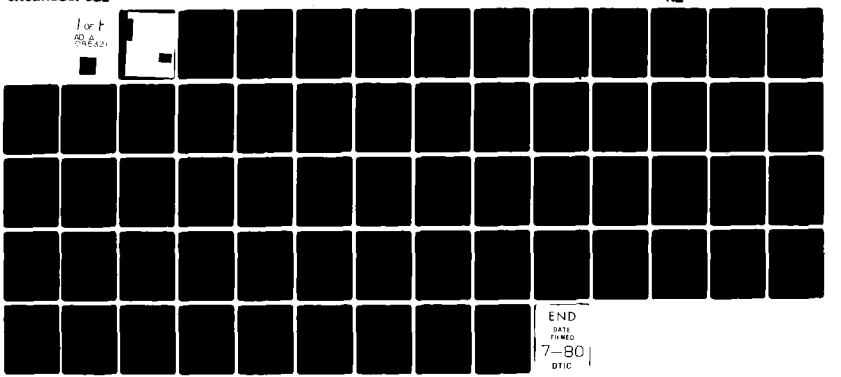
AD-A085 321 DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER FORT GOR--ETC F/G 5/1
ANNUAL RESEARCH PROGRESS REPORT, FISCAL YEAR 1979,(U)
OCT 79 A J LLOYD

UNCLASSIFIED NL



SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER MED-300	2. GOVT ACCESSION NO. AD-A085321	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) (6) ANNUAL RESEARCH PROGRESS REPORT, Fiscal Yr 1979		5. TYPE OF REPORT & PERIOD COVERED ANNUAL - FY 79 6. PERFORMING ORG. REPORT NUMBER
7. AUTHOR(s) (10) ANDREE J. LLOYD, PhD Lieutenant Colonel, MSC		8. CONTRACT OR GRANT NUMBER(s) (12) LC
9. PERFORMING ORGANIZATION NAME AND ADDRESS Clinical Investigation Service Dwight David Eisenhower Army Medical Center Fort Gordon, Georgia 30905		10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS (11)
11. CONTROLLING OFFICE NAME AND ADDRESS Commander Dwight David Eisenhower Army Medical Center, Fort Gordon, Georgia 30905		12. REPORT DATE 1 October 1979 13. NUMBER OF PAGES 63 Pages
14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office) Office of The Surgeon General Department of the Army Washington, D.C. 20314		15. SECURITY CLASS. (of this report) UNCLASSIFIED 15a. DECLASSIFICATION/DOWNGRADING SCHEDULE
16. DISTRIBUTION STATEMENT (of this Report) APPROVED FOR PUBLIC RELEASE: DISTRIBUTION UNLIMITED.		
17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)		
18. SUPPLEMENTARY NOTES THE FINDINGS IN THIS REPORT ARE NOT TO BE CONSTRUED AS AN OFFICIAL DEPARTMENT OF THE ARMY POSITION UNLESS SO DESIGNATED BY OTHER AUTHORIZED DOCUMENTS.		
19. KEY WORDS (Continue on reverse side if necessary and identify by block number)		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number)		

DD FORM 1 JAN 73 1473 EDITION OF 1 NOV 65 IS OBSOLETE

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

4/11/11

FOREWARD

The Clinical Investigation Service of the Dwight David Eisenhower Army Medical Center has had a very successful year. During the past fiscal year there were 38 publications and 49 presentations. Twenty-six protocols were completed during this fiscal year and 18 were terminated.

For their continued effort in supporting the growth of the Clinical Investigation Service, a special note of thanks must be given to COL Henry A. Robinson, Jr., Chief, Professional Services and to the Clinical Investigation Service Committee, COL James W. Reed, Chief, Department of Medicine, Chairman; COL George Powell, Chief, Department of Surgery; COL Eric Nelson, Chief, Department of Psychiatry and Neurology; COL Ronny Sayers, Chief, Department of Pathology; LTC William Baxley, Chief, Department of Family Practice. The support of all these individuals has been most appreciated and has resulted in the success that the Clinical Investigation program presently enjoys.

Day by day operations of the Clinical Investigation Service, editorial assistance in protocol development, manuscript review; as well as coordination of the Clinical Investigation Committee meetings, Institutional Review Board meetings, other administrative meetings associated with the Clinical Investigation activity, and finally, coordination with the Clinical Investigation Division at Health Services Command, could not have been operated in an efficient manner without the assistance of Ms. Rosina Martinez, whose efforts are exemplified in this annual report. Her assistance is gratefully acknowledged by the entire staff of the Clinical Investigation Service.

ANDREE J. LLOYD, PhD
Lieutenant Colonel, MSC
Assistant Chief,
Clinical Investigation Service

REPORT OF TOTAL ACTIVITIES OF CLINICAL INVESTIGATION SERVICE

Fiscal Year 1979

A. Objectives

The Clinical Investigation Service is organized as an independent research, development and teaching service, operating directly under the supervision of the Chief, Professional Services, DDEAMC. It is composed of three sections: (1) The Research Laboratories Section; (2) The Clinical Research Section; and (3) The Southwest Regional Animal Support Facility. The Clinical Investigation Service operates under the guidance of the Clinical Investigation Committee, composed of Chiefs of the following Departments; Department of Medicine, Department of Surgery, Department of Psychiatry & Neurology, Department of Pathology and Department of Family Practice.

The Clinical Investigation Service was established to stimulate and provide support for research and development and teaching activities for elements of DDEAMC. Through the Research Laboratories Section this service provides available laboratory facilities and support in terms of academic and technical knowledge. This service instructs, guides and teaches research fellows, residents, other trainees and all other staff in the laboratory related research activities relevant to their requirements. As a clinical research section, The Clinical Investigation Service aids in the planning and development, support and execution of experimental clinical studies designed to improve diagnostic, therapeutic and rehabilitation methods and procedures in human subjects. The Clinical Investigation Service further provides and maintains animals as needed and approved for DDEAMC elements; furthermore, it supervises the appropriate, humane, and approved usage of animals.

B. Technical Approach

Manpower

Name	Rank	MOS	Title
Cowan, George S.M., Jr.	COL	61J8N	Chief
Lloyd, Andree J.	LTC	68T9B	Res Psychologist
Arensman, John B.	MAJ	64A00	Veterinarian
Hannan, Charles J., Jr.	CPT	68Z00	Physiologist
Harris, Richard W.	CPT	68J00	Microbiologist
Jones, Frederick Jr.	SSG	91T20	Animal Sp (Acting NCOIC)
Lohr, Edward M.	SP5	92D10	Chem Lab Sp
Blanco, Diana T.	SP5	01H20	Biological Science Asst
Lorh, Patricia S.	SP4	91T10	Animal Sp
Crawford, Nettie L.	SP4	74F10	Programmer/Analyst
Martin, Tommy	SP4	92B10	Med Lab Tech
Horner, Jack A.	GS13	01301	Res Histologist
McPherson, James C. III	GS11	01320	Biochemist
Patterson, Robert A.	GS9	00181	Psychology Technician
Whisenant, Willie	GS7	00645	Medical Technician

Manpower

Name	Rank	MOS	Tit
Martinez, Rosina	GS6	01087	Editorial Assistant
Stapleton, Agnes	GS3	00322	Clerk Typist (Temporary)
Silas, Bill E.	WG5	07706	Animal Caretaker

C. Progress

Protocol Disposition FY 79

	Completed	Terminated	Ongoing to FY 80
FY 78	9	5	30
FY 79	26	18	19
	35	23	49

D. Funding FY 79

Civilian Personnel (to include benefits)	$105,323.90
Consumable Supplies	80,962.94
Civilian contracts (to include consultants)	4,300.00
TDY	3,711.03
Publications	490.34
MEDCASE	83,222.00
Other	3,685.17
Military	151,098.56
	$436,596.00

TABLE OF CONTENTS

PUBLICATIONS AND PRESENTATIONS

CLINICAL INVESTIGATION SERVICE

PRESENTATIONS:

Hannan, C.J., Lloyd, A.J., McCloskey, J.J.: Difference between right or left one-hour artery occlusion in the gerbil stroke model. Presented at Annual Meeting Georgia Academy of Sciences, 20-21 April 1979, Augusta, GA. (C)

Lloyd, A.J., Traylor, J.A.: Sensory isolation--An alternative to biofeedback. Presented at Annual Meeting Georgia Academy of Sciences, 20-21 Apr 79, Augusta, GA. (C)

McPherson III, J.C., Mahesh, V.: Effect of progesterone, 5αDihydroprogesterone, 20 αHydroxyprogesterone or 17αHydroxyprogesterone alone or in combination with Estradiol on serum gonadotropins in immature female rats. Presented at Annual Meeting Georgia Academy of Sciences, 20-21 April 1979, Augusta, GA. (C)

Horner, J.A., Cowan Jr., G.S.M.: Scanning electron microscope image enhancement by applied sample bias. Presented at Annual Meeting Georgia Cademy of Sciences, 20-21 April 1979, Augusta, GA. (C)

Arensman, J.B., Cowan, Jr., G.S.M.: Mechanism of pulmonary artery perforation by indwelling, flow-directed catheters. Presented at Annual Meeting Georgia Academy of Sciences, 20-21 April 1979, Augusta, GA. (C)

Cowan, Jr., G.S.M., Trueblood, J., White, E.: Nomenclature for computerized study of microscopes from 1590 onwards. Presented at Annual Meeting Georgia Academy of Sciences, 20-21 April 1979, Augusta, GA. (C)

Osteen, K.G., McPherson III, J.C., Mahesh, V.: Radioimmunoassay of rabbit gonadotropins and the response of gonadotropins to castration in New Zealand rabbits. Presented at Annual Meeting Georgia Academy of Sciences, 20-21 April 1979, Augusta, GA. (C)

Costoff, A., McPherson III, J.C., Mahesh, V.: Effect of cryptorchid and hemicryptorchid on serum gonadotropins in adult rats. Presented at Annual Meeting Georgia Academy of Sciences, 20-21 April 1979, Augusta, GA. (C)

Holdredge, T., Cowan Jr., G.S.M.: Effects of antibioyivd on yhr oxyhemoglobin in dissociation curve. Presented at Annual Meeting Georgia Academy of Sciences, 20-21 April 1979, Augusta, GA. (C)

McPherson Jr., J.C., Berdanier, C.D., Harms, W.S., McPherson III, J.C.: The effect of non-ionic surface active agents on gastric emptying in the rat. Presented at Annual Meeting Georgia Nutritional Council, March 1979, Atlanta, GA. (C)

Beckwith, M.M. & Cowan, G.S.M.: Microvascular, surgically reimplanted full-thickness skin graft model characterization. Presented at Annual Meeting Georgia Academy of Sciences, 20-21 April 1979, Augusta. GA. (C)

Fitzpatrick, G.M., Cowan, G.S.M., Bell, J.W.: The hematologic effects of rigorous training upon a cohort of US Army trainees. Presented at Annual Meeting Georgia Academy of Sciences, 20-21 April 1979, Augusta, GA. (C)

Bell, J.W., Cowan, G.S.M., Harrell, H.C. Jrl: A widespread phenomenon of low blood hematocrits among US Army populations in training. Presented at Annual Meeting Georgia Academy of Sciences, 20-21 April 1979, Augusta, GA. (C)

Fisher, J.G. & Lloyd, A.J.: Concepts of oral health in the military environment. Presented at Annual Meeting Georgia Academy of Sciences, 20-21 April 1979, Augusta, GA. (C)

Mahesh, V.B. & McPherson, J.C.III: Modulation of gonadotropin secretion by steroids. Presented, 5th International Congress on hormonal steroids, New Delhi, India, 24-28 October 1978.

McPherson, J.C. Jr., McPherson, J.C. III, et al: Experimental fat embolism and voluntary food consumption in the rat. Presented, XIV Regional Lipid Meeting, Vanderbilt University, 4-5 October 1979, Nashville, TN. (C)

Lloyd, A.J.: Causes and consequences of job stress. Presentation at Georgia Mental Health Association, 3 October 1979, Augusta, GA. (C)

Lloyd, A.J.: Report of biofeedback in clinical cases. Presented at Department of Psychiatry Residents Seminar, Augusta College, November 1979, Augusta, GA. (C)

McPherson Jr., J.C., McPherson III, J.C., Costoff, A., Harms, W.A.: The fat embolism syndrome (FES) in the rat: Protective effect of pretreatment with a non-ionic surface-active agent (NISAA). Presented at Federation of American Societies for Experimental Biology, 1-10 April 1979, Dallas, TX. (C)

Cowan, Jr., G.S.M., Horner, J.A., White, E.: X-ray spectrometric analysis of historical artefacts. Presented at Southeastern Electron Microscopy Society, 24-26 May 1979, Athens, GA. (C)

Horner, J.A., Cowan Jr., G.S.M.: In situ thermometry of SEM samples. Presented at Southeastern Electron Microscopy Society, 24-26 May 1979, Athens, GA. (C)

PUBLICATIONS:

Hannan, C.J., Lloyd, A.J., McCloskey, J.J.: Difference between right or left one-hour carotid artery occlusion in the gerbil model. Ga J Sci, 37(2):97, Apr 79. (C)

Lloyd, A.J. & Traylor, J.A.: Sensory isolation--An alternative to biofeedback. Ga J Sci, 37(2):95, Apr 79. (C)

McPherson III, J.C. & Mahesh, V.: Effect of Progesterone, 5 αDihydro-progesterone, 20 αHydroxyprogesterone or 17 αHydroxyprogesterone alone or in combination with estradiol or serum gonadotropins in immature female rats. Ga J Sci, 37(2):95, Apr 69. (C)

Horner, J.A. & Cowan, G.S.M.: Scanning electron micrscope image enhancement by applied sample bias. Ga J Sci, 37(2):92-93, Apr 79. (C)

Arensman, J.A. & Cowan, G.S.M.: Mechanisms of pulmonary artery perforation by indwelling flow-directed catheters. Ga J Sci, 37(2):96, Apr 79. (C)

Beckwith, M.M. & Cowan, G.S.M.: Microvascular, surgically reimplanted full-thickness skin graft model characterization. Ga J Sci, 37(2): 108, Apr 79. (C)

Cowan, G.S.M., Trueblood, J., White, E.: Nomenclature for computerized study of microscopes from 1590 onwards. Ga J Sci, 37(2):115, Apr 79. (C)

Fitzpatrick, G.M., Cowan, G.S.M., Bell, J.W.: The hematologic effects of rigorous training upon a cohort of US Army trainees. Ga J Sci, 37(2):99, Apr 79. (C)

Bell, J.W., Cowan, G.S.M., Harrell, H.C.: A widespread phenomenon of low blood hematocrits among US Army populations, Ga J Sci, 37(2):98, Apr 79. (C)

Fisher, J.G. & Lloyd, A.J.: Concepts of oral health in the military environment, Ga J Sci, 37(2):109, Apr 79. (C)

Osteen, K.G., McPherson, J.C. III, Mahesh, V.B.: Radioimmunoassay of rabbit gonadotropins and the response of gonadotropins to castration in New Zealand rabbits. Ga J Sci, 37(2):104, Apr 79. (C)

McPherson, J.C. Jr., Berdanier, C.D., Harms, W.S., McPherson, J.C. III: The effect of non-ionic surface active agents on gastric emptying in the rat. Georgia Nutritional Council, Vol. III:3, Mar 79. (C)

Mahesh, V.B. & McPherson, J.C. III: Modulation of gonadotropin secretion by steroids. IN: Recent Advances in Reproduction and Regulation of Fertility. G.P. Talwan, Ed., Elsevier/North-Holland 1979, pp 9-18. (C)

Costoff, A., Mahesh, V.B., Knudsen, J.F., McPherson, J.C. III: The uterus in the rat approaching puberty and the effect of steroids on its growth. IN: Biological Perspectives of the Uterus. J.T. Velardo and B.A. Kasprow, Eds., Dowden, Hutchinson and Ro-s, Stroudsburg, PA., 1979, In Press. (C)

Mahesh, V.B.,and McPherson, J.C. III: Regulation of Gonadotropin secretion by estradiol and progesterone. IN: Endocrinology of the Ovary. R. Schoolar Ed., 1979, pp. 109-129. (C)

McPherson, J.C. III & Mahesh, V.B.: Dose related effect of a single injection of progesterone on gonadotropin secretion and pituitary sensitivity to LHRH in Estrogen-primed castrate female rats. Biol Repro, 20:763-772, 1979. (C)

McPherson, J.C. Jr, McPherson, J.C. III & Harms, W.S.: Intravenous non-ionic surface-active agents and voluntary food consumption in the rat. J Nutri, 1979, In Press. (C)

McPherson, J.C. III and Mahesh, V.B.: Influence of estrogen-progestin combinations on gonatropin secretion in castrate female rats. Biol Repro, 1979, In Press. (C)

Cowan, G.S.M. Jr. & Horner, J.A.: Direct grounding tool for examination of uncoated specimens in the scanning electron microscope. Rev Sci Instrum, 50(10):1314, Oct 1979. (C)

Pashley, D.H., Livingston, M.J. Reeder, O.W., Horner, J.A.: Effects of the degree of tubule occlusion on the permeability of human dentine in vitro. Archs Oral Biol, 23:1127-1133, 1979.

DEPARTMENT OF MEDICINE

PRESENTATIONS:

Tenholder, M.F.: Metastatic endobronchial plasmacytoma. Presented at US Army Pulmonary Symposium in Denver, Colorado, 12 Sep 79.

Aton, J.K., Kinstrey, T.E.: Verruccous carcinoma arising in a thermal burn scar. Presented at Symposium, 4th World Congress, International Society of Tropical Dermatology, Sep 23-27, 1979, New Orleans, LA.

PUBLICATI

Burgess, R.E., Burgess, V.F., Dibella, N.J.: Brain Metastases in small cell carcinoma of the lung. JAM, Vol 242, pp 2084-6, 1979.

Stafford, C.T., Arnold, D.J.: Systemic allergic reaction to adriamycin. Cancer Treatment Reports, Vol 63(1) Jan 79.

Aton, J.K., Shavin, J.S., Jones, T.M., Abele, D.C., Smith,J.G. Jr.: Mucha-Habermann's disease in children. Arch Dermatol, Vol 114, Nov 78.

Guill, M.A., Odom, R.B.: Larva migrans complicated by Loeffler's syndrome. Arch Dermatol Vol 114, Oct 78.

Guill, M.A., Goette, D.K., Knight, C.G., Peck, C.C., Lupton, G.P.: Erythema multiforme and urticaria. Arch Dermatol Vol 115, Nov 78.

Guill, M.A., Odom, R.B.: Evans Blue dermatitis. Arch Dermatol Vol 115, Sep 79.

DEPARTMENT OF SURGERY

PRESENTATIONS:

Lennox, K.W.: Scrotal masses. Presented at 14th Annual Family Practice Symposium, 16-20 Oct 78, Augusta, GA.

Ciliax, D.: Establishing an affective hearing conservation program. Presented at the Military Audiology Seminar, Nov 78, San Francisco, CA.

Watkins, T., Holt, G.R., Yoder, G.R.: Tympanometry in tympanic membrane disease. Presented at the Military Aduiology Seminar, Nov 78, San Francisco, CA. (C)

Watkins, T., Holt, G.R., Yoder, M.G. & McCloskey, J.: Recovery of supra-threshold auditory test function after removal of C.P.A. tumors. Presented at a) American Auditory Society Meeting, Oct 79, Dallas, Tx, b) Audiological Resources Association Meeting, Oct 79, Columbia, SC; and c) Military Audiology Seminar, Nov 79, Atlanta, GA. (C)

Watkins, T., Holt, G.R., Yoder, M.G. & Garcia, A.: Impedance following tonsillectomy. Presented at the American Academy of Otolaryngology, Oct 79, Dallas, Tx. (C)

Ciliax, D.: Status of audiology and hearing conservation programs at Army installations in the Southeast medical region. Discussion Leader, Military Audiology Seminar, Nov 79, Atlanta, Ga.

PUBLICATIONS:

Weldon, T.E., Kursh, E., Novak, L.J. & Persky, L.: Combination radiotherapy & chemotherapy in murine bladder cancer. Urology, Vol XIV(1):Jul 79

Watkins, T., Holt, G.R., Yoder, M.G. & Garcia, A.: Impedance following tonsillectomy. Otolaryn & Head & Neck Surg, Vol 87(4):Jul-Aug 79. (C)

DENTAL ACTIVITY

PRESENTATIONS:

Fisher, J.: Concepts of oral health in the military environment. Presented at Annual Meeting Georgia Academy of Science, April 29, Augusta, GA. (C)

Payne, T.F.: Vesiculo-Erosive disease. Presented at USAIDR Advanced Oral Path Course, 6 Apr 79, WRAMC

Payne, T.F.: The incidence of environmentally related lip pathology among active duty army personnel. Presented at American Academy of Oral Path, 24 Apr 79, San Diego, CA.

PUBLICATIONS:

Payne, T.F., Lewis, K.: An evaluation of the dental-medical history. J. Mil Med, Vol 143(11):pp 785-788, Nov 78.

Seng, G., Ruppell, W., Nance, J., Pompura, J.: The use of amalgam inserts for supplemental retention in tooth structure. J. of Gen Dentistry pending publication (accepted Mar 79)

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

PRESENTATION:

Broadnax, D.O.: The effectiveness of prophylactic oral doxycycline in reducing postoperative morbidity in patients undergoing vaginal hysterectomy. Armed Forces District of Amer Coll of OB-GYN, 3 Oct 79.

DEPARTMENT OF PATHOLOGY

PRESENTATIONS:

Malloy, Wilbur W.: Frozen blood, recent technical considerations. International Society for Clinical Laboratory Technology, 14 Jul 79, Augusta, GA.

Wells, D.L.: Clinical toxicology as a career. CSRA Section of American Chemical Society, 15 Nov 78.

Boe, G.P.: Personnel management for laboratory supervisors-a potpourri. (1 day workshop), Annual Meeting - International Society for Clinical Laboratory Technology, 23 Aug 79, Chicago, Ill.

PUBLICATIONS:

Dubose, C.M., Welch, E.T. et al.: Immobilization and Kinetic studies of an erythropoietin generating factor. Biochem Med, Vol 17, 1978.

Neal, W.A., Welch, E.T., et al.: Apparent heterogenity of erythropoietin. Biochem Med, Vol 20, 1978.

Neal, W.A., Welch, E.T., et al.: Isolation and partial characterization of an erythropoietin inhibitory factor. J. Biol Chem, Accepted for publication Oct 79.

Welch, E.T., Neal, W.A. et al.: The inactivation of erythropoietin stimulating factors (ESP) with hydrolytic enzymes. Biochem Med, accepted for publication Aug 79. In Press.

Neal, W.A., Lewis, J.P., Welch, E.T., et al.: Inhibition of erythropoiesis by components from human plasma and urine. J. Lab Clin Med, Accepted for publication July 1979. In Press.

Welch, E.T., Neal, W.A., Lewis, J.P., et al.: Prostaglandins Associated with the production of erythropoiesis regulatory factors. International Prostaglandin Congress, May 1979. In Press.

Neal, W.A., Lewis, J.P., Welch, E.T., et al.: Inhibition of erythropoiesis by plasma components from sheep, goats, and rabbits. Amer J. Vet Res, Vol 40(4) 1979.

Shroyer, E.L., Kelly, S.T., Taylor, P.C., et al.: Three serologic types of adenovirus infections of owl monkeys. Amer J. Vet Res, Vol 40(4)pp 532-36, Apr 79.

Boe, G.P.: Share the burden of building education. Lab World, 30:2, Feb 79.

DEPARTMENT OF FAMILY PRACTICE

PRESENTATIONS:

Young, M.: Type B hepatitis and coma in a first trimester patient. Sixth Annual Meeting of the USAFP, 2-7 Apr 79.

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY

PRESENTATIONS:

Armitage, D.T.: Delusions. Emory Univ Coll of Med Psych, 9 Feb 79.

Armitage, D.T.: The ALI test of insanity in military psychiatry. WRAMC CME Program in Psych. 15 Dec 78.

Armitage, D.T.: Legal responsibility in mental health care. VAH Psych, Augusta, GA. 28 Jun 79.

Patterson, W.: Medical problems in the psychiatric patient. Ga Sch of Mental Health & Mental Retardation, 7 Dec 78.

Patterson, W.: Medical services and examination of psychiatric patients. Ga Sch of Mental Health & Mental Retardation, 14 Feb 79.

Guyden, T.E.: Pharmacologic treatment of depression. Dept of Nursing, Medical College of Georgia, 25 Apr 79.

Guyden, T.E.: Hypnosis: History, Concepts, and Clinical Uses. Medical Corp Officers Wives Club, 10 Jan 79.

McCormack, J.C.: New interrelationships between the family and the professional. Medical College of Georgia School of Nursing. 6 Mar 79.

McCormack, J.C.: Treatment contracts for depressed adult outpatients. Medical College of Georgia School of Nursing, 25 Apr 79.

Granger, J.A.: Teaching family evaluation and therapy. Amer Assoc of Family & Marriage Counselors, 14 Oct 78.

Granger, J.A.: Family assessment and therapy. William Hall Psych Inst, 10 Nov 78.

Granger, J.A.: Peer evaluation process. Amer Assoc of Psych Services for Children, 11 Nov 78.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Biofeedback Training Through the Use of Reduced Sensory/ Perceptual Environment (RSPE).

WORK UNIT NO.: 78-4

PRINCIPAL INVESTIGATOR: Andree J. Lloyd, PhD, LTC, MSC

ASSOCIATE INVESTIGATOR: Charles J. Hannan, Jr., PhD, CPT, MSC

OBJECTIVES

To determine the effectiveness of behavioral training programs on self-awareness and control of psychophysiological activity in the human and its applicability to the treatment of psychosomatic symptoms.

TECHNICAL APPROACH

Patients will be randomly assigned to a biofeedback or non-biofeedback group as referred to the clinic for musculoskeletal headaches. An alternative method will involve assignment to a biofeedback group or control group. The treatment plan will involve the use of electromyographic, temperature, EEG, EKG, and pulse wave velocity for recordings and feedback. In accord with established clinic practices, patients will be given 10 training sessions, twice per week whith a 1 and 3 month follow-up session.

PROGRESS

Several subjects were begun on the protocol in early FY 79, at which time it was determined that the isolated environment of the clinic room assigned for biofeedback training was not sufficient. Numerous distractors were noted to have interfered with the results including noise emanating from the logistics section located directly above the Psychiatry Clinic. Data collection was terminated at this point, at which time the principal investigator considered alternative techniques to assess this variable.

STATUS: Terminate for resubmission at a later date.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: A Vascular Occlusion Stroke Model: I. A Technique for Evaluating Therapeutic Approach and Predisposing Factors.

WORK UNIT NOs.: 78-5 (78-6, 78-12)

PRINCIPAL INVESTIGATOR: CPT Charles J. Hannan, Jr., PhD

ASSOCIATE INVESTIGATORS: LTC Andree J. Lloyd, PhD
MAJ John J. McCloskey, MC

OBJECTIVES

To evaluate behavioral changes and correlate this with the histopathological severity of an induced inschemic infarction (stroke) in the Mongolian gerbil.

TECHNICAL APPROACH

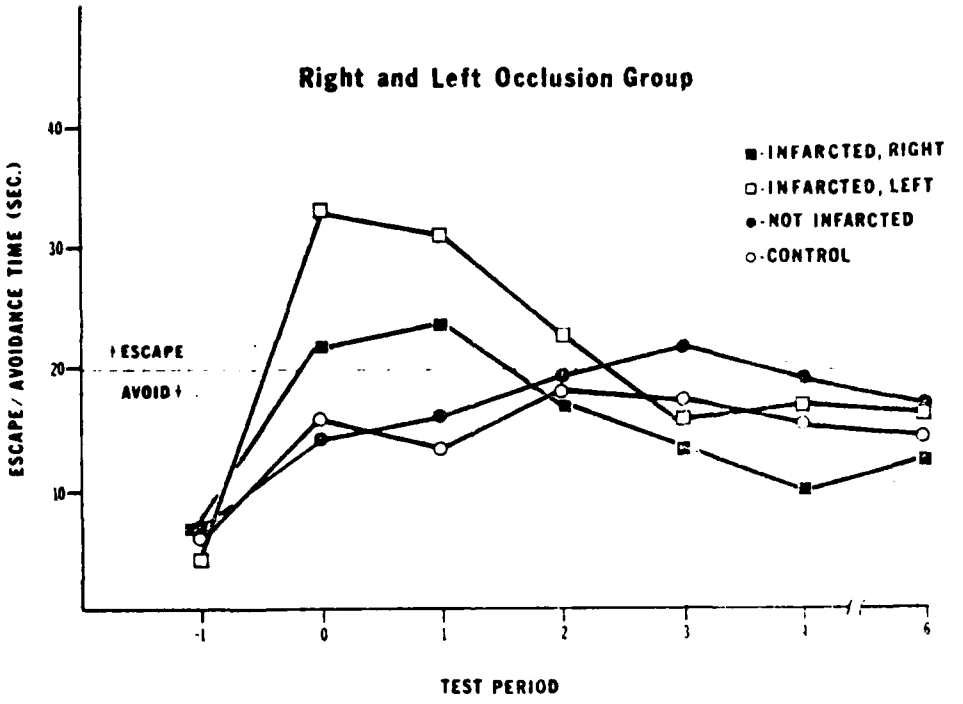
See Progress.

PROGRESS

Stroke Model I: The Rapid Avoidance Test of Gerbils After Unilaterial Cerebral Ischemia. Ninety male Mongolian gerbils completed 6 daily evaluations on the rapid avoidance test (RAT)in an attempt to quantitate the effects of cerebral ischemia produced by occluding a common carotid artery. Animals were trained in a shuttle box on a RAT schedule of 4 escape trails (tone and shock presented simultaneously for 40 sec) followed by 2 avoidance trials (20 sec of tone then 20 sec of tone and shock) with a 5 minute intertrial interval. Criterion for entry into the study was at least one successful response in the avoidance trials. One hundred and ninety six gerbils were trained with 26.5% rejected for not meeting the criterion. Animals were randomly assigned to groups for 1) right, or 2) left carotid artery occlusion, and 3) surgical controls. Animals were given the RAT just prior to surgery (animals failing to avoid were also rejected); at 3,5,or 7 hours after surgery; and then on 1,2,3,4 and 6 days post surgery. If animals died or were judged to be physically unable to perform the RAT they were eliminated from the study and additional animals were trained so that each group contained at least 30 animals at the end of the study. Of 104 animals entered into the occlusion groups, 40 died (right occlusion 17/49, left 23/55), therefore 64 occluded animals completed the study. Infarctions were histologically demonstrated in 14 of the 64 (21.9%) surviving animals (9 left, 5 right hemisphere). Mean values of performance on the RAT exhibited differences between groups, with animals which were found to be

infarcted doing poorer than non infarcted or control animals, and left side infarcted animals doing worse than those with right side infarctions. No measure of escape/avoidance time or patterns of time was uniquely predictive of infarction, although significant population tendencies were found.

		NORMAL 55.1%	INFARCTED 10.2%	DIED 34.7%
RIGHT OCCLUSION	(n:49)	27	5	17
LEFT OCCLUSION	(n:55)	23	9	23
		41.8%	16.4%	41.8%



Stroke Model II: Difference Between Right or Left One Hour Carotid Artery Occlusion in the Gerbil Stroke Model. This study employed behavioral evaluation of a version of the gerbil stroke model in which cerebral ischemia was induced in 39 male animals under ketamine anesthesia (44mg/kg) by occluding either the right or left common carotid artery for one hour with a hemostatic clip. Behavioral analyses consisted of a roto-bar test of motor coordination and a 15-minute open field test (OFT) of free ranging behavior (specific measures were frequency counts of ambulation, rearing, grooming, micturation and defecation). Animals were first trained to a roto-bar duration criterion of 40 seconds, after which they were given an OFT prior to the carotid occlusion. A second OFT was given 24 hours after the carotid occluding clips were removed and a third 7 days post occlusion. Rotor-bar retention was measured for each of 7 days post occlusion. The animals were perfusion fixed for histologic examination of representative brain areas using standard methods. The OFT revealed a significant difference (99% confidence level) among groups for the grooming measure only. A histogram of the number of sessions for each gerbil to reach criterion on the rotor-bar task revealed a biomodal distribution. The fast and slow learners were equally distributed between the experimental groups (right or left occlusion). Rotor-bar performance was demonstrated to be effected (95% confidence level) by either right or left carotid artery occlusion and continued for the 7 days following one hour occlusion. These different behavioral actions between the right and left carotid artery occlusion groups were surprising in the light of the relatively minor ischemic insult used (histologically demonstrated infarction was present in only 2 animals).

Stroke Model III: Characteristics of the Interresponse Time of the Mongolian Gerbil. The interresponse time (IRT) on a fixed ratio 40 schedule for food-pellet reinforcement was measured in male, outbred, Mongolian gerbils. IRT was determined using a latency distribution sort paradigm with 10 counter bins which were accessed a 100-msec intervals. The IRT pattern was characteristic for each animal, remained intact during extinction and when animals were given 50 mg/kg of amitriptyline intraperitoneally for 7 days.

Status: Ongoing

Publications/Presentations:

Hannan, Charles J., Andree J. Lloyd and John T. McCloskey. 1979. The rapid avoidance test of gerbils after unilateral cerebral ischemia. Soc. Neurosci. Abst. 5:512.

Hannan, Charles J., and Andree J. Lloyd. 1979. Characteristics of the interresponse time of the Mongolian gerbil. Bulletin of the Psychonomic Soc. 14:260.

Hanna, Charles J., Andree J. Lloyd, and John T. McCloskey. 1979. Difference between right or left one hour carotid artery occlusion in the gerbil stroke model. Georgia J. Sci. 37:97(abs).

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of a Custom-made Collimator for the Scintillation Camera.

WORK UNIT No.: 78-7

PRINCIPAL INVESTIGATOR: Charles J. Hannan, Jr., PhD, CPT, MSC

OBJECTIVES

Evaluation of the imaging quality of a collimator constructed from tantalum tubing using various isotopes and phantoms.

TECHNICAL APPROACH

Three types of evaluations will be conducted on the new tantalum collimator:

a. Resolution. The resolution index or full width at half maximum (FWHM) of the line-spread function (LSF) will be used as a measure of the overall resolution of the collimator for a given scintillation camera.

b. Sensitivity. Plane sensitivity will be used to measure the tantalum collimator sensitivity since it is independent of depth under ideal conditions. Which requires that the plane source covers the field of view uniformly and that attenuation, penetration and scatter be negligible.

c. Thyroid Phantom. A lucite thyroid phantom will be imaged with the new collimator and other commercially available collimators for comparison.
All
All these evaluations will be done with Technetium-99m and Xenon-133.
There will be some time involved in adapting the tantalum collimator to the face of the scintillation cameras available in the Nuclear Medicine Service.

PROGRESS

Until we are able to use animals with the nuclear medicine isotope imaging equipment it is impossible to continue with this protocol.

Status: Terminated

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Scanning Electron Microscope (SEM) Image Enhancement Techniques for Biological Samples.

WORK UNIT NO.: 78-32

PRINCIPAL INVESTIGATOR: Jack A. Horner, DAC

ASSOCIATE INVESTIGATOR: George S.M. Cowan, Jr., MD, LTC, MC

OBJECTIVES

To investigate several considered approaches to increasing the information content of SEM images with a corresponding reduction in specimen irradiation, alteration, and damage.

TECHNICAL APPROACH

Signal:noise ratios will be measured using "A Scope" waveform monitoring as a function of all operating parameters. One such parameter never before fully studied is the effect of placing a bias voltage directly on the sample itself. It is expected that the application of a positive bias voltage of as little as 50 volts will completely retard the production of secondary electrons. The application of anegative bias voltage, on the other hand, is espected to result in an increased secondary electron emission coefficient (yield). It is further expected that surface topography, specimen tilt, and detector geometry will also affect the benefit of the applied specimen bias.

Test specimens to be utilized in this study will consist of uniplanar as well as irregular biological materials. These are readily available in the laboratory. In addition to these, several non-biological materials will be examined including polished aluminum stubs and sheets of fractured styrofoam.

PROGRESS

Extensive work and two publications were completed during the first year of this project and reported in the annual report for FY78. During FY79 additional studies were conducted to investigate the extent and nature of specimen heating due to electron beam bombardment in the SEM. It was found that significant but generally overlooked heating did occur. When examing frozen specimens this heating can easily raise the local temperature to above the ice sublimation point; since temperature measurement devices are typically located in adjacent areas there results a 30-40 C discrepancy between the viewed area and the monitored area. We have devised a micromanipulator controlled thermocouple junction to allow direct placement in the viewing area, thus resulting in more accurate measurements.

Status: Completed (PR) (P)

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Antidepressants: I. Radioimmunoassay for Plasma Levels.

WORK UNIT NO.: 78-37

PRINCIPAL INVESTIGATOR: CPT Charles J. Hannan, Jr., PhD

ASSOCIATE INVESTIGATORS: MAJ William Shivers, MC
LTC Andree J. Lloyd, PhD

OBJECTIVES

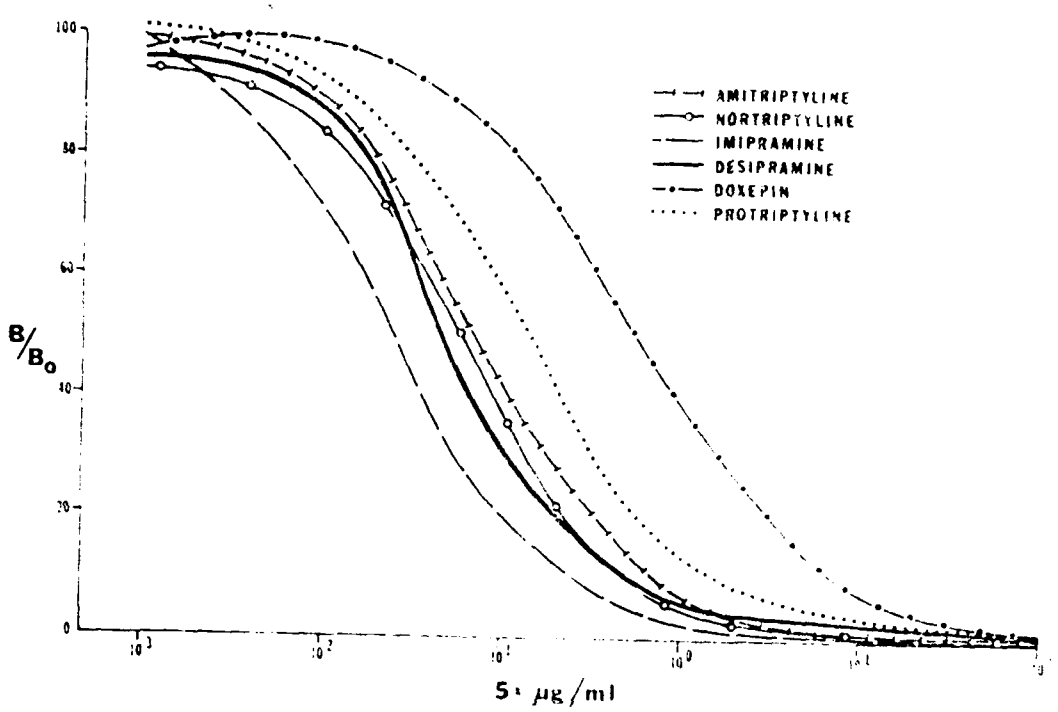
Production of a highly specific antibody from desipramineconjugated bovine albumin in rabbits will provide the basis for a radioimmunoassay (RIA). Maguire et al (1978) has demonstrated that antisera to nortriptyline can be applied to the measurement of all other tricyclic antidepressants with little modification.

TECHNICAL APPROACH

See Progress.

PROGRESS

Antiserum was produced in rabbits which was found to be adequate to determine plasma levels of all the clinically available tricyclic antidepressants (TCA). This tool provides a means of titrating the proper TCA plasma levels in depressed patients and maximizes the chances of a successful treatment. Antigen was prepared by conjugating desipramine to bovine serum albumin (BSA) via succinic anhydride and a carbodiimide reaction. The conjugate, after purification by dialysis, was shown to contain desipramine by UV and fluorometric spectroscopy. Six rabbits were innoculated subcutaneously with a divided dose of 2 mg conjugate in a slurry with Freund's complete adjuvant. After eleven weeks a booster injection was given to each rabbit. One week later animals were exsanguinated by cardiac puncture and the serum collected. Diluting with phosphate buffered saline (PBS), pH 7.5, the optimum concentration of antiserum was found to be 1:300 with our assay conditions, which are as follows in the order they are added: 0.2 ml 0.05 M EDTA in PBS with 1:400 normal rabbit serum; 0.015 ml ^{3}H-imipramine, 2.5 uCi/ml; 0.01 ml unknown or standard; 0.2 ml antibody, 1:300 dilution; 0.5 ml PBS with 1% BSA. This was incubated at 4 C for 2 hours with appropriate control tubes and a second antibody used to separate the free from the bound fraction.



Status: Completed.

Publications/Presentations:

Shivers, William F., and Charles J. Hannan. 1979. Tricyclic antidepressant determinations by radioimmunoassay. Soc. Neurosci, Abstr. 5:662.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: The Validation of a Non-Invasive Continuous Measure of Blood Pressure Changes in Humans.

WORK UNIT NO.: 79-5

PRINCIPAL INVESTIGATORS: Andree J. Lloyd, PhD, LTC, MSC
James Wilkin, MD, LTC, MC
Charles J. Hannan, PhD, CPT, MSC

OBJECTIVES

To establish a relationship between pulse wave velocity and intra-arterial pressure changes for use with biofeedback treatment of hypertension.

TECHNICAL APPROACH

Adult patients scheduled for diagnostic test in cardiology clinic were used in this study, no effort was made to control age or sex in patients selected. Consents for the addition of the pulse wave velocity determined by QRS wave of the EKG to index finger latency accompanied cardiac output and arterial pressures obtained during standard catheterization procedures.

PROGRESS

Data was collected on eight adult patients and linear regression analyses were conducted on the relationship of systolic and diastolic blood pressure with these latencies determined by the above cited pulse wave velocity. Analyses have been completed; data is being prepared for publication and/or presentation.

STATUS: Completed.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: The Effects of Biofeedback Relaxation Training on Patients with Essential Hypertension.

WORK UNIT NO.: 79-6

PRINCIPAL INVESTIGATORS: Andree J. Lloyd, LTC, PhD, MSC
James Wilkin, LTC,MD, MC
Eleanor Thomas, CPT, ANC
Charles J. Hannan, CPT, PhD, MSC

OBJECTIVES

To assess the effectiveness of biofeedback training on the reduction and long-term management of essential hypertension.

TECHNICAL APPROACH

Twenty-four adult patients selected from the hypertension clinic, Cardiology Service will be used in the study. Twelve patients will be randomly assigned to control group, continuing with the hypertension clinic routine already established in Cardiology Service. The second group of patients will be provided with standard EMG relaxation procedures using frontalis muscle as part of the standard biofeedback treatment approach. Throughout the 6-week treatment period both groups would be requested to provide 24-hour urine samples for analysis of various metabolites demonstrated to be related to stress reactions.

PROGRESS

Several of the biochemical assays anticipated for use were not available with the initiation of the project; therefore, the project was tabled until these capabilities had been developed.

STATUS: Terminated, to be resubmitted when procedures have been developed further.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Control of Gonadotropin Secretion in the Male Rat.

WORK UNIT NO.: 79-7

PRINCIPAL INVESTIGATOR: James C. McPherson, III

ASSOCIATE INVESTIGATORS: None

OBJECTIVES

To determine the combined effect of estrogenic and androgenicmic or androgenic and androgenic steroids on gonadotropin secretion in the immature male rat.

TECHNICAL APPROACH

Castration with steroid replacement in the sensitive immature male rat with appropriate controls.

PERSONNEL: Diana Blanco

FUNDING: $520.00

PROGRESS

Animal studies 60% completed with basic statistics comparing body weight and secondary sexual organ weights on a body weight basis. One more animal experiment is necessary for completion plus radioimmunoassays for FSH and TLH.

STATUS: Ongoing

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Mechanisms of Pulmonary Artery Perforation by Flow Directed Catheters

WORK UNIT NO.: 79-16

PRINCIPAL INVESTIGATORS: MAJ J. Bruce Arensman, DVM, VC
COL George S.M. Cowan, MD, MC

OBJECTIVES

To investigate mechanism of pulmonary artery perforation by Flow Directed Catheters.

TECHNICAL APPROACH

Under general anesthesia and after a left thoracotomy, a flow directed catheter of the Swan-Ganz type is introduced (via the jugular vein) into the left pulmonary arterial vasculature and passed to the wedge position. Forceful attempts to perforate the arterial wall are made, and the results evaluated using radiopaque dye and radiography. Pulmonary hypertension is then induced by inflating a baloon in the left atryium. After a period of hypertension of at least 30 minutes forceful attempts to perforate the pulmonary artery are repeated to include radiopaque dye and radiographs. During all experimental phases left arterial, pulmonary arterial and central venous pressures are measured.

PERSONNEL: 2 technicians, part time

PROGRESS

Data from five canines has been collected. This data supports our hypotheses that: pulmonary hyptertension is a major contributing factor to pulmonary artery rupture by flow directed catheters. Additionally, we have demonstrated, via a physical model, that upon balloon inflation the tip of these catheters are driven off center and into the vessel wall, thus increasing the likelihood of penitration.

STATUS: Complete (PR) (P)

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Gastrointestinal Hormones in Non-ionic Surface Active Agent Induced Delay of Gastric Emptying

WORK UNIT NO.: 79-19

PRINCIPAL INVESTIGATOR: James C. McPherson, III

ASSOCIATE INVESTIGATORS: George Cowan, Jr.
J.C. McPherson, Jr.

OBJECTIVES

To determine the effect of IV administration of non-ionic surface active agents on circulating levels of cholecystokinia and secretion.

TECHNICAL APPROACH

IV administration of agents following fasting followed by tube feeding and sacrifice at time intervals to determine cholecystokinia and secretion levels.

PERSONNEL: George Cowan, Jr.
J.C. McPherson, Jr.

FUNDING: $735.00

PROGRESS

Animals procured to produce CCK and secretion antibodies for development of RIA's. RAI for CCK and secretion begun.

STATUS: Ongoing

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Examination of Multimicrobial Abscesses in Animal Models I: Development of Abscess Implantation Methodology.

WORK UNIT NO.: 79-20

PRINCIPAL INVESTIGATOR: Richard W. Harris, CPT, MSC

ASSOCIATE INVESTIGATORS: John B. Arensman, DVM, MAJ, VC
William L. Moore, MD, COL, MC

OBJECTIVES

To determine the most effective methods for examination of bacterial abscesses in an animal model involving continuous sampling.

TECHNICAL APPROACH

Double encapsulated gelatin capsules were implanted both retroperitoneally and subcutaneously with either sterile fecal material or sterile fecal material with Bacteroides fragilis (CDC strain 5462). Sampling was performed by aspiration of the palpable abscess with an 18 gauge syringe. Excision of the abscess was performed at two weeks.

PROGRESS

Both sterile and bacterial implants produced abscesses of similar size and composition. The sterile implants were not contaminated based on repeated bacterial isolation attempts. The subcutaneous implant model was found to produce easily palpable abscesses that were easily sampled. The retroperitoneal implants were not easily located and invaded deep into the peritoneal cavity. The subcutaneous implant model will be used for continuous sampling of bacterial abscesses.

STATUS: Ongoing.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: The Experimental Fat Embolism Syndrome: an Electron Microscopic Study of Lung in Three Models.

WORK UNIT NO.: 79-21

PRINCIPAL INVESTIGATOR: Jack A. Horner

ASSOCIATE INVESTIGATORS: James C. McPherson, III
James C. McPherson, Jr.
G.S.M. Cowan, Jr.

OBJECTIVES

Experimental fat embolism syndrome is usually induced by one of five techniques: (I) fracture of the femur of an animal, (II) injection of extracted or homogenized adipose tissue from a same species donor, (III) injections of olive oil or purified triolein, (IV) injection of oleic acid, or (V) injection of mineral oil (all injections given intravenously). In this study the similarity and differences, if any, in these last three techniques (olive oil, oleic acid, and mineral oil) will be investigated.

TECHNICAL APPROACH

Fat embolism is a major (although frequently undiagnosed unless severe) complication in patients with fractures of the long bones and/or severe trauma (1). The etiological mechanism of this syndrome is still unsettled. The two mechanisms most widely accepted are (I) fat from the bone marrow of fractured bones or traumatized adipose tissue enter into small broken veins and travel to the lung where blockage of the capillaries and arterioles occur and (II) after trauma, the circulating lipoproteins in blood coalesce to form globules of fat large enough to block the capillaries of the lung (2). In addition, once the fat has blocked a capillary or arteriole, the pathogenic events which follow are unclear. The major effect may be a simple blockage but some investigators believe the most harmful effects result from the release of free fatty acids from the "trapped" fat globules in the lung (2). This study will attempt to establish the differences which could be important in the clinical syndrome by examining a mineral oil model (pure blockage with no possible release of free fatty acid from the globules), oleic acid (effect of free fatty acid only), and olive oil (fat capable of hydrolysis to yield free fatty acids). This study may add to our basic understanding of the events in the pathogenesis of the clinical fat embolism syndrome and suggest the basis of new methods of treatment.

PROGRESS

Due to delays in obtaining certain needed supplies and the inability of the animal support facility to accomodate additional rats the start up of this project was delayed until the end of FY79.

STATUS: Ongoing.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Examination of Multimicrobial Abscesses in Animal Models II: Morphological and Bacteriological Comparison.

WORK UNIT NO.: 79-23

PRINCIPAL INVESTIGATOR: Richard W. Harris, CPT, MSC

ASSOCIATE INVESTIGATOR: Jack A. Horner, DAC

OBJECTIVES

To examine morphological, bacteriological, and physiological parameters of an animal abscess model involving continuous *in vivo* sampling.

TECHNICAL APPROACH

Double encapsulated gelatin capsules were implanted subcutaneously with either sterile fecal material or sterile fecal material with *Bacteroides fragilis* (CDC strain 5462). Sampling was performed by aspiration of the palpable abscess with an 18 gauge syringe. Excision of the abscess was performed at two weeks to examine parameters from subcutaneous abscesses. Purulent aspirates were examined for bacterial colony counts, WBC differentials and total counts. Abscesses were excised at the termination of the experiment for examination.

PROGRESS

Colony counts were consistent between rabbits with identical implants. All abscesses were of similar composition and size. An extensive sampling experiment is being designed from this initial data to peripheral blood studies, bacterial colony counts, abscessWBC examination and histopathology of the abscess.

STATUS: Ongoing.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Hematologic and Biochemical Effects of Xylazine on Dogs.

WORK UNIT NO.: 79-31

PRINCIPAL INVESTIGATOR: MAJ J. Bruce Arensman, DVM, VC

ASSOCIATE INVESTIGATORS: James C. McPherson, PhD
COL George S.M. Cowan, Jr., MD, MC

OBJECTIVES

To evaluate the effects of the Tranqulizer Xylazine on Hematologic, Biochemical, and Insulin levels in dogs and compare to known response ruminants.

TECHNICAL APPROACH

Follwing the administration of Xylazine (1 mg/kg) IV blood samples will be drawn and analyzed for CBC, SMAC, and insulin levels. These values will be compared to baseline values.

PROGRESS

Preliminary work has been accomplished and actual implementation of this protocol is imminant.

STATUS: Ongoing

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Effect of Length of Administration and Dose of Testosterone on Serum Gonadotropins and Secondary Sexual Organs in the Male Rat.

WORK UNIT NO.: 79-32

PRINCIPAL INVESTIGATOR: James C. McPherson, III

OBJECTIVES

To determine the effect of dose and length of administration of testosterone on serum gonadotropins in the immature male rat.

TECHNICAL APPROACH

Castration followed by testosterone replacement for 5 or 7 days at dose levels based on a 70 gm and a 100 gm body weight.

PERSONNEL: Diana Blanco

FUNDING: $440.00

PROGRESS

Animal studies completed basic statistics on body weight and secondary sexual organ weights in preparation. Radioimmunoassay to be performed for FSH and LH to complete project.

STATUS: Ongoing

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Chemoimmunotherapy of Carcinoma of the Large Bowel.

WORK UNIT NO: 77-4 (Satellite Protocol of WRAMC 7406)

PRINCIPAL INVESTIGATORS: Daniel J. Arnold, MD, MAJ, MC
Irwin B. Dabe, MD, MAJ, MC

OBJECTIVES

To investigate the therapeutic efficacy of BCG by dermal scarification in patients with carcinoma of the colon or rectum when combined with 5-FU and combination 5-FU and MeCCNU.

TECHNICAL APPROACH

Patients eligible for this protocol can be put into four broad groups based on the extent of disease:

Type II Patients (Stage B_1) - Extension into but not through muscularis
(Stage B_2) - Extension to or through serosa; negative nodes
III Patients (Stage C_1) - Limited to serosa; positive nodes
(Stage C_2) - Extension through serosa; positive nodes
IV Patients - Locally metastatic disease beyond lymphatics, the bulk of which can be removed, but with some tumor remaining.
- Cannot tolerate surgery.
- Tumor of such size or fixed so that surgery would not be undertaken.
V Patients (Stage D) - Distant metastases

Surgery Protocol - Surgical resection of colon and rectal cancer is undertaken when there are no medical or surgical contraindications and the patient consents to surgery.

Radiotherapy Protocol - "Curative intent" for type IV2 patients
"Palliative intent" for type V patients

Chemotherapy Protocol -
Type II and III - Starting about 3 weeks after surgery, but no later than 6 weeks, or when in the judgement of the physician the patient can tolerate chemotherapy, these patients will receive 5-FU 10 mg/kg p.o. day 1 through 5 each 28 days. If the first two courses are well tolerated without toxicity, this dose will be increased to 15 mg/kg. Chemotherapy will continue at least 2 years.

77-4 (Continued)

Type IV2 - After 2 weeks (10 doses) of radiation, these patients will be treated as V patients.

Type IV1 - About 3 weeks after surgery, these patients will be treated as V patients.

Type IV3 - If after radiotherapy the patient is operable and the tumor is completely resectable, the patient will begin chemotherapy as a type II patient. If the tumor is not completely resectable, they will be treated as type V patients. If after radiotherapy the patient is felt to be inoperable he will be treated as a type V patient.

Type V - Will be treated with combined 5-FU and MeCCNU instead of 5-day 5-FU infusion:
5-FU 325 mg/m^2 daily I.V. days 1-5 and 36-40 (1 cycle)
MeCCNU 150 mg/m^2 p.o. day 1

Each cycle is repeated every 10 weeks (day 71).

Immunotherapy Protocol -

Type II and III - Patients randomized to receive BCG will have it administered on days 8, 15, 22 of the chemotherapy cycle for three courses then every 2 weeks (days 8 and 22) thereafter for at least 2 years.

Type IV and V - Patients randomized to receive BCG will have it administered on day 22, 27, 57, etc.

The BCG will be a lyophilized preparation (Phillip Roxane high viability Pasteur BCG). It will be administered as directed on the BCG procedure sheet. For severe local reactions, the next dose of BCG will not be given.

PROGRESS

No patients entered into this study.

Status: Terminated

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Minoxidil as an Antihypertensive in Patients Refractory to Available Medications.

WORK UNIT NO: 77-8 (Satellite Protocol of FAMC)

PRINCIPAL INVESTIGATOR: James H. Wilkin, MD, LTC, MD

OBJECTIVES

To test the hypothesis that minoxidil is an effective alternative treatment for hyptertension refractory to available medications. To assess any side effects or untoward reactions.

TECHNICAL APPROACH

Qualified patients are, after full laboratory evaluation, given medications in a standardized system evaluating response, laboratory, abnormalities and side effects.

PROGRESS

One female patient was entered into study in May 1977 with severe hypertension. She has been treated since that time with Minoxidil, Inderal, and Lasix as per the Minoxidil Protocol. She has had no adverse reaction (except for the expected hair growth), and has had well controlled hypertension. She is anticipated to continue on the above treatment. No other patients were entered into this study. Minoxidil has been marketed.

STATUS: Terminated.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Velban, Bleomycin and CIS-Platinum in the Treatment of Head and Neck Malignancies.

WORK UNIT NO: 77-11 (Satellite Protocol of WRAMC 7701)

PRINCIPAL INVESTIGATORS: Daniel J. Arnold, MD, MAJ, MC
Irwin B. Dabe, MD, MAJ, MC

OBJECTIVES

To evaluate the efficacy of the combination of velban, bleomycin and cis-platinum in squamous cell carcinoma of the oral cavity recurring after radiation/surgery or provious chemotherapy. To evaluate the efficacy of this regimen as pre-operative or pre-radiation treatment in preventing recurrence.

TECHNICAL APPROACH

Pre-Operative/Pre-Radiation Induction

Velban 4.0 mg/m^2 IV day 1
Bleomycin 15 mg IM qd days 1-7
Cis-platinum 60 mg/m^2 IV day 8, plus mannitol and fluids
This regimen can be repeated every three weeks, if tolerated, as long as there is continued tumor regression, up to a maximum of three courses. Following surgery/radiation/rocovery from myelosuppression the patient will be continued on the induction regimen until the total dose of bleomycin reaches 250 mg/m^2 (approximately four induction courses).

PROGRESS

No patients entered into study.

Status: Terminated.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Comparative Study of Adriamycin versus Daunorubicin for Induction and 4-Week versus 8-Week Cycle of Maintenance Chemotherapy in Acute Myelocytic Leukemia.

WORK UNIT NO.: 77-13 (Satellite Protocol of WRAMC 7721)

PRINCIPAL INVESTIGATORS: Daniel J. Arnold, MD, MAJ, MC
Irwin B. Dabe, MD, MAJ, MC

OBJECTIVES

a. To test whether Daunorubicin at a reduced dose of 30 mg/M^2 produces complete remissions with the same frequency as Daunorubicin at the standard dose of 45 mg/M^2, and whether the same duration of remission and the same survival are produced by both doses.

b. To test whether another anthracycline, Adriamycin, at a dose of 30 mg/M^2 produces complete remissions with the same frequency as Daunorubicin at the standard dose of 45 mg/M^2, and whether the same duration of remission and the same survival are produced by both doses.

TECHNICAL APPROACH

a. To test whether the duration of remission is equivalent in patients receiving maintenance chemotherapy at 8 week intervals when compared will also be made with respect to survival -rom onset of the protocol and from the onset of maintenance.

b. To test whether prolonged exposure to anthracyclines (Daunorubicin and Adriamycin) in maintenance, as achieved by the use of reduced doses (30 mg/M^2), increases the duration of remission as compared to the standard dose of Daunorubicin (45 mg/M^2) given to the same cumulative total dose.

PROGRESS

No patients entered into this study.

Status: Terminated

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Evaluation of Adriamycin and CIS-Platinum Combination Chemotherapy in Treatment of Malignant Disease. A Phase II Study.

WORK UNIT NO.: 77-14 (Satellite Protocol of WRAMC 7501)

PRINCIPAL INVESTIGATORS: Daniel J. Arnold, MD, MAJ, MC
Irwin B. Dabe, MD, MAJ, MC

OBJECTIVES

a. To evaluate the antitumor activity of the combination of adriamycin and Cis-platinum in previously untreated malignancies that have a low order or response to conventional modes of therapy such as head and neck carcinoma, squamous and adenocarcinoma of the lung, metastatic transitional cell carcinoma of the bladder and renal cell carcinoma.

b. To evaluate the antitumor activity of this combination in malignancies that have become regractory to conventional modes of therapy such ALL, AML, Hodgkin's disease and non-Hodgkin's lymphoma, oat cell carcinoma of the lung, adenocarcinoma of the prostate, soft tissue sarcoma, and multiple myeloma.

TECHNICAL APPROACH

Adriamycin 60 mg/m^2 IV day 1 every 21 days
Cis-platinum 60 mg/m^2 IV day 1 every 21 days

PROGRESS

No patients entered into this study.

Status: Terminated

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Phase I-II Study of High Dose Methotrexate (MTX) with Citrovorum Factor Rescue for Children and Adults with Metastatic Osteosarcoma and Advanced Giliomas of the Brain

WORK UNIT NO.. 77-15 (Satellite Protocol of WRAMC 7606)

PRINCIPAL INVESTIGATORS: Daniel J. Arnold, MD, MAJ, MC
Irwin B. Dabe, MD, MAJ, MC

OBJECTIVES

To evaluate the efficacy and kinetics of high dose methotrexate in the treatment of malignant neoplasms in adults and children.

TECHNICAL APPROACH

Vincristine 2 mg/m^2; maximum dose 2 mg, to be followed by Methotrexate infusion in doses varying from 100-500 mg/kg IV over 6 hours and followed by Citrovorum rescue 15 mg/m^2 IV every 6 hours for 12 doses beginning 2 hours after completion of the methotrexate infusion.

PROGRESS

No patients entered into this study.

Status: Terminated

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Comparative Trial of Tamoxifen and Fluoxymesterone plus Tamoxifen in Metastatic Breast Cancer. (NCI B132)

WORK UNIT NO.: 77-16 (Satellite Protocol of WRAMC 7408)

PRINCIPAL INVESTIGATORS: Daniel J. Arnold, MD, MAJ, MC
Irwin B. Dabe, MD, MAJ, MC

OBJECTIVES

Response rates and durations will be compared to assess the relative therapeutic benefit of the two regimens. The quality of survival will be assessed in the two regimens. Prognostic importance of a variety of pretherapy stratification factors will be evaluated.

TECHNICAL APPROACH

Regimen A - Tamoxifen 2.0 mg/m^2 p.o. t.i.d.

Regimen B - Fluoxymesterone 7.0 mg/m^2 p.o. b.i.d.
Tamoxifen 2.0 mg/m^2 p.o. t.i.d.

The dose of tamoxifen will gradually be increased.

PROGRESS

No patients entered into this study.

Status: Terminated

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: (B-134) Phase I-II Evaluation of Dibromodulcitol in Previously Treated Patients w/Metastatic Carcinoma of the Breast.

WORK UNIT NO.: 77-17 (Satellite Protocol of WRAMC 7307)

PRINCIPAL INVESTIGATORS: Daniel J. Arnold, MD, MAJ, MC
Irwin B. Dabe, MD, MAJ, MC

OBJECTIVES

All patients with histologically proven cancer of the breast who are less than 70 years old, who have evidence of progressive disease and who have had prior exposure to chemotherapy are eligible for this protocol.

Dibromodulcitol is an active agent according to a cooperative study group. Further evaluation of this drug is indicated in patients who have been treated with and are resistant to standard modes of therapy.

TECHNICAL APPROACH

There is one treatment schedule:
Dibromodulcitol---mg/m^2 by mouth on days 1-10 of each 21 day cycle. Each patient will receive at least one full cycle and a second cycle if there is no progressive disease. If there is improvement the drug will be continued until there is progression of disease.

PROGRESS

No patients entered into this study.

Status: Terminated.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: 1979 Fire Ant Study Protocol, Part I.

WORK UNIT NO: 78-38

PRINCIPAL INVESTIGATOR: Chester T. Stafford, M.D., COL, MC

ASSOCIATE INVESTIGATORS: Robert B. Rhoades, M.D.
Betty B. Wray, M.D.

OBJECTIVES

To compare the skin test reactivity to fire ant venom and its components with whole body extracts (WBE) of fire ants in patients allergic to stings of the imported fire ant.

TECHNICAL APPROACH

Four colonies of S. invicta (Buren) were identified, marked and preserved by the Pest Control Branch, DFAE (Directorate Facilities Army Engineers) on the Fort Gordon U.S. Army Reservation. Ant specimens from each of the colonies were positively identified as S. invicta by Professor William Buren, University of Florida, Gainesville. Fresh ant specimens were dug from these mounds approximately three times weekly. Abdominal segments of S. invicta workers were separated at the petiole (waist) from the head and thorax segements, which were left intact and processed separately. Venom was then milked from the abdominal segment under direct vision, using a dissecting microscope according to the method of Murray Blum. The venom was collected in one microliter capillary tubes, which were then stored at -8°C until ready for use. Ten to twenty ant specimens were required to fill each capillary tube. Approximately 60 microliters of venom were collected by this method. The glass tubes were ground under 50% glycerin in a mortar and pestle and subsequently rinsed with 50% glycerin. The glass was removed by centrifugation. This mixture was then "frozen" until ready for use. Extracts were prepared from this mixture by the method of Rapp and Arbesman and frozen until ready for use. The venom aqueous phase and alkaloid phase were prepared by the method described by Rhoades, et al. Twenty one-microliter capillary tubes were inserted into a standard non-heparinized hematocrit tube, the end heat-sealed, then centrifuged in a micro-hematocrit centrifuge. A line of demarcation between the aqueous and alkaloid phase was visualized using the dissecting microscope and the tubes were broken at that point with the aid of a glass file. The aqueous phase was then prepared by grinding the combined aqueous phase portions under normal saline in a mortar and pestle with rinses by normal saline. The glass was removed by centrifugation.

78-38 Continued

In preparation of the alkaloid phase, a similar technique was used but the material was ground under 50% glycerin. Amount of lypholized venom after reconstitution: Whole fire ant venom in glycerin 1-ml; Aqueous (with saline) 3 vials each with 0.7-ml; Alkaloid (with glycerin) 2 vials each with 0.7-ml; Fire ant Invicta (Greer) 2 vials 2-ml each; Front end stock dilution 1-ml. Sterilization of venom and other fire ant extracts is being performed by millipore filtration. Human volunteer subjects who have experienced systemic allergic reactions to the sting of the imported fire ant within the past two years will be skin tested under conditions of informed consent. Skin test are being prepared with eight serial 1:10 dilutions from the stock extract of each component. The vials are labeled 1 through 8, with 8 being the most dilute solution. Subjects will be skin tested on the upper extremities with each of the antigens being administered simultaneously with progression to the next most concentrated vial every 15 minutes until subject either demonstrates no reaction through vial 2 or demonstrates a 3+ or greater skin test response (3+ reaction equals 5 mm wheal, which is equal to or greater than positive control with 0.001 mcg/ml of histamine base). In vitro analysis of enzyme activity of fire ant venom and other fire ant extract components is currently being studied with the API ZYM Enzyme Substrate System (Analytab Products, Division of Ayerst Laboratories, Inc.)

PERSONNEL: Fire ant specimens were collected by Allergy Clinic Laboratory Technician, DDEAMC. Venom was collected by individual hired and trained by one of the associate investigators, Dr. Rhoades. Preparation of fire and extracts, lypholization, sterilization, preparation of skin test materials and initial enzyme analysis was accomplished with the technical assistance of personnel assigned to the Division of Allergy and Clinical Immunology, Medical College of Georgia.

FUNDING: Consumable supplies - API ZYM Enzyme Substrate System, $95.00.

PROGRESS

As outlined above, fire ant venom and its components have been prepared and are currently being sterilized by millipore filtration. Initial skin tests of human volunteer subjects will soon be accomplished under conditions of informed consent.

STATUS: Ongoing.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Application of the Vascular Waterfall Hypothesis to the Cerebral Circulation.

WORK UNIT NO.: 78-8

PRINCIPAL INVESTIGATOR: Ronald F. Bellamy, MD, COL, MC

OBJECTIVE

Recent work suggests that vascular beds may behave as if they contain a segment having the hydraulic characteristics of a collapsible tube. This approach to vascular physiology is generally known as the vascular waterfall hypothesis, and has been applied with considerable success in the coronary circulation. The objective of this protocol will be to apply the vascular waterfall hypothesis to the cerebral circulation with special reference to the effects of various concentrations of CO_2 and jugular venous hypertension on carotid pressure-flow relations.

TECHNICAL APPROACH

The experimental subjects will be 30-50 lb mongrel dogs. Dogs will be anesthesized with IV sodium pentobarbital (30mg/kg) and ventilated by a respirator through an endotracheal tube. Ventilation will be with various mixtures of O_2, N_2, and CO_2. Through an incision in the neck, the right carotid artery, both vagus nerves and both internal jugular veins will be isolated. The external carotid artery will be ligated and an electromagnetic flow probe placed around the common carotid artery. Carotid flow will be measured in conjunction with a Biotronex sine wave flow meter. Cerebral perfusion pressure will be measured with a pressure transducer connected to a small caliber polyvinyl tube inserted by the Barger technique proximal to the flow probe. A bipolar electrode will be inserted into one or both vagus nerves and connected to a Grass S9 stimulator. In a previous study it was found that the following stimulation parameters frequently arrested the heart for 2-5 seconds; voltage -20 -40 Hertz. In certain preparations jugular venous pressure will be measured by inserting a catheter upstream to the site where the vein will be occluded. The occluder will be either a snare or a stout silk suture. Both veins will be occluded simulatenously. In certain preparations, a left anterior thoracotomy will be performed and the aortic arch exposed. Cranial hypertension will be induced by occlusion of the arch distal to the left subclavian artery. Cranial hypotension will be induced by either partial occlusion of the ascending aorta or occlusion of the left common carotid in conjunction with partial occlusion of the right carotid proximal to the instrumentation. Snares and arterial clamps will be used to occlude the vessels. Phasic flow and pressure will be recorded at a paper speed of 50-100 mm/sec using an Electronics for Medicine

78-8 Continued

physiologic recorder. Arterial blood gas samples will be withdrawn from the carotid catheter. CPFR will be constructed from phasic tracings by measuring pressure and flow at 0.1 second intervals during diastoles prolonged by vagal stimulation. The data will be fitted by linear regression. The slopes and intercepts of the control and intervention CPFR will be compared using a "t" test statistic. The test will be performed at the α=0.05 level (two tail).

PROGRESS

None. Lack of time has prevented the investigator from performing the experimentation.

STATUS. Terminated

78-14 (Continued)

at specified times following surgery. Analysis of these data should provide valuable information on the frequency and relative time of occurrence of postoperative complications. Analysis may also reveal baseline characteristics (preoperative and operative) related to the occurrence of complications. For this reason, it is important that when reporting results on Core subjects (both implant and control), only complications or adverse effects present at the time of the evaluations be reported on the Postoperative Report form.

PROGRESS

MAJ Silverman is in the process of coordinating technical, administrative and supply requirements commensurate with the use of Intra Ocular Lenses and their implantation.

STATUS. Ongoing

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Intraocular Lens Clinical Study.

WORK UNIT NO.: 78-14

PRINCIPAL INVESTIGATOR: Freeman I. Howard, M.D., COL, MC

ASSOCIATE INVESTIGATOR: Harris N. Silverman, M.D., MAJ, MC

OBJECTIVES

Intraocular lenses are now subject to the regulations of the Medical Device Amendments of 1976. These regulations require that a clinical investigation be conducted to determine the safety and efficacy of each type of intraocular lens for each lens manufacturer. The results of this investigation will be submitted to the Food and Drug Administration (FDA) for approval for the continued marketing of the device. Pending this approval, ALL implant patients are required to be followed and reported on periodically as part of the clinical investigation. All ophthalmic surgeons who intend to implant lenses must be designated as an investigator in the clinical studies sponsored by one or more of the lens manufacturers. In order to perform meaningful, constructive research and also provide our patients with the finest, most comprehensive care, this study is proposed.

TECHNICAL APPROACH

All investigators will implant intraocular lenses in those patients who meet the strict selection criteria outlined in the protocol operative technique. They will follow the same schedule of patient evaluations for all implant subjects and will be required to submit the minimum data required by the FDA to monitor the safety of intraocular lens implants. In a Core Investigation, investigators will provide additional detail of postoperative evaluations in order to provide the scientific data necessary to determine appropriate label claims and warnings and to support the manufacturer's application for pre-market approval. Additionally, Core Investigation will include non-implant control subjects to provide an appropriate c ontext to assess the relative safety and efficacy of intraocular lens implants.

Core investigators will submit Postoperative Reports on each of the six postoperative evaluations required by the FDA as well as the preoperative/ Operative Report for both implant and control subjects. The purpose of the Postoperative Reports is to provide an assessment of clinical status

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Cyclobenzaprine, Chlorzoxazone with Acetominophen, Diazepam, and Biofeedback in lower Back Pain.

WORK UNIT NO.: 78-18

PRINCIPAL INVESTIGATOR: Jack K. Tippens, MD, LTC, MC

ASSOCIATE INVESTIGATORS: Kenneth E. Nelson, MD, COL, MC
Alonzo N. Diodene, MD, LTC, MC
Andree J. Lloyd, PhD, MAJ, MSC
Charles J. Hannan, PhD, CPT, MSC

OBJECTIVES

To evaluate the effectiveness of cyclobenzaprine, chlorzoxazone with acetominophen, diazepam, placebo, and biofeedback in the treatment of lower back pain.

TECHNICAL APPROACH

All drugs and treatment procedure are recommended as adjunctive treatment for lower back pain. Measures will include electromyographic assessment of general and specific muscle tensions and a questionnaire to evaluate the patients' subjective response and the physicians' evaluation of the therapies. Patients will be selected by the Orthopedic Service and randomly assigned to the study group. Drugs will be administered by a double-blind procedure.

PROGRESS

The study was never undertaken due to a drastic reduction in the number of orthopedic surgeons and a limited amount of time to conduct such an investigation. Since the establishment of the protocol, several other studies have been done at other medical centers which have documented the effectiveness of Flexoril as a muscle relaxant and it is now on the hospital formulary. No further action is planned in reference to this protocol.

STATUS: Terminated

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: The Effect of Coronary Sinus Occlusion on Coronary Pressure Flow Relations.

WORK UNIT NO.: 79-10

PRINCIPAL INVESTIGATOR: Ronald F. Bellamy, COL, MC, USA

OBJECTIVES

To investigate the effect of occlusion of the coronary sinus or coronary pressure-flow relations with special reference to the effect of chronic coronary venous hypertension and to the effect of pre-existing osmotic diuresis.

TECHNICAL APPROACH

Conventional vascular physiology is predicated on the assumption that the back pressure opposing flow in a vascular bed is venous pressure. The vascular waterfall concept radically reinterprets circulatory phenomena. The vascular bed is conceived of as containing a segment, presumably located in the microcirculation, having the hydraulic characteristics of a collapsible tube. The back pressure opposing flow in the pressure at the site of collapse, and is determined by vasomotor tone and tissue pressure. If the waterfall concept should ultimately be shown to be correct, much of vascular physiology and especially the interpretation of resistance data will need to be reconsidered.

PROGRESS

Fifteen experiments were performed, of which five may be considered successful. Of particular importance were two experiments which demonstrated that coronary sinus occlusion during profound osmotic diuresis did not affect coronary artery flow. Results from a third experiment were incorporated into a paper presented at the October 1978 meeting of the American Physiological Society.

STATUS: Terminated

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Hematologic Phenomena During Basic Combat Training.

WORK UNIT NO.: 76-5

PRINCIPAL INVESTIGATOR: John W. Bell, MAJ, MSC

ASSOCIATE INVESTIGATORS: George S.M. Cowan, MD, LTC, MC
Glen M. Fitzpatrick, 1LT, MSC

OBJECTIVES

To examine in depth the low hematocrit phenomenon that occurs in the Basic Combat Trainee (BCT) at different points in the BCT cycle and with view to correlating hematological, chemical, urine, diet, historical, physical and other data to explain the cuase of the low bl-od hematocrits in the BCTs.

TECHNICAL APPROACH

a. Each of 84 randomly selected BCT soldiers had 28 ml of venous blood collected into vacutainer tubes at four different times over a 12-week period. The different sampling times corresponded with the 1st, 4th, 8th and 12th weeks of BCT. The blood samples were analyzed by the technican SMAC chemistry analyzer, the Hemalog 8 and Hemolog D blood analyzers. Urinalysis total serium iron binding capacity and reticulocyte counts were also performed at each sampling interval. A questionnaire was filled out by each BCT soldier at the time of collection of the first blood sample. PT scores were obtain on all test subjects at the end of their training.

b. Statistical analysis will include a distribution analysis by histograms of each of the measured parameters, namely hemoglobin, hematocrit, red blood cell count, white blood cell count, platelet count, each of the different white cell counts, each of the SMAC parameters, serium iron, iron binding capacity and reticulocyte counts. Linear regression for mulae of the above will also be determined against PT scores and other data sets. Paired t-tests using recruits' initial versus subsequent values of each chemistry/hematological study will be derived and checked for significance at the PLO.OS level. Chi-square analysis will be performed with the questionnaire answers searching for any relationship between any abnormalities found and the trainee's history.

PROGRESS

As a result of our recent studies of more than 16,000 potential blood donors, we concluded that US Army BCTs have significantly lower PCVs than non-BCTs of similar ages and geographical locations. Questioning if these low PCVs

76-5 Continued

developed before or during training, 82 BCTs were randomly chosen from platoons and sampled in the 1st, 4th, 8th and 12th training weeks. Automated CBCs (Hemalog 8) and differential counts (Hemalog D), history and diet questionnaire, weights, reticulocyte counts, urinalyses and chemical profiles (SMAC) were obtained from each subject at each sampling period. Some hematological results:

STUDY	WEEK 1	S.E*	WEEK 4	S.E*	WEEK 8	S.E*	WEEK 12	S.E*
PCV	42.56	0.29	41.66	0.27	40.17	0.26	43.08	0.42
TIBC	328.6	3.9	325.9	5.1	339.3	4.6	350.7	9.3
% SAT Fe	27.9	1.2	25.5	1.1	27.5	1.3	29.7	2.7
Serum Fe	93.5	3.6	83.7	4.2	91.2	4.1	99.3	7.3
MCV	92.12	0.40	90.19	0.49	87.23	0.56	87.02	0.95
Retics	1.21	0.05	1.13	0.05	1.25	0.05	1.03	0.10

*Standard Error of the Mean

These alterations are possibly phenomena associated with "athletic anemia"; a failing MCV has not been previously described in this context. The last four weeks of training are less stressful, with considerably reduced exercises. We conclude that reductions in PCVs occur as a result of training. The exact mechanisms for these alterations remain to be explained.

STATUS: Terminated

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Comparison of API-20E and Micro-Media Enteric Identification Systems.

WORK UNIT NO.: 78-30

PRINCIPAL INVESTIGATOR: Charles L. Lamke, LTC, MSC

ASSOCIATE INVESTIGATORS: David A. Wall, GS-9
Hugh M. Gelston, Jr., CPT, MSC

OBJECTIVES

To determine the following: The reliability of each system for the identification of each system for the identification of Enterobacteriaceae; the cost effectiveness of each system; ease of test performance with each system, the accuracy of each biochemical test of both systems; and the ease of identification of organisms using the "coder" supplied with each system.

TECHNICAL APPROACH

1. Each system will be evaluated using the following parameters:

   a. Correct identification of the Enterobacteriaceae.

   b. Quality control of materials.

   c. Accuracy of each biochemical test.

   d. Ease of test performance.

   e. Cost/test.

   f. Technician time required for complete organism identification.

   g. Total time required for complete organism identification.

2. All clinical isolates with suspected Enterobacteriaceae will be inoculated, as per protocol, into both systems.

3. Complete identification will be accomplished according to the following scheme:

   a. API-20E: All organisms will be identified by using the analytical profile index developed by analtab products.

78-30 Continued

b. MICRO-ID: All organisms will be identified by using Carr-Scarborough's analytical profile.

4. All discrepancies involving organism identification will be resolved by using the conventional methodology as recommended by the CDC.

5. If, after 150 of the Micro-ID panels have been used, a representative sample of all genera has not been isolated, lyophilized stock cultures of clinical isolates will be used to achieve representative sampling of all genera.

PERSONNEL: Charles L. Lamke, LTC, MSC
David A. Wall, GS-9
Hugh M. Gelston, Jr., CPT, MSC

FUNDING: None needed. All equipment and supplies provided by Carr-Scarborough Microbiologicals.

PROGRESS

All of the laboratory work has been completed and the data collected. The project is in the final stages of data compilation.

STATUS: Ongoing.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Patient Request for Psychiatric Care.

WORK UNIT NO.: 78-17

PRINCIPAL INVESTIGATOR: Willie M. Patterson, MD, MAJ, MC

OBJECTIVES

The determination of underlying reasons for seeking psychiatric care will provide information directly applicable to the structure, operation and provision of various psychiatric services at this facility.

TECHNICAL APPROACH

The patient population will consist of 150 patients each from Community Mental Health Activity and Psychiatry Clinic, DDEAMC. Each new patient will be requested to complete a checklist of reasons for requesting psychiatric care. This data will be analyzed along with pertinent demographic data. Results from each facility will then be compared to each other as well as published results from the civilian community.

PROGRESS

Data collected and analyzed. In process of writing manuscript. Expect to complete and submit for publication by April 80.

STATUS: Completed

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Incidence of PCP-related psychosis.

WORK UNIT NO.: 79-17

PRINCIPAL INVESTIGATOR: Willie M. Patterson, MAJ, MC,

OBJECTIVES

To determine the incidence of PCP-related psychosis in the military population admitted at DDEAMC.

TECHNICAL APPROACH

The effects of PCP are quite variable and cases have described a schizophrenic-like picture, post-psychotic depression, and a typical manic syndrome (6,7,8). It is possible that patients are admitted to psychiatric facilities and labeled schizophrenic when, in reality, they have a PCP-related psychosis. It is proposed that by a toxicological screening, proper identification could be facilitated for appropriate diagnosis, treatment, and disposition. It is also proposed to see if there is a significant incidence of PCP-related psychosis in our population.

Urine screening has been shown to be a useful tool in detecting PCP. Urine toxicology for PCP would be tested on all active duty admitted from post and on A.D. airevac's from regional hospitals with less than 7 days' hospitalization. Along with the urine test a serum sample will be run on all post admissions. The patient population will consist of all active duty who display unusual, bizarre, or psychotic behavior from the post or regional hospitals.

No attempt will be made to differentiate between PCP schizophreniform psychosis, first break schizophrenia, or PCP exacerbation of chronic undifferentiated schizophrenia at this time. Primary goal is to determine if a significant incidence of PCP related psychosis can be elucidated.

It is hoped that a complete drug history and a thorough evaluation of clinical manifestations may help differentiate some of the above diagnosis and be used for future research.

PROGRESS

In data collection phase which ends in May.

STATUS: Ongoing.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Effectiveness of Calcium Hydroxide as a Root Canal Cleanser.

WORK UNIT NO.: 79-1

PRINCIPAL INVESTIGATOR: Michael J. Langan, DMD, CPT, DC

OBJECTIVES

To evaluate the effectiveness of calcium hydroxide as a cleansing and debridement agent within root canals.

TECHNICAL APPROACH

Using an *in vivo* approach with dogs, routine endodontic procedures will be accomplished to at least a size of 40 file with continued irrigation using water. Upon completion of this, the teeth will be randomly divided into 2 groups. Group 1, the control group, will be treated with water irrigation alone. Group 2 will be filled to their apices with a paste of reagent grade calcium hydroxide and water. In each group, a cotton pellet will be inserted into the canals and temporarily sealed. A period of one week will elapse before the teeth will be extracted. The canals will then be cleansed with water and minimal instrumentation, cross-sectioned by a Buehler Isomet diamond saw and studied under the scanning electron microscope. After this non-destructive study, the teeth will be prepared for microscopic investigation as described by Senia and colleagues. The canals will be investigated for presence of pulpal tissue and debris as well as the elemental concentration of calcium and phosphorus related to the areas.

PROGRESS

Using three dogs of varying ages, routine endodontic therapy was performed on six mandibular and four maxillary premolars per animal. After cleaning and shaping of the root canals, the teeth were randomly divided into two groups. The control group received no further treatment. The root canals of the experimental group were filled with reagent grade calcium hydroxide and water. All teeth were sealed with cavit and one week was allowed to elapse before the animals were sacrificed. The teeth were disected free and prepared for examination. The root canal of both groups were viewed under scanning electron microscopy and light microscopy. It was found that the root canal system was well cleansed in the coronal two thirds of both groups. However, the apical one-third was not devoid of debris

79-1 (Continued)

in either group. It appeared that calcium hydroxide did not improve the cleaning ability of the root canal systems. Calcium hydroxide was not detrimental to the PDL or supporting structures. We were unfortunately unable to determine if calcium hydroxide affected residual tissue tags or tissue at the accessory canal-major canal interface.

Status: Completed

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Scanning Electron Microscopic Evaluation of Debridement and Subsequent Healing Following sodium Hypochlorite Solution - Citric Acid Curettage Therapy of Animal Periodontal Tissues

WORK UNIT NO.: 79-2

PRINCIPAL INVESTIGATOR: Jodie Buehler, CPT, DC

ASSOCIATE INVESTIGATOR: Kenneth L. Heitman, COL, DC

OBJECTIVES

Sodium Hypochlorite solution - citric acid currettage has been advocated by many practitioners and investigators as an effective means of total debridement of ulcerated, inflamed, edematous soft tissue pockets. Although it is used by many practitioners, more study of its effectiveness and post treatment healing needs to be examined.

TECHNICAL APPROACH

Adult mixed breed and sex mongrel dogs weighing 10-20 kilograms each, will be anesthetized with sodium pentobarbitol 25 mg per kilogram, and an oral-esophageal airway to maintain a patent airway. Different buccal gingival sulcus areas around designated teeth will be treated at different intervals to eliminate coincidental findings, chemical curettage will be performed on the buccal gingival tissue associated with one quardrant of teeth while the sometime mechanical curettage (control) will be performed on the buccal gingival sulcus tissues associated with the mirror image teeth. Six dogs, three female and three male, will be used. Half the dogs will have gingival sulcus tissues from the maxilla treated while treated while the other half will be treated with mechanical curettage to provide specimens of 0,3,7 and 14 days at the time the dogs are terminated. The specimens will then be removed in a block section, individualized and placed in coded bottles containing cocadylate buffered 3.5% glutaraldehyde for a minimum of 24 hrs. The tissue will then be dissected away from the underlying bone using a No. 15 Rand Parker scapel tharting spical to the deepest portion of the gingival sulcus and continuing coronally through the epithelial attachment area. Specimens will then be left in fixative again for a minimum of 48 hrs, after which they will be rinsed in a cocadylate buffered sucrose solution and put through an etband and critical point dehydration sequence. The specimens will then be mounted on coded aluminum tubs with silver paint and coated with 200A oz gold using a Technics Model V ion sputtering apparatus. Examination of the tissue specimens will be performed in an ISI Model Super II Mini-SEM Scanning Electron Microscope operated at 25 kEv.

79-2 Continued

Photographic recordings will be accomplished using a Polaroid type 55 P/N film, comparison of specimens of same time periods will be made and noted.

PROGRESS

All technical procedures are completed. All approval signatures obtained on thesis. Thesis turned into CID and Hospital Medical Library. Paper for publication presently being worked up.

STATUS: Complete

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Bullet Size Determination by Use of X-rays.

WORK UNIT NO.: 79-12

PRINCIPAL INVESTIGATOR: George E. Peters, GS9

ASSOCIATE INVESTIGATOR: LTC George Cowan, MD

OBJECTIVES

To determine if the theory of x-rays and angulation as proposed will yield the same or comparable results when done under actual conditions to determine bullet caliber size in a patient.

TECHNICAL APPROACH

To determine the precise depth location and exact dimensions of a foreign object or lesion in a patient. Brensic application, if this technique is validated, could be most valuable to definitively establish bullet calibre in assault victims in whom the bullet has not or cannot be removed. Under general endotracheol anesthesia, different calibre bullets will be acutely implanted in (8 mixed mongrel) dogs and x-rays will be made to determine if the determination of caliber size can be made under actual conditions using calibrated standard bullets, raiographic scale and angulations. This will involve that not all bullets sizes can be determined since shapes and sizes are often destroyed by the force of impact. Determination will be made by implanting bullets to determine their depth. Animals will be terminated at the end of each experiment. Data will be analyzed by comparing the results of the implanted bullets as measured, using the calibrated techniques, by a radiologist (double-blind) with the actual known bullet calibre.

PROGRESS

This project has not been started since no dogs have been made available for the project. Project not yet started.

STATUS: Ongoing.

DEPARTMENT OF THE ARMY
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905
CLINICAL INVESTIGATION SERVICE

INVESTIGATION PROJECT RESUME

TITLE: Detection of Tricyclic Antidepressants in Dried Blood Stains Using Radioimmunoassay

WORK UNIT NO.: 79-24

PRINCIPAL INVESTIGATOR: Mr. Clement G. Smetana

ASSOCIATE INVESTIGATORS: CPT Charles J. Hannan, Jr., PhD
MAJ William F. Shivers, MC

OBJECTIVES

This study will employ the sensitivity and selectivity of radioimmunoassay in the examination of dried blood-stains for the presence of drugs. It will improve techniques to the range of picograms in the quantitation of drugs in physiological fluids which have been dried as is often the case in criminal investigations.

TECHNICAL APPROACH

Initially, whole blood will be spiked with the antidepressant at various concentrations and bloodstains will then be made. Employing a standard curve, one can determine the durability of the drug in the stain over a period of weeks or months under various storage conditions. In addition, one can then compare stains made by blood with drug concentrations added to mimic those normally found in patient samples noting the quantity of stain required, variation in quantity of the drug present and detectability limitations. Examinations will also include determining optimum conditions for extraction of the drug from the stain.

PROGRESS

This particular study was able to successfully distinguish stains containing 5 nanograms of desipramine, from stains, not containing the drug. Although the elution time was 24 hours the actual procedure could be completed in less than six hours, and a number of stains could be run at once. Finally, methods and techniques applied in bloodstains could easily be adapted to other physiological fluids such as saliva, which will be done by this investigator in another project, very shortly.

Status: Completed

Presentation: Presented informally to DDEAMC Clinical Investigation Service on June 12, 1979.