. *Pediatr.Res.* 39(4):63A, 1996.

Submitted manuscripts:

Luchetti, J.M., Hashiro, G.M., Nakamura, K.T., and Uyehara, C.F.T. Inducible nitric oxide synthase inhibition selectively augments pulmonary vasoconstriction in hypoxic neonatal piglets. (Submitted to *J. Pharmacol. Exp. Thera*)

Detail Summary Sheet

Prot No: TAMC 10A95

Status: Ongoing

TITLE: Gene Expression Alterations of Endothelin and Endothelin Receptors in the Kidney During the Development of Hypertension in Spontaneously Hypertensive Rat

Start date: Mar 95

Est Comp Date: Feb 98

Principal Investigator: Catherine F.T. Uyehara, PhD

Department/Section: Clinical Investigation/Pharmacology
Facility: TAMC

Associate Investigator: Wen Qun Lee; John R. Claybaugh, PhD; MAJ William F. Nauscheutz, MS

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/31/96
Decision: Continue

OBJECTIVE: (a) To characterize changes in gene expression of endothelin (ET) isopeptides in the segmented nephron during the critical developmental phase of genetic hypertension in the spontaneously hypertensive rat (SHR); (b) To characterize changes in gene expression of ET receptors in the segmental nephron during the critical developed phase of genetic hypertension in SHR.

TECHNICAL APPROACH: Endothelin mRNA and endothelin receptor mRNA will be isolated from different nephron segments of SHR and WKY rats at various stages of development.

ADDENDUM (Jan 96): Added animals.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

mRNA isolation techniques have been perfected. Good probes for endothelin subtypes are still being developed.

This project was submitted for grant funding from the American Heart Association Hawaii Affiliate and the Pharmaceutical Manufacturers Association in FY96. Project received good scientific merit reviews from both organizations although it did not meet funding cutoffs.

Detail Summary Sheet

Prot No: TAMC 11L96

Status: Ongoing

TITLE: Influence of Maternal Exercise Stress on Production of Placental Vasoactive Substances in the Placental Perfusion Model

Start date: Dec 95

Est Comp Date: Dec 98

Principal Investigator: Catherine F.T. Uyehara, PhD

Department/Section: Clinical Investigation/Pharmacology
Facility: TAMC

Associate Investigator: MAJ Glenn R. Markenson, MC

Key Words: pregnancy; exercise; placenta; nitric oxide; endothelin; eicosanoids

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/31/96
Decision: Continue

OBJECTIVE: To explore possible fetoprotective changes in the human placenta that may occur during exercise.

TECHNICAL APPROACH: Using an in vitro dual perfused placenta cotyledon model, the effects of hypoxia, hypoglycemia, hyperthermia, or increased vasopressin (stressors that occur with maternal exercise) on local production of prostacyclin, thromboxane, nitric oxide, and endothelin will be assessed. In addition, the transfer of vasopressin across the placenta, as well as the role of endogenous nitric oxide mediation of placental vasomotor tone will be studied.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

Preliminary establishment of perfused placenta model has been done. Project is currently awaiting acquisition of 2 peristaltic perfusion pumps that can deliver non-pulsatile flow for accurate pressure measurements, as well as time availability of investigators. Techniques for determination of nitric oxide synthase in tissue samples via Western blot have been developed.

This project was submitted to the Defense Women's Health Research Program for funding in FY96. Project received high scientific merit review rating although it did not meet funding cutoff.

Detail Summary Sheet

Prot No: TAMC 17A96

Status: Ongoing

TITLE: Role of Endogenous Nitric Oxide in Hypoxia-Induced Pulmonary Hypertension in the Neonatal Piglet

Start date:

Est Comp Date: Feb 99

Principal Investigator: Catherine F.T. Uyehara, PhD

Department/Section: Clinical Investigation/Pharmacology
Facility: TAMC

Associate Investigator: Kenneth T. Nakamura, MD; Wen Qun Lee; MAJ James M. Luchetti, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/31/96
Decision: Continue

OBJECTIVE: To identify the mechanism of endogenous nitric oxide action in the lung.

TECHNICAL APPROACH: Pharmacological study.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

No work has been conducted on this study; the protocol is on hold pending minor editorial changes. Also, Dr. Luchetti PCS'd; Dr. Uyehara will take over as Principal Investigator.

Detail Summary Sheet

Prot No: TAMC 26A95

Status: Ongoing

TITLE: Influence of Agents That Affect Renal Sodium Handling on the Development of Hypertension in Spontaneously Hypertensive Rat

Start date: Mar 96

Est Comp Date: Jun 98

Principal Investigator: Catherine F.T. Uyehara, PhD

Department/Section: Clinical Investigation/Pharmacology
Facility: TAMC

Associate Investigator:

Key Words: sodium excretion; neonatal rats; genetic hypertension; prehypertensive stage

Funding: FY 95:

FY 96:

Periodic Review Date: 10/31/96

Gifts:

Decision: Continue

OBJECTIVE: To determine if manipulation of sodium excretion, during an early critical period of hypertension development, will alter the long-term course of blood pressure control.

TECHNICAL APPROACH: Captopril, furosemide, amiloride, and water (control) will be administered daily to rats from 3 to 7 weeks of age. Renal clearance studies of conscious, chronically catheterized newborn rats are performed. Rats are instrumented with arterial, venous, and stomach catheters and a bladder cannula. Urine flow, sodium excretion, glomerular filtration (inulin clearance), renal blood flow (PAH clearance) and free water clearance in response to a 2% body weight water or saline intragastric load are assessed.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

Study is a continuation of series of experiments started on a former protocol. Experiments with captopril and furosemide are underway.

Detail Summary Sheet

Prot No: TAMC 54A94

Status: Ongoing

TITLE: Evaluation of the Effectiveness of Antihypertensive Agents in Preventing End-Stage Renal Disease in Spontaneously Hypertensive Rats

Start date: Jul 94

Est Comp Date: Aug 97

Principal Investigator: Catherine F.T. Uyehara, PhD

Department/Section: Clinical Investigation/Pharmacology
Facility: TAMC

Associate Investigator: COL L. Harrison Hassell, MC; COL Robert B. Hill, MC

Key Words: converting enzyme inhibitor; calcium channel blocker; b-blocker; diuretic; glomerular filtration; renal blood flow; renal clearance

Funding: FY 95:

FY 96:

Periodic Review Date: 10/31/96

Gifts: VA/DOD appl

Decision: Continue

OBJECTIVE: To determine & compare the effectiveness of four different classes of antihypertensive agents in preventing progression of renal disease/deterioration in essential hypertension (HT).

TECHNICAL APPROACH: Studies will be performed using uninephrectomized SHR chronically instrumented with arterial, venous, and stomach catheters for blood pressure measurements, blood sampling, and drug administration. Rats will be assigned to one of five different regimens (control (no treatment); converting enzyme inhibitor; calcium channel blocker; diuretic; beta-blocker). Rats will be divided into 2 groups to be studied at 2 different treatment periods (early HT = 6 to 18 weeks of age; established HT = 24 to 36 weeks of age), and further divided into 2 subgroups for antihypertensive therapy to be aimed at 2 different levels of target blood pressure control (low = $MAP < 90$; moderate = $105 < MAP < 115$).

Renal function will be assessed in the middle of antihypertensive therapy and again at the end of the 12 week treatment period. Kidneys will be examined for changes in histology at the end of the 12 week treatment period to determine if normal histopathological changes associated with progressive renal failure were altered.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

Preliminary work with animal model was begun and then stopped due to unavailability of investigators' time for this project. Because of the intensive labor requirements of this project, it will be difficult to complete without extramural funds to hire a technician. Thus, this work was again put on hold pending extramural funding and time availability of investigators.

Detail Summary Sheet

Prot No: TAMC 64A94

Status: Ongoing

TITLE: Tissue, Organ, and Body Fluid Samples for In Vitro Testing Procedures

Start date: Sep 94

Est Comp Date: Aug 97

Principal Investigator: Catherine F.T. Uyehara, PhD

Department/Section: Clinical Investigation/Pharmacology

Facility: TAMC

Associate Investigator: John R. Claybaugh, PhD; MAJ William F. Nauscheutz, MS; Wen Qun Lee; Kenneth T. Nakamura, MD; David Easa, MD

Key Words: assays; methodologies; mechanisms (cellular, molecular, histological, biochemical)

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/31/96
Decision: Continue

OBJECTIVE: Maximize use of research animals thru harvested tissue and fluid samples.

TECHNICAL APPROACH: Tissues and fluid samples from animals slated for euthanasia after use in other protocols, or animals to be culled from existing animal colonies. These tissue and fluid samples will be used for in vitro examination of cellular activation, molecular mechanisms, and histological and biochemical status using a variety of methodologies including receptor binding, second messenger, reverse transcription, and polymerase chain reaction assays; histological assessments; ELISA; GC/MS and HPLC analysis; and radioimmunoassays. All data obtained will be used for characterization and/or establishment of in vitro procedures, as well as serve as a source of reference values for our laboratories.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

Tissue and blood samples have been harvested for successful development of mRNA electrophoresis, PCR, Western-blot analyses, and receptor binding and function assays. This project has continued to play an important role in the efficient use of tissues and organs which permit reduction of animals used for research.

Detail Summary Sheet

Prot No: TAMC 37H94

Status: Terminated

TITLE: Bacterial Vaginosis and Reestablishment of a Healthy Vaginal Ecosystem: A Double-blind, prospective, randomized study of the Effects of Treatment With Oral Metronidazole and Lactobacillus Acidophilus

Start date:

Est Comp Date: Jan 97

Principal Investigator: CPT Mark S. Williams, MC

Department/Section: Family Practice/
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Terminated

OBJECTIVE: To assess the short and long-term efficacy of two different treatments for bacterial vaginosis.

TECHNICAL APPROACH: Double-blind, prospective, randomized study.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study never started and is now terminated.

Detail Summary Sheet

Prot No: TAMC 22H95

Status: Terminated

TITLE: (Protocol 1003-01) A Double-Blind, Randomized, Phase III, Multicenter Study of Suramin and Hydrocortisone Versus Hydrocortisone and Placebo in the Treatment of Patients With Metastatic, Hormone-Refractory Prostate Carcinoma (Stage D2)

Start date: Aug 95

Est Comp Date:

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 2/27/96

Gifts: IND-Suramin / HMJFAMM

Decision: Terminated

OBJECTIVE: (1) To determine Suramin's effect on pain, performance status, PSA, disease response, quality of life and survival in patients with hormone-refractory prostate carcinoma; (2) To evaluate the safety of Suramin.

TECHNICAL APPROACH: Double-blind, placebo-controlled, randomization of Suramin and Hydrocortisone versus Hydrocortisone and Placebo in the treatment of patients with metastatic, hormone-refractory prostate carcinoma (Stage D2).

MODIFICATIONS #1,2,3 (May95): Administrative clarifications.

MODIFICATION #4 (Jun95): Administrative changes.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

No TAMC patients were enrolled in this study. This study site was closed and the IRB notified of this status on 23 Apr 96.

Detail Summary Sheet

Prot No: TAMC 47H96

Status: Ongoing

TITLE: (URCC 1190M) Control of Vasomotor Symptoms Associated With Tamoxifen Therapy in Women With Breast Cancer

Start date: Sep 96

Est Comp Date:

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: (1) To compare the effectiveness of clonidine hydrochloride or placebo given orally for the control of hot flashes and other vasomotor symptoms associated with tamoxifen therapy in women with breast cancer. (2) To examine whether time since menopause, duration of tamoxifen therapy, or baseline frequency of hot flashes predicts for response to clonidine.

TECHNICAL APPROACH: Randomized drug treatment with clonidine or placebo for a total of two months.

PROGRESS:

No. of Subjects Enrolled - To Date:	
During FY96:	

Detail Summary Sheet

Prot No: TAMC 28H93

Status: Ongoing

TITLE: Prevalence of Antiphospholipid Antibodies in Isolated Mitral Valve Prolapse

Start date: May 93

Est Comp Date: Sep 94

Principal Investigator: CPT Brian M. Cuneo, MC

Department/Section: Medicine/

Facility: TAMC

Associate Investigator: MAJ Robert J. Wozniak, MC; MAJ Richard J. Timmons Jr, MC;
CPT Diane K. Noyles, MC; CPT William A. Rollefson, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 3/26/96

Gifts:

Decision: Continue

OBJECTIVES: Case-control study.

TECHNICAL APPROACH: Patients with MVP will be compared to a group of age and sex-matched controls without a history of cardiac or rheumatic disease, or other systemic disease processes that may affect APAB levels. All subjects and controls will have blood samples taken for analysis of anti-cardiolipin antibodies, lupus anticoagulant, VDRL, ANA, anti-DNA antibody, and RPR.

PROGRESS: No. of Subjects Enrolled - To Date: 42
During FY96: 0

There have been no additional patients enrolled since the last progress report, but investigators wish to keep the protocol active and intend to complete the project during FY96.

Detail Summary Sheet

Prot No: TAMC 18H95

Status: Terminated

TITLE: A Five-Year Observational Study to Evaluate Clinical Response and Recurrence Rate in the Treatment of Basal Cell Carcinoma with Fluorouracil/Epinephrine Injectable Gel

Start date: Aug 95

Est Comp Date:

Principal Investigator: LTC Cary L. Dunn, MC

Department/Section: Medicine/Dermatology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 2/27/96

Gifts: IND-5FU epi gel / HMJFAMM

Decision: Terminated

OBJECTIVE: Utilizing 5-FU/epi injectable gel treatment, objectives are (1) to describe the clinical response rate at three months post treatment, (2) to describe the recurrence rate in patients with a clinical response at three months post treatment, (3) to confirm and evaluate the long-term safety and efficacy in patients with basal cell carcinoma.

TECHNICAL APPROACH: Treatment of basal cell carcinoma with 5-FU/epi injectable gel.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 5H93

Status: Ongoing

TITLE: Skin Manifestations in Patients with Hepatitis C Virus

Start date: Feb 93

Est Comp Date: Indef

Principal Investigator: CPT Samuel J. Eallonardo, MC

Department/Section: Medicine/

Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 9/24/96

Gifts:

Decision: Continue

OBJECTIVES: To determine dermatologic manifestations of Hepatitis C Disease in a military population.

TECHNICAL APPROACH: The study will be an observation, data collection study. Hepatitis C Virus (HCV) positive patients will be selected from a pool of patients who are currently participating in an HCV study which is currently being conducted by the Gastroenterology department.

PROGRESS: No. of Subjects Enrolled - To Date: 21
During FY96: 0

There were no adverse results. There have been no publication or presentations. I believe I am required to present the completed work to the Dept of Medicine prior to my graduation (on or about Jun 96).

Detail Summary Sheet

Prot No: TAMC 59H96

Status: Ongoing

TITLE: A Study to Evaluate the Effects of Triple Therapy for 10 and 14 Days with Lansoprazole, Clarithromycin, and Amoxicillin on the Eradication of Helicobacter Pylori

Start date: Nov 96

Est Comp Date:

Principal Investigator: MAJ Steven W. Hammond, MC

Department/Section: Medicine/Gastroenterology
Facility: TAMC

Associate Investigator: Patricia L. Blanchette, MD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/24/96
Decision: Continue

OBJECTIVE: To compare the safety and efficacy of triple therapy with lansoprazole, clarithromycin, and amoxicillin for 10 versus 14 days for the eradication of Helicobacter pylori from the gastric mucosa of patients with active duodenal ulcer or a history of duodenal ulcer.

TECHNICAL APPROACH: Randomized, double-blind, parallel-group, active-controlled, triple therapy study.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Before study implementation was approved, the sponsor had closed the study to accrual. No patients from TAMC were enrolled onto study.

Detail Summary Sheet

Prot No: TAMC 17H93

Status: Ongoing

TITLE: Direct Cardiac Effects of Exercise Training in Post-MI Patients

Start date: Mar 93

Est Comp Date: Jun 97

Principal Investigator: G. Harley Hartung, PhD

Department/Section: Medicine/Cardiology

Facility: TAMC

Associate Investigator: MAJ Robert J. Wozniak, MC; CPT Brian M. Cuneo, MC;
CPT William A. Rollefson, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 2/27/96

Gifts: None

Decision: Continue

OBJECTIVES: To test the hypotheses: (1) Cardiac rehabilitation can lead to improved exercise tolerance (2) Changes in myocardial diastolic function and mass occur with exercise that may contribute to enhanced exercise performance.

TECHNICAL APPROACH: Interval echo and graded exercise treadmill.

PROGRESS: No. of Subjects Enrolled - To date: 25
During FY96:

Summary of preliminary results: Despite improvement in exercise tolerance, no changes could be demonstrated in diastolic left ventricular function.

Conclusion: Improvement in exercise capacity as a result of exercise training does not appear to be related to changes in left ventricular diastolic function.

Preliminary results on first 12 patients presented at the American College of Sports Medicine Meeting, Jun 94, and published in Medicine and Science in Sports and Exercise 26:S32, 1994.

There have been no adverse effects.

Detail Summary Sheet

Prot No: TAMC 33S96

Status: Ongoing

TITLE: Effects of Continued Exercise on Outcomes in Cardiac Rehabilitation: A Followup/Questionnaire Study

Start date: Jun 96

Est Comp Date:

Principal Investigator: G. Harley Hartung, PhD

Department/Section: Medicine/Cardiology
Facility: TAMC

Associate Investigator: MAJ Anita Jones, MC; MAJ Edward Chu, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To define or determine in follow-up, cardiac rehabilitation outcomes in patients who continue to exercise compared with those who become relatively inactive.

TECHNICAL APPROACH: This will be a follow-up mail/telephone questionnaire study with comparison of two groups dichotomized on the basis of study questions.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 22H92

Status: Completed

TITLE: The Observational Data Base Project: A Community-Based Longitudinal of HIV-Infected Individuals

Start date: Mar 92

Est Comp Date: Indef

Principal Investigator: Arthur C. Johnson III, MD

Department/Section: Medicine/Infectious Disease
Facility: TAMC

Associate Investigator: COL Joel D. Brown, MC; Margo Heath-Chiozzi, MD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Completed

OBJECTIVE: 1) To obtain a periodic profile of the HIV patient population being seen by primary care physicians working in different community-based programs in the United States and Canada. 2) To assist community clinicians in estimating the number of patients at particular community-based sites who may be eligible for specific controlled clinical trials. 3) To document which drugs, drug combinations, and other therapies are currently being used for treatment and prophylaxis of HIV-related infections, and document how the uses of these therapies change over time. 4) To answer questions about the progression of HIV disease in different patient populations, including information about prognostic markers, presenting cofactors, and changing manifestations of HIV illness over time. 5) To permit comparisons of community-based study participants with other HIV-infected populations. 6) To provide an opportunity for community clinicians to gain expertise in the conduct of scientifically sound clinical research.

TECHNICAL APPROACH: Data will be collected on standardized case report forms every three to six months. Data categories include demographic and other baseline information as well as current symptoms, diagnoses, lab values and treatments. In most cases, data will be collected by interview during the patient's regularly scheduled clinic appointment. If this is not feasible, data may be collected by retrospective chart review. Patients will not be scheduled for special office visits for the ODB project and no special laboratory tests will be ordered.

PROGRESS: No. of Subjects Enrolled - To Date: 20
During FY96: 0

Nothing to report.

Detail Summary Sheet

Prot No: TAMC 31H96

Status: Ongoing

TITLE: Studies on HIV-1-associated Malignancies in Hawaii

Start date: Jun 96

Est Comp Date:

Principal Investigator: Arthur C. Johnson III MD

Department/Section: Medicine/Infectious Disease

Facility: TAMC

Associate Investigator: COL Robert B. Hill, MC; Lucille H. Kimura, PhD; Ross E. Newmann, BS

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 4/23/96

Gifts: CRADA (collaboration)

Decision: Continue

OBJECTIVE: (1) To develop the Hawaii HIV-Associated Malignancies, Biological Fluids and Tissue Bank Program to collect malignant tissues from Hawaii's HIV-infected patients for local and national studies focusing on the pathogenesis of HIV-associated malignancies; (2) To clarify the phenotypic and genotypic characteristics of the Kaposi's sarcoma (KS)-associated herpesvirus and its distribution in individual KS patients; (3) to identify sequences-specific point mutations involved in disease progression or cancer causation; (4) to study the genetic variability of HIV in tumor tissues and in peripheral blood mononuclear cells (PBMC) and other bodily fluids from patients with HIV-associated malignancies.

TECHNICAL APPROACH: Routine hematology, histological staining and flow cytometry will be performed on collected tissues and fluids.

PROGRESS:

No. of Subjects Enrolled - To Date:	
During FY96:	

Detail Summary Sheet

Prot No: TAMC 34H96

Status: Ongoing

TITLE: The Effect of Procrit on the Quality of Life of HIV-Infected Patients

Start date: Jun 96

Est Comp Date:

Principal Investigator: Arthur C. Johnson III, MD

Department/Section: Medicine/Infectious Disease
Facility: TAMC

Associate Investigator: Ross E. Newmann, BS

Key Words:

Funding: FY 95:
Gifts: CRADA(\$)

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: To determine the effectiveness of PROCRT in alleviating anemia and its impact on the quality of life of anemic HIV-infected patients who are receiving AZT therapy either alone or in combination with other anti-retroviral agents.

TECHNICAL APPROACH: Four month open-label study using PROCRT.

MODIFICATION (Jun96): Added inclusion criteria.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 43L96

Status: Ongoing

TITLE: Preservation of Fluorescent-antibody Labelled Lymphocytes for Flow Cytometric Analyses Among HIV-infected Asian/Pacific Island Populations

Start date: Aug 96

Est Comp Date:

Principal Investigator: Arthur C. Johnson III, MD

Department/Section: Medicine/Infectious Disease
Facility: TAMC

Associate Investigator: COL Robert B. Hill, MC; Lucille H. Kimura, PhD; Ross E. Newmann, BS

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 7/23/96

Gifts: CRADA (collaboration)

Decision: Continue

OBJECTIVE: To develop new techniques to analyze T-cell subsets from geographically isolated populations in the developing world.

TECHNICAL APPROACH: Freeze fixed cells and analyze them for T-cell subsets using flow cytometry.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: TAMC 5H92

Status: Completed

TITLE: Household Transmission of Hepatitis C Virus in Military Populations

Start date: Jan 92

Est Comp Date: Oct 96

Principal Investigator: MAJ Steven P. Lawrence, MC

Department/Section: Medicine/Gastroenterology

Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 2/27/96

Gifts:

Decision: Completed

OBJECTIVE: To determine the prevalence of HCV markers in household member of patients positive for the anti-hepatitis C antibody.

TECHNICAL APPROACH: Individuals identified with hepatitis C, their spouses, and family members are being offered to be followed in a protocol which evaluates for possible household transmission of hepatitis C. Hepatitis C antibody is checked by ELISA, RIBA, and PCR methods every six months for one year.

PROGRESS: No. of Subjects Enrolled - To Date: 108
During FY96: 0

Study is completed.

Detail Summary Sheet

Prot No: TAMC 36H95

Status: Ongoing

TITLE: A Phase II Study of Fludarabine Phosphate in Mantle Cell Lymphoma

Start date: Oct 95

Est Comp Date:

Principal Investigator: MAJ Susan K. Morgan, MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator: COL Jeffrey L. Berenberg MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: (1) To evaluate the response rate and response duration of patients with mantle cell lymphoma when treated with fludarabine; (2) To assess the toxicity of fludarabine in patients with mantle cell lymphoma.

TECHNICAL APPROACH: Fludarabine treatment per protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 1

At present, there is one patient enrolled on this protocol. He is a 78 y/o gentleman who has tolerated the therapy well without adverse side effects. His disease has responded to the therapy. His last cycle was administered 8/26.

Detail Summary Sheet

Prot No: TAMC 22H93

Status: Ongoing

TITLE: Clinical Predictors Of Acne Keloidalis Nuchae

Start date: Apr 93

Est Comp Date: Indef

Principal Investigator: MAJ Scott A. Norton, MC

Department/Section: Medicine/Dermatology

Facility: TAMC

Associate Investigator: COL Carver G. Wilcox, MC; MAJ Curt P. Samlaska, MC;
LCDR Christopher P. Schmidt

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 3/26/96

Gifts:

Decision: Continue

OBJECTIVES: To determine what causes acne keloidalis nuchae (AKN) and who gets AKN.

TECHNICAL APPROACH: We will assess statistically other cutaneous disorders and historical events (such as shave-type haircuts) to determine what is associated with AKN. These associations may suggest the cause of the disorder and may furthermore permit identification of individuals at risk for AKN so that they may be cautioned to avoid the causative activities.

PROGRESS: No. of Subjects Enrolled - To Date: 70
During FY96: 10

Study ongoing. We have added another 10 patients to the database. This is a demographic questionnaire and not a treatment study; no clinical intervention involved. Seventy patients enrolled to date. Haven't started numbers (data) crunching.

Detail Summary Sheet

Prot No: TAMC 16H96

Status: Ongoing

TITLE: Precose: Resolution of Optimal Titration to Enhance Current Therapies (P.R.O.T.E.C.T.)

Start date: Feb 96

Est Comp Date:

Principal Investigator: COL Thomas J. Taylor, MC

Department/Section: Medicine/Endocrinology
Facility: TAMC

Associate Investigator: Edward Jai; MAJ Gregory B. Hughes, MC

Key Words:

Funding: FY 95:
Gifts: CRADA

FY 96:

Periodic Review Date: 1/23/96
Decision: Continue

OBJECTIVE: To assess tolerability, safety, and effectiveness of PRECOSE when the dosage is titrated slowly upward in patients diagnosed with non-insulin-dependent diabetes mellitus (NIDDM).

TECHNICAL APPROACH: Prospective, multicenter, open-label, non-comparative dose titration study.

PROGRESS:

No. of Subjects Enrolled - To Date:	
During FY96:	

Detail Summary Sheet

Prot No: TAMC 28H96

Status: Ongoing

TITLE: Staff Education of AHCPR Guidelines

Start date: May 96

Est Comp Date:

Principal Investigator: COL Laurie J. Davis, AN

Department/Section: Nursing/
Facility: TAMC

Associate Investigator: MAJ Donna F. Williams, AN; LTC Sharon S. DeRuvo, AN;
LTC Sandra L. Stuban, AN; LTC Analiza Padderatz, AN; MAJ Charlotte Depew, AN

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 4/23/96
Decision: Continue

OBJECTIVE: (1) To evaluate the effect of educating nursing staff on the 1992 Agency for Health Care Policy and Research (AHCPR) pressure ulcer guidelines on select provider and clinical outcomes, and (2) To compare two approaches of teaching nursing personnel within the military health care setting the AHCPR pressure ulcer guidelines.

TECHNICAL APPROACH:

PROGRESS: No. of Subjects Enrolled - To Date:
 During FY96:

Detail Summary Sheet

Prot No: TAMC 38H96

Status: Ongoing

TITLE: Preterm Labor: PCR Method Identifying Amniotic Bacteria

Start date:

Est Comp Date:

Principal Investigator: COL Laurie J. Davis, AN

Department/Section: Nursing/
Facility: TAMC

Associate Investigator: LTC Thomas H. Miller, AN; MAJ Glenn R. Markenson, MC; MAJ Nathan J. Heoeldtke, MC; MAJ Curtis L. Yeager, MS; CPT Aldous K. Wade, MS

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To develop bacteria-specific DNA primer sets and probes as a tool for typing bacteria in the PCR positive AF samples to differentiate clinical significant organisms from less threatening skin contaminants acquired during amniocentesis.

TECHNICAL APPROACH: Laboratory analysis.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 23H95

Status: Ongoing

TITLE: Peri and Post Operative Ketorolac and Management of Pain in Patients Undergoing Anterior Cruciate Ligament Reconstruction

Start date: Sep 95

Est Comp Date:

Principal Investigator: 2LT Kay Hadley, AN

Department/Section: Nursing/
Facility: TAMC

Associate Investigator: CDR John H. Wilckens, MC; MAJ Diana L. Ruzicka, AN;
MAJ Theresa Taylor, AN

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: To evaluate the effects of ketorolac on postoperative pain, nausea, vomiting, frequency of breakthrough pain, and length of hospital stay following Anterior Cruciate Ligament reconstruction surgery.

TECHNICAL APPROACH: Double-blind pain-regimen randomization.

MODIFICATION #1 (Aug96): Added associate investigator, change in route of administration.

MODIFICATION #2 (Sep96): Medication changes.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Roche Laboratories to supply research drugs and moneys for expenses. CRADA has been approved by all appropriate areas on our part. Awaiting okay from Roche Legal Department on the CRADA. We do not anticipate any problems. Start up will hopefully be in July. Have received national attention awards even without yet starting.

Detail Summary Sheet

Prot No: TAMC 25S96

Status: Ongoing

TITLE: Cancer Patients' Knowledge and Satisfaction Related to Pain Management Methods Used in Acute Care Settings on Oahu

Start date: Apr 96

Est Comp Date:

Principal Investigator: 1LT Lou Anne Johnston, AN

Department/Section: Nursing/
Facility: TAMC

Associate Investigator: Pat Kalua, MS; Cecilia Gordon, BSN; 1LT Paula K. Rubison, AN;
CPT Leslie Tuchmann, AN

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Continue

OBJECTIVE: To formulate a baseline of knowledge about patient satisfaction with the pain control methods currently used in the major medical centers on Oahu.

TECHNICAL APPROACH: Data will be gathered using a patient questionnaire/interview, chart review and institutional audit tool.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: TAMC 47H92

Status: Completed

TITLE: The Effect of Preoperative Teaching on Uncertainty in Surgical Patients

Start date: Sep 92

Est Comp Date: Mar 94

Principal Investigator: LTC Theresa V. Jones, AN

Department/Section: Nursing/Surgical
Facility: TAMC

Associate Investigator: LTC Sharon S. DeRuvo, AN

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Completed

OBJECTIVES: The purpose of this descriptive study is to determine using a repeated measures design (A X S) : What is the level of uncertainty in surgical patients prior to a structured preoperative teaching program? What is the effect of structured preoperative teaching on uncertainty prior to surgery? What is the level of uncertainty in surgical patients after surgical intervention? There are no medications involved in this study.

TECHNICAL APPROACH: A convenience sampling of 2 categories (same day surgery - DSA and ambulatory surgery - ASC) of adult (>18 yrs of age) patients who received their preoperative teaching in the Pre-admission Unit were randomly assigned to 1-of-4 groups and completed a 32-item Likert form scale survey entitled " Michsel Uncertainty in Illness Scale for Adults" at either 2 or 3 different times during the surgical experience:

Group: A	Time 1	Teaching	Time 2	Surgery	Time 3
Group: B	Time 1	Teaching		Surgery	Time 3
Group: C		Teaching	Time 2	Surgery	Time 3
Group: D	Time 1	Teaching	Time 2	Surgery	Time 3

MODIFICATION (Oct 92): Study design modification (four groups: one pre-test & one-of-three randomized post-test)

PROGRESS: No. of Subjects Enrolled - To Date: 144
During FY96: 0

It was found that some of the questions of the survey tool were reversed in meaning with respect to the survey tool scale. The data was re-entered into the computer. The study is now completed. Reports are being written for study presentation.

Detail Summary Sheet

Prot No: TAMC 29H95

Status: Ongoing

TITLE: Association of Fatigue and Preterm Birth in Active Duty Military Women

Start date: Aug 95

Est Comp Date: Oct 96

Principal Investigator: MAJ Nanette Liberatore, AN

Department/Section: Nursing/
Facility: TAMC

Associate Investigator: CDR Janice C. Stinson, NC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 7/23/96

Gifts: Tri-Svc Nrsg Grant

Decision: Continue

OBJECTIVE: (1) Describe the external environmental demands (marital status, social support, housing occupation, rank, life events, ethnicity) and internal environmental demands (age, diet patterns, weight gain, smoking, alcohol, sleep disturbance, depression, anxiety) as correlates of fatigue in pregnant active duty women; (2) Determine the relationship between the perception of fatigue severity at 22-26 weeks gestation and the incidence of preterm birth in active duty women; (3) Determine the relationship between self-reported occupational fatigue at 22-26 weeks gestation in active duty military women and the incidence of preterm birth.

TECHNICAL APPROACH: This study is a two-phase descriptive prospective cohort design in which participants are asked to provide information using questionnaires and a diary. In the second phase, the investigator will review inpatient records from the intrapartum hospitalization to review outcomes.

MODIFICATION (Jan96): Expand subject pool; added advertisement.

PROGRESS: No. of Subjects Enrolled - To Date: 58
During FY96: 58

Total number of enrolled subjects is 360 from a total of 4 sites including TAMC. No adverse effects.

Presentations: Literature review for study presented at all 4 sites (TAMC, Portsmouth, San Diego, Travis)

Preliminary results presentations scheduled for:

Nursing Research Symposium, Ft Eustice VA, Jun 96

Naval Medical Center, San Diego, Jun 96

TAMC, Jul 96

Detail Summary Sheet

Prot No: TAMC 32S96

Status: Ongoing

TITLE: Measuring the Acceptance of Adopting Computer-Based Patient Records by Healthcare Professionals

Start date: Jun 96

Est Comp Date:

Principal Investigator: MAJ Anita H. McCowen, AN

Department/Section: Nursing/
Facility: TAMC

Associate Investigator: Michele A. Vaineharrison, BS; COL Laurie J. Davis, AN; LTC Jo Ann Moyers, AN; MAJ Carolyn J. Johnson, AN

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To determine/identify the differences of attitudes towards and the acceptance level of computer-based patient record.

TECHNICAL APPROACH: Descriptive survey.

PROGRESS: No. of Subjects Enrolled - To Date:
 During FY96:

Detail Summary Sheet

Prot No: TAMC 65S94

Status: Completed

TITLE: The Use of Plants and Other Alternative Medicines by Contemporary Peoples of Hawaii

Start date: Oct 94

Est Comp Date: Dec 95

Principal Investigator: Patricia Nishimoto, DNS

Department/Section: Nursing/Medicine Hematology-Oncology
Facility: TAMC

Associate Investigator: Nina L. Etkin, PhD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Completed

OBJECTIVE: To investigate the use of plants and other alternative medicines from a biobehavioral perspective that explores the cultural constructions of "folk" preventive and therapeutic strategies and links that to pharmacologic assessments through laboratory and literature study of botanicals and commercial preparations.

TECHNICAL APPROACH: Survey.

PROGRESS: No. of Subjects Enrolled - To Date: 76
During FY96: 0

Study is completed; 76 patients have been enrolled since the official start (approximately one year ago). There were no untoward effects. Data analysis is being completed.

Detail Summary Sheet

Prot No: TAMC 15R96

Status: Ongoing

TITLE: The Learning and Using New Approaches to Research (LUNAR) Project: A Description of the Population of Individuals Who Seek Health Care at Emergency Departments

Start date: Dec 95

Est Comp Date:

Principal Investigator: MAJ Kristen L. Palaschak, AN

Department/Section: Nursing/
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 1/23/96
Decision: Continue

OBJECTIVE: To describe the Emergency Department (ED) consumer of the 1990's--ie, (a) to examine ED consumers' demographic profile; (b) to examine the differences in use of the ED according to demographic characteristics; (c) to examine the relationships among selected emergency care variables.

TECHNICAL APPROACH: Descriptive study examining medical records.

PROGRESS: No. of Subjects Enrolled - To Date:
 During FY96:

Detail Summary Sheet

Prot No: TAMC 57H96

Status: Ongoing

TITLE: Emergency Department (ED) Visits for Asthma in Hawaii: Assessing the Relative Contributions of Disease Severity and Patient Self Management

Start date: Oct 96

Est Comp Date:

Principal Investigator: MAJ Kristen L. Palaschak, AN

Department/Section: Nursing/
Facility: TAMC

Associate Investigator: Edwin P. Gramlich, MD; Beth E. Waitzfelder, MA

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/24/96
Decision: Continue

OBJECTIVE: To determine (1) the extent to which Emergency Department (ED) visits for asthma are a result of poor self-management by patients as opposed to disease severity, (2) the proportion of patients who are familiar with self-management techniques, (3) the proportion of patients not utilizing self-management skills among those who are familiar with them, (4) factors related to the employment of self-management skills among patients who are familiar with them.

TECHNICAL APPROACH: This is a descriptive study, using focus groups and a patient questionnaire to profile asthma patients who visit EDs in Hawaii.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: TAMC 2H96

Status: Ongoing

TITLE: Thiopental Versus Propofol: A Study of the Incidence of Postoperative Nausea and Vomiting

Start date: Nov 95

Est Comp Date:

Principal Investigator: CPT Michelle Rosecrans, AN

Department/Section: Nursing/
Facility: TAMC

Associate Investigator: CPT Donald L. VanDam, AN; CPT Frederick Rice, AN;
CPT Jacqueline A. Sheehan, AN; CPT William P. Barras, AN; 1LT Brad Robison, AN

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 1/23/96
Decision: Continue

OBJECTIVE: To compare preoperatively administered thiopental vs propofol in the incidence of postoperative nausea and vomiting.

TECHNICAL APPROACH: Double-blind study design.

MODIFICATION (Jan96): Dose change.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: TAMC 24S96

Status: Ongoing

TITLE: Evaluation of the Effects of a Pain Management Service on Provider and Patient Outcomes

Start date: Apr 96

Est Comp Date:

Principal Investigator: MAJ Diana L. Ruzicka, AN

Department/Section: Nursing/
Facility: TAMC

Associate Investigator: LTC Don J. Daniels, MC; CPT Margaret A. Collier, AN; 1LT Lou Anne Johnston, AN; 1LT Doris E. Grimes, AN; 1LT Sylvia F. Perez, AN; COL Laurie J. Davis, AN; LTC Sharon S. DeRuvo, AN

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Continue

OBJECTIVE: To evaluate the efficacy of the Pain Management Service . Specifically, to investigate whether the Pain Management Service resulted in better educated health care providers, improved documentation, and increased patient comfort and satisfaction.

TECHNICAL APPROACH: Pretest-posttest questionnaire/survey.

PROGRESS:

No. of Subjects Enrolled - To Date:	
During FY96:	

Detail Summary Sheet

Prot No: TAMC 56H96

Status: Ongoing

TITLE: A Description of Military Preschool Children's Home Environment in Oahu Using the Home Screening Questionnaire

Start date: Sep 96

Est Comp Date:

Principal Investigator: 1LT Jennifer A. Whitton, AN

Department/Section: Nursing/

Facility: TAMC

Associate Investigator: CPT Amanda McNulty, AN

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 9/24/96

Gifts:

Decision: Continue

OBJECTIVE: To identify the correlation between parental age, marital status, socioeconomic status, and parental education and the high risk status for developmental delay.

TECHNICAL APPROACH: Home Screening Questionnaire.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: TAMC 16S93

Status: Completed

TITLE: A Comparison of the Perceived Stressors and Coping Strategies between Two Different Age Groups of Newly Accessed Army Nurse Corps Officers

Start date: Jun 93

Est Comp Date: Jun 94

Principal Investigator: LTC Paulette L. Williams, AN

Department/Section: Nursing/
Facility: TAMC

Associate Investigator: LTC Lorna R. Chatmon, AN; LTC Bridget A. Davis, AN; MAJ Gloria G. Woods, AN; MAJ Janis P. Tyrell-Smith, AN; 1LT Bernita L. Johnson, MS

Key Words: stress; hardiness; nurses; Army

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Completed

OBJECTIVES: This is a cross-sectional descriptive, comparative study design. No medications are involved in this study. Type of subject population observed: Newly accessed Army Nurses assigned to Tripler Army Medical Center.

TECHNICAL APPROACH: A total of 125 questionnaires were distributed to TAMC newly accessed Army Nurses. Four different tools were administered to include an open-ended questionnaire. Presently the data is being collected for statistical analysis.

PROGRESS: No. of Subjects Enrolled - To Date: 250
During FY96: 0

Data collection and analysis is completed. Study is complete. There were no differences between the groups in their stress levels. There were differences between the two groups for APRT pass rate and weight standards. The group over 35 did better than the group under 35.

Detail Summary Sheet

Prot No: TAMC 38H94

Status: Completed

TITLE: Effect of Placental Removal On Postcesarean Endometritis

Start date: Apr 94

Est Comp Date: Nov 94

Principal Investigator: CPT Deborah S. Lasley, MC

Department/Section: Obstetrics & Gynecology/
Facility: TAMC

Associate Investigator: MAJ Michael K. Yancey, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Completed

OBJECTIVE: To determine if there is a difference in placental removal methods (spontaneous versus manual extraction) with regards to postoperative infectious morbidity.

TECHNICAL APPROACH: Random assignment of 200 women scheduled for cesarean deliveries to one-of-two different placental removal treatment groups. Then subsequent comparison (with respect to frequency of endometritis & wound infection) of these groups.

PROGRESS: No. of Subjects Enrolled - To Date: 159
During FY96: 96

Total US participants: 331

Total TAMC participants: 159

Completing the number crunching now.

Presented to American college of Obstetrics and Gynecology Armed Forces District in Reno, Nevada (Nov 1994).

Detail Summary Sheet

Prot No: TAMC 69H94

Status: Completed

TITLE: The Relationship of Bacterial Contamination and Interleukin-6 in Amniotic Fluid in Preterm Labor and Delivery

Start date: Oct 94

Est Comp Date: May 95

Principal Investigator: MAJ Glenn R. Markenson, MC

Department/Section: Obstetrics & Gynecology/
Facility: TAMC

Associate Investigator: Rodger K. Martin, PhD; MAJ Michael K. Yancey, MC; MAJ Katherine Foley, MC

Key Words:

Funding: FY 95: FY 96:
 Gifts: MRDC DWHRP \$ to MAMC

Periodic Review Date: 3/26/96
Decision: Completed

OBJECTIVE: (a) To determine differences in gestation length between pregnancies with and without bacteria in the amniotic fluid detected utilizing the polymerase chain reaction (PCR); (b) To ascertain the relationship between the presence of bacteria detected using the PCR and elevated concentrations of interleukin-6 in amniotic fluid.

TECHNICAL APPROACH: Prospective amniotic fluid collection.

PROGRESS: No. of Subjects Enrolled - To Date: 44
During FY96: 44

The study is completed, the total number of patients enrolled from TAMC was 44.

Results: A total of 54 patients were enrolled (10 from MAMC), and of these 36 (67%) delivered preterm. The mean age of entry was 32.5 weeks, and the mean age at delivery was 35.6 weeks. 32 (60%) were positive for bacteria by PCR. In all cases where bacteria cultures were positive, the PCR study was positive. 9.2% of patients were culture positive. The PCR positive group has significantly lower birthweights and time from amniocentesis to delivery. Although the PCR positive group delivered earlier, this was not statistically significant. 9 samples were positive for elevated IL-6, 6 of which were PCR positive and 3 negative.

Conclusions: PCR is a sensitive technique for detecting bacteria in amniotic fluid. Pregnancy outcomes are different between PCR positive and negative studies in amniotic fluid. Not all pregnancies with elevated IL-6 had evidence of bacteria by PCR in the amniotic fluid.

Detail Summary Sheet

Prot No: TAMC 7H95

Status: Ongoing

TITLE: Epidural Anesthesia, An Aid to External Cephalic Version

Start date: Dec 94

Est Comp Date:

Principal Investigator: CPT John A. Murphy, MC

Department/Section: Obstetrics & Gynecology/
Facility: TAMC

Associate Investigator: MAJ Michael K. Yancey, MC; LTC Don J. Daniels, MC; MAJ Glenn R. Markenson, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: (a) To determine the impact of epidural anesthesia on the success rate of External Cephalic Version (ECV); (b) To confirm the safety of utilizing epidural anesthesia for ECV.

TECHNICAL APPROACH: Prospective randomization of patients with a breech or transverse lie into ECV with or without epidural.

PROGRESS: No. of Subjects Enrolled - To Date: 30
During FY96: 0

The number of successful ECV's with and without epidural anesthesia are about the same. It is too early to make any conclusions. There have not been any poor outcomes in the epidural or the no epidural group.

Detail Summary Sheet

Prot No: TAMC 56H94

Status: Terminated

TITLE: Intrapartum Chemoprophylaxis for Group B Stretococcus in Otherwise Low Risk Obstetrical Patients-Impact on Maternal Complications and Neonatal Early-Onset Group B Streptococcal Disease

Start date: Aug 94

Est Comp Date: Jul 96

Principal Investigator: CPT Holly L. Olson, MC

Department/Section: Obstetrics & Gynecology/
Facility: TAMC

Associate Investigator: MAJ Michael K. Yancey, MC; MAJ Jeffrey V. Paul, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Terminated

OBJECTIVE: (1) Determine whether intrapartum antibiotic prophylaxis for "low-risk" pregnant women who are known to be GBS carriers significantly reduces the incidence of maternal post-partum complications such as GBS cystitis, pyelonephritis, and endometritis & neonatal early-onset GBS sepsis; (2) Determine the incidence of complications (eg allergic reactions, anaphylaxis) from intrapartum antibiotic prophylaxis; (3) Determine the percentage of women who would choose to receive intrapartum antibiotic prophylaxis despite the risk of anaphylaxis.

TECHNICAL APPROACH: Randomized, double-blind, placebo-controlled study.

PROGRESS: No. of Subjects Enrolled - To Date: 9
During FY96: 0

There were no subjects enrolled onto study during the past year. Study is unable to be completed due to recent protocol changes in CDC guidelines and also for lack of patient willingness to participate in placebo arm of trial.

Detail Summary Sheet

Prot No: TAMC 29H96

Status: Ongoing

TITLE: Hyperspectral Fluorescence Imaging of Cervical Topography, with Comparison to the Papanicolaou Smear and Cervical Histopathology - A Pilot Study

Start date:

Est Comp Date:

Principal Investigator: MAJ Mary F. Parker, MC

Department/Section: Obstetrics & Gynecology/
Facility: TAMC

Associate Investigator: Gregory C. Mooradian, PhD; Dennis M. O'Connor, MD; LTC James E. Mark, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 4/23/96
Decision: Continue

OBJECTIVE: (1) To correlate cervical spectral images with colposcopic appearances, Pap smear results, and cervical histopathology; (2) To determine if the SETS hyperspectral fluorescence imaging technique has the potential to discriminate among different types of cervical lesions in-situ.

TECHNICAL APPROACH: Correlation of cervical spectral images with colposcopic appearances, Pap smear results, and cervical histopathology.

MODIFICATION (Sep96): Added control group.

PROGRESS: **No. of Subjects Enrolled - To Date:**
 During FY96:

Detail Summary Sheet

Prot No: TAMC 71H94

Status: Completed

TITLE: The Transplacental Transfer of Sulbactam Sodium when Co-administered with Ampicillin to Laboring Patients with Chorioamnionitis

Start date: Oct 94

Est Comp Date: Jun 95

Principal Investigator: CPT John C. Stitt, MC

Department/Section: Obstetrics & Gynecology/
Facility: TAMC

Associate Investigator: MAJ Michael K. Yancey, MC; MAJ Glenn R. Markenson, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Completed

OBJECTIVE: To determine the percent transfer of sulbactam sodium when co-administered with ampicillin in laboring patients with clinical intraamniotic infections.

TECHNICAL APPROACH: Maternal and umbilical cord blood level correlations.

PROGRESS: No. of Subjects Enrolled - To Date: 19
During FY96: 0

Study was completed 10 Dec 95.

Sulbactam was noted to cross the placenta to the fetus when administered to laboring patients with chorioamnionitis. Presentation of these results is planned for the ACOG Armed Forces Distric Meeting in Nashville, TN this fall.

Detail Summary Sheet

Prot No: TAMC 20H96

Status: Ongoing

TITLE: A Pilot Study of the Impact of Glucose Loading on Acute Changes in the Amniotic Fluid Index in Gestational Diabetics vs. Pregnant Non-Diabetics

Start date: Apr 96

Est Comp Date:

Principal Investigator: CPT William L. Sun, MC

Department/Section: Obstetrics & Gynecology/
Facility: TAMC

Associate Investigator: MAJ Glenn R. Markenson, MC; MAJ Michael K. Yancey, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Continue

OBJECTIVE: To determine the effects of a 100 gm glucose load on the amniotic fluid index in diabetic and non-diabetic pregnancies.

TECHNICAL APPROACH: Subjects will receive an ultrasound and give a blood sample for a baseline prior to ingesting a 100 gm glucose solution. A blood sample will be drawn every hour for 3 hours for glucose levels. After the glucose testing is complete, another ultrasound will be performed.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 32H94

Status: Ongoing

TITLE: Efficacy of Prepidil Gel Versus Pharmacy Prepared Prostaglandin E2 Gel for Pre-induction Cervical Ripening

Start date: Mar 94

Est Comp Date: Dec 94

Principal Investigator: CPT David L. Williams, MC

Department/Section: Obstetrics & Gynecology/
Facility: TAMC

Associate Investigator: LTC Romeo P. Perez, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 2/27/96

Gifts: NO GIFT 3/31/94

Decision: Continue

OBJECTIVE: To determine the effectiveness of two cervical ripening gels: one prepared at our pharmacy, and one commercially prepared called Prepidil.

TECHNICAL APPROACH: Double-blind prospective design.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study was approved by the IRB, but has not been implemented due to procurement-formulation difficulties.

Detail Summary Sheet

Prot No: TAMC 19H96

Status: Ongoing

TITLE: Double-blind Placebo-controlled Evaluation of Azithromycin for Treatment of Cat Scratch Disease (CSD)

Start date: Mar 96

Est Comp Date:

Principal Investigator: COL James W. Bass, MC

Department/Section: Pediatrics/
Facility: TAMC

Associate Investigator: LTC Judy M. Vincent, MC; MAJ Denise M. Demers, MC;
MAJ Francis J. Malone, MC; COL Donald A. Person, MC; COL Joel D. Brown, MC; Cheryl
L. Sisler, MD; Debora S. Chan, RPH; Leonard N. Slater, MD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Continue

OBJECTIVE: To evaluate the clinical effectiveness of treatment of patients with typical Cat Scratch Disease (CSD) with azithromycin.

TECHNICAL APPROACH: Prospective, double-blind placebo-controlled treatment determined by randomization.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

New start.

Detail Summary Sheet

Prot No: TAMC 60H91

Status: Completed

TITLE: Comparison of Mupirocin (Bactroban), Bacitracin, and Cephalexin (Keflex) in the Treatment of Impetigo in Children

Start date: Oct 91

Est Comp Date: Oct 93

Principal Investigator: CPT Theresa M. Becker, MC

Department/Section: Pediatrics/

Facility: TAMC

Associate Investigator: COL James W. Bass, MC; Debora S. Chan, RPH; MAJ Francis J. Malone, MC; COL L. Harrison Hassell, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 8/27/96

Gifts:

Decision: Completed

OBJECTIVE: To compare the efficacy of these three regimens in the treatment of impetigo in children in a prospective double blinded fashion.

TECHNICAL APPROACH: Double-blind clinical trial. Patient given cream to apply topically and liquid to take p.o. (one active agent (Bactroban, Bacitracin or Keflex); the other is placebo). Patient reseen at 5 & 10 days of therapy to evaluate efficacy.

PROGRESS: No. of Subjects Enrolled - To Date: 32

During FY96: 3

Since I have returned from maternity leave in January, we have enrolled 3 new patients. One had to be eliminated because the diagnosis was wrong. The study is completed. Manuscript in progress.

Detail Summary Sheet

Prot No: TAM 3S95

Status: Ongoing

TITLE: Infant Care Practices and Their Relationship to Gastroesophageal Reflux

Start date: Dec 94

Est Comp Date: Mar 96

Principal Investigator: LTC Charles W. Callahan Jr., MC

Department/Section: Pediatrics/

Facility: TAMC

Associate Investigator: Cheryl L. Sisler, MD; MAJ Cheryl Little, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 12/5/95

Gifts:

Decision: Continue

OBJECTIVE: To assess the relationship, if any, between infant care practices and gastroesophageal reflux (GER).

TECHNICAL APPROACH: Questionnaire

PROGRESS: No. of Subjects Enrolled - To Date: 380

During FY96: 0

There were 380 patient questionnaires completed. Data processing is underway. No adverse events. An initial paper has been submitted for publication (Jan96).

Detail Summary Sheet

Prot No: TAMC 73H94

Status: Ongoing

TITLE: Event Recordings of High Risk Infants on Apnea Monitors

Start date: Mar 95

Est Comp Date: Oct 96

Principal Investigator: LTC Charles W. Callahan Jr., MC

Department/Section: Pediatrics/
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95: FY 96:
 Gifts: collab from KMCWC/UH

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: To assess and compare the incidence of important events documented by monitoring in siblings of SIDS victims, infants with apnea of infancy, preterm infants, and normal infants; (b) To determine the antecedent medical, demographic, behavioral and physiologic characteristics that predict the incidence of clinically important events documented by monitoring; (c) To assess the association between the occurrence of clinically important events documented by monitoring and adverse neurodevelopmental status at one-year of age; (d) To assess the compliance achieved during documented monitoring and the factors that influence compliance.

TECHNICAL APPROACH: Event recordings in the home.

PROGRESS: No. of Subjects Enrolled - To Date: 16
During FY96: 5

This study is part of a National Institutes of Health Multi-Center Trial of the impact of home health monitoring on infants at risk for SIDS. Tripler is one of the two major sites on Oahu, with Kapiolani the second. The study is progressing slowly, and the NIH granted a three year extension to the study this summer and we hope to continue to enroll patients through next summer.

No major publications have been made since the study is still in the data collection phase.

Detail Summary Sheet

Prot No: TAMC 26D84

Status: Ongoing

TITLE: Use of Sodium Allopurinol to Control Hyperuricemia in Patients with no Therapeutic Alternative

Start date: Sep 84

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: COL Jeffrey L. Berenberg MC; MAJ Paul Fishkin, MC

Key Words: hyperuricemia; allopurinol

Funding: FY 95:
Gifts: Allopurinol

FY 96:

Periodic Review Date: 7/23/96
Decision: Continue

OBJECTIVE: To provide a water soluble form of allopurinol that can be given intravenously to patients with hyperuricemia who are too ill to take oral medication.

TECHNICAL APPROACH: This is a "convenience" protocol to make an uncommonly required dosage form available for use without the need for individual, special exception approval of the committee for each patient. This study also centralizes and simplifies the procedures for requesting the drug for patients. It is anticipated that 1-2 patients a year will be treated on this protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 12
During FY96: 0

No changes, protocol to continue as a "convenience protocol" for use on an as-needed basis. Status is ongoing.

Detail Summary Sheet

Prot No: TAMC 14H96

Status: Ongoing

TITLE: A Pilot Study to Assess Vocal Changes in Children With Rheumatic Disease

Start date: Jan 96

Est Comp Date:

Principal Investigator: Lorna Hu, MS

Department/Section: Pediatrics/EFMP

Facility: TAMC

Associate Investigator: Dorothy D. Craven, MS; Lianne S. N. Wong, BS; COL Donald A. Person, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 2/27/96

Gifts:

Decision: Continue

OBJECTIVE: To determine if children with rheumatic diseases have measurable differences in fundamental voice frequencies from normative values, using the Visi-Pitch instrument.

TECHNICAL APPROACH: Vocal measurements will be obtained using the Visi-Pitch, a clinical instrument designed for the assessment and treatment of communication disorders.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY95:

Detail Summary Sheet

Prot No: TAMC 62H94

Status: Ongoing

TITLE: Umbilical Cord Interleukin-6 and CRP Levels in Early Predictors for Neonatal Sepsis

Start date: Dec 94

Est Comp Date: Dec 96

Principal Investigator: CPT Sarah L. Lavallee, MC

Department/Section: Pediatrics/

Facility: TAMC

Associate Investigator: MAJ Michael K. Yancey, MC; LTC Robert V. Jarrett, MC;
MAJ Rebecca C. Bent, MC; MAJ Jeffrey V. Paul, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 6/25/96

Gifts:

Decision: Continue

OBJECTIVE: To determine if elevated levels of IL-6 and CRP in cord blood of term infants delivered to women with chorioamnionitis are a sensitive and specific early predictor of neonatal sepsis.

TECHNICAL APPROACH: Umbilical cord blood levels.

PROGRESS: No. of Subjects Enrolled - To Date: 55
During FY96: 15

Nothing to report.

Detail Summary Sheet

Prot No: TAMC 33T93

Status: Completed

TITLE: Pediatric Intubation Training Utilizing the Feline Model

Start date: May 93

Est Comp Date: May 96

Principal Investigator: COL Donald A. Person, MC

Department/Section: Pediatrics/
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/30/96
Decision: Completed

OBJECTIVES: This training is designed to teach physicians and other health care professionals the basic knowledge and endotracheal intubation skills required to resuscitate a neonate (newborn) or infant.

TECHNICAL APPROACH: Laboratory simulation.

PROGRESS: No. of Subjects Enrolled - To Date: 119
During FY96: 0

All work on this project has been on hold for the past two years, pending animal importation.

Detail Summary Sheet

Prot No: TAMC 45H94

Status: Ongoing

TITLE: Leukocytes in Urine as Indicators of Renal Damage in Patients with Systemic Lupus Erythematosus

Start date: May 94

Est Comp Date: Dec 98

Principal Investigator: COL Donald A. Person, MC

Department/Section: Pediatrics/
Facility: TAMC

Associate Investigator: Lucille H. Kimura, PhD; Karen M. Yamaga, PhD; Barbara A. Brooks, PhD; James E. Musgrave, MD; COL L. Harrison Hassell, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To determine if analysis of cells found in the urine will aid in the detection of early kidney damage in patients with systemic lupus erythematosus (SLE) or other diseases (to categorize type of T cells that may be involved in nephritis; to determine chronicity of antigenic stimulation and identify cytokines that participate in inflammatory reaction).

TECHNICAL APPROACH: Characterization of mononuclear leukocytes from the urine of SLE patients by flow cytometry, immunocytochemistry and cytokine analysis.

PROGRESS: No. of Subjects Enrolled - To Date: 2
During FY96: 0

To date, 25 SLE patients have been studied. Adult patients were referred from Queen's Medical Center and pediatric patients from Kapiolani Medical Center and TAMC (2 patients).

Studies have concentrated on serial analysis of urine samples from 12 pediatric patients who visit the Lupus Clinic at Kapiolani Medical Center for routine monthly evaluation. Results from routinely ordered blood and urine tests have been used to indicate periods of disease flaring. As mentioned in the 1 Dec 95 Progress Report, a leukocyte mononuclear cell pattern of the urine sediment was observed on initial diagnosis or during active kidney disease.

Most of the urine mononuclear cells were monocytes, as determined by light microscopy and flow cytometry using light scatter and three-color immunofluorescence. The remainder of the mononuclear cells were T lymphocytes, with a higher proportion of T suppressor (CD8+) cells than T helper (CD4+) lymphocytes. Although corticosteroids are known to suppress T helper cells, resulting in low CD4:CD8 peripheral blood ratios, the ratios in urine were even lower. The role of CD8+ T cells in lupus nephritis will continue to be a focus of this study.

Another area of study has been the characterization of T cell cytokine mRNA expression in urine cells. At present, the low yield of lymphocytes in urine has precluded their isolation for cytokine analysis. However, as a first approximation, comparative reverse transcriptase (RT)-PCR has been done on urine cell populations either predominantly epithelial or mononuclear. The epithelial cells did not express IL-2, IL-6 or IFN-gamma, but did have IL-4 mRNA and TNF-alpha mRNA. Urine mononuclear cells expressed IL-4, TNF-alpha, IFN-gamma and IL-6. In one patient studied, IFN-gamma mRNA was detected in both blood and urine mononuclear cells, however, only urine cells expressed IL-4 mRNA.

Extensive analysis of IL-6 has begun because it has been detected in urine samples from patients with mesangial proliferative glomerulonephritis but not other types of glomerulonephritis. Studies of chemokines that attract monocytes are being planned to determine the reason for the predominance of monocytes in urine samples.

ADVERSE EFFECTS: None

PRESENTATIONS: None

PUBLICATIONS: Data are being summarized for potential publication.

Detail Summary Sheet

Prot No: TAMC 46H94

Status: Ongoing

TITLE: Childhood Myositis Heterogeneity Study

Start date: May 94

Est Comp Date: Indef

Principal Investigator: COL Donald A. Person, MC

Department/Section: Pediatrics/
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To examine a large cohort of childhood idiopathic inflammatory myopathies (IIM) patients nationwide to see if similar serologic and immunogenetic markers delineate groups of children with myositis who share similar clinical features, disease courses, responses to therapy and prognosis. In addition, a serum, plasma, and lymphocyte bank will be established for future studies.

TECHNICAL APPROACH: Serologic and immunogenetic marker delineation.

PROGRESS: No. of Subjects Enrolled - To Date: 6
During FY96: 2

Two (2) abstracts presented at recent ACR (American College of Rheumatology) meeting and published in Arthritis and Rheumatism.

Currently updating protocol, per CIRO's request.

Detail Summary Sheet

Prot No: TAMC 40H96

Status: Ongoing

TITLE: A Pilot Study of Neuropsychological Outcome in Children with Kawasaki Disease

Start date: Aug 96

Est Comp Date:

Principal Investigator: COL Aileen B. Thong, MC

Department/Section: Pediatrics/Developmental
Facility: TAMC

Associate Investigator: LTC Frederick N. Garland, MS; Nancy R. Holmes, PhD; CPT Edwin C. Supplee, MS; COL Donald A. Person, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: To define the relationship between Kawasaki Disease and subsequent learning and behavioral problems.

TECHNICAL APPROACH: Longitudinal study of children diagnosed and treated for Kawasaki Disease.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 14H91

Status: Ongoing

TITLE: Perinatal HIV Infection: Epidemiology and Natural History

Start date: Feb 91

Est Comp Date: Feb 96

Principal Investigator: LTC Judy M. Vincent, MC

Department/Section: Pediatrics/Infectious Disease

Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 2/27/96

Gifts:

Decision: Continue

OBJECTIVE: 1) To develop a standardized procedure for diagnosis and management of pregnant women who are infected with human immunodeficiency virus (HIV) and their newborn infants; 2) To systematically collect clinical, laboratory, and epidemiologic data describing the course and natural history of perinatal HIV infection.

TECHNICAL APPROACH: Pregnant women who are HIV positive will be approached by the principal investigator and asked for permission to follow them for the effect of their pregnancy over the course of their HIV infection and also to follow their infant with physical exams and lab tests (HIV culture and PCR) to determine whether the infant has acquired the infection.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

Same report as last year. There have been no adverse effects. No conclusions thus far. No HIV+ women delivered babies in since FY1995. This protocol still has value in case the situation arises.

Detail Summary Sheet

Prot No: TAMC 21H96

Status: Ongoing

TITLE: Antimicrobial Drug Suspensions: A Blind Comparison of Taste of Thirteen Commonly Prescribed Oral Liquids Including Clarithromycin, Cefuroxime and Azithromycin

Start date: Mar 96

Est Comp Date:

Principal Investigator: Debora S. Chan, RPH

Department/Section: Pharmacy/
Facility: TAMC

Associate Investigator: MAJ Denise M. Demers, MC; COL James W. Bass, MC; John R. Claybaugh, PhD; LTC David A. Kotzin, MS

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Continue

OBJECTIVE: To rate the perception of taste, texture, smell and aftertaste of thirteen oral, liquid amoxicillin suspensions in thirty, blinded adult volunteers.

TECHNICAL APPROACH: Taste test.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 27L95

Status: Ongoing

TITLE: Stability of Extemporaneously Prepared Lactobacillus Acidophilus 27%
Suppositories

Start date: Aug 95

Est Comp Date: Dec 96

Principal Investigator: Debora S. Chan, RPH

Department/Section: Pharmacy/
Facility: TAMC

Associate Investigator: Bardwell Eberly, MT

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 7/23/96
Decision: Continue

OBJECTIVE: To determine the growth activity of Lactobacillus acidophilus (LA) bacteria when extemporaneously prepared as suppositories over a 60-day period in an attempt to determine guidelines for an acceptable expiration date.

TECHNICAL APPROACH: Laboratory cultures.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

This is a basic science (lab) study. Working on baseline data and calibration of instrumentation.

Detail Summary Sheet

Prot No: TAMC 60L94

Status: Ongoing

TITLE: Stability of Cholestyramine 5% in an Ointment Base

Start date: Oct 94

Est Comp Date: Dec 96

Principal Investigator: Debora S. Chan, RPH

Department/Section: Pharmacy/
Facility: TAMC

Associate Investigator: MAJ Nelson W. Rebert, MS

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: To determine the exchange capacity and the chloride content of Questran Light 5% cholestyramine base and 5% cholestyramine standard prepared in the ointment base Aquaphor over a 90-day period in an attempt to determine guidelines for an acceptable expiration date.

TECHNICAL APPROACH: Laboratory study.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

There are no patients enrolled because study is a basic science (lab) study. Working on baseline data and calibration of instrumentation.

Detail Summary Sheet

Prot No: TAMC 52H96

Status: Ongoing

TITLE: Granisetron/Dexamethasone vs Ondansetron/Dexamethasone in the Prevention of Acute Nausea & Vomiting Due to Cisplatin Chemotherapy Regimens: A Multicenter, Triple-Blind, Randomized, Parallel Group Study

Start date: Sep 96

Est Comp Date:

Principal Investigator: CPT Laurel S. Fields, MS

Department/Section: Pharmacy/
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: (1) To assess the antiemetic efficacy of granisetron versus ondansetron in the prevention of acute nausea and vomiting in highly emetogenic chemotherapy regimens. (2) To assess the safety of each study regimen in terms of side effect profiles.

TECHNICAL APPROACH: This is a randomized, triple-blind, multicenter, parallel group study of patients comparing ondansetron + dexamethasone or granisetron + dexamethasone for the prevention of acute nausea and vomiting.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 27H94

Status: Ongoing

TITLE: Comparison of Amoxicillin, Cefixime, and Cefpodoxime in Pediatric Patients

Start date: Feb 94

Est Comp Date: Dec 94

Principal Investigator: Susan K. Higa, RPH

Department/Section: Pharmacy/
Facility: TAMC

Associate Investigator: Debora S. Chan, RPH; COL James W. Bass, MC; Priscilla J. Alfaro, MD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/96
Decision: Continue

OBJECTIVE: To determine compliance rates for three different drugs.

TECHNICAL APPROACH: Compliance rate assessment among six groups of patients (3 drugs x 2 assessment days).

PROGRESS: No. of Subjects Enrolled - To Date: 45
During FY96: 0

Enrollment of patients temporarily halted in order to perform power analysis. Analysis of specimens collected began in Dec 95.

Detail Summary Sheet

Prot No: TAMC 36H96

Status: Ongoing

TITLE: Cost-Effectiveness of Misoprostol vs Omeprazole in the Prevention of NSAID-Associated Significant Gastrointestinal Symptoms in High Risk Patients as it Relates to Total Resource Utilization

Start date: Aug 96

Est Comp Date:

Principal Investigator: Blain H. Yoshinobu, PharmD

Department/Section: Pharmacy/
Facility: TAMC

Associate Investigator: Edward Jai; COL James McKoy, MC; MAJ Steven P. Lawrence, MC; C. Buckner; MAJ Steven W. Hammond, MC; LTC David A. Kotzin, MS

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To determine the cost-effectiveness of misoprostol vs omeprazole in the prevention of NSAID-associated significant occurrences of symptoms and problems in high risk patients as it relates to total resource utilization in order to improve clinical and cost outcomes at Tripler Army Medical Center.

TECHNICAL APPROACH: Patients will be randomized to one-of-two treatment groups and followed for six months. Total resource utilization (visits, consults, hospitalizations) will be assessed.

MODIFICATION (Jul96): Design change.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 55H96

Status: Ongoing

TITLE: Child Abuse Potential Inventory Questionnaire and Analysis

Start date: Oct 96

Est Comp Date:

Principal Investigator: JoEllen Cerny, MSN

Department/Section: Preventive Medicine/ASPECTS

Facility: TAMC

Associate Investigator: Kathryn English, MPA

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 9/24/96

Gifts:

Decision: Continue

OBJECTIVE: (1) To determine if risk factors for child abuse can be identified in the ASPECTS patient population. (2) To determine whether participation in the ASPECTS program helps reduce the potential for child abuse.

TECHNICAL APPROACH: Questionnaire.

PROGRESS:

No. of Subjects Enrolled - To Date:	
During FY96:	

Detail Summary Sheet

Prot No: TAMC 30H92

Status: Terminated

TITLE: An Evaluation of Initial Two-Step Tuberculin Skin Testing at Tripler Medical Center

Start date: May 92

Est Comp Date: Aug 94

Principal Investigator: Annette Vares,

Department/Section: Preventive Medicine/OCH

Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Terminated

OBJECTIVE: To determine the prevalence of the so-called "booster effect" in a population of health care workers at a large military medical center.

TECHNICAL APPROACH: Apply standard Tuberculin Skin Test to all inprocessing employees to evaluate the usefulness of the procedure in the management of tuberculosis control programs.

PROGRESS: No. of Subjects Enrolled - To Date: 900
During FY96: 0

Data collected on 900 persons. The study was terminated upon COL Mumm's retirement.

Preliminary results presented to the US Army Preventive Medicine Officers Symposium.

Detail Summary Sheet

Prot No: TAMC 49H92

Status: Terminated

TITLE: The Safety of Using ELISA c100-3 Hepatitis C Testing in the Screening of Random Blood Donors

Start date: Oct 92

Est Comp Date: Oct 94

Principal Investigator: Stephen Yamada, MT

Department/Section: Preventive Medicine/Health Physics Ofc
Facility: TAMC

Associate Investigator: MAJ Kent C. Holtzmuller, MC; COL Joseph C. Woods, MC;
MAJ Mark Pitt, MC; COL Maria H. Sjorgren, MC; Thomas W. McGovern

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Terminated

OBJECTIVES: This study will be done to evaluate the Hepatitis C ELISA test, a test which has poor sensitivity and specificity, in comparison with more advanced tests, the 4-RIBA and RNA polymerase chain reaction.

TECHNICAL APPROACH: Subjects are selected based on their Hepatitis C test results. Those who test initially positive and have 2 subsequent repeat negatives on the same specimen are approached to participate in the study. Subjects are identified from the blood bank donor population as well as patients that are being evaluated for possible Hepatitis C infections.

PROGRESS: No. of Subjects Enrolled - To Date: 17
During FY96: 0

With the increase sensitivity of the newer ELISA HCV test, there were few patients who fit the criteria for enrollment into this study. Study was terminated in January 1996 due to insufficient subjects.

Detail Summary Sheet

Prot No: TAMC 3H96

Status: Ongoing

TITLE: Which Patients Will Require Psychiatric Readmission? Prospective Development and Validation of a Multivariable Predictive Model

Start date: Dec 95

Est Comp Date:

Principal Investigator: CPT Timothy R. Berigan, MC

Department/Section: Psychiatry/
Facility: TAMC

Associate Investigator: CPT Nathan S. Ellis, MC; MAJ Charles C. Engel Jr, MC; Raymond A. Folen, PhD; Marsha H. Graham, MSN

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/24/96
Decision: Continue

OBJECTIVE: To use patient, provider, and administrative data to develop a mathematical model defining the relative risk of readmission for each patients admitted to an inpatient psychiatric service at Tripler AMC.

TECHNICAL APPROACH: This is a descriptive, prospective, cohort study where each patient will be followed for 6 months after discharge and readmissions recorded.

MODIFICATION (Jan96): Risk change.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

This is a program development/evaluation as opposed to a research project.

Detail Summary Sheet

Prot No: TAMC 12H93

Status: Ongoing

TITLE: A Double Blind Study to Compare the Efficacy of Carbamazepine (CBZ) + Trazodone (TZD) versus Clonidine (CLD) + Trazodone (TZD) in the treatment of Post Traumatic Stress Disorder (PTSD)

Start date: Mar 93

Est Comp Date: Indef

Principal Investigator: MAJ Charles C. Engel Jr, MC

Department/Section: Psychiatry/
Facility: TAMC

Associate Investigator: MAJ Douglas W. Adams, MC; LTC Stephen C. Vance, MC; Edward S. Kubany, PhD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVES: The clinical picture of PTSD may include symptom clusters related to anxiety, mood, sleep disturbance and poor impulse control. The overall objective of this proposed study is to compare the efficacy of CBZ and CLD in combination with an antidepressant TZD in reducing target symptoms of PTSD in Vietnam Veterans.

TECHNICAL APPROACH: Treatment protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study has never been implemented - attempting to obtain funding support.

Detail Summary Sheet

Prot No: TAMC 31H95

Status: Ongoing

TITLE: Prevalence and Impact of Primary Care Somatization Patterns in Hawaii

Start date: Aug 95

Est Comp Date: Indef

Principal Investigator: MAJ Charles C. Engel Jr, MC

Department/Section: Psychiatry/

Facility: TAMC

Associate Investigator: Edwin P. Gramlich, MD; Beth E. Waitzfelder, MA; Neal Palafox, MD, MPH; LTC Dale S. Vincent, MC; LTC David D. Ellis, MC; Ann-Marie Horvath, MA

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 7/23/96

Gifts:

Decision: Continue

OBJECTIVE: (1) To study the prevalence of somatization among Hawaii resident attending primary care; (2) To determine the relationship of health care utilization and functional disability to somatization in this population; and (3) To study whether somatization prevalence and associated health care use and functional disability is different for different ethnic groups.

TECHNICAL APPROACH: Cross-sectional study of primary care patients at the time of clinical presentation.

ADDENDUM (Oct95): Revised consent.

PROGRESS: No. of Subjects Enrolled - To Date: 320

During FY96: 320

Essentially, all patients have been enrolled in FY96. Data collection is virtually complete and the project is on autopilot at this point. Dr. L. Harrison Hassell has agreed to be the PI upon my departure.

Detail Summary Sheet

Prot No: TAMC 39H93

Status: Ongoing

TITLE: A Double-blind Study to Compare the Efficacy of Carbamazepine (CBZ) Versus Diazepam (DZM) in the Treatment of Alcohol Withdrawal Syndrome (AWS)

Start date: Jun 93

Est Comp Date: Mar 96

Principal Investigator: CPT Jeffrey S. Harazin, MC

Department/Section: Psychiatry/
Facility: TAMC

Associate Investigator: LTC Wayne B. Batzer, MC; Thomas F. Ditzler, PhD; COL Russell D. Hicks, MC; CPT Janet M. Viola, AN; Anthony J. Holzgang, MD; Mary W. MacMillan

Key Words:

Funding: FY 95:
Gifts: VA-DOD appl

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVES: This study is necessary to substantiate or reject the hypothesis that Carbamazepine (CBZ) is more effective than Diazepam (DZM) in treating alcohol withdrawal syndrome (AWS).

TECHNICAL APPROACH: Double-blind study to compare carbamazepine (CBZ) vs diazepam in alcohol study.

MODIFICATION (Apr 95): Change evaluation tests.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

No patients have been enrolled in the study; we are still awaiting an answer on possible funding.

Detail Summary Sheet

Prot No: TAMC 50H94

Status: Completed

TITLE: Prevalence of Hepatitis C Virus in Alcoholics at an Inpatient Alcoholism Recovery Facility

Start date: Jun 94

Est Comp Date: Indef

Principal Investigator: Marjorie Heberle, MD

Department/Section: Psychiatry/Tri-SARF
Facility: TAMC

Associate Investigator: LTC Wayne B. Batzer, MC; MAJ Kent C. Holtzmuller, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Completed

OBJECTIVE: (a) To determine the prevalence/relationship of HCV and alcoholic intake; and
(b) To assess behavioral and environmental risk factors which might affect transmission.

TECHNICAL APPROACH: Blood draw & questionnaire following inpatient rehabilitation.

PROGRESS: No. of Subjects Enrolled - To Date: 326
During FY96: 0

Data collection was completed in FY95. Total number of subjects was 326; 21 were IV drug users. Total number of subjects positive for HCV antibody was 8, and seven of these were IV drug users. No publication so far.

Detail Summary Sheet

Prot No: TAMC 15H95

Status: Ongoing

TITLE: An Analysis of the Speech of Thought Disordered Subjects

Start date: Apr 95

Est Comp Date:

Principal Investigator: CPT Elizabeth W. Oates, MC

Department/Section: Psychiatry/

Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 4/23/96

Gifts:

Decision: Continue

OBJECTIVE: To evaluate speech patterns of patients with psychiatric conditions.

TECHNICAL APPROACH: Tape-recorded speech analysis.

PROGRESS: No. of Subjects Enrolled - To Date: 3

During FY96: 0

Hope to tape one to two more subjects then move into analysis phase. Recruitment has been slow and only three patients enrolled to date. No other findings/events to report.

Detail Summary Sheet

Prot No: TAMC 53H96

Status: Ongoing

TITLE: Proverb Interpretation in an Active Duty Population

Start date: Sep 96

Est Comp Date:

Principal Investigator: CPT Elizabeth W. Oates, MC

Department/Section: Psychiatry/
Facility: TAMC

Associate Investigator: CPT Scott D. Uithol, MC; MAJ Willard F. Quirk Jr, MC;
CPT Nathan S. Ellis, MC; CPT Harold J. Tiffany; MAJ Charles C. Engel Jr, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: To examine the sensitivity and specificity of proverb interpretation (between two groups: in-patient psychiatric evaluation setting versus active duty personnel)

TECHNICAL APPROACH: Cross sectional study.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

New start.

Detail Summary Sheet

Prot No: TAMC 37H96

Status: Ongoing

TITLE: Comparison of Methylphenidate and Guanfacine in a Child and Adolescent Outpatient Population with Attention-Deficit/Hyperactivity Disorder

Start date:

Est Comp Date:

Principal Investigator: CPT Jeffrey W. Weiser, MC

Department/Section: Psychiatry/
Facility: TAMC

Associate Investigator: David S. Weiss, PhD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To determine the efficacy and side-effects of methylphenidate and guanfacine in a preschool and school-age population diagnosed with Attention-Deficit/Hyperactivity Disorder (ADHD), with attention to subpopulations of ADHD and to effectiveness for aggressive behavior.

TECHNICAL APPROACH: Study will be done using a partially blinded (teacher and continuous performance task rater), double cross-over design.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 9H96

Status: Ongoing

TITLE: The Prevalence of Acute Stress Disorder (ASD) and Posttraumatic Stress Disorder (PTSD) in Miscarriage

Start date: Feb 96

Est Comp Date: Jun 96

Principal Investigator: CPT Stephen V. Bowles, MS

Department/Section: Psychology/
Facility: TAMC

Associate Investigator: MAJ Larry C. James, MS; MAJ Michael K. Yancey, MC; Raymond A. Folen, PhD; Vivian Alamodin, MA

Key Words: ASD; PTSD; miscarriage; coping

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/96
Decision: Continue

OBJECTIVE: The objectives of this study are to accurately quantify the extent to which the diagnostic criteria for ASD and PTSD are met in post-miscarriage women, and to determine if particular coping styles predict those likely to suffer from ASD or PTSD.

TECHNICAL APPROACH: Study design: One hundred females; 50 in the experimental group (miscarriage) and 50 in the control group (pregnant). At about one week post miscarriage and for pregnant women approximately one week after pregnancy confirmed, participants will be given a demographic questionnaire, Posttraumatic Stress Diagnostic Scale, the COPE, Revised Life Orientation Test and the Stanford Acute Stress Reaction Questionnaire. Participants will then be given these questionnaires again (excluding the demographic questionnaire) at around 30 days after the initial testing.

MODIFICATION (Apr 96): Add control group and questions

PROGRESS: No. of Subjects Enrolled - To Date: 71
During FY96: 71

Findings suggest that 7 of the experimental participants had ASD symptomatology and 1 experimental participant had PTSD symptomatology. Data has been analyzed and will be submitted for publication.

Detail Summary Sheet

Prot No: TAMC 13R95

Status: Completed

TITLE: Causes of Recidivism in a Smoking Cessation Program

Start date: Mar 95

Est Comp Date: Mar 96

Principal Investigator: Raymond A. Folen, PhD

Department/Section: Psychology Service/
Facility: TAMC

Associate Investigator: Marielis Faue, MA; MAJ Larry C. James, MS

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Completed

OBJECTIVE: To analyze demographic and smoking behavior variables for the purpose of predicting recidivism and developing effective intervention strategies.

TECHNICAL APPROACH: Record review & a one-year follow up phone questionnaire.

PROGRESS: No. of Subjects Enrolled - To Date: 111
During FY96: 0

Study completed Data acquired and analyzed; preparing final report. There were no adverse effects.

Presentation: Paper presented at the 1996 Hawaii Psychological Association Conference.

Publication: Paper submitted to Military Medicine.

Detail Summary Sheet

Prot No: TAMC 28S95

Status: Completed

TITLE: The Assessment of Chronic Fatigue Syndrome and Systemic Lupus Erythematosus With the Minnesota Multiphasic Personality Inventory-2

Start date: Aug 95

Est Comp Date: Feb 96

Principal Investigator: Raymond A. Folen, PhD

Department/Section: Psychology Service/
Facility: TAMC

Associate Investigator: MAJ Larry C. James, MS; Terri Needels, PhD; Catherine Garrett

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 7/23/96
Decision: Completed

OBJECTIVE: To determine significant relationships between the MMPI-2 profile configurations (ie, 'conversion-V' or 'neurotic triad') of the CFS and SLE samples, respectively, and develop normative data for these populations in order to account for their realistic concerns and valid complaints of physical disease.

TECHNICAL APPROACH: Minnesota Multiphasic Personality Inventory-2 (MMPI-2) administration and collection of some demographic information.

PROGRESS: No. of Subjects Enrolled - To Date: 36
During FY96: 0

Data collected; data analyzed. Study and final report has been completed. No adverse effects.

Presentation: Paper presented at the 1996 Hawaii Psychological Association Conference.

Detail Summary Sheet

Prot No: TAMC 33S95

Status: Completed

TITLE: An Investigation of the CHAMPUS (Civilian Health and Medical Program of the Uniformed Services) mental health referral system in Hawaii: A Survey of Patient Satisfaction and Services Received after Referral to a CHAMPUS provider by Tripler Army Medical Center

Start date: Oct 95

Est Comp Date:

Principal Investigator: Raymond A. Folen, PhD

Department/Section: Psychology Service/
Facility: TAMC

Associate Investigator: David Ross, MA; LTC Frederick N. Garland, MS; MAJ Larry C. James, MS; Dennis G. McLaughlin, PhD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Completed

OBJECTIVE: Gather, record and analyze demographic & patient satisfaction information regarding the current CHAMPUS referral system/service.

TECHNICAL APPROACH: Patient satisfaction survey.

PROGRESS: No. of Subjects Enrolled - To Date: 52
During FY96: 0

Initially identified CHAMPUS-referred patients, then completed 52 interviews in 1995; none in 1996. Preliminary data analysis is completed; preliminary results presented at the 1996 Hawaii Psychological Association Conference. Final data analysis nearing completion. No adverse effects.

Detail Summary Sheet

Prot No: TAMC 34H95

Status: Ongoing

TITLE: The Outcome Efficacy of Weight Management Programs: A Comparison Between Inpatient and Outpatient Weight Management Programs

Start date: Jan 96

Est Comp Date:

Principal Investigator: MAJ Larry C. James, MS

Department/Section: Psychology Service/
Facility: TAMC

Associate Investigator: Raymond A. Folen, PhD; MAJ Mark K. Davis, MS; CPT Christine L. Edwards, SP

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: (1) To identify the most efficacious treatment model in terms of clinical and cost benefits; (2) To identify the variables that increase the likelihood of long-term weight management and treatment compliance.

TECHNICAL APPROACH: Repeated-measures using three different weight management groups.

PROGRESS: No. of Subjects Enrolled - To Date: 40
During FY96: 40

We currently have 40 patients enrolled in the study. Study breakdown includes 13 females, 27 males; 9 are officers and 31 are enlisted.

Detail Summary Sheet

Prot No: TAMC 53H94

Status: Ongoing

TITLE: Incidence and Predictors of Stress, Depression and Impairment During Internship

Start date: May 94

Est Comp Date: Jul 95

Principal Investigator: Michael Kellar, PsyD

Department/Section: Psychology/
Facility: TAMC

Associate Investigator: F. Tania Monihan, MSW; Raymond A. Folen, PhD; MAJ William F. Miser, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 2/27/96

Gifts:

Decision: Continue

OBJECTIVE: (1) To determine the incidence of depression, housestaff stress syndrome and impairment during a military internship; (2) To identify potential predictors of those who will maladapt to the stresses of internship.

TECHNICAL APPROACH: Questionnaires/surveys administered throughout intern year.

PROGRESS: No. of Subjects Enrolled - To Date: 34
During FY96: 0

We have completed data acquisition (Aug 95) and are in the process of review/analysis. There have been no reported adverse effects; no results or conclusions as of yet.

Detail Summary Sheet

Prot No: TAMC 8S96

Status: Ongoing

TITLE: American Soldiers' Perceptions of Heterosexual Masculinity: A Determinant in Attitudes Toward Homosexuality (a dissertation in partial fulfillment of the requirement for a PhD in clinical psychology)

Start date: Jan 96

Est Comp Date:

Principal Investigator: CPT Rebecca I. Porter, MS

Department/Section: Psychology Service/Psychology

Facility: TAMC

Associate Investigator: MAJ Sally C. Harvey, MS; CPT Mark E. Bolte, MS

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 12/5/95

Gifts:

Decision: Continue

OBJECTIVE: To examine male soldiers' attitudes toward sexuality.

TECHNICAL APPROACH: Correlational survey of male active duty soldiers.

PROGRESS: No. of Subjects Enrolled - To Date: 0

During FY96: 0

Detail Summary Sheet

Prot No: TAMC 23H96

Status: Ongoing

TITLE: Remote Radiation Therapy Treatment Planning (RRTTP) Project

Start date:

Est Comp Date:

Principal Investigator: MAJ Brian J. Goldsmith, MC

Department/Section: Radiology/
Facility: TAMC

Associate Investigator: John Matthews, DSci; Don D. Tolbert, PhD; Kenneth Cole, PhD

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 3/26/96

Gifts:

Decision: Continue

OBJECTIVE: To develop a 3-D Remote Radiation Therapy Treatment Planning system.

TECHNICAL APPROACH: Prototype treatment planning system.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Awaiting administrative file requirements before a start letter is issued.

Detail Summary Sheet

Prot No: TAMC 20H95

Status: Terminated

TITLE: Prostate Cancer Staging With Magnetic Resonance Imaging Using an Endorectal Coil

Start date: Jul 95

Est Comp Date:

Principal Investigator: COL Mark F. Hansen, MC

Department/Section: Radiology/
Facility: TAMC

Associate Investigator: COL George E. Deshon, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Terminated

OBJECTIVE: To determine the sensitivity, specificity, and accuracy of endorectal coil MR imaging.

TECHNICAL APPROACH: Patients clinically suspected of having prostate carcinoma will undergo transrectal ultrasound (TRUS). And patients with positive cytology for prostate cancer will undergo endorectal coil MRI 14 days after the TRUS.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

There were no subjects enrolled onto study since study was approved. The unavailability (time & interest) of a succeeding PI has resulted with study termination.

Detail Summary Sheet

Prot No: TAMC 4H96

Status: Ongoing

TITLE: Post-Marketing Surveillance of Reactogenicity to Licensed Plague Vaccine
Manufactured by Greer Laboratories, Inc

Start date: Dec 95

Est Comp Date: Oct 97

Principal Investigator: CPT Dale G. Wallis, SP

Department/Section: Schofield Barracks/
Facility: TAMC

Associate Investigator: COL Kelly T. McKee Jr, MC

Key Words: plague vaccine; reactogenicity

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/24/96
Decision: Continue

OBJECTIVE: To identify if there is a difference in the occurrence or distribution of reactions after each injection dose in this vaccination series; specifically to verify rates of common reactions, unusual reactions and reaction pattern to the 3d inoculation.

TECHNICAL APPROACH: Post-Marketing Surveillance Study - from the time of receipt of the first vaccination until completion of the series, data collection will consist of providing survey forms to recipients to report common and non-common adverse reactions.

PROGRESS: No. of Subjects Enrolled - To Date: 401
During FY96: 401

10 subjects were dropped to date, due to flu-like symptoms, prolonged deployment, or PCS.

Detail Summary Sheet

Prot No: TAMC 26T92

Status: Completed

TITLE: Microsurgery Training for Orthopaedic Residents Using Rat Vessels

Start date: May 92

Est Comp Date: May 96

Principal Investigator: MAJ Mark Bagg, MC

Department/Section: Surgery/Orthopedics

Facility: TAMC

Associate Investigator:

Key Words: microvascular repair; microneurorrhaphy

Funding: FY 95:

FY 96:

Periodic Review Date: 5/31/96

Gifts:

Decision: Completed

OBJECTIVE: To train residents in the repair of arteries and veins approximately one millimeter in diameter.

TECHNICAL APPROACH: Laboratory training using rat arteries and nerves, and inspection of repaired results.

PROGRESS: No. of Subjects Enrolled - To Date: N/A

During FY96: N/A

The Principal Investigator (PI) started to write a new protocol in the new format; however, he was unsuccessful in finding a successor for this protocol. A second extension to do a single lab & train two interns prior to the PI's departure from Tripler was approved. Study is now completed.

Detail Summary Sheet

Prot No: TAMC 32H83

Status: Ongoing

TITLE: Prospective Study of the Use of Urinary D-Lactate Levels in Evaluation of the Acute Abdomen

Start date: Jul 83

Est Comp Date: Indef

Principal Investigator: COL Peter J. Barcia, MC

Department/Section: Surgery/
Facility: TAMC

Associate Investigator:

Key Words: urinary D-lactate; acute abdomen

Funding: FY 95:
Gifts: None

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: To determine the usefulness of serum D-lactate levels in the evaluation of the acute abdomen.

TECHNICAL APPROACH: Patients evaluated for acute abdominal pain will have urinary D lactate and creatinine specimens collected every 12 hours from the initial evaluation until four collections postoperatively or it is determined the patient does not have an acute abdomen. In addition, ten preoperatively to serve as controls.

PROGRESS: No. of Subjects Enrolled - To Date: 100
During FY96: 0

This study is on hold but much closer to beginning. MAJ N. Rebert bringing GCLC Mass Spect machine on line to measure levels. Dr. D Morrison, has training in this field and interested. Should have updated proposal by Sep 96 to begin accruing patient data again.

Detail Summary Sheet

Prot No: TAMC 46H96

Status: Ongoing

TITLE: Designing Successful Telemedicine Systems: A User-centered Approach

Start date: Aug 96

Est Comp Date:

Principal Investigator: Deborah P. Birkmire, PhD

Department/Section: Surgery/

Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 7/23/96

Gifts:

Decision: Continue

OBJECTIVE: To develop an instrument to asesess the knowledges, skills, and abilities of personnel needed to operate telemedicine systems.

TECHNICAL APPROACH: Random assignment to one-of-two communication block assembly task groups.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

New start.

Detail Summary Sheet

Prot No: TAMC 54H96

Status: Ongoing

TITLE: Treatment of Retropatellar Pain Syndrome in a Population of Marines

Start date: Jan 97

Est Comp Date:

Principal Investigator: LT Marc E. Brodsky, MC

Department/Section: Surgery/
Facility: TAMC

Associate Investigator: CPT Gary Sherwood, BSC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: (1) To discover measurable parameters that differentiate Marines with and without Retropatellar pain syndrome (rpps). (2) To develop a rehabilitation program to facilitate an early return to full duty in Marines who acquire rpps.

TECHNICAL APPROACH:

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 3H94

Status: Ongoing

TITLE: Sodium Iodate in Quick Preoperative Preparation of Hyperthyroid Patients

Start date: Dec 93

Est Comp Date: Dec 95

Principal Investigator: LTC Lawrence P.A. Burgess, MC

Department/Section: Surgery/Otolaryngology

Facility: TAMC

Associate Investigator: CPT Richard L. Bailey, MC; CPT Sharon M. Tomaski, MC; COL Michael Bornemann, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 8/27/96

Gifts:

Decision: Continue

OBJECTIVE: The objective of this prospective study is to show that sodium iodate, in a 3 day preoperative course, is a safe and time-efficient means to render the hyperthyroid patient chemically and clinically euthyroid preoperatively.

TECHNICAL APPROACH: Three-day preop preparation with sodium iodate followed by thyroidectomy performed in the usual and customary fashion. Pre- and postoperative labs to be compared for statistical validity. Clinical response/operative complications to be recorded. Postop patient follow-up identical to nonstudy thyroidectomies.

PROGRESS: No. of Subjects Enrolled - To Date: 6
During FY96: 1

Enrolled 6; incomplete data on 1. No untoward results from medication, with initial data mirroring what was seen in retrospective review. Results/conclusions pending. No operative complications related to study.

Detail Summary Sheet

Prot No: TAMC 50H96

Status: Ongoing

TITLE: Tele-proctored Functional Endoscopic Sinus (FES) Surgery

Start date: Oct 96

Est Comp Date:

Principal Investigator: LTC Lawrence P. A. Burgess, MC

Department/Section: Surgery/Otolaryngology

Facility: TAMC

Associate Investigator: LTC Leslie J. Peters, MS; Deborah P. Birkmire, PhD

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 8/27/96

Gifts:

Decision: Continue

OBJECTIVE: To establish empirically, the efficacy and safety of tele-proctored endoscopic sinus surgery.

TECHNICAL APPROACH:

PROGRESS:

No. of Subjects Enrolled - To Date:	0
During FY96:	0

Detail Summary Sheet

Prot No: TAMC 51H96

Status: Ongoing

TITLE: Comparison of Video-otoscopic Examination to Physical and Microscopic Examinations

Start date: Oct 96

Est Comp Date:

Principal Investigator: LTC Lawrence P. A. Burgess, MC

Department/Section: Surgery/Otolaryngology
Facility: TAMC

Associate Investigator: LTC Leslie J. Peters, MS; Deborah P. Birkmire, PhD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: To establish the efficacy of video-otoscopy for the evaluation of middle ear pathology.

TECHNICAL APPROACH: Video-otoscopic examinations will be compared to examinations by physical otoscopy and microscopy for signs of pathology in the middle ear.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 15T94

Status: Ongoing

TITLE: Porcine Laparoscopy Training Laboratory for Gynecologists and General Surgeons

Start date: Dec 93

Est Comp Date: Dec 96

Principal Investigator: LTC Paul R. Cordts, MC

Department/Section: Surgery/General Surgery

Facility: TAMC

Associate Investigator: COL Samuel R. Heth, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 10/15/96

Gifts: EQ loan

Decision: Continue

OBJECTIVE: To familiarize, train and upgrade gynecology and general surgery residents and staff in current laparoscopic techniques and instruments, and with open stapling techniques.

TECHNICAL APPROACH: Surgical training laboratory.

ADDENDUM (Jul95): Include training for OB-GYN.

PROGRESS: No. of Subjects Enrolled - To Date: N/A

During FY96: N/A

General Surgery and OB-GYN alternate every other month participating in the porcine laparoscopy lab. The residents and staff feel that this is an extremely valuable learning (ongoing training) session. We train four residents per lab under supervision of one staff with help and advice of Auto-suture technicians. During FY96, there were 8 labs (4 for General Surgery; 4 for OB-GYN), and 32 residents trained.

Detail Summary Sheet

Prot No: TAMC 35H96

Status: Ongoing

TITLE: A Pilot Study of Anatomic and Physiologic Changes in Lower Extremity Venous Hemodynamics Associated With Pregnancy

Start date: Jun 96

Est Comp Date:

Principal Investigator: LTC Paul R. Cordts, MC

Department/Section: Surgery/General Surgery
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To better define the physiologic effects of pregnancy on veins of the leg.

TECHNICAL APPROACH: Routine tests (bilateral lower extremity duplex & air plethysmography) will be performed in the vascular laboratory on 10 adult pregnant volunteers.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 11A95

Status: Completed

TITLE: A Comparison of Surgical Techniques to Reduce Fat Embolism Production from Insertion of an Uncemented Hip Prosthesis in a Goat Model

Start date: Feb 95

Est Comp Date:

Principal Investigator: CPT E. Schuyler DeJong, MC

Department/Section: Surgery/Orthopedics

Facility: TAMC

Associate Investigator: CPT Jeffrey Saenger, MC; LTC Gregg W. Taylor, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 10/15/96

Gifts:

Decision: Completed

OBJECTIVE: (a) Determine if meticulous femoral canal preparation before insertion of an uncemented hip prosthesis reduces the incidence and/or severity of fat embolization; (b) determine if venting the femur remote to the insertion site of an uncemented hip prosthesis lessens the incidence and/or severity of fat embolization; (c) determine if medullary canal pressure is affected by meticulous canal preparation or venting.

TECHNICAL APPROACH: Surgical treatment on animals as above.

PROGRESS: No. of Subjects Enrolled - To Date: N/A

During FY96: N/A

Previous findings included fat embolization in one of the provocatively treated animals, with no fat emboli in the other 9-of-10 animals. There were no labs conducted in FY96.

Dr. DeJong left Tripler this summer. Study has been completed.

Detail Summary Sheet

Prot No: TAMC 58H96

Status: Ongoing

TITLE: Hawaii Quality and Cost Consortium (HQCC) TURP Outcomes Study

Start date: Oct 96

Est Comp Date:

Principal Investigator: COL George E. Deshon, MC

Department/Section: Surgery/Urology

Facility: TAMC

Associate Investigator: Edwin P. Gramlich, MD; Beth E. Waitzfelder, MA

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 9/24/96

Gifts:

Decision: Continue

OBJECTIVE: (1) To develop community based outcomes benchmarks for TURP. (2) To determine whether the confidential comparison of individual hospital results to aggregate results improves overall outcomes for TURP. (3) To evaluate the concordance of multiple outcomes measures for TURP.

TECHNICAL APPROACH: This longitudinal study involves the collection of functional status, quantitative measures of impairment, and quality of life measures prior to the TURP procedure and at six months following surgery.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 16H94

Status: Completed

TITLE: Recombinant Adenovirus-mediated Cytokine Gene Transfer into Human Breast Cancer

Start date: Jan 94

Est Comp Date: Jan 98

Principal Investigator: MAJ David M. Euhus, MC

Department/Section: Surgery/General Surgery
Facility: TAMC

Associate Investigator: James S. Economou, MD, PhD; Lucille H. Kimura, PhD; COL Robert B. Hill, MC

Key Words: breast cancer; recombinant adenovirus; gene transfer

Funding: FY 95: **FY 96:**

Periodic Review Date: 8/27/96

Gifts: no MRDC breast cancer \$

Decision: Completed

OBJECTIVE: (1) Determine the efficiency of recombinant adenovirus-mediated gene transfer into human breast cancer in vitro and in vivo; (2) Assess the in vitro and in vivo growth rate and survival of lacZ transduced breast cancer cells; (c) Characterize the immunological effects of IL-2 gene transfer into human breast cancer.

TECHNICAL APPROACH: Experimental.

MODIFICATION (Dec94): Design change.

PROGRESS: No. of Subjects Enrolled - To Date: 34
During FY96: 8

Conditions for optimal gene transfer of the lacZ gene were determined in a cultured cell line. High levels of IL-2 production have been obtained in genetically modified breast cancer cells. Experiments are now beginning to assess the influence of IL-2 production by tumor cells on the generation of autologous anti-tumor cell mediated immunity.

Presentations:

1) Euhus D. High Efficiency Adenoviral-Mediated Gene Transfer in Human Breast Cancer Cells. Society of Surgical Oncology, Boston MA, 1995, Oral Presentation.

- 2) Euhus D, Kimura L. Cytokine-Mediated Gene Therapy of Human Breast Cancer Characterization of Tumor Infiltrating Lymphocytes Elaborated by Transduced Organoid Cultures. Gary Wratten Surgical Symposium, Boston MA, 1995, Oral Presentation.
- 3) Wilkinson N, Euhus D. Cytokine Gene Transfer in Human Breast Cancer. Hawaiian Surgical Association, Ko Olina HI, 1995, Oral Presentation.
- 4) Euhus D, Kimura L. Characterization of Lymphocytes Infiltrating Breast Cancers and Surrounding Normal Breast Tissue. 18th Annual San Antonio Breast Cancer Symposium, 1995, Poster Presentation.
- 5) Euhus D, Kimura L, Arnold B. Activation of Tumor Infiltrating Lymphocytes Cytotoxic for Autologous Breast Cells by Interleukin-2 Gene Transfer. Society of Surgical Oncology, Atlanta, 1996, Accepted for Oral Presentation.
- 6) Euhus D, Kimura L, Arnold B. Expansion of CD3+CD56+Lymphocytes Correlates with Induction of Cytotoxicity by Interleukin-2 Gene Transfer in Human Breast Tumor Cultures. Submitted Ann Surg Oncol, 1996.

Detail Summary Sheet

Prot No: TAMC 66H94

Status: Completed

TITLE: Influence of Parenteral Progesterone Administration on the Prevalence and Severity of Mastodynia in Active Duty Servicewomen: A Multi-Institutional Case-Control Study

Start date: Nov 94

Est Comp Date: Apr 96

Principal Investigator: MAJ David M. Euhus, MC

Department/Section: Surgery/General Surgery
Facility: TAMC

Associate Investigator: Catherine F.T. Uyehara, PhD; Holly Kailani, RN; CPT Mary V. Mirto, MC

Key Words: mastodynia; progesterones; active duty servicewomen

Funding: FY 95:

FY 96:

Periodic Review Date: 7/23/96

Gifts: MRDC DWHRP \$

Decision: Completed

OBJECTIVE: (1) To assess the efficacy of progesterones in the prevention and treatment of mastodynia; (2) To determine the prevalence and quantitate the severity of mastodynia among active duty servicewomen; (3) To quantitate the impact of mastodynia on productivity and military readiness; (4) To assess whether health care providers are meeting the expectations of women with mastodynia.

TECHNICAL APPROACH: Questionnaires.

PROGRESS: No. of Subjects Enrolled - To Date: 2773

During FY96: 950

Funding was obtained from USAMRMC. The study is closed to enrollment. There have been no adverse effects noted. The study was ongoing at various participating MTFs.

Presentation:

Influence of Parenteral Progesterones on the Prevalence and Severity of Mastodynia in Premenopausal Women. Gary P. Wratten Surgical Symposium, Breckenridge CO, Apr 95.

Detail Summary Sheet

Prot No: TAMC 33H94

Status: Completed

TITLE: A Comparison of Continuous Infusion Morphine (PCA) vs Intramuscular Morphine on the Duration of Post-laparotomy Ileus - A Randomized Prospective Trial

Start date: Feb 94

Est Comp Date: Feb 96

Principal Investigator: CPT Jorge E. Foianini, MC

Department/Section: Surgery/General Surgery
Facility: TAMC

Associate Investigator: MAJ David M. Euhus, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Completed

OBJECTIVE: To compare duration of post-laparotomy ileus in patients randomly assigned to either continuous intravenous morphine infusion via a patient controlled analgesia machine (PCA) or periodic intramuscular morphine injections. To test the null hypothesis: compared to periodic intramuscular morphine injections, PCA does not prolong post-laparotomy ileus.

TECHNICAL APPROACH: Comparison of patients randomized to either intramuscular morphine or intravenous morphine via a PCA pump.

PROGRESS: No. of Subjects Enrolled - To Date: 23
During FY96: 0

The study is now closed and I am analyzing the data.

Detail Summary Sheet

Prot No: TAMC 60R96

Status: Ongoing

TITLE: Complications of Endoscopic Sinus Surgery in a Residency Training Program: A Retrospective Review and Meta Analysis

Start date: Sep 96

Est Comp Date:

Principal Investigator: LCDR Rick D. Gross, MC

Department/Section: Surgery/Otolaryngology
Facility: TAMC

Associate Investigator: MAJ Mark F. Sheridan, MC; LTC Lawrence P.A. Burgess, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 10/22/96

Gifts:

Decision: Continue

OBJECTIVE: To determine complication rates among patients undergoing functional endoscopic sinus surgery (FESS) in 1995.

TECHNICAL APPROACH: Retrospective chart review.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

New start.

Detail Summary Sheet

Prot No: TAMC 27H96

Status: Ongoing

TITLE: Laparoscopic Directed Biopsy in Hepatitis C Patients

Start date: Apr 96

Est Comp Date:

Principal Investigator: CPT Jeffrey T. Healy, MC

Department/Section: Surgery/General Surgery
Facility: TAMC

Associate Investigator: MAJ Steven P. Lawrence, MC; COL Joseph C. Woods, MC;
MAJ David M. Euhus, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Continue

OBJECTIVE: (1) To document the macroscopic appearance of the liver in patients with serologic evidence of Hepatitis C infection and biochemical evidence of chronic hepatitis; (2) To determine the degree of focal involvement and the sampling variability from multiple biopsies; (3) To determine the concordance between macroscopic and histologic diagnosis and document any improvement in diagnostic yield.

TECHNICAL APPROACH: Patients will undergo a laparoscopic examination of the liver and guided biopsy. The abdomen is distended with gas and the scope is introduced through an incision in the navel. The liver is then examined carefully for abnormalities and biopsies are taken using a special needle. A biopsy will be taken from the normal appearing areas of the left and right lobe of the liver. The procedure will be videotaped.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

New start.

Detail Summary Sheet

Prot No: TAMC 61H94

Status: Ongoing

TITLE: The Use of EMLA, a Topical Anesthetic of Prilocaine and Lidocaine, in Preoperative Anesthesia for Adult Outpatient Circumcisions

Start date: Nov 95

Est Comp Date:

Principal Investigator: MAJ James R. Jezior, MC

Department/Section: Surgery/Urology
Facility: TAMC

Associate Investigator: LTC Joel M. Sumfest, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: To demonstrate the effectiveness of EMLA as a topical anesthetic for adult outpatient circumcisions.

TECHNICAL APPROACH: As above.

PROGRESS: No. of Subjects Enrolled - To Date: 22
During FY96: 22

Twenty-two subjects: 11 randomized to placebo & 11 to EMLA cream have been treated with an interim evaluation to assess efficacy of the anesthetic cream as outlined in the protocol.

Pre circumcision pain expectation	EMLA 5.8	Placebo 5.9
Pain associated to penile injection	EMLA 1.1	Placebo 2.2
Pain associated to circumcision	EMLA 1.8	Placebo 3.1

(scale 0-10)

No complications attributed to the use of EMLA cream.

Detail Summary Sheet

Prot No: TAMC 14T95

Status: Ongoing

TITLE: Surgical Skill Practicum for the Advanced Trauma Life Support Course of the American College of Surgeons Utilizing Anesthetized Goats (Caprine Sp)

Start date: Apr 95

Est Comp Date: Apr 98

Principal Investigator: MAJ Robert E. Johnson, MC

Department/Section: Surgery/Otolaryngology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/15/96
Decision: Continue

OBJECTIVE: To train physicians and related health care providers in the surgical techniques used in managing and diagnosing thoracoabdominal trauma.

TECHNICAL APPROACH: Surgery Lab.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

Two labs were held during FY96, with a total of 32 students trained and certified in ATLS.

Detail Summary Sheet

Prot No: TAMC 67T94

Status: Terminated

TITLE: Porcine Laparoscopy Training Laboratory in Advanced Laparoscopic Surgical Techniques and Teleproctoring

Start date: Oct 94

Est Comp Date: Aug 97

Principal Investigator: MAJ George Lisehora, MC

Department/Section: Surgery/General Surgery
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/31/96
Decision: Terminated

OBJECTIVES: To train surgeons and surgical residents in advanced laparoscopic surgical techniques.

TECHNICAL APPROACH: Intensive study and drilling of laparoscopic techniques in the dry and animal laboratory.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

There were no labs held in FY96. Dr. Lisehora has ETS'd and there is no further interest, so study is terminated.

Detail Summary Sheet

Prot No: TAMC 48H96

Status: Ongoing

TITLE: The Effectiveness of Voice Therapy Using Telecommunications Technology

Start date: Oct 96

Est Comp Date:

Principal Investigator: Pauline Mashima, MA

Department/Section: Surgery/Oto-Speech
Facility: TAMC

Associate Investigator: LTC Leslie J. Peters, MS; Deborah P. Birkmire, PhD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: To evaluate the feasibility, effectiveness, and efficacy of using telecommunications technology in delivering speech-language pathology services, specifically in the treatment of patients with voice disorders.

TECHNICAL APPROACH: (1) Data will be collected to establish validity of videoconferencing, then (2) clinical outcomes will be compiled to propose possible future or expanded applications.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: TAMC 5A96

Status: Ongoing

TITLE: Comparison of Types of Polypropylene Mesh in a Rat Model of Ventral Hernia

Start date:

Est Comp Date: Oct 99

Principal Investigator: CPT Cal S. Matsumoto, MC

Department/Section: Surgery/General Surgery

Facility: TAMC

Associate Investigator: MAJ Michael A. J. Sawyer, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 10/31/96

Gifts:

Decision: Continue

OBJECTIVE: To examine three different commercially-available polypropylene meshes and compare their ability to withstand tearing forces.

TECHNICAL APPROACH: See protocol.

PROGRESS: No. of Subjects Enrolled - To Date: N/A
During FY96: N/A

A start letter has not yet been issued for this project.

Detail Summary Sheet

Prot No: TAMC 1H96

Status: Ongoing

TITLE: Varicocele Pain Questionnaire and Survey

Start date: Sep 96

Est Comp Date:

Principal Investigator: MAJ Charles E. Payne, MC

Department/Section: Surgery/Urology
Facility: TAMC

Associate Investigator: COL William G. Kennon III, MC; COL George E. Deshon, MC;
MAJ Larry C. James, MS; MAJ Stephen K. Lee, MS

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/24/96
Decision: Continue

OBJECTIVE: To determine the effectiveness of surgery in men who are presently receiving operations for painful varicoceles, and attempt to determine if personality profiles can predict which patients will receive the most relief from surgery.

TECHNICAL APPROACH: Outcomes-based survey.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

New start.

Detail Summary Sheet

Prot No: TAMC 49H96

Status: Ongoing

TITLE: Evaluation and Patient Triage of Middle Ear Effusion From Video-otoscopic Images

Start date: Oct 96

Est Comp Date:

Principal Investigator: LTC Leslie J. Peters, MS

Department/Section: Surgery/Otolaryngology
Facility: TAMC

Associate Investigator: Deborah P. Birkmire, PhD

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: To establish protocols for the evaluation of video-otoscopic images of middle ear effusion.

TECHNICAL APPROACH: Visual markers in otoscopic images will be measured to determine their relationship to degree of hearing loss and tympanogram findings in cases of otitis media.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

New start.

Detail Summary Sheet

Prot No: TAMC 52H94

Status: Ongoing

TITLE: CEA and Prolactin Levels in Bile, Blood, and Peritoneal Washings as a Staging and Prognostic Tool

Start date: Jun 94

Est Comp Date: Jun 98

Principal Investigator: MAJ Patricio Rosa, MC

Department/Section: Surgery/General Surgery
Facility: TAMC

Associate Investigator: COL Yeu-Tsu M. Lee, MC; COL Joseph C. Woods, MC

Key Words: CEA; Prolactin; blood; portal; peritoneal washings

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To determine if CEA and Prolactin levels in bile, blood, and peritoneal washings are an effective staging and prognostic tool.

TECHNICAL APPROACH: Prospective study where CEA and Prolactin test results will be correlated with clinical findings at laparotomy, gross and microscopic features of the tumor, and patients' conditions during follow-up visits.

PROGRESS: No. of Subjects Enrolled - To Date: 50
During FY96: 8

No adverse effects. WeÆve enrolled 50 total subjects to-date. One-third of the way; two more years to complete study. Please direct all future correspondence regarding this study directly to Dr. Y-T. Lee since I will no longer be stationed at Tripler.

Detail Summary Sheet

Prot No: TAMC 30H95

Status: Ongoing

TITLE: A Randomized, Prospective, Double-blind Trial of Prophylactic Low-dose Lipid-delivered Amphotericin B in Patients at High Risk for Fungal Infection

Start date: Jan 96

Est Comp Date: Indef

Principal Investigator: MAJ Michael A. J. Sawyer, MC

Department/Section: Surgery/General Surgery

Facility: TAMC

Associate Investigator: CPT Jeffrey M. Nelson, MC; Elwin D. H. Goo, PharmD;
LTC Kathleen M. Sheehan, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 7/23/96

Gifts:

Decision: Continue

OBJECTIVE: To determine if prophylactic administration of low-dose systemic amphotericin B decreases the prevalence of invasive candidal infections in high-risk intensive care unit patients.

TECHNICAL APPROACH: Randomized, prospective, double-blind prophylactic low-dose lipid-delivered Amphotericin B administration.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

A start letter was received, yet no patients entered to-date.

Detail Summary Sheet

Prot No: TAMC 35H95

Status: Ongoing

TITLE: Blood Warming and Posttransfusion Oxygen Consumption

Start date: Jan 96

Est Comp Date: Jan 98

Principal Investigator: MAJ Michael A. J. Sawyer, MC

Department/Section: Surgery/General Surgery

Facility: TAMC

Associate Investigator: LTC Kathleen M. Sheehan, MC

Key Words: blood warming; oxygen consumption

Funding: FY 95:

FY 96:

Periodic Review Date: 8/27/96

Gifts:

Decision: Continue

OBJECTIVE: To determine if posttransfusion increases in oxygen consumption are related to increased demands for thermogenesis secondary to transfusion of cold packed red blood cells.

TECHNICAL APPROACH: Randomized prospective trial using blocked randomization in groups of six.

PROGRESS: No. of Subjects Enrolled - To Date: 6
During FY96: 4

Six patients enrolled on study.

Detail Summary Sheet

Prot No: TAMC 2H94

Status: Ongoing

TITLE: Inadequacy of Inspiratory-Limb Humidity Delivered by Commercially-Available Heated Humidifiers with Heated-Wire Circuits

Start date: Oct 93

Est Comp Date: Nov 96

Principal Investigator: CPT Michael J. Snyder, MC

Department/Section: Surgery/
Facility: TAMC

Associate Investigator: Morad Akhonzadeh; Maria L. Smedegaard

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: To identify discrepancy between in vivo and in vitro efficiency of heated humidifiers and compare types of chambers.

TECHNICAL APPROACH: Measure delivered humidity by evaporation and compare function during patient use, relative to 100% RH at 37.0°C.

PROGRESS: No. of Subjects Enrolled - To Date: 33
During FY96: 0

No patients have been enrolled in the study for some time and no publications nor presentations have been produced. The study is ongoing but stalled. Accrual target is 39.

Detail Summary Sheet

Prot No: TAMC 13H96

Status: Ongoing

TITLE: Jugular Vein Patency and Function in Head and Neck Cancer

Start date: Nov 95

Est Comp Date:

Principal Investigator: Mark Syms, MD

Department/Section: Surgery/Otolaryngology

Facility: TAMC

Associate Investigator: MAJ Mark F. Sheridan, MC; MAJ Christopher A. DeMaioribus, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 1/23/96

Gifts:

Decision: Continue

OBJECTIVE: To evaluate the patency and flow rate of both jugular veins of patients before functional neck dissection (FND), radiation therapy or treatment with both modalities.

TECHNICAL APPROACH: Jugular vein patency and flow rate will be measured by venous duplex imaging at pretreatment and every three months after the initiation of treatment for one year.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Nothing to report.

Detail Summary Sheet

Prot No: TAMC 5H95

Status: Ongoing

TITLE: A Double Blind Comparison of the Efficacy & Safety of Extended Outpatient Treatment with Subcutaneous Normiflo vs Placebo for the Prevention of Venous Thromboembolism in Patients After Hip or Knee Replacement Surgery

Start date: Aug 95

Est Comp Date:

Principal Investigator: LTC Gregg W. Taylor, MC

Department/Section: Surgery/Orthopedics
Facility: TAMC

Associate Investigator: MAJ Craig R. Bottoni, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/22/96
Decision: Continue

OBJECTIVE: To compare the safety and efficacy of extended outpatient treatment with Normiflo versus placebo for the prevention of venous thromboembolism (DVT/PE) following hip or knee replacement surgery.

TECHNICAL APPROACH: Inpatient unblinded treatment with Normiflo, and outpatient with either Normiflo or placebo.

MODIFICATION #1 (Mar95): Design change and patient instructions.

MODIFICATION #2 (May95): Design change to pre-op screening.

MODIFICATION #3 (Aug 95): Change in therapy schedule, personnel names & telephone numbers.

MODIFICATION #4 (Aug 96): Allows dosing & therefore participation in outpatient setting thru day 10.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study enrollment was placed on hold pending approval of a CRADA (resources support) and receipt of a start letter. We hope to accrue subjects by weekÆs end and plan to conduct the study as outlined in the protocol design.

Detail Summary Sheet

Prot No: TAMC 30H96

Status: Ongoing

TITLE: Time Course and Intubating Conditions for Diluted Rocuronium

Start date: Jun 96

Est Comp Date:

Principal Investigator: Andrew Topf, MD

Department/Section: Surgery/Anesthesiology

Facility: TAMC

Associate Investigator: CPT David C. Joss, AN; CPT Ramachandra J. Lahori, MC;
MAJ Amy M. Ertter, AN; CPT Charles M. Price, AN; CPT Geselle McKnight, AN

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 4/23/96

Gifts: CRADA (reimburse drug)

Decision: Continue

OBJECTIVE: To determine if intubation conditions can be improved by changing the concentration of Rocuronium.

TECHNICAL APPROACH: Randomized, blind, prospective, pilot study.

MODIFICATION (May96): Study design change.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

New start.

Detail Summary Sheet

Prot No: TAMC 16H95

Status: Completed

TITLE: Capnometer-Assisted Feeding Tube Placement

Start date: May 95

Est Comp Date:

Principal Investigator: CPT Stanley M. Zagorski Jr, MC

Department/Section: Surgery/General Surgery

Facility: TAMC

Associate Investigator: MAJ Michael A.J. Sawyer, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 5/28/96

Gifts:

Decision: Completed

OBJECTIVE: To evaluate the efficacy of CO2 monitoring as an adjunct to ensure proper placement of nasoenteral feeding tubes.

TECHNICAL APPROACH: Monitoring of CO2 during feeding tube placement.

PROGRESS: No. of Subjects Enrolled - To Date: 36

During FY96: 20

No adverse effects noted. Expect to be done end of November 95. Data suggest that carbon dioxide monitoring may aid in feeding tube placement and decrease inadvertent placement into the bronchial tree. We are all excited at the potential that this modality has in improving patient care and safety. We are also considering a follow up study to further examine and demonstrate its usefulness in the clinical setting.

Detail Summary Sheet

Prot No: TAMC 34H92

Status: Ongoing

TITLE: A Prospective, Randomized Study of Triple-Lumen Venous Catheter Infections in the Subclavian Versus Femoral Location

Start date: Aug 92

Est Comp Date: Indef

Principal Investigator: CPT Stanley M. Zagorski Jr, MC

Department/Section: Surgery/General Surgery
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 7/23/96
Decision: Continue

OBJECTIVE: To show that the rate of infection of indwelling subclavian venous triple-lumen catheters is significantly less than that of indwelling femoral venous triple-lumen catheters.

TECHNICAL APPROACH: A prospective randomized study using adult patients of either sex whose TLVC site(s) originate(s) in the surgical intensive care unit (SICU) at TAMC. Each patient will be randomized and each new site on the same patient will be randomized. Procedures and site complication rate will be monitored and compared.

PROGRESS: No. of Subjects Enrolled - To Date: 96
During FY96: 4

Adverse effects - none outside of those normally associated with catheter insertion. Estimated completion date-June 1996.

There have been no publications or presentations to-date.

Detail Summary Sheet

Prot No: GOG 92(94)

Status: Terminated

TITLE: Treatment of Selected Intermediate Risk Patients With Stage 1B Carcinoma of the Cervix After Radical Hysterectomy and Pelvic Lymphadenectomy: Pelvic Radiation Therapy Versus No Further Therapy

Start date: Mar 94

Est Comp Date: Indef

Principal Investigator: MAJ Mary F. Parker, MC

Department/Section: Obstetrics & Gynecology/
Facility: TAMC

Associate Investigator: MAJ Marianne M. Young, MC; MAJ Brian J. Goldsmith, MC;
COL Jeffrey L. Berenberg, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Terminated

OBJECTIVE: (1) To determine the value of adjunctive pelvic radiation in the treatment of Stage 1B carcinoma of the cervix, but with selected intermediate risk factors; (2) To determine the recurrence-free interval, survival and patterns of failure in these patients; (3) To determine the morbidity of adjunctive pelvic radiation following radical hysterectomy.

TECHNICAL APPROACH: Treatment protocol with six weeks of radiation for one treatment arm; no further treatment for the other treatment arm.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

We are currently unable to adequately support accrual and follow-up for this protocol at TAMC.

No publications to date.

Results of study not yet available.

Detail Summary Sheet

Prot No: GOG 119(93)

Status: Ongoing

TITLE: A Study of the Use of Provera and Tamoxifen Citrate (NSC #180973) for the Treatment of Advanced Recurrent or Metastatic Endometrial Carcinoma

Start date: Sep 93

Est Comp Date: Indef

Principal Investigator: MAJ Mary F. Parker, MC

Department/Section: Obstetrics & Gynecology/
Facility: TAMC

Associate Investigator: COL Eric R. Salminen, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVES: (1) To determine the efficacy of tamoxifen citrate plus intermittent administration of PROVERA (Medroxyprogesterone Acetate) in patients with recurrent or metastatic endometrial carcinoma; (2) To determine the side effects of such treatment in patients with this disease.

TECHNICAL APPROACH: All patients will receive tamoxifen citrate 40 mg p.o. daily. During alternate weeks, patients will receive, in addition, PROVERA 200 mg daily. PROVERA will be given during week 2, 4, 6, 8 etc.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Ongoing study, group-wide in GOG. No presentations or publications to date.

Detail Summary Sheet

Prot No: GOG 123(94)

Status: Terminated

TITLE: A Randomized Comparison of Radiation Therapy and Adjuvant Hysterectomy Versus Radiation Therapy and Weekly Cisplatin and Adjuvant Hysterectomy in Patients With Bulky Stage 1B Carcinoma of the Cervix

Start date: Mar 94

Est Comp Date: Indef

Principal Investigator: MAJ Mary F. Parker, MC

Department/Section: Obstetrics & Gynecology/
Facility: TAMC

Associate Investigator: MAJ Marianne M. Young, MC; MAJ Brian J. Goldsmith, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 12/5/95

Gifts:

Decision: Terminated

OBJECTIVE: (1) To determine if weekly cisplatin infusion improves local regional control and survival when added to radiation therapy plus extrafascial hysterectomy; (2) To determine the relative toxicities of these two treatment arms.

TECHNICAL APPROACH: Treatment protocol with two treatment arms noted above.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

We are currently unable to adequately support accrual and follow-up on this protocol at TAMC. No publications to date.

Results of study not yet available.

Detail Summary Sheet

Prot No: GOG 136(95)

Status: Ongoing

TITLE: Acquisition of Human Ovarian and Other Tissue Specimens and Serum to be Used in Studying the Causes, Diagnosis, Prevention and Treatment of Cancer

Start date: Jan 95

Est Comp Date: Indef

Principal Investigator: MAJ Mary F. Parker, MC

Department/Section: Obstetrics & Gynecology/
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: (a) To accomplish the collection of human ovarian tissue specimens and serum within GOG participating institutions; (b) to provide a repository for long-term storage of ovarian tumor, tissue and serum; (c) to make available tumor tissue and serum for proposed projects conducted by GOG investigators (internal bank) and researchers nationally (external bank).

TECHNICAL APPROACH: Tissue banking.

PROGRESS: No. of Subjects Enrolled - To Date: 2
During FY96: 0

No adverse effects, publications or presentations.

Detail Summary Sheet

Prot No: POG 7799(93)

Status: Ongoing

TITLE: Rare Tumor Protocol For Childhood Solid Tumor Malignancies, Ancillary Study

Start date: Apr 93

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 3/26/96

Gifts:

Decision: Continue

OBJECTIVES: The purpose of the rare tumor protocol is to: (1) establish a central repository for slides and/or blocks from all rare tumors (benign and malignant); (2) determine the morphologic variation of rare tumors; (3) correlate the morphology of these lesions with patient's subsequent course; (4) allow the POG pathologist to serve as a diagnostic consult.

TECHNICAL APPROACH: Provision of tissue material and data regarding malignancy diagnosis treatment and disease response on patients <18 yrs of age with rare solid tumors.

PROGRESS: No. of Subjects Enrolled - To Date: 3
During FY96: 0

Abstracts:

Sacroccocygeal germ cell tumors in children. Lab Invest 52:5P, 1985

Pathology of Germ Cell Tumors of Childhood. Med Paediatr Oncol 15:293, 1987

Pancreaticoblastoma, a Tumor of Uncommitted Primordium. Lab Invest 70:5P, 1994

Publications:

Cancer 58:2579, 1986

Human Pathol 21:805, 1990

J Pediatr Surg 25:583, 1990 (Letter to the Editor)

J Pediatr Surg 27:796-797, 1992 (Letter to the Editor)

Detail Summary Sheet

Prot No: POG 8158(83)

Status: Completed

TITLE: NWTs Long Term Follow-up Study

Start date: Jul 83

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words: Wilms' tumor

Funding: FY 95:

FY 96:

Periodic Review Date: 3/26/96

Gifts:

Decision: Completed

OBJECTIVE: To examine the late consequences of successful treatment given for Wilms' tumor.

TECHNICAL APPROACH: Pediatric patients and adolescent patients under 18 years of age with Wilms' tumor will be eligible. Treatment will be as outlined in the study protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study closed to enrollment 9/1/95. No TAMC patients were entered into this protocol. This is a nontherapeutic study designed to gather epidemiologic and late effects data on long term (>5yrs) survivors of Wilms' tumor. No Tripler patients have been registered to date. Nationally 4012 patient registrants are eligible for this study; 2424 are in continuous followup; 973 are actively being pursued for follow-up.

Abstract

AACR 27:204, 1986

Pediatr Res 35:161A, 1994.

Publications:

J Natl Cancer Inst 80:592-595, 1988

Cancer 67:331-336., 1991

JCO (August), 1995.DIR

Detail Summary Sheet

Prot No: POG 8633(89)

Status: Ongoing

TITLE: 8633/34: The Treatment of Children Less Than Three Years of Age With Malignant Brain Tumors Using Postoperative Chemotherapy and Delayed Irradiation

Start date: Feb 93

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 4/23/96
Decision: Continue

OBJECTIVES: 8633 - To determine if the use of postoperative chemotherapy in children less than 36 months of age with malignant brain tumors will allow for the delay of cranial irradiation for 12 months in children 2-3 years at diagnosis and 24 months for those less than two years old. To estimate the response (CR or PR) to two cycles of cyclophosphamide and vincristine in children with measurable tumor at the initiation of chemotherapy. To estimate the objective response rate (CR, PR, SD) and disease control interval with this multi-agent chemotherapy regimen. To estimate the disease control interval, recurrence-free survival, and survival for children following chemotherapy and radiation therapy in each disease category. To establish the acute and chronic toxicities of this approach, including neurological, neuropsychological, endocrine, and somatic effects. 8634 - To estimate the response rate, disease control interval, recurrence-free survival, and survival of those children who, after having progression of disease on chemotherapy (#8633), are subsequently treated with surgery and radiation therapy or radiation therapy alone.

TECHNICAL APPROACH: Treatment of children with a diagnosis of malignant brain tumor under 3 years of age, with chemotherapy initially with goal of controlling disease and delaying XRT until 3-4 years of age to minimize XRT-associated CNS toxicity.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Protocol 8633 is completed for accrual; 8634 is ongoing. There are no current TAMC patients on protocol.

Detail Summary Sheet

Prot No: POG 8650(89)

Status: Ongoing

TITLE: National Wilms' Tumor Study 4

Start date: Jul 89

Est Comp Date: Jul 95

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words: Wilms' tumor

Funding: FY 95:

FY 96:

Periodic Review Date: 5/28/96

Gifts:

Decision: Continue

OBJECTIVE: To compare the relapse-free and overall survival rates of 1) stages I and II FH patients and stage I anaplastic patients treated with conventional CT vs pulse-intensive CT with vincristine and actinomycin D; 2) patients with stage III and IV FH Wilms' and stage I-IV CCSK who are treated with conventional CT vs pulse-intensive CT with vincristine, actinomycin D, and Adriamycin + XRT; 3) patients with stage II-IV anaplastic Wilms' who are treated with vincristine, actinomycin D, and Adriamycin vs those three drugs in combination with cyclophosphamide and XRT; 4) patients with stage II-IV FH and stage I-IV CCSK who are treated for 6 mos vs approximately 15 mos post-nephrectomy.

TECHNICAL APPROACH: Patients with stage I-IV favorable histology (FH) or stage I-IV anaplastic Wilms' tumor, or stage I-IV clear cell sarcoma of the kidney (CCSK). Must have undergone nephrectomy, but no prior CT or XRT. Must be <16 yrs of age. Followed: Must have stage I-IV anaplastic Wilms' tumor, stage I-IV CCSK, or stage I-IV malignant rhabdoid tumor of the kidney. Must have a medical or social reason precluding randomization (see Sec. 4.122), including age >16 yrs. Registered: 1) Patients with histologically confirmed mesoblastic nephroma or diagnosis other than Wilms', anaplastic, clear cell, or rhabdoid tumor (to include those patients who have been previously treated or who have died post-op); OR 2) patients who have received prior therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 5
During FY96: 0

Study was closed to accrual in Sep 94. Nationally 3230 patients have been registered, as of 13 Jan 95. Statistical analysis is incomplete at this time. Cytosan containing regimen advantageous for patients with diffuse anaplasia and advanced stage disease. Pulse intensive arms for favorable histology disease appear less costly and not associated with greater hematologic toxicity.

Publications

Cancer 62:270-273, 1988

J Clin Oncol 8:1525-1530, 1990

Detail Summary Sheet

Prot No: POG 8653(90)

Status: Ongoing

TITLE: 8653/54: Protocol for the Study of Childhood Soft Tissue Sarcomas (STS) Other than Rhabdomyosarcoma and its Variants - A POG Phase III Study

Start date: Jan 91

Est Comp Date: Jan 97

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: A. To determine whether adjuvant chemotherapy with vincristine, Adriamycin, cyclophosphamide, and actinomycin D (VACA) increases the relapse-free survival (RFS) of patients with localized soft tissue sarcoma (STS) who are in complete response (CR) status after surgery with or without post-operative radiation (Protocol 8653).

B. To compare VACA with VACA plus STIC (VACAD) therapy in regard to CR and RFS rates in patients with (1) metastatic STS at diagnosis or (2) previously "untreated" recurrent STS (patients) on the no chemotherapy control arm of "adjuvant" study 8653 or (3) localized persistent gross residual STS after surgery and radiation therapy (Protocol 8654).

TECHNICAL APPROACH: Patients on 8653 undergo surgery +- XRT and then are randomized to observation only or multiagent chemotherapy (Vincristine, Adriamycin, Cytosan - alternated with Vincristine, Adriamycin-D, Cytosan) for 52 weeks. Clinical Group III and IV (8654) are randomized to two different chemotherapy regimens lasting 78 weeks. Each arm receives XRT.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

This study is closed for active treatment. Protocol 8653 has been completed for accrual since 1992; 8654 closed to accrual in Sep 94. No Tripler patients were entered on this study while nationally, Protocol 8653 accrued 99 patients and 8654 accrued 75 patients.

Toxicity noted has primarily been hematologic and GI and infection. Data not yet mature and statistical analysis ongoing but data to date does not show advantage of addition of chemotherapy to treatment of localized STS responsive to surgery + XRT (POG 8653 patients). POG 8654 data also demonstrates that STIC does not offer an EFS advantage for patients randomized to VACA + STIC arm.

Abstract: ASCO, 1992; S1OP, 1992 (8653)

Detail Summary Sheet

Prot No: POG 8828(90)

Status: Ongoing

TITLE: Late Effects of Treatment of Hodgkin's Disease

Start date: Jul 90

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words: Hodgkin's disease

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: Primary: (1) To estimate the incidence of various late effects seen in patients with Hodgkin's disease treated by the regimens of POG #8625/26 and POG #8725; (2) To compare the two treatment arms of POG #8625/26 and the two treatment arms of POG #8725 for the incidence of the above late effects. Secondary: (1) To attempt to identify disease and treatment-related factors and post-treatment factors which contribute to specific late effects; (2) To attempt to identify pre-treatment factors, on-treatment and/or post-treatment factors which predict high risk of specific late effects.

TECHNICAL APPROACH: Patients will have participated either in POG #8625 ("early stage" Hodgkin's disease) or POG #8725 ("late stage" Hodgkin's disease) therapeutic studies, or their successor studies. Data will be obtained to help identify patients long-term follow-up needs, particularly earlier recognition and management of high-incidence treatment toxicities. Should treatment arms of the therapeutic Hodgkin's protocols produce equivalent disease responses, this long-term toxicity data will be critical in the determination of the "better" treatment arm.

PROGRESS: No. of Subjects Enrolled - To Date: 2
During FY96: 0

This is a long term/late effects study - no data interpretation to date. 374 patients accrued groupwide to date. Accrual to this cancer control study is tied to registrations on frontline Hodgkin's therapeutic protocols.

Detail Summary Sheet

Prot No: POG 8829(91)

Status: Ongoing

TITLE: Protocol for a Case-Control Study of Hodgkin's Disease in Childhood (Survey)

Start date: Feb 91

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 4/23/96

Gifts:

Decision: Continue

OBJECTIVE: 1) To conduct the first interview case-control study of childhood Hodgkin's disease to learn more about the epidemiology of the disease in children; 2) To evaluate whether, on epidemiologic grounds, childhood Hodgkin's disease is distinct from the young adult and old adult diseases; 3) To evaluate the hypothesis that children with Hodgkin's disease have different patterns of infectious disease than do matched controls; 4) To assess day-care of children (with its attendant increased risk of infectious diseases acquired at early ages) as a risk factor for childhood Hodgkin's disease; 5) To evaluate the association between breast-feeding and risk of childhood Hodgkin's disease; 6) To evaluate association between indicators of socioeconomic status and childhood Hodgkin's disease; 7) To evaluate parental occupational exposure as risk factors for Hodgkin's disease in children; 8) To evaluate environmental exposures to wood and chemicals as possible risk factors in children; 9) To evaluate familial aggregation of Hodgkin's disease (and possibly increased risk of other malignancies or multiple sclerosis); 10) To evaluate risk factors of childhood - Hodgkin's disease separately for each histologic subtype of the disease, and by disease stage and age at diagnosis.

TECHNICAL APPROACH: Questionnaire administered by telephone interview of parents of patients <15 years of age with newly diagnosed Hodgkins (intergroup study involving POG and CCSG).

MODIFICATION (Jul96): Scientific & consent changes.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

624 patients registered nationally to date (POG and CCG), as of 7 Aug 95.

Publication:

Ambinder RF, et al. Epstein-Barr Virus and Childhood Hodgkins Disease in Honduras and The United States. Blood 81:462-467, 1993

Abstracts:

Yang P, et al. A Genetic Analysis of Hodgkin's Disease. Am J Human Genet 53(3):A391, 1993.

Detail Summary Sheet

Prot No: POG 8850(89)

Status: Ongoing

TITLE: Evaluation of Vincristine, Adriamycin, Cyclophosphamide, and Dactinomycin with or without the Addition of Ifosfamide and Etoposide in the Treatment of Patients with Newly-Diagnosed Ewing's Sarcoma or Primitive Neuroectodermal Tumor of Bone: A Phase III Intergroup Study

Start date: Jun 89

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words: Ewing's sarcoma

Funding: FY 95:

FY 96:

Periodic Review Date: 5/28/96

Gifts:

Decision: Continue

OBJECTIVE: Primarily: To determine and compare the EFS of patients treated with VP-16 and Ifosfamide in addition to standard therapy vs treatment with standard therapy alone. Secondly: a) Evaluate toxicities and adverse orthopedic outcomes associated with disease and therapies; b) Assess significance of tumor site, size, histology and EM pattern in determining outcome; c) Correlate imaging characteristics with response, prognosis, RT adequacy, and survival; d) Assess prognostic value of cellular DNA content and chromosome changes.

TECHNICAL APPROACH: Patients with newly diagnosed Ewing's sarcoma or PNET of bone will be evenly randomized to one of two treatment arms: Reg A-52 week course of chemo including Vincristine, Adriamycin, Cytosan, Actinomycin D with surgery and/or XRT as needed (standard therapy). Reg B-52 week including Ifosfamide and Etoposide as well as therapy employed in Regimen A. Third treatment arm for metastatic disease added (combinations of Vinc, Adria, Cytosan, Dactino, Ifos, VP-16).

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study closed to accrual in Jan 94. 520 patients accrued through POG and CCG.

Abstract:

Grier H; et al: Proc ASCO 13:421(1443), 1994.

Conclusions from study:

(1) Adding Ifosfamide and Etoposide to the standard regimen of VCR/Adriamycin/Cytosin/Dactinomycin improves the outcome in non-metastatic Ewing's Sarcoma and PNET of Bone.

	standard	+ifos/etoposide
overall survival:	56%	80%
event free survival:	50%	69%

(2) Outcome for metastatic patients on either regimen A (standard) or regimen B (standard + ifos/etoposide) is poor (2yr EFS-22%)

(3) Toxicity of regimen C is severe, predominately myelosuppression and GI toxicity. There is significant renal toxicity with this regimen that utilized an ifosfamide dose of 14 grams/m²/course (2.8 gm/m²/d x 5 days).

Detail Summary Sheet

Prot No: POG 8930(93)

Status: Ongoing

TITLE: A Comprehensive Genetic Analysis of Brain Tumors

Start date: Sep 93

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVES: To determine prospectively the clinical significance of abnormalities of cellular DNA content, as measured by flow cytometry in pediatric brain tumors. To determine the clinical implications of cytogenetic abnormalities found in pediatric brain tumors at diagnosis. To determine the clinical significance of amplification or rearrangement of specific cellular proto-oncogenes or allelic loss of recessively-acting loci in DNA extracted from pediatric brain tumors. To attempt to derive tumor cell lines and to provide a bank of frozen brain tumor tissue for use in further studies, especially molecular genetic studies.

TECHNICAL APPROACH: Submission of fresh tumor tissue and peripheral blood to central lab and tumor tissue bank at time of brain tumor diagnosis.

PROGRESS: No. of Subjects Enrolled - To Date: 5
During FY96: 3

399 POG patients registered to date. No data interpretation available. Several biologic studies have been approved utilizing specimens collected.

Detail Summary Sheet

Prot No: POG 8935(92)

Status: Completed

TITLE: A Study of the Biological Behavior of Optic Pathway Tumors

Start date: Mar 92

Est Comp Date: Mar 94

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 4/23/96

Gifts:

Decision: Completed

OBJECTIVE: Primary Objectives: a) To assess time to progression of optic pathway tumors (OPTs); b) To estimate the response rate of radiation therapy in children with OPTs, when measured at 2 years post-irradiation. Secondary Objectives: a) To assess differences in time to progression and response to treatment in patients with and without neurofibromatosis (NF); b) To assess incidence of progressive OPT in patients with NF; c) To assess long-term treatment effects in patients <21 years of age with optic pathway tumors; d) To assess the value of neurophysiologic techniques in assessing time to progression and response to treatment in patients with optic pathway tumors; e) To assess the effects of radiation therapy on neuropsychologic function associated with the region of the diencephalon.

TECHNICAL APPROACH: Patients followed with vision screening and imaging studies of tumor. If tumor progressing, patients <5 years of age are treated on POG #8936 (chemo protocol). If >5 years of age (or if progresses on POG #8936), patient randomized for treatment with XRT or 2) with surgery $\rightarrow$ XRT.

If chiasmatic tumor, treatment is XRT.

PROGRESS: No. of Subjects Enrolled - To Date: 2
During FY96: 0

Study completed accrual by 3/1/94. One hundred fifteen patients enrolled groupwide to date. Fifty-two of the 106 eligible patients were newly diagnosed. Survival data as of Apr 95: Survival of 3-4 yrs 92%; progression free survival 77%.

Detail Summary Sheet

Prot No: POG 8936(93)

Status: Completed

TITLE: Phase II Study of Carboplatin (CBDCA) in the Treatment of Children with Progressive Optic Pathway Tumors

Start date: May 93

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Completed

OBJECTIVES: (1) To assess the responses rate to carboplatin (CBDCA) in children <5 years of age with optic pathway tumors (OPTs); (2) To assess the efficacy of CBDCA in delaying progression of disease.

TECHNICAL APPROACH: Patients followed with vision screening and imaging studies of tumor. If tumor progressing, patients < 5 years of age are treated on POG #8936 (chemo protocol). If > 5 years of age (or if progresses on POG #8936), patient randomized for treatment with XRT or 2) with surgery + XRT.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study completed accrual on 3/1/94. 51 patients enrolled groupwide to date. No unexpected toxicities. 1 PR, 36 mixed responses to therapy; 10 progressed.

Detail Summary Sheet

Prot No: POG 9000(91)

Status: Completed

TITLE: ALinC #15 Laboratory Classification (C) Protocol

Start date: Feb 91

Est Comp Date: Feb 95

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 4/23/96

Gifts:

Decision: Completed

OBJECTIVE: 1) To continue to characterize the biologic findings of the acute lymphoblastic and undifferentiated leukemias (immunologic markers, ploidy (DNA index), karyotyping, morphology) and their relationship, as prognostic factors for attaining and maintaining remission; 2) To apply to therapy selection, the determination that ploidy and certain structural chromosomal abnormalities predict poor prognosis; 3) To learn whether outcome is related to patient differences in methotrexate availability as measured by sequential determination of red blood cell (RBC) methotrexate (MTX) and folate levels; 4) To determine the frequency of myeloperoxidase (MPO) gene expression in the blast cell population of all newly diagnosed cases of infant leukemia, in an effort to improve detection of early stages of myeloid lineage; 5) To determine by in vitro testing if there is inadvertent stimulation of infants' lymphoblasts by hematopoietic growth factors (HGF); 6) To evaluate the usefulness of PCR technique in detecting minimal residual disease in patients with disease demonstrating t(9;22) or t(1;19) chromosomal abnormalities.

TECHNICAL APPROACH: Submission of blood and bone marrow aspirate samples of newly diagnosed ALL patients to designated reference labs for disease/type verification and additional biologic information for disease response prognostication.

PROGRESS: No. of Subjects Enrolled - To Date: 8
During FY96: 0

3021 patients accrued groupwide. 2439 of these enrolled on various treatment protocols (determined by disease type and risk assessment) as of 11/15/94.

Abstracts:

Intl Soc for Analytical Cytology 5:43, 1991

Cytometry 5:43, Abst #143, 1991

Proc ASPHO #15, 1992

Modern Pathol 6:86a, 1993

Proc ASCO 12:319, 1993

Proc ASCO 12:316, 1993

Am J Hum Genet 53:342A, 1993 (poster)

Blood 92(10):190A, 1993 (poster)

ASCO Educational Book 124-130, 1994

Publications:

Genes Chromosomes Cancer 4:211-216, 1992

Blood 80:2826-2834, 1992

Cancer Res 52:3811-3813, 1992

Leukemia 7:2064-2068, 1993

Blood 82(10):3098-3102, 1993

Blood 82(4):1086-1091, 1993

Blood 81(8):2110-2117, 1993

Blood 81(11):3052-3062, 1993

Comput Methods Program Biomed 40:269-277, 1993

JCO 11(7):1361-1367, 1993

Cancer Genet Cytogenet 68:34-41, 1994

Blood 84:570-573, 1994

Blood 83:330-335, 1994

Detail Summary Sheet

Prot No: POG 9005(91)

Status: Ongoing

TITLE: ALinC #15: Dose Intensification of Methotrexate and 6-Mercaptopurine for ALL in Childhood - A Pediatric oncology Group Randomized Phase III Study

Start date: Feb 91

Est Comp Date: Jul 94

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 4/23/96
Decision: Continue

OBJECTIVE: To determine, in a randomized trial, whether intensification with intermediate-dose methotrexate (ID MTX), and intravenous 6-mercaptopurine (IV 6-MP) is superior or inferior to repeated low-dose, oral methotrexate (LD MTX) and IV 6-MP or ID MTX alone for prevention of relapse in children with ALL in first remission and at lower risk for relapse.

TECHNICAL APPROACH: Treatment of newly diagnosed in remission non-T, non-B ALL patients >12 months and <21 years of age with two arm randomized study of intensification with intermediate dose MTX and IV-6MP vs repeated low-dose, oral MTX and IV-6MP followed by a common maintenance therapy of weekly IM MTX and daily p.o. 6-MP. Additional arm of ID MTX added for randomization.

MODIFICATION (Nov94): Status change.

PROGRESS: No. of Subjects Enrolled - To Date: 8
During FY96: 0

Accrual completed 9/1/94. 1304 registrations noted by end of Sep 94. 97% CR rate of evaluable patients across all strata. No unusual toxicity to date. Data collection and analysis ongoing.

Arm A vs Arm B - data interpreted on favoring Arm A.

Arm A vs Arm C - data unavailable at this time.

Detail Summary Sheet

Prot No: POG 9006(91)

Status: Ongoing

TITLE: ALinC #15: Up-front 6-MP/Methotrexate vs Up-front Alternating Chemotherapy for Acute lymphocytic Leukemia in Childhood - A Pediatric Oncology Group Randomized Phase III Study

Start date: Feb 91

Est Comp Date: May 94

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 4/23/96
Decision: Continue

OBJECTIVE: To compare, in a randomized trial of children with ALL at higher risk for relapse, the efficacy and toxicity of a) 12 early intensive courses of IV methotrexate (MTX) plus IV 6-mercaptopurine (6-MP) vs b) 12 early intensive courses of alternating intensive chemotherapy combinations (6-MP/MTX, VM-26/Ara-C, vincristine/prednisone/PEG L asparaginase/daunomycin/Ara-C).

TECHNICAL APPROACH: Treatment of newly diagnosed non-T, non-B ALL patients, 1-21 years of age with poor prognostic features but with successful remission induction, on a two arm randomized study of intensification therapy with IV MTX/6-MP vs three alternating chemotherapy pairs (MTX/6MP, VM-26/Ara-C, daunomycin/Ara-C) to be followed by a common maintenance therapy of weekly IM MTX and by mouth daily 6-MP.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

(Early accrual closed in Jan 94. Re-opened for accrual single arm pilot in Jun 94.) Closed by data monitoring board in Jan 94 at 95% initial accrual objective based on early difference in efficacy favoring Arm B (the more toxic arm re: infections and allergic reactions). Study was re-opened as single arm pilot study in Jun 94 (not yet activated at TAMC). 476 eligible POG patients accrued to date. 96.5% CR rate across all strata. Data collection and analysis ongoing.

Publications:
ASCO, 1995 (submitted)

Detail Summary Sheet

Prot No: POG 9031(91)

Status: Ongoing

TITLE: High-Stage Medulloblastoma

Start date: Sep 91

Est Comp Date: Mar 96

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: (a) To compare the 2-year event-free survival (EFS) of children with newly-diagnosed high-risk medulloblastoma who are treated with cisplatin and VP-16 pre-irradiation vs post-irradiation. (b) To define the toxicity and activity of pre-irradiation cisplatin/VP-16 in patients with newly-diagnosed high-risk medulloblastoma. (c) To determine whether achievement of a measurable tumor response (PR and CR) to pre-irradiation cisplatin/VP-16 has prognostic significance for children with failure to achieve a measurable response (SD or PD). (d) To define the toxicity and activity of post-irradiation cisplatin/VP16 in patients with newly-diagnosed high-risk medulloblastoma. (e) To determine if C-myc amplification in medulloblastoma is associated with an adverse prognosis.

TECHNICAL APPROACH: Randomized study between two treatment arms. Treatment arm I involves upfront chemotherapy followed by XRT then additional chemotherapy. Treatment arm II administers XRT upfront followed by chemotherapy. Chemotherapy doses and combinations, XRT and total treatment period are the same for both arms.

MODIFICATION (Feb95): Therapy & eligibility changes.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

141 eligible POG patients accrued. Worst toxicities are hematologic. Arm specific response data remains masked but overall number of failures is small for this short follow-up to date. Closed to accrual 26 Mar 96.

Publications: J Neuro Oncology 11:1-15, 1991.

Detail Summary Sheet

Prot No: POG 9046(93)

Status: Completed

TITLE: Molecular Genetic Analysis of Wilms' Tumor, A POG Cancer Biology Study

Start date: May 93

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Completed

OBJECTIVES: (1) To define the patterns of tumor-specific loss of constitutional chromosomal heterozygosity in a large series of Wilms' tumors and associated nephrogenic rests (nephroblastomatosis); (2) To correlate these patterns with clinicopathologic findings; (3) To physically localize gene mutations and chromosome abnormalities from specific categories of Wilms' tumors; (4) To clone genes associated with Wilms' tumor; (5) To establish a bank of molecularly and cytogenetically characterized Wilms' tumors with matched constitutional tissue.

TECHNICAL APPROACH: Submission of frozen tumor tissue and fresh whole blood at initial diagnosis for tissue/blood banking and cytogenetic studies.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

430 eligible POG patients registered as of 4/95; one patient from TAMC. Analysis ongoing.

Publications:

Maw MA, et al: A third Wilms' tumor locus on chromosome 16q. Cancer Res 52:3094-3098, 1992.

Rainer S, et al: Relaxation of imprinted genes in human cancer. Nature 36:747-749, 1993.

Grundy P, et al: Uniparental Disomy Occurs Infrequently in Wilms Tumor Patient. Am J Hum Genet 54:282-289, 1994.

Grundy P, et al: Loss of Heterozygosity for Chromosomes 16q and 1p in Wilms Tumors Patients Predicts an Adverse Outcome. *Cancer Res* 54:2331-2333, 1994.

Bordeesy N, et al: Anaplastic Wilms Tumor: A Subtype Displaying Poor Prognosis, Harbors p53 Gene Mutations. *Nature Genetics* 7:91-92, 1994.

Varanasi R, et al: Fine Structure Analysis of the WT1 Gene in Sporadic Wilms' Tumor. *Proc Natl Acad Sci USA* 91:3554-3558, 1994.

Steeman MJC, et al: Loss of Imprinting of IGF2 is Linked to Reduced Expression and Abnormal Methylation of H19 in Wilms' Tumor. *Proc Natl Acad Sci USA* 91:3554-3558, 1994.

Published Abstracts:

Li FP, et al: Inherited WTI Mutations in Wilms' Tumor. *Molecular and Clinical Genetics of Childhood Renal Tumors*, Philadelphia PA, 1995.

Grundy P, et al: Clinicopathologic Correlates of Loss of Heterozygosity in Wilms' Tumor. *Molecular and Clinical Genetics of Childhood Renal Tumors*, Philadelphia PA, 1995.

Shearer P, et al: Homozygous Deletions Affecting 16q 22-23 Wilms' Tumor: Detection by Fluorescence in situ Hybridization (FISH). *Molecular and Clinical Genetics of Childhood Renal Tumors*, Philadelphia PA, 1995.

Detail Summary Sheet

Prot No: POG 9047(90)

Status: Ongoing

TITLE: Neuroblastoma Biology Protocol

Start date: May 90

Est Comp Date: May 95

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To characterize the biological nature of neuroblastoma.

TECHNICAL APPROACH: Referral of fresh unfixed tumor material plus serum and plasma to POG reference laboratories.

MODIFICATION #1 (Nov94): Consent revised.

MODIFICATION #2 (Feb95): Eligibility changes.

PROGRESS: No. of Subjects Enrolled - To Date: 3
During FY96: 1

POG data reveals 1188 registrants groupwide (610 registered on therapeutic protocols as well). Data collection ongoing.

Publications:

Oncogene 5:1615-1618, 1990

J. Clin Invest 88:341-345, 1991

Cancer Res 51:1596-1599, 1991

J. Clin Oncol 9:581-591, 1991

Numerous' per POG meeting agenda.

DNA Index	≤ 1 (%) 303 (32)	≥ 1 (%) 657 (68)	missing 109	unsatisfactory 79		
LDH	≤ 1500 (%) 710 (79)	≥ 1500 (%) 193 (21)	missing 245			
N-myc	amplified (%) 166 (18)	not amplified 763 (82)	missing 219			
STAGE	A (%) 213 (21)	B (%) 92 (9)	C (%) 234 (23)	D (%) 798 (39)	DS (%) 85 (8)	missing 128

Detail Summary Sheet

Prot No: POG 9048(92)

Status: Ongoing

TITLE: Treatment of Children with Localized Malignant Germ Cell Tumors

Start date: Mar 92

Est Comp Date: Mar 95

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 12/5/95

Gifts:

Decision: Continue

OBJECTIVE: a) To determine whether $< 85\%$ of patients with immature teratomas or Stage I malignant testicular germ cell tumors will have long-term event-free survival when treated with surgery alone, and to estimate a time after which disease recurrence for these patients is very unlikely; b) To determine whether a long-term event-free survival of $< 85\%$ can be achieved for children with Stage II malignant testicular germ cell tumors and Stage I and II ovarian germ cell tumors who are treated with four courses of chemotherapy with cisplatin, etoposide, and bleomycin (PEB); c) To evaluate the prognostic significance of histology, site, and size of the primary lesion(s); extension of disease into local tissues; and extent of lymph node involvement; d) To determine whether initial levels and subsequent changes in tumor markers, specifically alpha-fetoprotein (FP), beta-human chorionic gonadotropin (HCG), and LDH, correlate with initial response, ultimate outcome, and disease recurrence.

TECHNICAL APPROACH: Treatment of primary localized (Stage I-II) gonadal germ cell tumors with surgical resection, followed by chemotherapy if evidence of residual disease.

MODIFICATION (Mar95): Status change.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Intergroup study, closed to accrual 15 Mar 95. Currently, there are 126 CCG registrants and 106 POG registrants. Response masked. Little toxicity reported. Disease Free survival:

Surgery alone @ 2 years ---- 90.17 (SE 16.3)

Surgery + PEB @ 2 years--- 94.87 (SE 15.3)

Detail Summary Sheet

Prot No: POG 9049(92)

Status: Ongoing

TITLE: (Int-0097) - A Study of High-Risk Malignant Germ Cell Tumors in Children

Start date: Mar 92

Est Comp Date: Mar 95

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: a) To compare the efficacy with respect to survival and event-free survival (EFS) of two chemotherapeutic regimens. A high-dose cisplatin, etoposide, and bleomycin (HDP/EB), or standard-dose cisplatin, etoposide, and bleomycin (PEB) in the treatment of children with high-risk malignant germ cell tumors; b) To evaluate the prognostic significance of histology, site, and size of the primary lesion(s), sites of metastasis, and extent of lymph node involvement.

TECHNICAL APPROACH: This is a randomized study involving 2 chemotherapy treatment arms. Treatment Arm I involves high-dose cisplatin/etoposide/bleomycin. Arm II involves standard dose cisplatin/etoposide/bleomycin.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

For this intergroup study currently there are 284 POG and CCG registrants evaluable for toxicity. Response remain masked. Overall survival @ 3 yrs: 71.97 (SE 12.1). Significant nonhematologic toxicities include ototoxicity (13 grade 3/4), nephrotoxicity (Fanconi-like syndromes or renal insufficiency), persistent hypertension, rare pulmonary dysfunction and peripheral neuropathy.

Publications: Hawkins E, et al: Occult Malignancy in Neonatal Sacrococcygeal Teratomas: A Report from a Combined POG and CCG Study. Am J Ped Hem/Onc 15:406, 1993.

Detail Summary Sheet

Prot No: POG 9082(90)

Status: Ongoing

TITLE: Protocol for the Development of Intervention Strategies to Reduce the Time Between Symptom Onset and Diagnosis of Childhood Cancer

Start date: Sep 90

Est Comp Date: Sep 96

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 8/27/96

Gifts:

Decision: Continue

OBJECTIVE: (1) To describe the constellation of signs and symptoms which occur prior to the definitive diagnosis of childhood cancer; (2) To evaluate factors which may be associated with the length of time between the onset of symptoms and diagnosis; (3) To determine if the pattern of symptoms and the length of time between symptom onset and diagnosis influence prognosis independent of treatment and the stage of disease at diagnosis; (4) To provide information which may be used to develop intervention strategies aimed at reducing the interval between onset of symptoms and diagnosis.

TECHNICAL APPROACH: All patients at the time of registration on a POG frontline therapeutic protocol will be surveyed for historical information regarding signs/symptoms and illness duration preceding diagnosis of cancer. This data will be analyzed for information which may be used to develop intervention strategies designed to reduce the interval between onset of illness and diagnosis with the intent to improve long-term diagnosis.

MODIFICATION #1 (Mar95): Status change.

MODIFICATION #2 (Aug 96): Amendment #3.

PROGRESS: No. of Subjects Enrolled - To Date: 10
During FY96: 0

2016 patients accrued to study groupwide to date. Data completeness is excellent.

Publications:

J. Pediatr 119(5):725-732, 1991

Detail Summary Sheet

Prot No: POG 9130(92)

Status: Ongoing

TITLE: Treatment of Newly-Diagnosed Astrocytomas

Start date: Mar 92

Est Comp Date: Mar 97

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: a) Determine the beneficial effects of irradiation in newly diagnosed low-grade astrocytomas of the brain in childhood; b) Define the role of surgical resection in newly diagnosed low-grade astrocytomas of the brain in childhood; c) To determine if adjuvant radiation therapy improves progression-free survival following incomplete surgical resection in children 5 - 21 years old with newly diagnosed low-grade astrocytomas of the brain; d) To document the natural history of newly diagnosed low-grade astrocytomas of the brain in patients receiving radical surgical resection as the sole treatment modality; e) To determine and compare the late effects and neuropsychological sequelae of the various treatments in a large group of children with slow growing brain tumors likely to have long-term progression-free survival of cure.

TECHNICAL APPROACH: Treatment of low grade astrocytomas following maximal surgical resection with either 1) supportive care or 2) randomization between irradiation and supportive care or 3) physician's choice of supportive care or irradiation, with determination based on % residual disease, age of patient and neurologic stability.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

Through 14 Jul 95, there were 531 patients registered. Randomized portion of protocol was closed due to low accrual. Study remains open as a natural history study. There has not been an excessive rate of relapse in death.

Detail Summary Sheet

Prot No: POG 9132(94)

Status: Ongoing

TITLE: Hyperfractionated Irradiation for Posterior Fossa Ependymoma

Start date: Feb 94

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC;
MAJ Marianne M. Young, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 12/5/95

Gifts:

Decision: Continue

OBJECTIVE: (1) To determine the feasibility of using hyperfractionated irradiation to the posterior fossa and upper cervical canal to treat newly-diagnosed patients with posterior fossa ependymoma, and to determine the toxicity of this treatment; (2) To evaluate the response of children with incompletely-resected posterior fossa ependymoma to hyperfractionated irradiation; (3) To estimate the disease control interval and pattern of failure of children with posterior fossa ependymoma following treatment with surgery and hyperfractionated irradiation.

TECHNICAL APPROACH: Treatment of children *36 months and *21 years of age, at diagnosis of posterior fossa ependymoma (without supratentorial or spinal cord involvement), with hyperfractionated XRT.

MODIFICATION (Mar95): Status change.

PROGRESS: No. of Subjects Enrolled - To Date: 0

During FY96: 0

46 patients registered to date. Of 18 evaluable patients with less than complete resections, 4 have had PR, 9 have stable disease, 2 have had progressive disease, 3 too early to report. 10 treatment failures as of 27 Apr 95, 9 of which occurred in patients with ependymoma NOS; one had anaplastic tumor. No unusual toxicities described. One second malignancy reported (ALL) proximate to XRT felt not to be causally related to XRT.

Detail Summary Sheet

Prot No: POG 9135(91)

Status: Ongoing

TITLE: Pre-Radiation Chemotherapy for Children with Supratentorial Malignant Gliomas and Poorly-Differentiated Embryonal Tumors

Start date: Sep 91

Est Comp Date: Mar 95

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: a) To estimate the response of children with supratentorial malignant glioma or poorly-differentiated embryonal tumors (PDET)s to three cycles of either BCNU plus continuous-infusion cisplatin or cyclophosphamide plus continuous-infusion cisplatin or cyclophosphamide plus continuous-infusion etoposide (VP-16); b) To determine the acute and sub-acute toxicities of these combination chemotherapies; c) To estimate prospectively, using neuroimaging studies and CSF cytology, the incidence of neuraxis tumor dissemination at diagnosis in children with measurable residual tumor following initial surgery.

TECHNICAL APPROACH: Randomized study between two 2-drug pre-radiation therapy chemotherapy regimens (cisplatin/BCNU vs VP-16/cyclophosphamide).

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

113 patients accrued to study to date. Too early for data analysis report. No unexpected toxicities. Accrual met and closed to entry 16 Oct 95.

Detail Summary Sheet

Prot No: POG 9136(91)

Status: Ongoing

TITLE: Phase I/II Dose Escalating Trial of Hyperfractionated Irradiation In Treatment of Supratentorial Malignant Tumors of Childhood

Start date: Sep 91

Est Comp Date: Sep 95

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: a) To determine the feasibility of using limited volume hyperfractionated radiation therapy to treat children with localized supratentorial malignant glioma (Group A); b) To determine the feasibility of using hyperfractionated craniospinal irradiation to treat children with poorly-differentiated supratentorial embryonal tumors (PNETs) or supratentorial malignant gliomas associated with neuraxis dissemination (Group B); c) To determine the acute and subacute toxicities associated with hyperfractionated supratentorial brain irradiation (at 2 dose levels) and prior intensive chemotherapy (per #9135) for children with localized supratentorial malignant gliomas (Group A); d) To determine the acute and subacute toxicities associated with hyperfractionated craniospinal irradiation and prior intensive chemotherapy (per #9135) for children with disseminated supratentorial malignant gliomas and supratentorial PNETs (Group B); e) To estimate the incidence of neuraxis tumor dissemination at the time of diagnosis and at disease recurrence or progression in children with malignant supratentorial malignant gliomas and PNETs; f) To estimate the event-free survival for children with supratentorial malignant gliomas and PNETs who are treated with hyperfractionated radiation therapy + induction chemotherapy per #9135.

TECHNICAL APPROACH: Treatment of supratentorial malignant tumors of childhood with one of two hyperfractionation XRT regimens, determination based on presence or absence of neuraxis dissemination. Provision for dose escalation exists for both regimens.

MODIFICATION (Feb95): Status change.

PROGRESS: No. of Subjects Enrolled - To Date: 0
 During FY96: 0

To date, 42 patients accrued groupwide to study. Response remains masked. No unexpected toxicities reported. Study was closed to accrual 2/15/96.

Detail Summary Sheet

Prot No: POG 9150(92)

Status: Ongoing

TITLE: IRS-IV Stage 1 Disease

Start date: Nov 91

Est Comp Date: Feb 97

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 9/24/96

Gifts:

Decision: Continue

OBJECTIVE: a) To compare the progression-free survival rates of patients receiving vincristine-actinomycin-D-cyclophosphamide (VAC) vs patients receiving vincristine-ifosfamide-actinomycin (VAI) for treatment of rhabdomyosarcoma and undifferentiated sarcoma; b) To compare hyperfractionated radiation therapy (RT) to conventional RT in regard to local relapse rates, and early/acute toxicity and late effects; c) To investigate the relationship between immunohistochemical pattern of tumor and prognosis, and to evaluate newly identified immunohistochemical markers in diagnosis; d) To correlate clinical features of disease and prognosis with tumor cytogenetics, DNA index and amplification or rearrangement of specific cellular proto-oncogenes; e) To provide a bank of frozen tumor tissue for use in tumor biology studies; f) To evaluate the use of recombinant G-CSF as a supportive measure, limiting its use to those patients with documented need for amelioration of hematopoietic toxicity.

TECHNICAL APPROACH: Treatment of Stage I rhabdomyosarcoma and undifferentiated sarcoma with chemotherapy (randomized between VAC and VAI) → XRT (conventional or hyperfractionated), based on disease clinical group.

MODIFICATION #1 (Mar95): Therapy changes.

MODIFICATION #2 (Jul95): Eligibility changes.

PROGRESS: No. of Subjects Enrolled - To Date: 0
 During FY96: 0

Currently, there are 211 eligible (CCG & POG combined) registrants. No toxic deaths. Data analysis ongoing.

Detail Summary Sheet

Prot No: POG 9151(92)

Status: Ongoing

TITLE: IRS-IV Stage 2 and 3 Disease

Start date: Nov 91

Est Comp Date: Feb 97

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/24/96
Decision: Continue

OBJECTIVE: a) To compare the progression-free survival rates of patients receiving vincristine-actinomycin-D-cyclophosphamide (VAC) vs patients receiving vincristine-actinomycin-ifosfamide (VAI) for treatment of rhabdomyosarcoma and undifferentiated sarcoma; b) To compare hyperfractionated radiation therapy (RT) to conventional RT in regard to local relapse rates, and early/acute toxicity and late effects; c) To investigate the relationship between immunohistochemical pattern of tumor and prognosis, and to evaluate newly identified immunohistochemical markers in diagnosis; d) To correlate clinical features of disease and prognosis with tumor cytogenetics, DNA index and amplification or rearrangement of specific cellular proto-oncogenes; e) To provide a bank of frozen tumor tissue for use in tumor biology studies; f) To evaluate the use of recombinant G-CSF as a supportive measure, limiting its use to those patients with documented need for amelioration of hematopoietic toxicity.

TECHNICAL APPROACH: Treatment with chemotherapy and radiation therapy with specific treatment determined by randomization between three arms involving three different triple drug combinations and, for clinical Group III disease, additional randomization between conventional and hyperfractionated XRT.

MODIFICATION #1 (Mar95): Therapy changes.

MODIFICATION #2 (Jul95): Eligibility changes.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

Currently there are 391 patients registered intergroup. Data analysis ongoing.

Five toxic deaths in Stages I - III:	regimen	etiology
	VAC PRA	inf sepsis
	VAC PRA	inf sepsis
	VAI	inf sepsis/pulm
	VAI	inf sepsis/pulm
	VAC	CNS

Detail Summary Sheet

Prot No: POG 9152(92)

Status: Completed

TITLE: IRS-IV Stage 4 and/or Clinical Group IV Disease

Start date: Nov 91

Est Comp Date: Nov 97

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 9/24/96

Gifts:

Decision: Completed

OBJECTIVE: a) To rank order three treatment strategies according to progression-free survival (PFS) and overall survival rates for rhabdomyosarcoma (RMS) and undifferentiated sarcoma. These strategies compare vincristine-melphalan (VM) vs ifosfamide-VP-16 (IE) upfront and as part of maintenance chemotherapy (with VAC) for responders, all patients receiving radiation therapy. Since the pilot study of the ID regimen (CCSG-6881, POG-8889, NCI-INT-0092) already has accrued sufficient patients, data from the pilot study will be used for these analyses, and therefore, the ID regimen is omitted from this protocol; b) To determine whether there is clinical cross-resistance between the drug pairs used upfront and subsequent vincristine-actinomycin D-cyclophosphamide (VAC) therapy in patients who achieve less than a CR to the induction doublets; c) To investigate the relationship between immunohistochemical pattern of tumor and prognosis, and to evaluate newly identified immunohistochemical markers in diagnosis; d) To correlate clinical features of disease and prognosis with tumor cytogenetics, DNA index and amplification or rearrangement of specific cellular proto-oncogenes; e) To provide a bank of frozen tumor tissue for use in tumor biology studies; f) To evaluate the use of recombinant G-CSF as a supportive measure, limiting its use to those patients with documented need for amelioration of hematopoietic toxicity.

TECHNICAL APPROACH: Randomization to chemotherapy upfront of VM or IE followed by 12 weeks of standard VAC + XRT, then additional VM or IE with VAC, if initially responsive, or courses of VAC alone if not initially responsive.

MODIFICATION (Mar95): Therapy changes.

PROGRESS: No. of Subjects Enrolled - To Date: 0
 During FY96: 0

A total of 135 patients were registered intergroup; none at Tripler. Data analysis ongoing.
Study closed to accrual 3/1/95.

There were 3 toxic deaths: (a) regimen IE-infection/sepsis-pulmonary; (b) VM veno-occlusive diagnosis; (c) VM infection/sepsis-pulmonary.

Detail Summary Sheet

Prot No: POG 9153(92)

Status: Ongoing

TITLE: IRS Laboratory Evaluation

Start date: Nov 91

Est Comp Date: Nov 95

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/24/96
Decision: Continue

OBJECTIVE: a) To prospectively correlate clinical features and outcome of newly diagnosed children with rhabdomyosarcoma with cytogenetic abnormalities of their tumors; b) To measure cellular DNA content by flow cytometry of tumor cells and correlate the DNA index of tumor stem lines with clinical features and treatment response of children with rhabdomyosarcoma; c) To determine prospectively the clinical significance of amplification or rearrangement of specific cellular proto-oncogenes or allelic loss of recessively acting loci in DNA extracted from pediatric rhabdomyosarcomas; d) To attempt to derive tumor cell lines and to provide a bank of frozen rhabdomyosarcoma tumor tissue for use in further studies, especially molecular genetic studies; e) To determine the degree of specificity of monoclonal antibody probes, 4.2A8, 5.1H11, and 3.1G11, for childhood rhabdomyosarcoma.

TECHNICAL APPROACH: Submission of blood and tumor tissue samples for biologic studies.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

No current groupwide registration figures. Overall fresh tissue received on 39% (310/804); frozen tissue 17% (135/804); overall frozen & fresh 44% (355/804).

Abstracts:

Pappo AS, et al. ASCO Proc 12:211, 1993

Pappo AS, et al. MPO 21:549, 1993

Publications:

Pappo AS, et al. Tumor cell DNA content predicts outcome in children and adolescents with clinical Group III embryonal rhabdomyosarcoma. *J Clin Onc* 11:1901-1905, 1993.

Detail Summary Sheet

Prot No: POG 9160(92)

Status: Completed

TITLE: Idarubicin, Cytosine Arabinoside for Multiply Recurrent or Refractory Lymphoblastic Leukemia - A Pediatric Oncology Group Phase II Study

Start date: Mar 92

Est Comp Date: 12/5/95

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Completed

OBJECTIVE: a) The major objective is to estimate the reinduction rate with cytosine arabinoside (ARA-C) and idarubicin for children with ALL in first marrow relapse who fail reinduction therapy on POG #9110 (SIMAL #6 pilot) or on the planned open SIMAL #6 randomized study. This drug combination will also be explored in children with ALL in third or later bone marrow relapse; b) A uniform maintenance therapy consisting of alternating cycles of ifosfamide/VP-16 and idarubicin/cytosine arabinoside will be studied for children who achieve complete remission and who are not candidates for bone marrow transplantation. All patients will receive granulocyte colony-stimulating factor (G-CSF) following induction chemotherapy, and continuation treatment. The duration of bone marrow remission will be estimated; c) Central nervous system prophylactic therapy, as well as treatment for active CNS disease, will also be provided by the combination of intravenous Ara-C and idarubicin. The duration of CNS remission will be estimated; d) The toxicity of this induction and uniform maintenance chemotherapy will also be determined; e) The pharmacology of idarubicin and its metabolite idarubicinol will be studied, emphasizing the intracellular concentrations within leukemic cells.

TECHNICAL APPROACH: Induction therapy with ARA-C and idarubicin to be followed by maintenance therapy of alternating cycles of ifosfamide/VP16 and idarubicin/ARA-C, for those who achieve remission with the induction regimen.

PROGRESS: No. of Subjects Enrolled - To Date: 0
 During FY96: 0

73 patients currently registered groupwide. Idarubicin and Ara-C in combination effectively induce marrow hypoplasia. Response remains masked. Major associated toxicities remain fever, neutropenia, with occasional sepsis.

Study was closed to accrual 1 Nov 94 with a total accrual of 83 patients groupwide (0 patients from TAMC). Approximately 35% of patients achieved CR. Those continued on chemotherapy alone had brief remissions (median 69 days). However, 8 patients had remissions >100 days. Eleven patients went to BMT, 3 still alive, one at >600 days after BMT.

Detail Summary Sheet

Prot No: POG 9170(91)

Status: Ongoing

TITLE: Etoposide and Ifosfamide Plus G-CSF in Children With Recurrent Sarcoma; Including Soft Tissue Sarcoma, Ewing's Sarcoma, Rhabdomyosarcomas and Osteosarcoma, a Pediatric Oncology Group Pilot Study

Start date: Sep 91

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: a) To establish the qualitative and quantitative toxicity of Etoposide (VP-16), ifosfamide (IFOS), and G-CSF administered to children whose cancer is refractory to standard therapy; b) To establish a dose level of Ifosfamide: MESNA with non-escalated doses of VP-16 and G-CSF that results in maximum-tolerable toxicity, which is predictable and reversible (MTD); c) To establish the acute and chronic dose-limiting toxicities (DLT) of the combination of VP-16, ifosfamide and G-CSF with increasing doses of ifosfamide in children; d) To determine if there is cumulative toxicity in children after administration of 3 cycles of therapy.

TECHNICAL APPROACH: Treatment of recurrent sarcomas with VP-16/IFOS/G-CSF with provisions for dose escalations of IFOS:MESNA for new patients as dosage tolerance allows

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study was closed to accrual in Jan 94. There are 52 patients enrolled on study. Fanconi's has been the most common dose limiting toxicity. MTD was established at dose level 4. Patients with refractory osteosarcoma had a higher than expected disease response.

Abstracts: Goorin A, et al: Proc of ASCO 13:425, 1994.

Detail Summary Sheet

Prot No: POG 9182(92)

Status: Ongoing

TITLE: HIV/Malignancy Biology Protocol

Start date: Mar 92

Est Comp Date: Mar 97

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/96
Decision: Continue

OBJECTIVE: a) To establish a national registry of pediatric AIDS-associated lymphomas and other malignancies and a repository of well-characterized tumor tissue, cells and sera from affected patient; b) To conduct prospective Phase I-III clinical trials of anti-cancer and anti-retroviral therapies aimed at improving outcomes and identifying critical determinants of risk; c) To identify the presence and quantify the viral burden of human immunodeficiency virus (HIV), Epstein-Barr virus (EBV), cytomegalovirus (CMV), human herpes virus 6 (HHV6), and herpes simplex virus (HSV) in the tumor tissue, peripheral blood cells, plasma, and cerebrospinal fluid of pediatric patients with lymphomas and other malignancies, and to characterize the effect of anti-cancer and anti-viral chemotherapy with regard to lymphoma stage, disease progression, host response, and toxicity; d) To conduct the first large-scale molecular epidemiologic study of risk factors related to development of HIV-related NHL in children by means of a case-control analysis of HIV-infection characteristics such as co infection with EBV, CMV, HHV6, Mycoplasma, the quantitative host viral burden, level of immunodeficiency, and other host characteristics.

TECHNICAL APPROACH: Establishment of a national registry of pediatric AIDS-associated lymphomas and other malignancies, as well as a repository of well-characterized tumor tissue, cells and sera from affected patients.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

91 patients total across all strata; 19 cases, 24 malignancy controls; 48 non-malignancy controls through 11 Sep 95.

Detail Summary Sheet

Prot No: POG 9201(95)

Status: Ongoing

TITLE: ALinC 16: Treatment for Patients With Lesser Risk Acute Lymphoblastic Leukemia - A Pediatric Oncology Group Phase III Study

Start date: Jan 95

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/96
Decision: Continue

OBJECTIVE: (a) To confirm the outstanding results in patients with lesser risk non-T, non-B acute lymphoblastic leukemia (ALL) treated in a fashion similar to the least intensive arm of POG 8602 (ALinC 14, Arm A); (b) to study laboratory correlates from POG 9400 and clinical correlates with outcome in pooling studies 9201, 9405, and 9406.

TECHNICAL APPROACH: Treatment protocol.

MODIFICATION #1 (Jul95): Consent revision includes toxicity update.

MODIFICATION #2 (Jul96): Editorial, therapy, eligibility, and consent changes.

MODIFICATION #3 (Aug96): Amendments #2-4

MODIFICATION #4 (Sep96): Editorial, therapy, and consent changes.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

Opened to groupwide accrual 15 Nov 94 with 59 patients enrolled through Jul 95. Data too early for results.

Detail Summary Sheet

Prot No: POG 9219(92)

Status: Ongoing

TITLE: Treatment of Patients With Localized Non-Hodgkin's Lymphoma - A Pediatric Oncology Group Phase IV Study

Start date: Sep 92

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVES: (a) To maintain a high cure rate with minimum toxicity for children with localized non-Hodgkin's lymphoma in favorable sites; (b) To analyze in a large group of patients with localized non-Hodgkin's lymphoma (by pooling data from POG #8314, #8719 and the current study) prognostic factors which may predict subgroups of patients with a poor prognosis within the subgroup of patients with localized non-Hodgkin's lymphoma (NHL).

TECHNICAL APPROACH: Treatment of localized NHL with induction chemotherapy of Cyclophosphamide, Adriamycin, Vincristine, Prednisons, and one course of consolidated therapy of same drugs with maintenance chemotherapy (oral 6-MP and Methotrexate) reserved for lymphoblastic lymphoma only.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

To date, 140 registered groupwise. Of the 59 currently evaluable patients, 129 had CR with 10 failures. Data monitoring continues.

Abstracts:

Lab Investigation 68:128A, 1993
MPO 21:532, 1993

Detail Summary Sheet

Prot No: POG 9220(93)

Status: Completed

TITLE: Phase III Randomized Trial of All-Trans Retinoic Acid Versus Cytosine Arabinoside and Daunorubicin Induction Therapy For Patients With Previously Untreated Acute Promyelocytic Leukemia - An Intergroup Study

Start date: Apr 93

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Completed

OBJECTIVES: (1) To compare the complete remission rate and disease-free survival of TRA to that achieved with conventional induction chemotherapy including Cytosine Arabinoside plus Daunorubicin in patients with previously untreated APL; (2) To compare the toxicities of TRA to those of Cytosine Arabinoside plus Daunorubicin as induction therapy in APL; (3) To determine the value of maintenance therapy with TRA.

TECHNICAL APPROACH: Treatment of newly diagnosed APL with induction therapy randomization between TRA vs chemotherapy of Daunorubicin/Ara-C with provision for treatment crossover if unresponsive to initial TRA.

MODIFICATION #1 (Feb 95): Amendment #5

MODIFICATION #2 (Mar 95): Status change.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

Nationally across all cooperative groups, 401 patients registered to date (24 thru POG). Lethal toxicity is comparable for both induction arms. Patient treated at TAMC had toxicity of pseudotumor cerebri, relapsed.

Detail Summary Sheet

Prot No: POG 9222(92)

Status: Completed

TITLE: Mitoxantrone, Etoposide and Cyclosporine (MEC) Therapy in Pediatric Patients with Recurrent or Refractory Acute Myeloid Leukemia

Start date: Jun 92

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 4/23/96
Decision: Completed

OBJECTIVE: a) To determine the remission rate and toxicity to mitoxantrone, etoposide and cyclosporine. b) To measure *mdr1* and topoisomerase 11 messenger RNA levels by polymerase chain reaction (PCR) in myeloid leukemia cells prior to starting therapy. c) To detect *mdr1* p-glycoprotein and function in leukemic blasts.

TECHNICAL APPROACH: Treatment with a combination of mitoxantrone, etoposide and cyclosporine (MEC).

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study was terminated to accrual in 15 Jun 94. Groupwide, there are 68 patients registered. Grade III-IV mucositis seen in 29% of patients. Clinical cardiotoxicities seen in 4 patients. (All patients had 200-490 mg/m² of anthracycline therapy prior to enrollment on study).

Response: CR 22
PR 9
Mixed 1
No Response 20
Increasing Dis 7
Early death 4Abstracts:
Non evaluable 5
TOTAL 68

Dahl G: A POG Phase II Trial of Mitoxantrone, Etoposide and Cyclosporine (MEC)
Other 4Therapy for Relapsed and Refractory
Acute Myelogenous Leukemia (AML). Blood 82:195A, 1993.
Am Hematol 68(Suppl 1):32A, 1994.

Detail Summary Sheet

Prot No: POG 9227(93)

Status: Ongoing

TITLE: Treatment of Patients with Recurrent or Refractory Hodgkins Disease, Wilms' Tumor, Ewing's Sarcoma, Rhabdomyosarcoma, or Other Soft Tissue Sarcomas With Cyclosporine-A, Actinomycin-D, Vincristine

Start date: Nov 92

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/24/96
Decision: Continue

OBJECTIVES: (a) To study the toxicity and efficacy of cyclosporine-A (CSA), actinomycin-D (ACT), and vincristine (VCR) in the treatment of recurrent or refractory Hodgkin's disease (HD), Wilms' Tumor, Ewing's Sarcoma, Rhabdomyosarcoma or other soft tissue sarcomas; (b) To assess the prevalence of P-glycoprotein (P-gp) in diagnostic and relapse tumor specimens from patients with recurrent or progressive HD; (c) To study the pharmacokinetics of high-dose CSA.

TECHNICAL APPROACH: Treatment of malignancies refractory to vincristine/Doxorubicin with vincristine/Actinomycin-D and cyclosporine-A to assess cyclosporine-A's role in overcoming drug resistance.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Currently, 31 patients accrued to study groupwide. Data too early for analysis.

Breakdown:

Hodgkins	14
Ewings	6
Rhabdomyo	6
Other soft tissue sarcomas	5

Strata for Wilms - closed due to lack of accrual.

Detail Summary Sheet

Prot No: POG 9233(92)

Status: Ongoing

TITLE: POG 9233/34: A Phase III Randomized Trial of Standard vs Dose-Intensified Chemotherapy for Children 3 Years of Age with a Central Nervous System (CNS) Malignancy Treated with or without Radiation Therapy

Start date: Jun 92

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVES: To prospectively test the concept of dose-intensified chemotherapy on selected brain tumors in patients <3 years of age at diagnosis and develop effective methods of treatment that will minimize late toxicities affecting immature and rapidly developing central nervous systems.

TECHNICAL APPROACH: Treatment of any patient <3 years of age at the time of diagnosis with histologically proven tumor types.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

Currently, there are 214 patients registered on POG 9233 groupwide. Only 12 have been accrued to POG 9234 to date. No unexpected toxicities to date. Response remains masked on 9234. Current response data on 9233: CR(79), PR(39), Failed (38), Not Eval (8), Unknown (18).

Detail Summary Sheet

Prot No: POG 9237(92)

Status: Completed

TITLE: Idarubicin for Recurrent and Progressive Brain Tumors

Start date: Aug 92

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 3/26/96

Gifts:

Decision: Completed

OBJECTIVE: a) To determine the efficacy of idarubicin (4-demethoxydaunomycin) in the treatment of patients with progressive/recurrent childhood brain tumors. b) To evaluate the toxicity of this drug when given as a single dose by four-hour infusion every 21 days. c) To evaluate the hematologic toxicity of the drug when given with growth factor Granulocyte-Colony Stimulating Factor (G-CSF) support. d) To determine the cerebrospinal fluid (CSF) and plasma levels of idarubicin/idarubicinol when given by this dosing schedule.

TECHNICAL APPROACH: Treatment for patients diagnosed with progressive/recurrent childhood brain tumors at age <21 years.

MODIFICATION #1 (Apr93): Amendment #2.

MODIFICATION #2 (Jul95): Status change.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study closed to accrual 5/1/95. Currently 92 patients accrued to study groupwide. Worst toxicities remain hematologic (expected). Brainstem (no CR/PR observed in 10 patients) glioma stratum has closed. Otherwise study too early for analysis.

Detail Summary Sheet

Prot No: POG 9239(92)

Status: Ongoing

TITLE: Treatment of Children with Newly-Diagnosed Brain Stem Glioma (BSG) Using Cisplatin as a Radiosensitizer with Either Conventional or Hyperfractionated Radiotherapy

Start date: Aug 92

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: a) To compare the time to neurologic and/or radiographic progression and overall survival in children with newly-diagnosed brain stem glioma (BSG) who are treated with 100mg/M2 of infusional cisplatin combined with conventional vs hyperfractionated radiotherapy. b) To determine the toxicities of combining 100mg/M2 of infusional cisplatin as a radiosensitizer with already-tested radiotherapy fractionation regimens in children with newly-diagnosed brain stem glioma.

TECHNICAL APPROACH: Treatment for patients ≥ 3 and < 21 years of age with newly-diagnosed tumor arising in the pons.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

To date, there are 112 patients accrued to study groupwide and was closed to accrual 3/26/96. Patient registered at TAMC subsequently relocated to the mainland and word received that patient died of progressive disease. Survival data of patients as of 10/26/95 showed in 20% at 1 year. Further analysis pending.

Detail Summary Sheet

Prot No: POG 9243(92)

Status: Ongoing

TITLE: Intermediate-Risk Neuroblastoma (Stage B - all ages, and Stages C, D, and DS <365 Days at Diagnosis)

Start date: Jun 92

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To evaluate the responses and survival to treatment arms A & B, to evaluate toxicities associated with these treatments, to determine whether G-CSF can improve dose interval and dose intensity, and determine toxicities associated with G-CSF use.

TECHNICAL APPROACH: Treatment of newly diagnosed patients age ≥ 1 and < 21 years of age with Stage B disease, age < 365 days with Stages B, C, D, or Stage DS (Evans IVS) disease. Patients with recurrent disease: age < 365 days, with Stage A disease at diagnosis and recurrent disease staged as B, C, or D; age ≥ 1 year, with Stage A disease at diagnosis and recurrent disease staged as B.

MODIFICATION #1 (Nov94): Eligibility changes.

MODIFICATION #2 (Mar95): Eligibility changes.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Two hundred forty-five patients currently accrued to study groupwide. Response/survival data too early to report. No unexpected toxicities. Study closed to further patient accrual.

Detail Summary Sheet

Prot No: POG 9244(93)

Status: Completed

TITLE: OPEC/OJEC Chemotherapy for Children Older than 1 year of age with INSS Stages 2B and 3 Neuroblastoma

Start date: Feb 93

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Completed

OBJECTIVES: (1) To estimate the rates of response and local control, and the progression-free and overall survival in children >1 year of age at diagnosis, with International Staging System (INSS) stage 2B/3 (POG stage C) neuroblastoma when treated with OPEC/OJEC (Vincristine/Etoposide (VP-16)/chemotherapy and second-look surgery; (2) To estimate the response to, and local control rates of radiotherapy in patients failing to achieve a complete remission (CR) with OPEC/OJEC chemotherapy and surgery; (3) To evaluate the toxicities associated with the OPEC/OJEC regimen; (4) To compare the degree of initial surgical resectability to the rate of CR, duration of remission, and survival; (5) To determine the value of the laboratory studies of biologic parameters on neuroblastoma (POG #9047) in relation to clinical presentation at diagnosis, response to therapy, and survival.

TECHNICAL APPROACH: Treatment of more advanced neuroblastoma with combination chemotherapy/surgery as well as local XRT for residual disease.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Fifty patients enrolled. Response data on 25 patients is available through end of therapy: 22 achieved CR, 4 with persistent/progressive diagnosis, 2 with persistent diagnosis at end of therapy, 2 progression at 11 & 17 months from diagnosis. Two patients died, 1 unexpectedly of respiratory failure three days after starting therapy and one shortly after completion of therapy.

No publications.

Detail Summary Sheet

Prot No: POG 9259(92)

Status: Ongoing

TITLE: Carboplatin in the Treatment of Newly-diagnosed Metastatic Osteosarcoma or Unresectable Osteosarcoma

Start date: Sep 92

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVES: (a) To estimate the duration of survival for patients presenting with newly diagnosed metastatic osteosarcoma or unresectable osteosarcoma who are treated with a multi-agent chemotherapy regimen preceded by induction therapy with carboplatin; (b) To determine the toxicity of carboplatin in previously untreated pediatric patients, and to determine whether it will compromise the ability to subsequently perform surgery or give other chemotherapy; (c) To evaluate whether the combination of body surface area and renal function more accurately predicts the degree of carboplatin-induced myelosuppression than body surface area alone; (d) To determine whether response to chemotherapy can be predicted by measurements of drug resistance in tumor samples obtained prior to treatment.

TECHNICAL APPROACH: Treatment of patients with metastatic or unresectable osteosarcoma with carboplatin initially to assess disease response followed by surgery and multiagent chemotherapy.

MODIFICATION (Nov94): Status notice.

PROGRESS: No. of Subjects Enrolled - To Date: 0
 During FY96: 0

37 patients accrued groupwide at closure 1 Nov 96. Most severe toxicities have been hematopoietic and associated infection (as expected).

	# eval	CR	PR	SD/MR	PD
primary	28	0	3	17	8
lung mets	29	3	1	8	17
bone mets	15	0	0	6	9

Detail Summary Sheet

Prot No: POG 9262(94)

Status: Ongoing

TITLE: A Phase II Study of Taxol in Children with Recurrent/Refractory Soft-tissue Sarcoma, Rhabdomyosarcoma, Osteosarcoma, Ewing's Sarcoma, Neuroblastoma, Germ Cell Tumors, Wilms' Tumor, Hepatoblastoma, and Hepatocellular Carcinoma, Hodgkin's Disease, Non-Hodgkin's Lymphoma, and Adenocarcinoma of the Colon

Start date: Mar 94

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts: Taxol by NCI

FY 96:

Periodic Review Date: 3/26/96
Decision: Continue

OBJECTIVE: (1) To determine the response rate of recurrent bone and soft tissue sarcomas, neuroblastoma, germ cell tumors, hepatoglastoma, and hepatocellular carcinoma to taxol in a phase II trial; (2) To further define the spectrum of taxol's toxicity in children.

TECHNICAL APPROACH: Treatment of patients with recurrent or refractory solid tumor diseases (of types specified) who were * 2years of age at initial diagnosis. Treatment consists of a 24-hr infusion of Taxol every 3 weeks for 1 year or until intolerable toxicity or progressive disease.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

All strata except Wilms' tumor closed 6/15/95. One hundred sixty-seven patients registered across all strata. Taxol generally well-tolerated.

2 CR (neuroblastoma, adenocarcinoma)
6 PR (3 Ewings/PNET; 3 RMS)
9 MR (neuroblastoma-1; Ewings PNET-6; RMS-2)

37 SD NBL-7	88 PD N3L-18
Ewing-4	Ewing-13
Osteosarcoma-6	Osteosarcoma-18
RMS-8	RMS-12
soft tissue sarc-7	STS-14
NHL-1	NHL-0
Germ cell-1	Germ cell-1
HBL/HCL-2	HBL/HCL-9
Adeno-1	Adeno-3

Detail Summary Sheet

Prot No: POG 9264(92)

Status: Ongoing

TITLE: Chemotherapy Regimen for Initial Induction Failures in Childhood ALL

Start date: Jun 92

Est Comp Date: Oct 96

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To estimate the complete remission rate for initial induction failures in childhood ALL based on an induction regimen of methotrexate and 6-mercaptopurine, a one year disease-free survival for initial induction failures in childhood ALL based on a new regimen, and to try and better characterize this unique subpopulation of patients with primary drug resistance using cDNA probes for the multidrug-resistant phenotype and obtain an oncogene profile.

TECHNICAL APPROACH: Treatment of any patient at age $\geq$ 21 years at time of initial diagnosis with acute lymphoblastic (T or B cell lineage) leukemia who exhibit initial induction failures.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Nineteen patients accrued to study groupwide to date. No response data at this time. Toxicities reported indicated that 2/32 cases associated with seizures. As of time study amended, 20 Jul 94, no further severe neurotoxicities observed. Response masked.

Detail Summary Sheet

Prot No: POG 9265(92)

Status: Ongoing

TITLE: Evaluation of 13-Cis Retinoic Acid in Children with Juvenile Chronic Myelogenous Leukemia

Start date: Aug 92

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: a) To estimate response rate to orally administered 13-cis retinoic acid (CRA) in patients with juvenile chronic myelogenous leukemia (JCML). b) To estimate duration of objective response in patients with JCML treated with CRA alone. c) To quantitate the toxicity associated with oral CRA therapy. d) To determine the relationship between in vivo response to CRA, in vitro "spontaneous" growth patterns after oral CRA, and CRA serum levels during therapy. e) To further evaluate the etiology of myeloproliferation in JCML.

TECHNICAL APPROACH: Treatment with cis-retinoic acid for children newly-diagnosed previously untreated JCML who are not immediate candidates for bone marrow transplantation.

PROGRESS: No. of Subjects Enrolled - To Date: 2
During FY96: 1

401 patients accrued to study at closure data Feb 95. Too early for data analysis. Both TAMC patients registered to date died of progressive disease. Data suggested that ATRA does not lead to a higher CR rate in decrease in induction mortality compared to conventional chemotherapy, but exposure to ATRA either as induction or after CR is achieved is associated with an improved 1 year survival

Abstract: Proc Int'l Symp on APL: A Curable Disease. Rome, Nov 93.

Publication: Blood 86 (10, supplement):488A, 1995.

Detail Summary Sheet

Prot No: POG 9280(92)

Status: Completed

TITLE: Neuroblastoma Epidemiology Protocol

Start date: Apr 92

Est Comp Date: Dec 95

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 12/5/95

Gifts:

Decision: Completed

OBJECTIVE: The primary objective of this study will be to evaluate the relationship between environmental exposures and the occurrence of neuroblastoma. The study will include the majority of all cases newly diagnosed in the United States and Canada each year, registered by the two clinical trials groups, the Children's Cancer Study Group and the Pediatric Oncology Group.

TECHNICAL APPROACH: Matched controls will be identified by using a random digit dialing procedure. Case and control parents will be interviewed by telephone. Clinical and biologic data collected as part of the cooperative group biological and therapeutic protocols will be used to define subgroups of patients. The role of risk factors for neuroblastoma within biologic subgroups will then be investigated.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

Study closed to accrual on 1 Dec 94. There are 201 POG registrants accrued to date on this intergroup study. No data analysis of yet.

Detail Summary Sheet

Prot No: POG 9284(92)

Status: Ongoing

TITLE: POG 9284/85: Barriers to Patient Enrollment on POG Frontline Therapeutic Clinical Trials and Development of Intervention Strategies to Increase the Proportion of Enrollments

Start date: Jun 92

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: a) Prospectively identify physician and patient factors associated with reasons as to why patients who are eligible for therapeutic protocols made available through the Pediatric Oncology Group (POG) are not enrolled onto study. b) Provide information which may be used to develop intervention strategies to decrease barriers to patient enrollment, thus increasing the number of enrollments to therapeutic protocols for patients for whom a protocol is available.

TECHNICAL APPROACH: Questionnaire completion.

MODIFICATION (Apr94): Editorial changes & revised consent.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

250 (191 cases, 79 controls) accrued to study to date. Data analysis ongoing.

Detail Summary Sheet

Prot No: POG 9310(94)

Status: Ongoing

TITLE: SIMAL #7: Escalating Rotational Drug Therapy After First Marrow Relapse of Non-T, Non-B ALL - A Pediatric Oncology Groupwide Pilot Study

Start date: Dec 93

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: Major objective: To increase the event-free survival (EFS) of children with acute lymphoblastic leukemia following first marrow relapse or first relapse in an extramedullary site other than CNS. Secondary objectives: (a) To determine the feasibility of giving G-CSF to patients with recurrent ALL and whether administration of G-CSF in continuation therapy will allow for escalation of myelotoxic agents known to be active in ALL; (b) Using a randomized design, to compare two induction delivery schedules for PEG L-asparaginase in terms of PEG-L-asparaginase pharmacokinetics, and surrogate measure such as asparaginase level, and change in asparaginase antibody level between day 0 and day 28.

TECHNICAL APPROACH: A rotating, escalating, weekly parenteral drug regimen will be used for continuation therapy. A single arm pilot study is planned.

MODIFICATION #1 (Nov94): Status change.

MODIFICATION #2 (Jul95): Editorial and therapy changes.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study closed to accrual 9/1/94. 148 patients accrued at the time of closure. Toxicities not unexpected.

Abstract: Proceedings ASCO 14:1038A, 1995.

Response	N	Percent
CR	130	89.6
PR	1	0.7
NR	10	6.9
Early	4	2.8
Total	145	100 %

DFS:	CR1 ≤ 24 mos 22.2% (SE 8.0)	CR1 ≥ 24 mos (@ 1 yr from diagnosis) 65.1% (SE 9.1)

Overall: 46.3% (SE 6.99)

Detail Summary Sheet

Prot No: POG 9315(95)

Status: Ongoing

TITLE: A Phase III Study of Large Cell Lymphomas in Children and Adolescents;
Comparison of APO vs APO+IDMTX/HDARA-C and Continuous vs Bolus Infusion of
Doxorubicin: A Pediatric Oncology Group Study

Start date: Feb 96

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: (1) To study whether intermediate-dose methotrexate/high-dose Ara-C administered during the maintenance phase can improve the event-free survival (EFS) of patients with advanced-stage large cell lymphoma (LCL); (2) To further characterize the immunophenotypic and morphologic correlates of pediatric LCL; (3) To compare efficacy and cardiotoxicity of doxorubicin given by continuous vs bolus infusion.

TECHNICAL APPROACH: Treatment protocol - randomization to either regimen A or B, as well as continuous vs bolus infusion of doxorubicin.

MODIFICATION (Jul96): Scientific, therapy, and consent changes.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

As of 26 Oct 95, a total of fifteen (15) patients have been registered groupwise. Too early to report results. Major toxicity was hematological with neutropenia and thrombocytopenia. Other toxicities were mostly G.I. including neurosis.

Detail Summary Sheet

Prot No: POG 9317(95)

Status: Ongoing

TITLE: Chemotherapy for Children with Advanced Stage (III/IV) Diffuse Undifferentiated Burkitt's Lymphoma and B-Cell ALL - A Pediatric Oncology Group Wide Phase III Study

Start date: May 95

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: (a) To evaluate the efficacy of adding VP-16/ifosfamide intensification to the treatment of patients with advanced-stage B-cell malignancies: Stage III & IV DU NHL and B-cell acute lymphoblastic leukemia (B-ALL); (b) To compare the toxicity and efficacy of high-dose Ara-C given by intermittent bolus (q 12 hour x 4) vs bolus/continuous infusion over 48 hours.

TECHNICAL APPROACH: Patients will be randomized at registration to receive high-dose Ara-C, throughout treatment, as a continuous infusion or by bolus administration and also to receive or not to receive intensification treatment following induction.

MODIFICATION (Jul96): Consent changes.

As of 26 Oct 95, 150 patients entered groupwide.
Response data: (of evaluable patients....)

Abstracts: Proc ASCO 14:490, 1995
Proc ASCO 13:453, 1994 DIR

Detail Summary Sheet

Prot No: POG 9332(96)

Status: Ongoing

TITLE: Topotecan for the Treatment of Recurrent or Progressive CNS Tumors, Phase II Study

Start date: Feb 96

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 1/23/96
Decision: Continue

OBJECTIVE: (a) To determine the efficacy of topotecan in the treatment of pediatric patients with progressive/recurrent central nervous system (CNS) tumors; (b) To evaluate the toxicity of topotecan when given as a 72-hour continuous IV infusion every 21 days; (c) To determine the plasma and CSF pharmacokinetics of topotecan when given by a 72-hour continuous infusion in children and adolescents with CNS tumors.

TECHNICAL APPROACH: Topotecan will be administered by continuous intravenous infusion daily x3 (over 72 hours), every 21 days. In the absence of progressive disease (PD), two cycles will be given to all patients.

PROGRESS: **No. of Subjects Enrolled - To Date:**
 During FY96:

Detail Summary Sheet

Prot No: POG 9340(94)

Status: Ongoing

TITLE: 9340/41/42: Treatment of Patients >365 Days at Diagnosis with Stage 4 and N-Myc Amplified Stage 2B/3 Neuroblastoma (A Phase II/III Study)

Start date: Oct 93

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 8/27/96

Gifts:

Decision: Continue

OBJECTIVE: 9340 - To evaluate the response to and toxicity of single-agent chemotherapy given prior to Phase III therapy to two successive subsets of untreated patients with INSS Stage 4 neuroblastoma. 9341/2 - To measure response rates and toxicity, event-free survival (EFS), survival, and patterns of failure of patients treated with 6 courses of induction chemotherapy followed by local radiotherapy and autologous bone marrow transplantation (ABMT); to measure response rates, toxicity, EFS, survival, and patterns of failure of patients whose families decline ABMT, and therefore receive an additional 5 courses of therapy plus G-CSF followed by local radiotherapy to the tumor bed; to further evaluate the toxicity of ABMT using cyclophosphamide/VP/CBDCA ablation plus local radiotherapy; to measure EFS, survival, and patterns of failure of patients who achieve a complete response or partial response or mixed response at the end of induction chemotherapy prior to ABMT; to further evaluate the biologic parameters of neuroblastoma as required for POG 9047, and to measure MDR-1 protein levels with correlation to clinical presentation at diagnosis, clinical course, response to therapy, and survival.

TECHNICAL APPROACH: Treatment of newly diagnosed metastatic or N-MYC amplified advanced neuroblastoma, *1yr of age, with alternating multiagent combination chemotherapy followed by autologous BMT. Phase II single agent therapy may be offered in upfront window for patients with metastatic disease.

MODIFICATION #1 (Mar95): Revised consent.

MODIFICATION #2 (Jul95): Scientific changes.

MODIFICATION #3 (Nov96): Status notice.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

Thirty-nine patients registered on 9340. Taxol accrual now completed and Topotecan initiated. Response to Taxol disappointing and two allergic reactions reported. 9340 closed to accrual 10/15/95; 9341 closed to accrual 1/22/96; 9342 open for "graduates" of 9341.

Response data:	9340	taxol	topotecan	topotecan + cyclo
CR		1	1	0
PR		4	11	7
Total		33	32	25

9341 CR 21
PR 29
Total 123

Abstract: Upfront Phase II therapy with Taxol and Topotecan. Med Ped Onc 25:243, 1995

Detail Summary Sheet

Prot No: POG 9354(96)

Status: Ongoing

TITLE: Phase III Evaluation of Intensified Vincristine, Doxorubicin, Cyclophosphamide, Ifosfamide, and Etoposide in the Treatment of Newly Diagnosed Ewing's Sarcoma or Primitive Neuroectodermal Tumor of Bone or Soft Tissue

Start date: Feb 96

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 1/23/96

Gifts:

Decision: Continue

OBJECTIVE: To compare the event-free survival (EFS) and survival of newly diagnosed patients with Ewing's sarcoma and Primitive Neuroectodermal Tumor (PNET) of bone or soft tissue receiving a 48 week standard regimen of vincristine, cyclophosphamide and doxorubicin alternating with ifosfamide and etoposide with G-CSF to those receiving a 30 week dose intensified regimen of the same chemotherapeutic agents.

TECHNICAL APPROACH: See treatment plan for general schema of therapy.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: POG 9360(94)

Status: Ongoing

TITLE: GM-CSF Randomization Plus High-dose "ICE" in the Treatment of Recurrent/Resistant Malignant Solid Tumors of Childhood, a Pediatric Oncology Group Phase II Study

Start date: Oct 94

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 8/27/96

Gifts: drugs

Decision: Continue

OBJECTIVE: a) To determine the antitumor activity and toxicity of the maximum-tolerated dose of ifosfamide and carboplatin plus etoposide (high-dose ICE) against childhood malignant solid tumors resistant to conventional chemotherapy; b) To define the most effective but least toxic dose of GM-CSF to be used to ameliorate the myelosuppression that accompanies ICE therapy.

TECHNICAL APPROACH: Patients will receive VP-16 + MESNA, ifosfamide, and CBDCA q 21-28 days, with GM-CSF on days 4-19 or until ANC $\geq 5,000/\mu\text{l}$ after the expected nadir. Patients will be evaluated for response after every other course of therapy. Therapy may continue as long as the patient continues to show response to therapy and experiences no unacceptable toxicity.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study closed to accrual 26 Mar 96. 124 patients entered on study groupwide over 7 strata. Response masked.

Detail Summary Sheet

Prot No: POG 9398(94)

Status: Ongoing

TITLE: 9398-T-4"D": Efficacy of rhG-CSF in an Intensive Treatment for T-Cell Leukemia and Advanced Stage Lymphoblastic Lymphoma of Childhood

Start date: Sep 94

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: a) To determine, in a randomized trial, whether rhG-CSF can reduce the period of neutropenia, hospital admissions for fever and neutropenia, and infectious episodes in a cohort of patients receiving multiagent chemotherapy for T-Cell leukemia or lymphoblastic lymphoma; (b) To determine whether, after different drug combinations, G-CSF reduces delays in chemotherapy.

TECHNICAL APPROACH: The study will incorporate G-CSF into a two-arm open labeled, randomized trial in the induction and two maintenance cycles.

MODIFICATION (Feb95): Status change.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study closed to accrual 15 Dec 94; no TAMC patients enrolled with 88 enrolled groupwide. As of Apr 96, CR 68, failed 7, unknown 13; major toxicity-hematologic.

Detail Summary Sheet

Prot No: POG 9400(95)

Status: Ongoing

TITLE: ALinC #16: Classification Protocol - A Pediatric Oncology Group Non-therapeutic Study

Start date: Jan 95

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: Classification data in routing for treatment studies.

TECHNICAL APPROACH: Blood and/or bone marrow samples.

MODIFICATION (Jul96): Editorial and scientific changes.

PROGRESS: No. of Subjects Enrolled - To Date: 5
During FY96: 2

As of 27 Apr 95, 269 registrants groupwide.

Classification only, 55

9400 callback induction only, 5

B-cell, 4

T-cell, 1

Precursor-B, 204

Detail Summary Sheet

Prot No: POG 9404(96)

Status: Ongoing

TITLE: T-Cell #4 Protocol Intensive Treatment for T-Cell Acute Lymphoblastic Leukemia and Advanced Stage Lymphoblastic Non-Hodgkin's Lymphoma

Start date: Aug 96

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 7/23/96
Decision: Continue

OBJECTIVE: Primary objectives of this study are (1) to determine, in a randomized trial, the effectiveness of high dose methotrexate (HD MTX) when added to a multi-agent chemotherapy backbone (DFCI 87-0001) proven effective in T-Cell acute lymphoblastic leukemias (T-ALL) and advanced stage non-Hodgkin's lymphoma (Lymphoblastic NHL), and (2) To determine, in a randomized trial, the role of the cardioprotectant Zinecard (DZR) in preventing cardiotoxicity in children with T-ALL and advanced stage Lymphoblastic NHL receiving an anthracycline based regimen.

TECHNICAL APPROACH: Treatment will span approximately 2 years and involve both outpatient (clinical visits) and inpatient (hospitalization) care.

PROGRESS:

No. of Subjects Enrolled - To Date:	
During FY96:	

Detail Summary Sheet

Prot No: POG 9405(95)

Status: Ongoing

TITLE: ALinC 16: Protocol for Patients With Newly Diagnosed Standard Risk Acute Lymphoblastic Leukemia - A Pediatric Oncology Group Phase III Study

Start date: Jan 95

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: (a) To determine the efficacy of a higher versus standard dose methotrexate (MTX) infusion during consolidation; (b) to determine the efficacy of delivering oral 6-MP on a once versus twice daily schedule during continuation; (c) secondary objectives are to study laboratory correlates from POG 9400 and clinical correlates with outcome in pooling studies 9201, 9405, and 9406; identify patients at risk for treatment failure; and assess the prognostic significance of the percent of marrow blasts after two weeks of induction therapy.

TECHNICAL APPROACH: Treatment protocol and laboratory correlation.

MODIFICATION #1 (Jul95): Consent revision includes toxicity update.

MODIFICATION #2 (Jan96): Accrual closure notice

MODIFICATION #3 (Feb96): Administrative changes.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96:

Groupwide, 155 patients have been enrolled through 7/31/95. Too early for report. Study is closed to accrual.

Detail Summary Sheet

Prot No: POG 9406(95)

Status: Ongoing

TITLE: ALinC 16: Protocol for Patients With Newly Diagnosed High Risk Acute Lymphoblastic Leukemia - A Pediatric Oncology Group Phase III Study

Start date: Mar 95

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 4/23/96
Decision: Continue

OBJECTIVE: To determine, in a randomized trial: (a) the efficacy of higher dose (2.5 gm/m²) intravenous methotrexate (MTX) infusions during Intensified Continuation therapy; (b) whether intensified continuation therapy delivering pulses of high dose araC (3gm/m² x 4 doses) with asparaginase rescue is superior to standard intensified continuation with pulses of VM-26/araC.

TECHNICAL APPROACH: Randomized treatment.

MODIFICATION #1 (Jul95): Consent revision includes toxicity update.

MODIFICATION #2 (Jul96): Editorial, scientific, therapy, eligibility, and consent revisions.

MODIFICATION #3 (Aug96): Amendments #3 & 4.

MODIFICATION #4 (Sep96): Editorial changes.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

97 patients enrolled through July 95, groupwide. Too early to report results.

Publications: None to-date.

Detail Summary Sheet

Prot No: POG 9407(96)

Status: Ongoing

TITLE: Induction Intensification and Allogeneic Bone Marrow Transplant in Infant ALL: A Pediatric Oncology Group Pilot Study

Start date: Jan 97

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: (1) To assess the feasibility of delivery of intensification in infant ALL using two courses of high dose methotrexate (HD MTX) followed by one course of cyclophosphamide/VP-16 during induction and later as consolidation. (2) To estimate event free survival (EFS) using shortened, intensive therapy in infant ALL. (3) To evaluate the feasibility and outcome of bone marrow transplantation (matched or one antigen mismatched related or unrelated donor) in infants with evidence of the 11123 (MLL gene rearrangement) abnormality detected by molecular analysis. (4) To investigate clinical prognostic features which may be associated with outcome in infants: disease status at Day 15, white blood cell count and age. (5) To investigate the correlation of biologic characteristics of the leukemia cells at diagnosis (POG 9400) with outcome.

TECHNICAL APPROACH: Chemotherapeutic regimen.

PROGRESS: No. of Subjects Enrolled - To Date:
 During FY96:

Detail Summary Sheet

Prot No: POG 9411(96)

Status: Ongoing

TITLE: SIMAL 9 - Treatment of Relapsed Non-T, Non-B Acute Lymphoblastic Leukemia with Intensive Chemotherapy - A Pediatric Oncology Group Pilot Study

Start date: Oct 96

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/24/96
Decision: Continue

OBJECTIVE: Primary objectives of this study are to: (1) Determine the feasibility and toxicity of delivering an intensive reinduction and consolidation chemotherapy regimen for children with acute lymphoblastic leukemia (ALL) following first bone marrow relapse, and (2) Compare the induction response rates for patients randomized to weekly PEG versus 3x a week E. coli asparaginase.

TECHNICAL APPROACH: Patients will be treated with intensive chemotherapy consisting of a modified "standard" reinduction combination followed by two intensive consolidation courses, followed by four courses of non cross resistant drug combinations for continuation therapy.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: POG 9412(96)

Status: Ongoing

TITLE: Treatment of Isolated CNS Relapse of Acute Lymphoblastic Leukemia-A Pediatric Oncology Group-Wide Phase II Study

Start date: Oct 96

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology

Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 9/24/96

Gifts:

Decision: Continue

OBJECTIVE: (1) To determine the efficacy and toxicity of intensified systemic treatment with delayed central nervous system irradiation for children with acute lymphoblastic leukemia (ALL) and isolated central nervous system disease. (2) To describe the efficacy of different intravenous chemotherapeutic agents in reducing or clearing CSF blasts in children with isolated CNS leukemia in an up-front Therapeutic Window. The first agent to be evaluated will be thiotepa.

TECHNICAL APPROACH: Patients will be treated with one year of intensive chemotherapy prior to proceeding with central nervous system irradiation.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study was only recently approved.

Detail Summary Sheet

Prot No: POG 9421(95)

Status: Ongoing

TITLE: Phase III Evaluation of Standard vs High Dose Ara-C Induction Followed by the Randomized Use of Cyclosporine A as an MDR Reversal Agent, Compared to Allogeneic BMT, in Childhood AML

Start date: May 95

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: (a) To determine the effect of high dose vs standard dose Ara-C induction on CR and EFS in Childhood AML; (b) To compare the EFS in Childhood AML after 3 cycles of consolidation with or without the MDR modulator CSA; (c) To compare the EFS between patients genetically randomized between allogeneic BMT and chemotherapy; (d) To evaluate the impact on EFS on various clinical and laboratory factors such as cytogenetics and MDR expression; (e) To confirm the superior response of Down syndrome patients utilizing standard induction and non-CSA containing consolidation, and identify specific biologic and pharmacokinetic characteristics in these patients.

TECHNICAL APPROACH: See protocol

MODIFICATION #1 (Jul96): Editorial & scientific changes.

MODIFICATION #2 (Sep96): Amendment #1 with consent changes.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 1

Through 2/96, 108 patients entered groupwide. Too early for data analysis at this time. Two early deaths related to infection. No unexpected or severe organ toxicities directly related to therapy.

Detail Summary Sheet

Prot No: POG 9436(96)

Status: Ongoing

TITLE: Phase II Study of Cyclophosphamide, Vincristine, and Carboplatin for Children With Progressive Astrocytoma

Start date: Sep 96

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: (1) To assess the response rate of cyclophosphamide in children less than or equal to 10 years of age with astrocytoma. (2) To estimate the two-year progression-free survival of a therapy program of cyclophosphamide, vincristine, and carboplatin.

TECHNICAL APPROACH: Chemotherapeutic regimen.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study was only recently approved.

Detail Summary Sheet

Prot No: POG 9440(96)

Status: Ongoing

TITLE: National Wilms Tumor Study-5: Therapeutic Trial and Biology Study

Start date: Jun 96

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Continue

OBJECTIVE: (1) To increase the survival rate of children with favorable histology (FH) Wilms tumor and other renal tumors of childhood; (2) To determine if loss of heterozygosity for chromosome 16q or 1p markers in tumor tissue and if increased DNA content in tumor cells is associated with a poorer prognosis for children with FH Wilms tumor; (3) To decrease the acute and long term morbidity of treatment of children with Wilms tumor by limiting initial therapy and employing a consistent retrieval therapy for patients who relapse after initial treatment; (4) To improve the survival and disease-free survival of patients with unfavorable histology tumors including Wilms tumor with diffuse anaplasia and clear cell sarcoma of the kidney by using a new treatment regimen that includes etoposide and cyclophosphamide and patients with malignant rhabdoid tumor of the kidney by using a new treatment regimen that includes carboplatin, etoposide and cyclophosphamide; (5) To study the biology and pathology of patients who present with bilateral Wilms tumor; (6) To conduct hypothesis-driven trials led by diagnostic radiologists in order to develop guidelines for radiographic evaluation of previously undiagnosed patients with unilateral and bilateral Wilms tumor and those on therapy; (7) To establish a biological samples bank containing touch preparations, paraffin blocks, frozen tumor, normal kidney tissue, serum and urine that will be available to scientists to evaluate additional potential biological prognostic variables or for the conduct of other research.

TECHNICAL APPROACH: See protocol.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: POG 9450(96)

Status: Ongoing

TITLE: Etoposide/Ifosfamide + G-CSF in the Treatment of Newly Diagnosed Metastatic Osteosarcoma or Unresectable Osteosarcoma

Start date: Feb 96

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC; COL Constance P. Hastings, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 1/23/96
Decision: Continue

OBJECTIVE: The primary objective of this study is to estimate the response rate to etoposide (VP), ifosfamide (IFOS), and G-CSF in patients presenting with newly-diagnosed metastatic osteosarcoma prior to treatment with other chemotherapy agents.

TECHNICAL APPROACH: See protocol treatment plan.

MODIFICATION (Jul96): Editorial & consent changes.

PROGRESS: No. of Subjects Enrolled - To Date:
 During FY96:

Detail Summary Sheet

Prot No: POG 9457(96)

Status: Ongoing

TITLE: Intensive Therapy With Growth Factor Support for Patients With Ewing's Tumor Metastatic at Diagnosis: A Pediatric Oncology Group Phase II Study

Start date: Jun 96

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Continue

OBJECTIVE: (1) To evaluate the response rate, and duration of response, in patients with Ewing's tumor metastatic at diagnosis treated with maximally intensified therapy; (2) To evaluate the response to new agents utilized in an upfront window. Initially, topotecan will be used as single agent. When the maximally tolerated dosages of the combination of topotecan and cyclophosphamide are available, the combination will be employed.

TECHNICAL APPROACH: Chemotherapy at maximal intensity.

PROGRESS:

No. of Subjects Enrolled - To Date:	
During FY96:	

New start.

Detail Summary Sheet

Prot No: POG 9461(96)

Status: Ongoing

TITLE: A Phase II Trial of Deferoxamine for the Treatment of Children With Refractory Lymphoblastic Leukemia and Lymphoma - A Pediatric Oncology Group Group-wide Study

Start date: Sep 96

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: (1) To determine the response rate of recurrent T-cell ALL, T-cell lymphoblastic lymphoma and B-precursor ALL to DFO in a phase II trial. (2) To further define the spectrum of toxicity of DFO in children with cancer. (3) To determine the relationship between serum DFO levels, toxicity and efficacy. (4) To determine the relationship between in vivo and in vitro sensitivity to the cytotoxic effects of DFO. (5) To determine the role of p53 and p16 tumor suppressor genes in T-cell ALL.

TECHNICAL APPROACH: Treatment protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study was only recently approved.

Detail Summary Sheet

Prot No: POG 9605(96)

Status: Ongoing

TITLE: ALinC #16 - Protocol for Patients With Newly Diagnosed Standard Risk Acute Lymphoblastic Leukemia (ALL)

Start date: Aug 96

Est Comp Date: Indef

Principal Investigator: COL Bruce A. Cook, MC

Department/Section: Pediatrics/Hematology-Oncology
Facility: TAMC

Associate Investigator: LTC Braden A. Shoupe, MC

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 7/23/96
Decision: Continue

OBJECTIVE: (1) To determine in a randomized trial whether the addition of 6 months of delayed intensification with divided dose oral methotrexate (ddMTX) improves event-free survival (EFS) of children with standard risk acute lymphoblastic leukemia (ALL).

TECHNICAL APPROACH: Treatment protocol.

MODIFICATION (Sep96): Editorial & eligibility changes.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

New start.

Detail Summary Sheet

Prot No: CRCH 9102(92)

Status: Ongoing

TITLE: Trial of Chemohormonal Therapy (Oral Etoposide plus Megestrol Acetate) for Advanced Gastric Carcinoma, Phase II

Start date: Jan 92

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words: etoposide; megestrol

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Continue

OBJECTIVE: To determine the response rate of advanced gastric carcinoma to oral etoposide given in combination with megestrol acetate.

TECHNICAL APPROACH: Patients agreeing to participate will receive etoposide (VP-16) orally for 21 days out of each 28 days and will receive megestrol acetate orally four times a day continuously. Both these medication will be continued until there is evidence of disease progression.

PROGRESS: No. of Subjects Enrolled - To Date: 3
During FY96: 0

Three patients were enrolled at TAMC. No unusual toxicity was encountered. No publications as of this date.

Detail Summary Sheet

Prot No: CRCH 9302(95)

Status: Ongoing

TITLE: Dietary Intervention Trial Among Early Stage Lung and Head and Neck Cancer
Patients: "9-A-Day Study"

Start date: Apr 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Continue

OBJECTIVE: To determine whether a daily diet of five servings of vegetables and four servings of fruits reduces the incidence of second primary malignancies among patients with in-situ or stages I-II head and neck cancer or in-situ or stage I squamous cell carcinoma of the lung.

TECHNICAL APPROACH: Participants will be randomized to an intensive intervention group (IIG) or a non-intensive intervention group (NIIG). Patients in IIG will receive an individualized dietary counseling program designed to increase their vegetable and fruit consumption to nine servings per day. Those in the NIIG will be advised to follow their usual diet. Compliance will be assessed by announced food recalls and serum carotenoid level measurements.

PROGRESS: No. of Subjects Enrolled - To Date: 7
During FY96: 3

To-date, 32 patients are enrolled on study.

Detail Summary Sheet

Prot No: DM 88-107

Status: Ongoing

TITLE: A Pilot Study to Test the Feasibility of Performing a Chemoprevention Trial of Alpha-Tocopherol in Oral Leukoplakia in Community Oncology Programs (CCOPS)

Start date: May 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 5/28/96

Gifts:

Decision: Continue

OBJECTIVE: (1) To determine if a chemoprevention trial of alpha-tocopherol for oral leukoplakia can be implemented in a CCOP setting; (2) To determine the efficacy of alpha-tocopherol in producing objective clinical remissions and pathological remissions in oral leukoplakia; (3) To monitor the toxicity of alpha-tocopherol given in a 24-week chemoprevention trial; (4) To measure the effect of alpha-tocopherol on micronuclei levels in the buccal mucosa in patients with oral leukoplakia; (5) To measure serum alpha-tocopherol levels in order to monitor compliance.

TECHNICAL APPROACH: Patients meeting the eligibility requirements will be registered in this pilot study. These patients will receive alpha-tocopherol 400 IU orally, twice daily for 24 weeks, and then discontinue the therapy. All patients will keep a drug calendar to be turned in at the time of all exams. A serum alpha-tocopherol level will be obtained prior to, at 6 weeks, and at the completion of the 24-week course of therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Nationwide, 73 patients enrolled on study.

Detail Summary Sheet

Prot No: DM 94-020

Status: Ongoing

TITLE: Colorectal Adenoma Chemoprevention Trial using Aspirin: A Phase III Study

Start date: May 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: (1) To determine whether aspirin 325 mg per day will decrease the number and size of new adenomas in a group of patients with Dukes' A and B1 cancer who have undergone curative surgical resection; (2) To assess whether aspirin will increase disease free survival.

TECHNICAL APPROACH: This study will be restricted to individuals who have undergone previous resection of colorectal cancer and who are therefore at increased risk for developing new colonic adenomas and cancer. Randomized subjects will receive either enteric coated aspirin 325 mg or lookalike placebo, one pill each day for their 3 or 4 years. Dukes A and B1 patients who have had recent surgery will take pills for four years. Dukes B2 and C patients and those Dukes A and B1 patients who are randomized after a follow-up colonoscopy will take pills for 3 years.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

No patients from TAMC; however, 151 patients enrolled nationwide.

Detail Summary Sheet

Prot No: NSABP B20(89)

Status: Ongoing

TITLE: A Clinical Trial to Determine the Worth of Chemotherapy and Tamoxifen over Tamoxifen Alone in the Management of Patients with Primary Invasive Breast Cancer, Negative Axillary Nodes and Estrogen Receptor Positive Tumors

Start date: Nov 88

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words: tamoxifen

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/22/96
Decision: Continue

OBJECTIVE: To determine if Methotrexate plus 5-fluorouracil plus Leucovorin plus Tamoxifen is more effective in terms of disease-free survival and survival than Tamoxifen alone in node negative estrogen receptor positive resected breast cancer. Also to determine if Cyclophosphamide plus Methotrexate plus 5-fluorouracil (CMF) plus Tamoxifen is more effective than Tamoxifen alone. Finally, to compare the 2 chemo programs to each other.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 1) Tamoxifen alone for 5 years, 2) Methotrexate, 5-fluorouracil and Leucovorin every 4 weeks for 6 cycles + Tamoxifen as above, or 3) CMF every 4 weeks for 6 cycles + Tamoxifen as above.

PROGRESS: No. of Subjects Enrolled - To Date: 2
During FY96: 0

No data available except toxicity information. Toxicity has been mild on both arms. Both patients at TAMC continue to do well. Study is closed to further accrual. Too early for analysis. No publications.

Detail Summary Sheet

Prot No: NSABP B21(93)

Status: Ongoing

TITLE: A Clinical Trial to Determine the Worth of Tamoxifen and the Worth of Breast Radiation in the Management of Patients with Node-negative, Clinically Occult, Invasive Breast Cancer Treated by Lumpectomy

Start date: Mar 93

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words: tamoxifen; occult breast

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVES: To determine the worth of adding tamoxifen to lumpectomy plus breast radiation in invasive breast cancer less than 1 cm. Also to compare lumpectomy plus tamoxifen (instead of radiation) versus lumpectomy plus radiation in these cancers.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to one of the following 3 therapies after their lumpectomy: (1) breast radiation plus placebo, (2) breast radiation plus tamoxifen, or (3) tamoxifen alone.

MODIFICATION (May96): Consent revision.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Accrual to this study is low. Study temporarily closed in order to evaluate data and feasibility of re-opening.

Detail Summary Sheet

Prot No: NSABP B23(91)

Status: Ongoing

TITLE: A Clinical Trial Comparing Short, Intensive AC +/- Tamoxifen with Conventional CMF +/- Tamoxifen in Node-negative Breast Cancer Patients with ER-Negative Tumors

Start date: Jul 91

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 7/23/96
Decision: Continue

OBJECTIVE: To determine in resected breast cancer patients with negative nodes whether 4 cycles of adriamycin plus cyclophosphamide (AC) is superior to six cycles of cyclophosphamide, methotrexate, 5-FU (CMF) and to determine if adding tamoxifen to either of the above 2 programs is more efficacious than each program by itself.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive either 1) adriamycin IV day 1 and cyclophosphamide IV day 1 with these drugs repeated every three weeks for four cycles or 2) cyclophosphamide p.o. day 1-14 plus methotrexate IV day 1 & 8 plus 5FU IV day 1 & 8 repeated monthly for six cycles. All patients will also be randomized to receive or not receive tamoxifen twice a day for five years.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

To date 518 patients have been registered on the study nationally and there has been one toxic death (due to sepsis). The one TAMC patient has finished chemotherapy and is doing well. The study is closed to accrual. Too early for analysis.

Detail Summary Sheet

Prot No: NSABP B24(91)

Status: Ongoing

TITLE: A Clinical Trial to Evaluate The Worth of Tamoxifen In Conjunction With Lumpectomy and Breast Irradiation for the Treatment of Noninvasive Intraductal Carcinoma (DCIS) of The Breast

Start date: Aug 91

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words: tamoxifen; intraductal

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Continue

OBJECTIVE: To determine if tamoxifen does or does not add to lumpectomy plus postoperative breast irradiation for noninvasive intraductal cancer (DCIS) in terms of preventing subsequent invasive breast cancers.

TECHNICAL APPROACH: Patients will be randomized after lumpectomy to receive either tamoxifen for at least 5 years plus radiation or to receive placebo for at least 5 years plus radiation.

PROGRESS: No. of Subjects Enrolled - To Date: 2
During FY96: 0

Study is permanently closed to accrual. Too early for analysis. No publications.

Detail Summary Sheet

Prot No: NSABP B25(92)

Status: Ongoing

TITLE: A Clinical Trial to Evaluate the Effect of Dose Intensification & Increased Cumulative Dose of Postoperative Adriamycin-Cyclophosphamide (AC) Therapy With G-CSF on the Disease-Free Survival & Survival of Patients With Primary Breast Cancer & Positive Axillary Node

Start date: Jun 92

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words: intensification; breast; adjuvant

Funding: FY 95:

FY 96:

Periodic Review Date: 5/28/96

Gifts:

Decision: Continue

OBJECTIVE: To determine 1) if giving the same total dose of chemotherapy over a shorter time period will improve disease-free and overall survival in patients with resected, node-positive breast cancer and 2) if giving higher doses of chemotherapy will improve these same parameters.

TECHNICAL APPROACH: Patients will be randomized to 1) 'standard' adriamycin IV and cytoxan IV given every 3 weeks for 4 cycles as used in NSABP's last study, or 2) the same drugs but with all the cyclophosphamide given over 2 cycles instead of 4, or 3) the same drugs for 4 cycles but with the cyclophosphamide doubled for all 4 cycles. All patients will get G-CSF subcutaneously day 2-15 to prevent low white counts and infection. All patients age 50 or more receive tamoxifen for 5 years also.

PROGRESS: No. of Subjects Enrolled - To Date: 2
During FY96: 0

The study is permanently closed to patient accrual. Too early for analysis. No publications. The total number of patients randomized into the trial is 2548.

Detail Summary Sheet

Prot No: NSABP C05(92)

Status: Ongoing

TITLE: A Clinical Trial to Assess the Relative Efficacy of 5-FU + Leucovorin with or without Interferon Alfa-2a in Patients with Dukes' B and C Carcinoma of the Colon

Start date: Feb 92

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Continue

OBJECTIVE: To determine if adding interferon to 5-FU and Leucovorin will improve disease-free survival and survival in patients with Dukes' B or C colon carcinoma which has been resected.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 1) 5 FU and leucovorin IV over 1 1/2 hours daily for 5 days each month for 6 months or 2) the same 5-FU and leucovorin plus interferon given SQ the day before, the days of, and the day after the 5-FU and leucovorin.

PROGRESS: No. of Subjects Enrolled - To Date: 5
During FY96: 0

Study is permanently closed. Too early for analysis. No publications as of æ95. Number of patients randomized to study is 2176; 34 patients declared ineligible and 19 withdrew consent to participate further in trial.

Detail Summary Sheet

Prot No: NSABP P1(96)

Status: Ongoing

TITLE: A Clinical Trial to Determine the Worth of Tamoxifen for Preventing Breast Cancer

Start date: Jul 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: The primary objective of this trial is to test whether long-term tamoxifen therapy is effective in (a) preventing the occurrence of invasive breast cancer and b) reducing mortality attributed to breast cancer. Other objectives are to: evaluate whether the administration of tamoxifen reduces mortality from cardiovascular disease; to evaluate the effect of tamoxifen on the incidence of bone fractures; and to evaluate toxicity and side effect of tamoxifen therapy in order to assess benefit versus risk resulting from the use of tamoxifen in women at increased risk of developing breast cancer.

TECHNICAL APPROACH: Participants will receive placebo/tamoxifen per protocol for a duration of at least 5 years.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: SWOG 8692(87)

Status: Completed

TITLE: Therapy in Premenopausal Women with Advanced, ER-positive or PgR Positive Breast Cancer: Surgical Oophorectomy vs. the LH-RH Analog, Zoladex, Phase III Intergroup

Start date: Oct 87

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator: COL Edward L. Sakas, MC

Key Words: zoladex; breast

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Completed

OBJECTIVE: To determine the response rate and response duration and survival associated with either medical or surgical castration in advanced breast cancer in premenopausal patients.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive an oophorectomy or receive a monthly SQ injection of zoladex until disease progression. At the time of disease progression patients will be offered the other arm of treatment (for example, zoladex patients will be offered oophorectomy).

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

One hundred-thirty-eight (138) patients were entered nationally. Two (2) deaths in oophorectomy, one attributable to palliative brain irradiation and one due to cardiac arrest. Study closed 7/15/95.

Detail Summary Sheet

Prot No: SWOG 8710(89)

Status: Ongoing

TITLE: Trial of Cystectomy Alone vs. Neoadjuvant M-VAC Plus Cystectomy in Patients with Locally Advanced Bladder Cancer

Start date: Nov 88

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator: COL Edward L. Sakas, MC; COL Martin L. Dresner, MC;
MAJ Evans Smoot, MS

Key Words: cystectomy

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/22/96
Decision: Continue

OBJECTIVE: To compare the survival of patients with locally advanced bladder cancer treated with either cystectomy alone or cystectomy plus chemotherapy with M-VAC (Methotrexate, Vinblastine, Adriamycin and Cisplatin).

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to receive 1) cystectomy alone or 2) 3 cycles of M-VAC chemotherapy and then cystectomy.

MODIFICATION (Jun96): SWOG revision #5

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

Nationally, 281 patients entered. Myelosuppression has been most common toxicity. One (1) patient in the cystectomy arm died from surgical problems.

Detail Summary Sheet

Prot No: SWOG 8711(89)

Status: Ongoing

TITLE: A Study of Reproductive Function in Patients with Testicular Cancer

Start date: Apr 89

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator: COL Edward L. Sakas, MC; MAJ Luke M. Stapleton, MC;
COL Martin L. Dresner, MC; MAJ Marianne M. Young, MC

Key Words: testicular cancer

Funding: FY 95:
Gifts: None

FY 96:

Periodic Review Date: 2/27/96
Decision: Continue

OBJECTIVE: To evaluate the natural history of seminal fluid and hormone parameters in patients with testicular cancer after orchiectomy and after other treatments such as retroperitoneal node dissection, chemotherapy, and radiation therapy.

TECHNICAL APPROACH: Patients agreeing to participate will have semen analysis beginning after orchiectomy and these will occur every 3 months for 3 years then every 6 months out to 5 years. Testosterone and FSH blood levels will also be done but only half as often as the semen analysis.

PROGRESS: No. of Subjects Enrolled - To Date: 5
During FY96: 0

Study closed due to lack of accrual. A total of 207 patients were accrued. Too early for analysis.

Detail Summary Sheet

Prot No: SWOG 8736(88)

Status: Ongoing

TITLE: Treatment of Localized Non-Hodgkin's Lymphoma: Comparison of Chemotherapy (CHOP) to Chemotherapy Plus Radiation Therapy

Start date: Jun 88

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator: COL Edward L. Sakas, MC; MAJ Evans Smoot, MS

Key Words: Non-Hodgkin's Lymphoma

Funding: FY 95:
Gifts: None

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To compare the survival rates and toxicity of two curative approaches in patients with localized (stage I & II), intermediate or high grade non-Hodgkin's lymphoma.

TECHNICAL APPROACH: Patients agreeing to participate in the study will be randomized to receive either 1) 8 cycles of chemotherapy (CHOP) or 2) 3 cycles of CHOP and then 4000 rads of radiation to the involved area.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Four hundred eight (408) patients registered on this study nationally. One (1) patient on the CHOP arm died from sepsis. No deaths on the CHPO + RT arm. Study closed to further accrual on 6/15/95. Too early for analysis.

Detail Summary Sheet

Prot No: SWOG 8794(89)

Status: Ongoing

TITLE: Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy

Start date: Dec 88

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator: COL Edward L. Sakas, MC; COL Martin L. Dresner, MC; MAJ Marianne M. Young, MC; MAJ Luke M. Stapleton, MC

Key Words: prostate carcinoma

Funding: FY 95:
Gifts: None

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: To compare in a randomized study the disease-free survival and overall survival of patients with completely resected Stage C prostate carcinoma (tumor through capsule or into seminal vesicles) given or not given adjuvant radiation therapy.

TECHNICAL APPROACH: Patients agreeing to participate in this study will be assigned to receive or not receive 6400 rads of radiation to the prostate bed.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

This study is ongoing; 216 patients have been entered to-date, nationally. Moderate toxicity secondary to irradiation was seen.

Detail Summary Sheet

Prot No: SWOG 8809(89)

Status: Ongoing

TITLE: A Phase III Study of Alpha Interferon Consolidation Following Intensive Chemotherapy with ProMACE-MOPP (Day 1-8) in Patients with Low Grade Malignant Lymphomas

Start date: Jan 89

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator: COL Edward L. Sakas, MC; MAJ Marianne M. Young, MC; MAJ Evans Smoot, MS

Key Words: ProMACE-MOPP

Funding: FY 95:

FY 96:

Periodic Review Date: 12/5/95

Gifts: None

Decision: Continue

OBJECTIVE: To determine the response rate and survival of low grade lymphoma patients treated with ProMACE-MOPP. Also to compare the disease-free survival in these patients who receive alpha interferon after chemotherapy compared to those who receive only the chemotherapy.

TECHNICAL APPROACH: Patients agreeing to participate will receive 6 cycles of ProMACE-MOPP (followed by limited field radiation if complete remission is not achieved with the ProMACE-MOPP) and then be randomized to receive or not receive low dose alpha interferon 3 times a week subcutaneously for 2 years.

PROGRESS: No. of Subjects Enrolled - To Date: 3
During FY96: 1

Nationally, 554 patients have been registered onto this study. There have been 13 toxic deaths, 9 related to infections. Major toxicity is hematological. Study was closed to accrual.

Detail Summary Sheet

Prot No: SWOG 8810(88)

Status: Completed

TITLE: Six Courses of 5-FU and Cis-platinum with Correlation of Clinical and Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinomas of the Head and Neck, Phase II

Start date: Jun 88

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator: COL Edward L. Sakas, MC; MAJ Luke M. Stapleton, MC

Key Words: squamous cell carcinoma

Funding: FY 95:
Gifts: None

FY 96:

Periodic Review Date: 2/27/96
Decision: Completed

OBJECTIVE: To determine if 6 cycles of Cis-platinum plus 5-FU will result in more complete remissions of locally advanced head and neck cancer than 3 cycles.

TECHNICAL APPROACH: Patients agreeing to participate will all receive 3 cycles of Cis platinum plus 5-FU. Patient who then achieve at least a partial remission (50% or more tumor shrinkage) will get 3 additional cycles. With less than partial, come off study.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

This study met sufficient accrual and is permanently closed, with no manuscript yet printed.

Detail Summary Sheet

Prot No: SWOG 8892(89)

Status: Ongoing

TITLE: A Study of Radiotherapy with and without Concurrent Cisplatin in Patients with Nasopharyngeal Cancer, Phase III

Start date: Aug 89

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words: nasopharyngeal cancer

Funding: FY 95:

FY 96:

Periodic Review Date: 7/23/96

Gifts: None

Decision: Continue

OBJECTIVE: To compare the complete response rate and survival of patients with Stage III or IV Nasopharyngeal cancer treated with definitive radiation versus those treated with definitive radiation plus Cisplatin.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive either 1) radiation (7,000 rads over 7 weeks) or 2) the same radiation plus 3 doses of concurrent Cisplatin (at 3 week intervals).

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

As of 6/30/95, 177 patients have entered on this study. Eleven (11) patients had grade 4 toxicity. One (1) toxic death (aspiration pneumonia).

Detail Summary Sheet

Prot No: SWOG 8894(89)

Status: Ongoing

TITLE: A Comparison of Bilateral Orchiectomy With or Without Flutamide for the Treatment of Patients with Histologically Confirmed Stage D2 Prostate Cancer

Start date: Nov 89

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/22/96
Decision: Continue

OBJECTIVE: To compare the survival of patients with metastatic (ie, D2) prostate cancer who undergo 1) a bilateral orchiectomy plus take a placebo or 2) a bilateral orchiectomy plus flutamide (an anti-androgen).

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to undergo 1) a bilateral orchiectomy and take placebo or 2) a bilateral orchiectomy and take flutamide.

PROGRESS: No. of Subjects Enrolled - To Date: 6
During FY96: 0

Nationally, 1350 patients were entered and there have been few serious toxicities. Three patients progressed, 2 crossed over. One (1) patient taken off study at patient's request. This study is permanently closed. Too early for analysis.

Detail Summary Sheet

Prot No: SWOG 8949(95)

Status: Ongoing

TITLE: A Randomized Comparison of Nephrectomy Followed by Interferon Alpha 2-b (Intron A) vs. Interferon Alpha 2-b (Intron A) Alone in Patients With Advanced Renal Cell Carcinoma

Start date: Jan 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: (1) To evaluate and compare the survival and response rates of patients with metastatic renal cell carcinoma receiving nephrectomy followed by Interferon Alpha-2b (Intron-A) vs Interferon Alpha-2b (Intron-A) alone; and (2) To evaluate morbidity and mortality associated with adjuvant nephrectomy in metastatic renal cell carcinoma.

TECHNICAL APPROACH: See protocol.

MODIFICATION (Jul96): Consent revision

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Nationwide, 165 patients are registered in study. Awaiting a start letter to begin patient enrollment.

Detail Summary Sheet

Prot No: SWOG 8952(90)

Status: Ongoing

TITLE: Treatment of Advanced Hodgkin's Disease - A Randomized Phase III Study
Comparing ABVD vs MOPP/ABV Hybrid

Start date: Apr 90

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To compare ABVD to the MOPP/ABV hybrid as therapy for patients with advanced Hodgkin's disease in terms of complete response rates, survival and toxicities.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 1) MOPP/ABV every 28 days for 8 cycles or 2) ABVD every 28 days for 8 cycles.

PROGRESS: No. of Subjects Enrolled - To Date: 6
During FY96: 1

As of 6/30/95, 817 patients have entered this study nationally. All five TAMC patients did well on this study (completed remission). Total of five probable treatment-related deaths on ABVD and 15 deaths on the MOPP/ABV hybrid. Of the five with ABVD, three were related to pulmonary toxicity, one due to infection and one possibly related to bleomycin. Of the 15 with MOPP/ABV, six were related to pulmonary toxicity, eight due to infection and one from myocardial infarction while recovering from pneumonia.

Detail Summary Sheet

Prot No: SWOG 8990(92)

Status: Ongoing

TITLE: (ECOG-9288, INT 0103): Combined Modality Treatment for Resectable Metastatic Colorectal Carcinoma to the Liver: Surgical Resection of Hepatic Metastases in Combination with Continuous Infusion of Chemotherapy

Start date: Mar 92

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To determine if the addition of local and systemic chemotherapy will improve the survival in metastatic colon cancer.

TECHNICAL APPROACH: Patients agreeing to participate must have only 1-3 liver metastases which appear resectable on scan. These patients will then be assigned to surgical resection of the metastases alone or surgical resection plus chemotherapy. The patients receiving chemotherapy will have a Hickman Catheter placed for venous access and will have catheter placed in the hepatic artery and this will be connected to an infusaid pump (at the time of surgery). Patients receiving chemotherapy will get floxuridine intra-arterially for 2 weeks out of each month for 4 months plus 5 fluorouracil via the Hickman (IV) for 2 weeks (constant infusion also) out of each month for 12 months.

MODIFICATION #1 (Oct96): Amendment #2.

MODIFICATION #2 (Jan97): Accrual closure.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

As of 6/30/95, 81 patients were registered on this study nationally. One (1) patient on the surgery alone arm died from hemorrhage. Seven (7) patients on surgery plus chemotherapy arm had six life threatening toxicities.

Detail Summary Sheet

Prot No: SWOG 9007(96)

Status: Ongoing

TITLE: Cytogenetic Studies in Leukemia Patients (A Companion Study to SWOG 9500(96))

Start date: Mar 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology

Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 2/27/96

Gifts:

Decision: Continue

OBJECTIVE: (1) To estimate the frequencies and prognostic significance of cytogenetic abnormalities in marrow or blood cells of leukemia patients prior to treatment on Southwest Oncology Group protocols and at various times in the course of their treatment; (2) To estimate correlations between the presence of cytogenetic features and of clinical, pathophysiological, cellular, or molecular characteristics in these patients; (3) To provide quality control for all Southwest Oncology Group cytogenetic data.

TECHNICAL APPROACH: Patients will receive treatment as directed by the treatment protocols on which they are registered. In addition to the diagnostic bone marrow sample, an additional 4 to 7 cc (less than 2 teaspoonfuls) will be obtained in a separate syringe to identify the chromosomal abnormalities that are present in patients who have acute leukemia.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9008(92)

Status: Ongoing

TITLE: Trial of Adjuvant Chemoradiation After Gastric Resection for Adenocarcinoma, Phase III

Start date: Oct 91

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/22/96
Decision: Continue

OBJECTIVE: To compare the overall and disease free survival in patients being treated with surgical resection only and in patients being treated with surgery plus adjuvant 5-FU and radiation.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized after surgical resection to receive either 1) clinical followup, or 2) 5 fluorouracil plus leucovorin IV bolus day 1 through 5 every 4 weeks for 5 cycles plus radiation therapy (4500 rads during the second cycle of 5 FU).

PROGRESS: No. of Subjects Enrolled - To Date: 3
During FY96: 0

As of 6/30/95, 357 patients were registered to this study nationally. Major toxicity on this study is hematological. Too early for any other analysis.

Detail Summary Sheet

Prot No: SWOG 9013(90)

Status: Completed

TITLE: A Prospective Randomized Comparison of Combined Modality Therapy for Squamous Carcinoma of the Esophagus: Local Regional Disease, Phase III

Start date: Sep 90

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words: esophagus; squamous carcinoma

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 8/27/96
Decision: Completed

OBJECTIVE: To compare the relapse rate and survival in patients with local regional esophageal cancer treated with surgery alone versus pre-op and post-op chemotherapy plus surgery.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive surgery alone or to receive 3 cycles of Cisplatin plus 5-FU then surgery, then 2 further cycles of Cisplatin plus 5-FU.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

As of 6/30/95, 425 patients were registered on this study nationally. The study is permanently closed to accrual (effective 31 Dec 95). The patient enrolled from TAMC has since expired.

Detail Summary Sheet

Prot No: SWOG 9015(93)

Status: Completed

TITLE: A Randomized Trial of Post-operative Chemotherapy Compared to Surgery Alone for Patients with Operable Non-small Cell Carcinoma of the Lung, Phase III

Start date: Nov 92

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words: lung carcinoma

Funding: FY 95:

FY 96:

Periodic Review Date: 12/5/95

Gifts:

Decision: Completed

OBJECTIVES: To compare the survival of patients with operable non-small cell lung cancer treated with surgical resection alone versus surgical resection combined with pre- and post-operative chemotherapy.

TECHNICAL APPROACH: Patients agreeing to participate and who have operable non-small cell lung cancer over 3 centimeters in size will be randomized to (1)surgery alone or (2) 2 cycles of carboplatin plus VP-16 followed by surgery and then 3 more cycles of the same chemotherapy.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study was closed to further accrual on 3/15/94. Too early for analysis. Replacement study for this group of patients is SWOG 9252 (this protocol has not been activated at TAMC yet).

Detail Summary Sheet

Prot No: SWOG 9019(92)

Status: Completed

TITLE: A Phase III, Randomized, Prospective Comparison Between Chemotherapy Plus Radiotherapy Together with Surgery for Selected Stage IIIa (Positive Mediastinal Nodes) and Selected Stage IIIb (No Malignant Effusion) Non-small Cell Lung Cancer

Start date: Aug 92

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words: Stage III lung cancer

Funding: FY 95:

FY 96:

Periodic Review Date: 6/25/96

Gifts:

Decision: Completed

OBJECTIVE: To determine whether concurrent chemotherapy and radiation therapy followed by surgical resection results in a significant improvement in progression-free and long term survival compared to the same chemotherapy plus standard radiation therapy alone for locally advanced non-small cell lung cancer.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive either 1) 4500 rads of radiation over 5 wks plus 2 cycles of simultaneous chemotherapy (cisplatin plus VP-16) followed by surgery or 2) the same 4500 rads plus the same 2 cycles of chemotherapy followed by another 1600 rads of radiation given simultaneously with 2 further cycles of VP-16 plus cisplatin (and no surgery).

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study was amended on 5/15/94 to include only Stage IIIB patients treated on standard induction therapy (no surgery) plus RT boost. Twenty-two (22) Stage IIIB patients are registered. One (1) patient has died of hypomagnesemia. A total of 130 patients have been registered as of 6/30/95.

Detail Summary Sheet

Prot No: SWOG 9023(95)

Status: Ongoing

TITLE: Cytogenetic and Flow Cytometric Analysis of Solid Tumors: Renal Cell Carcinoma:
A Companion Study to SWOG 8949

Start date: Jan 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: (1) To assess if cytogenetic abnormalities can predict clinical outcome (response to therapy and survival) of patients registered to the nephrectomy arm (Arm 1) of SWOG 8949; (2) To attempt to correlate cytogenetic abnormalities and DNA content analysis (DNA Index and S-Phase fraction) and assess the relationship of these to clinical outcome.

TECHNICAL APPROACH: Tumor cytogenetic measurements and flow cytometric data.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Nineteen (19) patients are registered in study nationwide. Pending start letter.

Detail Summary Sheet

Prot No: SWOG 9030(93)

Status: Completed

TITLE: Phase II Study of High Dose Ara-C/Mitoxantrone for the Treatment of Relapsed/Refractory Acute Lymphocytic Leukemia

Start date: Jul 93

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Completed

OBJECTIVE: To determine the complete response rate achieved in adult patients with relapsed or refractory ALL (acute lymphocytic leukemia) using the combination of high-dose Ara-C with mitoxantrone.

TECHNICAL APPROACH: Patients agreeing to participate will all receive high doses Ara-C daily for 5 days IV plus mitoxantrone on the 2nd day IV.

PROGRESS: No. of Subjects Enrolled - To Date: 2
During FY96: 0

Two patients were enrolled from TAMC. Study was closed to accrual in May 94, and now permanently closed due to insufficient response. Too early for analysis.

Detail Summary Sheet

Prot No: SWOG 9035(96)

Status: Ongoing

TITLE: Randomized Trial of Adjuvant Immunotherapy With an Allogeneic Melanoma Vaccine for Patients With Intermediate Thickness, Node Negative Malignant Melanoma (T3NOMO), Phase III

Start date: Jul 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: (1) To compare disease-free survival and overall survival between patients with T3NOM0 malignant melanoma who receive adjuvant immunotherapy with an allogeneic melanoma vaccine versus no adjuvant treatment. (2) To evaluate the toxicity of adjuvant immunotherapy with an allogeneic melanoma vaccine in patient sixth T3NOM0 malignant melanoma. (3) To explore the interaction between the patients' defined HLA types (ie, whether they are compatible with the HLA phenotypes of the vaccine) and the vaccine treatment effectiveness in terms of disease-free survival and overall survival.

TECHNICAL APPROACH: Random assignment to receive either the melanoma vaccine or close observation in patients with less severe cases of melanoma which have been surgically removed.

MODIFICATION (Jan97): Accrual closure notice.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9039(91)

Status: Ongoing

TITLE: Evaluation of Quality of Life in Patients with Stage D2 Cancer of the Prostate
Enrolled on SWOG 8894

Start date: Jan 91

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Continue

OBJECTIVE: To compare the quality of life of patients randomized to orchiectomy alone or orchiectomy plus flutamide (ie, studying patients who are enrolled on SWOG 8894, a companion protocol comparing the above two modes of hormone therapy of metastatic prostate cancer).

TECHNICAL APPROACH: In this study patients fill out a form about the quality of their life on hormone therapy. The form is fairly short.

PROGRESS: No. of Subjects Enrolled - To Date: 4
During FY96: 0

Nationally, 739 patients were entered. Too early for analysis.

Detail Summary Sheet

Prot No: SWOG 9040(90)

Status: Ongoing

TITLE: Intergroup Rectal Adjuvant Protocol, A Phase III Study

Start date: Oct 90

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words: rectal; adjuvant

Funding: FY 95:

FY 96:

Periodic Review Date: 10/22/96

Gifts:

Decision: Continue

OBJECTIVE: To determine the relative efficacy of 1) 5-FU, 2) 5-FU and leucovorin, 3) 5-FU and levamisole, and 4) 5-FU, leucovorin, and levamisole when combined with pelvic radiation in Dukes stage B2 and C rectal cancer.

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to one of four treatment arms. In arm one the patient will receive 5-FU daily for one week, repeated monthly for six cycles plus receive pelvic radiation for six weeks (5,000 rads). In arm two, the patient will receive the same 5-FU and radiation as in arm one, but get IV leucovorin with each 5-FU dose. In arm three, the patients get the same 5-FU and radiation as arm one but also receives levamisole p.o. with the first two and last two 5-FU cycles. In arm four, the patient receives 5-FU, radiation, leucovorin, and levamisole as in the above schedules.

PROGRESS: No. of Subjects Enrolled - To Date: 2
During FY96: 0

Study is permanently closed. No manuscript yet published. Too early for analysis.

Detail Summary Sheet

Prot No: SWOG 9041(95)

Status: Ongoing

TITLE: Chemoprevention of Recurrent Adenomas and Second Primary Colorectal Carcinoma, A Phase III Pilot Study

Start date: Jun 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: (1) To investigate the ability of SWOG to enroll sufficient numbers of patients with early stages of CRC with the intent of preventing subsequent adenomas or new primary carcinomas; (2) To monitor compliance in pill intake (dose taken), the drop out rate and the completion rate of yearly surveillance colonoscopy; (3) To monitor toxicities of calcium supplementation; (4) Gain group experience in measuring rates of recurrence for adenomas and development of primary carcinomas in the colon and rectum; (5) Assess feasibility of measuring intermediate markers, the proliferative activity by assaying the protein marker PCNA in uninvolved rectal mucosa samples.

TECHNICAL APPROACH: Patients with Stages 0.1 and II colorectal carcinoma must be registered within 550 days of the diagnosis. Patients meeting the eligibility requirements will be placed on placebo for 3 months during the run-in period. After successful completion of the run-in, patients will be randomized to regimens A or B. In regimen A, the patients will take 1800 mg of calcium, three 600 mg tablets of calcium carbonate, daily for five years. Patients in regimen B will receive three placebo pills, daily for five years. The pills will be supplied to patients every three months for the first two years and every six months for the next three years.

MODIFICATION (Jan 96): Consent revision.

PROGRESS: No. of Subjects Enrolled - To Date: 4
During FY96: 0

Nationwide, 73 patients enrolled in study.

Detail Summary Sheet

Prot No: SWOG 9108(93)

Status: Ongoing

TITLE: A Phase III Comparison of Fludarabine Phosphate vs Chlorambucil vs Fludarabine Phosphate + Chlorambucil in Previously Untreated B-cell Chronic Lymphocytic Leukemia

Start date: Nov 92

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/24/96
Decision: Continue

OBJECTIVES: To compare the response rates and progression-free survival in patients with untreated chronic lymphocytic leukemia and treated on one of the following therapeutic regimens: (1) chlorambucil, (2) fludarabine phosphate, or (3) fludarabine phosphate plus chlorambucil.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive either (1) chlorambucil po day one every 4 weeks, or (2) fludarabine phosphate IV slow push day 1 to 5 every 4 weeks or (3) both drugs at the same time (at reduced doses). Therapy is expected to continue about 6 months but this depends on the response.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

Arm 3 of study closed to further accrual as of 5/5/93. Data for this study was reviewed and it was concluded that overall survival and toxicities on this arm are worse than on either of the other 2 arms of this study. The one TAMC patient on this study was not randomized to this arm. This study was closed on 12/7/94.

Detail Summary Sheet

Prot No: SWOG 9114(95)

Status: Ongoing

TITLE: A Randomized Comparative Study of High Dose CPA/cDDP/BCNU and ABMT Versus Standard Dose CPA/cDDP/BCNU as Consolidation to Adjuvant CAF for Patients With Operable Stage II Or Stage III Breast Cancer Involving > 10 Axillary Lymph Nodes, Phase III

Start date: Jun 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 5/28/96

Gifts:

Decision: Continue

OBJECTIVE: (1) To determine whether adjuvant chemotherapy with four cycles of CAF followed by high dose combination CPA/cDDP/BCNU with autologous bone marrow support (ABMS), radiation therapy to the chest wall, and Tamoxifen therapy produces superior disease-free survival and overall survival to adjuvant chemotherapy with four cycles of CAF followed by standard dose CPA/cDDP/BCNU, radiation therapy to the chest wall, and Tamoxifen therapy (if hormone receptor positive or unknown) in patients with Stage II or III breast cancer involving 10 or more lymph nodes; and (2) To compare the toxicities experienced between the two programs.

TECHNICAL APPROACH: See protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

Nationwide, 685 patients registered on study.

Detail Summary Sheet

Prot No: SWOG 9133(96)

Status: Ongoing

TITLE: 9133/9208: Randomized Trial of Subtotal Nodal Irradiation Versus Doxorubicin Plus Vinblastine and Subtotal Nodal Irradiation for Stage I-IIA Hodgkin's Disease, Phase III (A Companion Study to SWOG 9208)/Health Status and Quality of Life (QOL) in Patients

Start date: Dec 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: The primary objective is to compare the progression-free and overall survivals of non-laparotomized patients with clinical Stage I-IIA Hodgkin's Disease treated with subtotal nodal irradiation alone or subtotal nodal irradiation plus 3 cycles of doxorubicin and vinblastine. Secondary study objectives: (a) To identify subgroups of patients whose outcomes are particularly affected by the regimen administered; (b) To follow patients for long term toxicities. An ancillary protocol (SWOG 9208) will serially determine the Quality of Life of patients treated on the two arms of this study.

TECHNICAL APPROACH: Treatment protocol consisting of: Group I - Standard subtotal nodal irradiation; Group II - Combined chemoradiotherapy with doxorubicin and vinblastine, for 3 cycles followed by subtotal nodal irradiation.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9205(96)

Status: Ongoing

TITLE: Central Prostate Cancer Serum Repository Protocol: A Companion Study to SWOG 9343

Start date: Sep 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 8/27/96

Gifts:

Decision: Continue

OBJECTIVE: (1) To store serum of patients with cancer of the prostate entered onto clinical trials conducted by the Southwest Oncology Group Genitourinary Committee. (2) To provide the serum of the above patients entered on Southwest Oncology Group studies for specific clinical-laboratory investigations (eg, evaluation of a new marker) outlined on separate Southwest Oncology Group protocols approved by the Genitourinary Committee Tumor Biology Subcommittee.

TECHNICAL APPROACH: Serum repository.

PROGRESS: No. of Subjects Enrolled - To Date:
 During FY96:

Detail Summary Sheet

Prot No: SWOG 9208(96)

Status: Ongoing

TITLE: Health Status and Quality of Life (QOL) in Patients with Early Stage Hodgkin's Disease: A Companion Study to SWOG 9133 (CALGB-9391), Ancillary

Start date: Dec 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: (a) To evaluate prospectively the health status and quality of life (QOL) of early stage Hodgkin's Disease patients receiving either subtotal nodal irradiation or short course chemotherapy plus subtotal nodal irradiation; (b) to describe the short-term, acute effects of two treatments for early stage Hodgkin's Disease patients on patient report of symptoms and on patient QOL; (c) To evaluate the intermediate and long-term effects of two treatments for early stage Hodgkin's Disease patients on patient QOL over five years.

TECHNICAL APPROACH: QOL assessments are to be completed per study calendar. Not all of the QOL questionnaires are administered at each time point. The CARES-SF and the Symptom and Personal Information Questionnaire are administered at each scheduled assessment: before initial registration, at 6 months, and annually for seven years.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9210(95)

Status: Ongoing

TITLE: A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma
Comparison of (1) VAD-P to VAD-P/Quinine for Induction; (2) Randomization of
Prednisone Dose Intensity for Remission Maintenance

Start date: Mar 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: (1) To compare the effectiveness of the VAD-P chemotherapy regimen when administered alone or in combination with the chemosensitizer quinine intended to block the emergence of multidrug resistance during remission induction in previously untreated patients with multiple myeloma. This will be evaluated in terms of response, overall and relapse-free survival, and P-glycoprotein expression prior to therapy and at the end of induction therapy in relation to the induction therapy arm; (2) To evaluate the chemosensitizing potential of quinine to reverse drug resistance in myeloma patients randomized to VAD-P induction who fail to achieve at least 25% regression with chemotherapy alone; (3) To compare the value of alternate day prednisone (10 mg) versus 50 mg of prednisone for remission maintenance for patients proven to achieve at least 25% regression. The effectiveness of the two maintenance arms will be compared in terms of the duration of relapse-free survival and overall survival from the time of randomization of maintenance therapy.

TECHNICAL APPROACH: Patients will be randomized to one or two induction arms.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

There are 171 patients registered on study nationally.

Detail Summary Sheet

Prot No: SWOG 9217(96)

Status: Ongoing

TITLE: Chemoprevention of Prostate Cancer With Finasteride (Proscar), Phase III, Intergroup

Start date: Dec 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 10/22/96
Decision: Continue

OBJECTIVE: Study is a chemoprevention trial of finasteride to reduce the incidence of prostate cancer in healthy men. The primary objective is to test the difference in the biopsy-proven prevalence of carcinoma of the prostate between a group of participants treated with finasteride and a group treated with placebo for seven years.

TECHNICAL APPROACH: Participants will be randomized to receive finasteride or a matched placebo.

MODIFICATION (Apr96): Amendment #5 with revised consent.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: SWOG 9221(95)

Status: Ongoing

TITLE: Phase III Double-Blind Randomized Trial of 13 Cis Retinoic Acid to Prevent Second Primary Tumors in Stage 1 Non-Small Cell Lung Cancer

Start date: Dec 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: (1) To evaluate the efficacy of 13-cis-retinoic acid (13-cRA) in reducing the incidence of SPTs in patients who have been treated for Stage I non-small cell lung cancer with complete surgical resection; (2) To evaluate the qualitative and quantitative toxicity of 13-cRA in a daily administration schedule; and (3) To compare the overall survival of patients treated with 13-cRA vs patients treated with placebo.

TECHNICAL APPROACH: This is a double-blind, placebo-controlled, randomized study designed to evaluate whether 13-cis retinoic acid will prevent second primary tumors in non-small cell lung cancer. This study is planned to be 7 years in duration with patient entry occurring during the first 3 years.

MODIFICATION #1 (Mar96): Consent revision.

MODIFICATION #2 (Jul96): Therapy and consent change.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Nationwide, 878 patients enrolled in study; none from TAMC.

Detail Summary Sheet

Prot No: SWOG 9252(96)

Status: Ongoing

TITLE: Prospective Randomized Trial of Postoperative Adjuvant Therapy in Patients with Completely Resected Stage II and Stage IIIa Non-Small Cell Lung Cancer, Intergroup

Start date: Oct 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/24/96
Decision: Continue

OBJECTIVE: (1) To determine if combination chemotherapy plus thoracic radiotherapy is superior to thoracic radiotherapy alone in prolonging survival in patients with completely resected Stage II and Stage IIIa non-small cell lung cancer. (2) To determine if combination chemotherapy plus thoracic radiotherapy is superior to thoracic radiotherapy alone in preventing local recurrence in patients with resected Stage II and Stage IIIa non-small cell lung cancer.

TECHNICAL APPROACH: Treatment protocol with either radiotherapy alone or concurrent radiotherapy and chemotherapy.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9303(95)

Status: Ongoing

TITLE: Phase III Study of Radiation Therapy, Levamisole and 5-Fluorouracil Versus 5-Fluorouracil and Levamisole in Selected Patients with Completely Resected Colon Cancer (INT-0130)

Start date: Apr 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 7/23/96
Decision: Continue

OBJECTIVE: To determine whether 5-FU, levamisole and radiation therapy results in superior overall survival when compared to 5-FU and levamisole without radiation therapy in the management of patients with completely resected pathologic stage T4b-N0-2 colon cancer and selected patients with T3N1-2 colon cancer.

TECHNICAL APPROACH: Participants in this study will be treated by either (a) one year of treatment with the chemotherapy drug 5-FU and levamisole or (b) one year of 5-FU and levamisole together with 5 to 5-1/2 weeks of radiation therapy. The choice of treatment will be made on a random basis.

MODIFICATION (Jul96): Eligibility chnages.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

No TAMC patients entered in study, but 148 patients nationwide.

Detail Summary Sheet

Prot No: SWOG 9304(95)

Status: Ongoing

TITLE: Postoperative Evaluation of 5-FU by Bolus Injection vs 5-FU by Prolonged Venous Infusion Prior to & Following Combined Prolonged Venous Infusion Plus Pelvic XRT vs Bolus 5-FU Plus Leucovorin Plus Levamisole Prior to & Following Combined Pelvic XRT Plus B

Start date: Apr 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 3/26/96

Gifts:

Decision: Continue

OBJECTIVE: To compare the effectiveness of 5-FU by bolus injection versus 5-FU by prolonged venous infusion given prior to and following combined pelvic irradiation plus protracted venous infusion (PVI) versus 5-FU by bolus injection plus levamisole plus leucovorin given prior to and following combined pelvic irradiation plus bolus 5-FU plus levamisole in the treatment of modified Astler-Coller Stages B2, B3, and C rectal cancer. This will be evaluated in terms of survival and relapse-free survival, relapse patterns and side effects.

TECHNICAL APPROACH: Eligible patients will be adults that have modified Astler-Coller Stages B2, B3, and C rectal adenocarcinoma, and registered to start treatment between 20 to 70 days after surgery. Subjects will be randomized to one of three treatment regimens. Treatments include chemotherapy, combined chemotherapy plus radiation therapy and post-radiation chemotherapy. Each of the three treatments will take 5-6 months to complete.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Nationwide, 337 patients enrolled in study.

Detail Summary Sheet

Prot No: SWOG 9310(96)

Status: Ongoing

TITLE: An Intergroup Phase II Combined Modality Treatment of Primary Central Nervous System Lymphoma

Start date: Mar 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Continue

OBJECTIVE: (1) To assess the rate of tumor response to combination chemotherapy prior to the start of radiation; (2) To compare survival using a combined modality approach to historical controls using radiotherapy alone; (3) To assess the long-term toxicity of this regimen; (4) Based upon the response rate and survival of patients enrolled in this study, to consider a randomized trial to compare chemotherapy alone versus chemotherapy plus radiation in an effort to reduce the morbidity of cranial irradiation.

TECHNICAL APPROACH: Treatment protocol (chemotherapy in addition to radiotherapy).

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9313(95)

Status: Ongoing

TITLE: Phase III Comparison of Adjuvant Chemotherapy with High-Dose Cyclophosphamide Plus Doxorubicin (AC) Versus Sequential Doxorubicin Followed by Cyclophosphamide (A-->C) in High-Risk Breast Cancer Patients with 0-3 Positive Nodes (Intergroup)

Start date: May 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To compare the disease-free survival, overall survival and toxicity of high-risk primary breast cancer patients with negative axillary lymph nodes or with one to three positive nodes treated with adjuvant high-dose chemotherapy with doxorubicin plus cyclophosphamide (AC), versus high-dose sequential chemotherapy with doxorubicin followed by cyclophosphamide (AC).

TECHNICAL APPROACH: Patients must have been diagnosed with primary invasive adenocarcinomas of the breast. Patients must have undergone an axillary node dissection, and at least six nodes must have been removed and examined. Nodal involvement by tumor must not exceed three positive nodes. Patients must be currently free of disease. Patients cannot have had any prior chemotherapy.

PROGRESS: No. of Subjects Enrolled - To Date: 2
During FY96: 0

There are 1095 patients enrolled in study nationally, to-date.

Detail Summary Sheet

Prot No: SWOG 9321(96)

Status: Ongoing

TITLE: Standard Dose Versus Myeloablative Therapy for Previously Untreated Symptomatic Multiple Myeloma

Start date: Jun 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: (1) To perform a randomized trial, in newly diagnosed patients with symptomatic multiple myeloma (MM), of standard therapy versus myeloablative therapy, in order to examine whether the greater tumor cytoreduction effected by intensive therapy and manifested by higher incidence of complete remission translates into extended overall survival and progression-free survival. (2) To randomize responding patients with greater than or equal to 75% tumor cytoreduction to interferon-alpha 2b (IFN) versus no maintenance in order to evaluate the role of IFN in MM.

MODIFICATION #1 (Jul96): Eligibility&therapy changes.

MODIFICATION #2 (Sep96): Amendment #12 with revised consent.

TECHNICAL APPROACH: Randomized trial comparing standard treatment and transplants in MM.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: SWOG 9327(96)

Status: Ongoing

TITLE: Randomized Phase II Pilot Study of Pentoxifylline (Trental) and Placebo in Patients With Metastatic Malignancy and Anorexia/Cachexia Syndrome

Start date: Aug 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 7/23/96
Decision: Continue

OBJECTIVE: (1) To evaluate the effect of pentoxifylline on the quality of life in patients with anorexia/cachexia syndrome related to malignancy; (2) To evaluate the effect of pentoxifylline on the nutritional status of patients with cancer cachexia and on various laboratory measurements of nutritional status; (3) To assess the feasibility of accruing patients with cancer cachexia in a cooperative group setting.

TECHNICAL APPROACH: Outpatient treatment protocol with quality of life assessments at various intervals during study.

PROGRESS: **No. of Subjects Enrolled - To Date:**
 During FY96:

Detail Summary Sheet

Prot No: SWOG 9332(95)

Status: Completed

TITLE: Phase III Trial of Adriamycin Versus Taxol Plus Adriamycin Plus G-CSF in Metastatic Breast Cancer Intergroup

Start date:

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Completed

OBJECTIVE: (1) To compare the objective response rate and time to progression of single-agent Adriamycin, single-agent Taxol, and the combination of Adriamycin and Taxol in patients with previously untreated metastatic breast cancer; (2) To compare the toxicity of Adriamycin, Taxol, and Adriamycin and Taxol given in combination; (3) To determine whether Taxol and Adriamycin exhibit crossover resistance to each other; (4) To compare the quality of life of patients who have received Taxol, Adriamycin, or the combination of Taxol and Adriamycin as first-line therapy for metastatic breast cancer; (5) To compare the quality of life of patients who have received Taxol or Adriamycin as second-line therapy; and (6) To evaluate the relation of steady state Taxol levels to therapeutic response and toxicity.

TECHNICAL APPROACH: A fixed sample design has been selected for this trial.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study is permanently closed effective 9/29/95. No TAMC patients on this study. Nationally, 667 patients were entered.

Detail Summary Sheet

Prot No: SWOG 9336(96)

Status: Ongoing

TITLE: A Phase III Comparison Between Concurrent Chemotherapy Plus Radiotherapy, and Concurrent Chemotherapy Plus Radiotherapy Followed by Surgical Resection for Stage IIIA (N2) Non-Small Cell Lung Cancer

Start date: Oct 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/24/96
Decision: Continue

OBJECTIVE: (1) To assess whether concurrent chemotherapy and radiotherapy followed by surgical resection results in a significant improvement in progression-free, median, and long-term survival compared to the same chemotherapy plus standard radiotherapy alone for patients with stage IIIa non-small cell lung cancer. (2) To evaluate the patterns of local and distant failure for patients enrolled in each arm of the study, in order to assess the impact of the therapy on local control and distant metastases. (3) To obtain exploratory descriptive information on the relationship of tobacco use, alcohol use and dietary patterns on toxicity and outcomes in males and females.

TECHNICAL APPROACH: Treatment protocol.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9338(95)

Status: Completed

TITLE: A Phase II Trial of Combination Therapy With 5-Fluorouracil, Alpha-interferon and Interleukin-2 (FUNIL) for Advanced Renal Cell Carcinoma

Start date:

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology

Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 2/27/96

Gifts:

Decision: Completed

OBJECTIVE: (1) To evaluate the response rate of metastatic or locally advanced renal cell carcinoma treated with "FUNIL" the three drug combination regimen consisting of 5-Fluorouracil, Alpha-interferon and Interleukin-2; and (2) To assess the qualitative and quantitative toxicities of the "FUNIL" regimen administered in a Phase II study.

TECHNICAL APPROACH: Initially, 20 eligible patients will be accrued. If one or no responses are observed, the study will be permanently closed and the regimen will not be advanced to further study. If at least two responses are observed in the first 20 patients, an additionally 15 patients will be accrued and the study permanently closed. Seven or more responses out of 35 will be considered evidence warranting further study of the regimen provided other factors such as toxicity and survival also appear favorable.

PROGRESS: No. of Subjects Enrolled - To Date: 0

During FY96: 0

Twenty (20) patients entered on study nationally, and none from TAMC. Temporary closure notice dated 9/1/95.

Detail Summary Sheet

Prot No: SWOG 9343(95)

Status: Ongoing

TITLE: Evaluation of Combined Androgen Suppression and Fixed Schedule Suramin in Patients with Newly Diagnosed Metastatic Prostate Cancer, Phase II

Start date: Jun 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: To assess the feasibility of fixed schedule suramin plus combined androgen suppression (orchiectomy plus flutamide, or LHRH agonist plus flutamide) in a cooperative group setting in patients with newly diagnosed Stage D2 prostate cancer. Feasibility evaluation is based on an assessment of the magnitude of suramin-related neurotoxicity or treatment interruption of four weeks or more.

TECHNICAL APPROACH: Patients will be described according to: orchiectomy plus flutamide vs LHRH agonist plus flutamide. Those patients meeting the eligibility criteria outlined in this study will be treated with androgen deprivation therapy (patient's choice: LHRH agonist or bilateral orchiectomy) and flutamide plus suramin and hydrocortisone.

MODIFICATION #1 (Aug96): Amendment #2 with revised consent.

MODIFICATION #2 (Sep96): Amendment #3 with revised consent.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Nationwide, 29 patients are registered in study.

Detail Summary Sheet

Prot No: SWOG 9347(96)

Status: Ongoing

TITLE: Phase III Comparison of Tamoxifen Versus Tamoxifen With Ovarian Ablation in Premenopausal Women With Axillary Node-negative Receptor - Positive Breast

Start date: Aug 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: (1) To compare the disease-free survival, overall survival, and toxicity of treatment in hormone receptor-positive, premenopausal women with axillary lymph node-negative breast cancer measuring 3 cm or less given adjuvant therapy with tamoxifen alone, or tamoxifen with ovarian ablation; (2) To obtain tumor tissue from these patients for future biologic studies of relevance to this patient population; (3) To compare menopausal symptoms, sexual function and quality of life in patients receiving tamoxifen alone with patients receiving tamoxifen plus ovarian ablation.

TECHNICAL APPROACH: This study will examine the role of ovarian ablation in hormone receptor-positive, lymph node-negative premenopausal women with breast cancer measuring 3 cm or less who are receiving adjuvant tamoxifen. The effect of treatment of patient quality of life will also be measured.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9349(95)

Status: Ongoing

TITLE: A Randomized II Trial of CHOP with G-CSF Support or ProMACE-CytaBOM with G-CSF Support for Treatment of Non-Hodgkin's Lymphoma

Start date: May 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: (1) To evaluate the effectiveness of dose intense CHOP chemotherapy regimen (cyclophosphamide, vincristine, doxorubicin, and prednisone) with G-CSF support and the dose intense ProMACE-CytaBOM chemotherapy regimen (cyclophosphame, doxorubicin, etoposide, prednisone, cytosine, arabinoside, bleomycin, vincristine, methotrexate and leucovorin) with G-CSF support in previously untreated patients with intermediate and high grade non-Hodgkin's lymphomas. The effectiveness of the regimens will be based on the estimate of the complete response rate, the time to treatment failure, and ultimately overall survival; (2) To assess the toxicities and side effects associated with the regimens; (3) To further utilize the central serum and tissue repositories enabling clinicopathologic correlations with the results of studies on the material collected.

TECHNICAL APPROACH: All patients must have biopsy proven intermediate or high grade non-Hodgkin's lymphoma except lymphoblastic lymphoma. Transformed lymphomas are not eligible. Patients assigned to the first treatment (Arm I) will receive five drugs consisting of cyclophosphame, doxorubicin, vincristine, prednisone (CHOP) plus G-CSF. The second treatment, ProMACE-CytaBOM (Arm II) will consist of chemotherapy with doxorubicin, bleomycin, cyclophosphamide, leucovorin, methotrexate, vincristine, prednisone, etoposide (VP-16), cytarabine (Ara-C) and trimethoprim sulfa plus G-CSF. Patients will be selected at random to participate in either Arm I or Arm II.

MODIFICATION (Jul96): Revised consent.

PROGRESS: No. of Subjects Enrolled - To Date: 1
During FY96: 0

One patient has been enrolled at TAMC.

Detail Summary Sheet

Prot No: SWOG 9401(96)

Status: Ongoing

TITLE: A Controlled Phase III Evaluation of 5-FU Combined With Levamisole and Leucovorin as Surgical Adjuvant Treatment Following Total Gross Resection of Metastatic Colorectal Cancer

Start date: Aug 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 6/25/96
Decision: Continue

OBJECTIVE: To determine in patients who have undergone complete gross surgical resection of metastatic colorectal cancer whether postoperative adjuvant chemotherapy with a new regimen of 5FU plus leucovorin plus levamisole will result in improved survival compared to postoperative adjuvant chemotherapy with a standard 5FU plus levamisole regimen.

TECHNICAL APPROACH: Randomization to one-of-two chemotherapy regimens.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9410(95)

Status: Ongoing

TITLE: Doxorubicin Dose Escalation With or Without Taxol, as Part of the CA Adjuvant Chemotherapy Regimen for Node Positive Breast Cancer: A Phase III Intergroup Study

Start date: Apr 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:

FY 96:

Periodic Review Date: 3/26/96

Gifts:

Decision: Continue

OBJECTIVE: (1) To determine which of three treatments using cyclophosphamide with different doses of doxorubicin will most positively affect the overall survival and disease-free survival of patients with early breast cancer who are treated with lumpectomy and radiotherapy; (2) to assess the interaction between Taxol and the varying doses of doxorubicin. Patients will be stratified into three categories based on the number of positive lymph nodes and then randomized into one of three treatment regimens, each using the agents cyclophosphamide and doxorubicin. Subsequently, patients will be rerandomized to receive - or not receive- Taxol.

TECHNICAL APPROACH: The total accrual period will be three years, with total accrual estimated at 5000. Eligible patients include those with operable, histologically confirmed adenocarcinoma of the breast and histologically involved axillary lymph nodes. Only women 18 or older are eligible. Patients must be registered within 84 days of their surgery. They will then receive four 21 cycles of cyclophosphamide plus a standard, moderate or high dose of doxorubicin. Patients who are randomized to receive Taxol will receive it in four 21-day cycles.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Nationwide, there are 934 patients registered in study.

Detail Summary Sheet

Prot No: SWOG 9413(96)

Status: Ongoing

TITLE: Phase II Treatment with Etoposide, Leucovorin, 5-Fluorouracil and Interferon Alpha 2B (ELFI) + G-CSF for Locally Advanced or Recurrent Pancreatic

Start date: Mar 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Continue

OBJECTIVE: To assess the response rate of 5-fluorouracil (5-FU), leucovorin, etoposide (VP-16) and interferon alpha 2b (ELFI) in patients with locally advanced or recurrent pancreatic adenocarcinoma; (2) To evaluate the qualitative and quantitative toxicities of this ELFI regimen.

TECHNICAL APPROACH: Above combination chemotherapy treatment will be repeated every 28 days for 6 cycles (24 weeks).

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Study was permanently closed to accrual, effective 3/1/96. No patients were enrolled to study from TAMC.

Detail Summary Sheet

Prot No: SWOG 9415(95)

Status: Ongoing

TITLE: Phase III Randomized Trial of 5-FU/Leucovorin/Levamisole Versus 5-FU Continuous Infusion/Levamisole as Adjuvant Therapy for High-Risk Resectable Colon Cancer, Intergroup

Start date: Apr 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Continue

OBJECTIVE: To compare the effectiveness of bolus 5-FU/leucovorin/levamisole versus continuous infusion 5-FU/levamisole as adjuvant therapy for patients with Stage B2, C1 or C2 colon cancer. This will be measured in terms of overall survival. Disease-free survival will be a secondary endpoint. The continuous infusion arm would be judged superior if the true increase in survival is 35%. An interim analysis will be done at 2/3 accrual and again at 1.5 years after the end of accrual if necessary.

TECHNICAL APPROACH: Eligible patients will be randomized to one of two treatments: 5-FU/leucovorin/levamisole or 5-U/levamisole. Following each of the initial two 8-week cycles, there will be one week of rest, followed by a resumption of chemotherapy. Laboratory tests will be performed on a regular basis to determine the effect of the treatment.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

There are no TAMC patients registered in study, but there are 55 patients nationally.

Detail Summary Sheet

Prot No: SWOG 9419(96)

Status: Ongoing

TITLE: Tumor Tissue Biopsy for Thymidylate Synthase Expression in Patients with Colorectal Cancer

Start date: Dec 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: (1) To measure thymidylate synthase (TS) expression by polymerase chain reaction in tumor biopsies prior to initiation of fluorinated pyrimidine based therapy in patients with disseminated colorectal cancer and correlate tumor response with level of TS expression; (2) To correlate TS expression in tumor tissue obtained during a potentially curative resection and disease-free survival in patients with Stage II and III large bowel cancer prior to receiving adjuvant therapy with 5-FU based regimen on targeted Southwest Oncology Group trials.

TECHNICAL APPROACH: This is a laboratory study on cancer tissue samples.

PROGRESS:

No. of Subjects Enrolled - To Date:	
During FY96:	

Detail Summary Sheet

Prot No: SWOG 9420(96)

Status: Ongoing

TITLE: A Phase III Trial of Continuous Low-dose Infusion Versus Intermittent High-dose Infusion of 5-Fluorouracil in Patients With Disseminated Colorectal Cancer

Start date: Dec 95

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 12/5/95
Decision: Continue

OBJECTIVE: (1) To determine thymidylate synthase gene expression within tumor biopsies of metastatic colorectal cancer and compare with response to therapy with 5-FU given by continuous low-dose versus high-dose intermittent infusion. (2) To determine if dose intensity of 5-FU administered for treatment of disseminated colorectal cancer impacts upon response and survival.

TECHNICAL APPROACH: Patients will be randomly assigned to receive one of two treatment arms.

MODIFICATION (May96): Title change.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9432(96)

Status: Ongoing

TITLE: Induction Chemotherapy Followed by High Dose Chemoradiotherapy with Autologous Stem Cell Rescue for Patients with Newly Diagnosed Ki67 Positive Diffuse Aggressive Lymphoma

Start date: Jan 97

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 9/24/96
Decision: Continue

OBJECTIVE: (1) To evaluate in a group-wide setting the overall survival, failure-free survival, and response rates of patients with diffuse aggressive non-Hodgkin's lymphomas that are Ki67 positive who are treated with chemotherapy followed by transplant therapy. Transplant therapy is total body irradiation (TBI), high-dose etoposide, cyclophosphamide and peripheral blood stem cell transplant (PGSCT). (2) To evaluate the toxicity of an aggressive program of intensive induction chemotherapy followed by autologous transplantation for this group of patients.

TECHNICAL APPROACH: See protocol.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9500(96)

Status: Ongoing

TITLE: A Phase II Study of 7 + 3 and High Dose Ara-C Induction Therapy with Sequential High-Dose Ara-C Consolidation Therapy for Adults with De Novo Acute Myeloid Leukemia

Start date: Mar 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Continue

OBJECTIVE: (1) To test whether an intensive 3+7+3 induction regimen of cytosine arabinoside (Ara-C) plus daunomycin (DNR) is sufficiently effective for previously untreated acute myeloid leukemia (AML) when used in a cooperative group setting to warrant its further investigation in Phase III trials; (2) To estimate 1 year disease free survival among AML patients on the 3+7+3 regimen; (3) To estimate the frequency and severity of toxicities on the 3+7+3 regimen; (4) To estimate the frequency of minimal residual disease (MRD) among AML patients who achieve complete remission on the 3+7+3 regimen; (5) To evaluate the feasibility of incorporating results of pretreatment molecular studies performed at the Southwest Oncology Group Myeloid Repository into stratification and treatment plans.

TECHNICAL APPROACH: Treatment protocol with chemotherapy.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9509(96)

Status: Ongoing

TITLE: A Randomized Phase III Trial of Paclitaxel Plus Carboplatin Versus Vinorelbine and Cisplatin in Untreated Advanced Non-small Cell Lung Cancer

Start date: Jun 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 5/28/96
Decision: Continue

OBJECTIVE: (1) To compare the effect of paclitaxel carboplatin to vinorelbine plus cisplatin on overall survival, progression-free survival and tumor response rate in patients with Stage IV and selected Stage IIIB non-small cell lung cancer. (2) To compare the toxicity of the two treatment regimens in patients with Stage IV and selected Stage IIIB non-small cell lung cancer.

TECHNICAL APPROACH: This is a randomized Phase III trial.

MODIFICATION #1 (Aug96): Eligibility changes.

MODIFICATION #2 (Sep96): Revised consent.

PROGRESS: No. of Subjects Enrolled - To Date: 0
During FY96: 0

Detail Summary Sheet

Prot No: SWOG 9514(96)

Status: Ongoing

TITLE: Phase III Double-Blind, Placebo-Controlled, Prospective Randomized Comparison of Adjuvant Therapy With Tamoxifen vs Tamoxifen and Fenretinide in Postmenopausal Women With Involved Axillary Lymph Nodes and Positive Receptors

Start date: May 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 4/23/96
Decision: Continue

OBJECTIVE: (1) To compare disease-free survival and overall survival of postmenopausal primary breast cancer patients with involved axillary nodes and positive estrogen or progesterone receptors who are treated with standard adjuvant tamoxifen vs tamoxifen and fenretinide; (2) To gain wider experience and toxicity information on the combination of tamoxifen and fenretinide; (3) To obtain tumor tissue from these patients for future biologic studies of relevance to this patient population.

TECHNICAL APPROACH: See protocol.

MODIFICATION (Jul96): Editorial and eligibility changes.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9515(96)

Status: Ongoing

TITLE: Phase III Intergroup Trial of Surgery Followed by (1) Radiotherapy Vs (2) Radiochemotherapy for Resectable High Risk Squamous Cell Carcinoma of the Head and Neck

Start date: Apr 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 3/26/96
Decision: Continue

OBJECTIVE: (1) To determine the efficacy of concurrent cisplatin and radiotherapy following surgical resection in patients who have advanced squamous cell carcinoma of the head and neck region; (2) To test whether the use of concurrent chemoradiotherapy following surgery increases locoregional control rates; (3) To determine if the patterns of first failure are changed by the use of concurrent chemoradiotherapy; (4) To determine whether the use of concurrent chemoradiotherapy prolongs disease-free survival and/or overall survival; (5) To compare the toxicity of concurrent chemoradiotherapy vs. radiation alone in the postoperative setting.

TECHNICAL APPROACH: Randomized treatment of either radiation therapy alone or in combination with chemotherapy. Treatment with one of the above will begin within 8 weeks of the surgery.

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

Detail Summary Sheet

Prot No: SWOG 9520(96)

Status: Ongoing

TITLE: Controlled Phase II Study of Doxorubicin and Paclitaxel as Frontline Chemotherapy for Women with Metastatic Breast Cancer

Start date: Mar 96

Est Comp Date: Indef

Principal Investigator: COL Jeffrey L. Berenberg MC

Department/Section: Medicine/Hematology-Oncology
Facility: TAMC

Associate Investigator:

Key Words:

Funding: FY 95:
Gifts:

FY 96:

Periodic Review Date: 2/27/96
Decision: Continue

OBJECTIVE: (1) To evaluate the complete remission rate of the doxorubicin plus paclitaxel combination in advanced breast cancer patients with no prior chemotherapy for metastatic disease and either no prior adjuvant chemotherapy or 1 prior adjuvant chemotherapeutic regimen (non-anthracycline or taxane containing). This evaluation will be made over six cycles of the combination regimen. (2) To test the combination of doxorubicin and paclitaxel for toxicity with particular emphasis on the degree of myelosuppression and the possible cardiac toxicity. These will be done in conjunction with a concurrently randomized control arm (of doxorubicin and cyclophosphamide) which will be used mainly to assess whether the new regimen has been tested in a patient population with historically expected rates of complete remission and congestive heart failure. This evaluation will be made over six cycles of the combination regimen.

TECHNICAL APPROACH: Chemotherapy treatment protocol. Patients will be randomized to receive one of two treatments (doxorubicin and paclitaxel (Taxol) versus doxorubicin and cyclophosphamide).

PROGRESS: No. of Subjects Enrolled - To Date:
During FY96:

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