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ANNUAL PROGRESS REPORT FISCAL YEAR 1978.(U)
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WILLIAM BEAUMONT ARMY MEDICAL CENTER

CLINICAL INVESTIGATIONS SERVICE

ANNUAL PROGRESS REPORT
FISCAL YEAR 1978

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

REPORT NO. 13

30 September 1978

CLINICAL INVESTIGATIONS (U)

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El Paso, TX

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19. KEY WORDS (Continue on reverse side if necessary and identify by block number)

Carcinoma
Catecholamines
Cardiology
Choline Phosphotransferase
Dentistry
Electron Microscopy
Gastroenterology
Gynecology
Infectious Disease

(over)

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

This report serves to detail the progress, status, and funding of approved projects conducted under protocol by staff members, interns, and residents at William Beaumont Army Medical Center. The varying projects as reported are classified according to the service or department to which the principal investigator belongs. Research conducted at WBAMC is categorized as either basic experimental medicine or trials and testing of clinical medicine procedures using the indigenous population for which this medical facility provides support.

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Item 19 cont'd
Insulin
Modulation Transfer Function
Myocardial Scanning
Nuclear Medicine
Obstetrics
Oncology
Oral Surgery
Orthopaedics
Otolaryngology
Pediatrics
Radioimmunoassay
Respiratory Disease
Surgery
Triiodothyronine

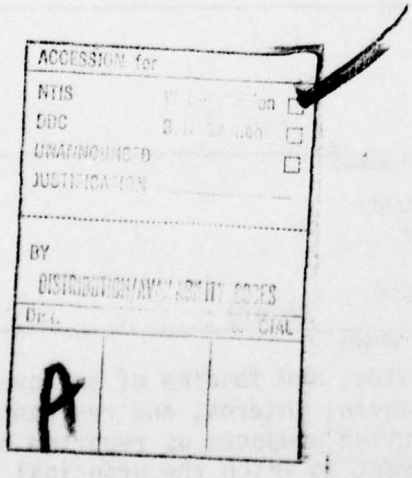


TABLE OF CONTENTS

FOREWORD

The Clinical Investigations Service, formerly Medical Research and Development, is entering its 14th year of operation. The Service continues to apply the best research principles and techniques available in an effort to obtain the most reliable results.

Budgetary and personnel turmoil and uncertainty marked much of FY78. Also resurfacing in several forms was the perennial challenge to justify our existence. In respect to the latter, it seems appropriate to reiterate the policy and objectives as outlined in Department of Defense Directive Number 6000.4 dated 7 April 1971:

"Clinical investigations is an essential component of optimum medical care and consists of the organized inquiry into clinical health problems, for the following purposes:

1. To achieve continuous improvement in the quality of patient care.

2. To provide experience in the mental discipline achieved by participation in such organized inquiries, and to provide experience for personnel who will ultimately be teaching chiefs in military hospitals and medical specialty consultants.

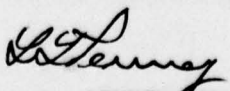
3. To maintain an atmosphere of inquiry because of the dynamic nature of the health sciences.

4. To maintain high professional standing and accreditation of advanced health education programs."

In spite of limitations of funds and trained personnel compared to previous years, the Service has fulfilled its mission in a productive manner. The investigators who actively pursued their projects, frequently utilizing their own hours from off-duty time and occasionally providing their own funds, are to be especially commended. All investigators for each work unit are identified in the respective reporting sections.

The contributions of the many nurses, technicians, corpsmen and administrative personnel who are vital to the successful implementation of clinical research projects are acknowledged.

I am grateful for the editorial and typographical assistance of Ms Peggy Casteel in the completion of this document and to the remaining staff of the Service for their varied areas of contribution.



L. L. PENNEY, M.D.
LTC, MC
C, Clinical Investigations Service

PAGE

Department of Pediatrics

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UNIT SUMMARY

OBJECTIVES

The Clinical Investigations Service of William Beaumont Army Medical Center was established 2 February 1965 as the Medical Research and Development Service. The mission is to promote and coordinate clinical research and directed basic research. The Service supports in-house research projects by AMEDD staff members, residents, and interns, assisting in the formulation, preparation, and promulgation of research protocols and final research publications. The service furnishes experimental design and statistical and technical expertise, develops and carries out special laboratory procedures, and provides general support in terms of equipment, supplies, and animal resources when necessary. The creative and inspirational environment and technical knowledge available serve to stimulate the undertaking of basic and clinical medical and paramedical research at William Beaumont Army Medical Center by staff members, and interns and residents in training, as well as provide a basic instructional facility to elucidate the principles and conduct of research.

In addition to the primary mission, as stated above, the Service is active in supporting several training and teaching programs involved with direct patient care. As examples, CPT Benedetto and now LT Klenke conduct a year-long health physics course supplemented with statistical review for the Nuclear Medicine Fellowship. LTC Penney provided a weekly statistics seminar for the perinatology Fellowship. The Biological Research Facility directly supported anesthesia and surgical assistance training procedures ranging from minor suturing techniques for the Clinical Specialist Course students through aortic bypass grafts for the surgical residents. These 114 procedures are enumerated below:

Non-Research Training Support Procedures, Biological Research Facility, WBAMC

Clinical Specialist Course suture training sessions	37
Surgical Residents major surgical procedures	23
Ob-Pediatric Residents and nurse training	42
Ob Resident surgical training, major procedures	5
Dentistry, major surgical procedures	3
Civilian medical student training	1
Surgery, thoracic surgical major procedures	1
Surgical staff major procedures	2

TECHNICAL APPROACH

The Clinical Investigations Service provides support for staff research projects under the guidelines of the Declaration of Helsinki, Clinical Investitation Program (AR 40-38), and the Use of Investigational Drugs in Humans and the Use of Schedule I controlled Drug Substances (AR 40-7). Research is conducted under protocols approved by the Research Committee (WBAMC HR 70-4), the Human Use Committee (WBAMC HR 40-38) and the Radioisotope Committee (WBAMC HR 40-37) where applicable. In those research protocols utilizing laboratory animals, the investigators follow guidelines set forth in "Guide for Laboratory Animal Facilities and Care," published by the Committee on the Guide for Laboratory Animal Facilities and Care of the Institute of Laboratory Animal Resources, National Academy of Sciences-National Research Council, and the criteria established by the American Association for Accreditation of Laboratory Animal Care.

MANPOWER

Title	SSI/MOS	Auth	Assigned	Name
Chief	60J	O-5	O-5	Penney, Larry L., MC
Nuc Med Sci/ Admin Off	68B	O-3	O-1	Klenke, WJ, MS
Biochemist/ Asst Chief	68E	O-3	O-4	Sellers, M.E MS(PhD)
Vet Lab Animal Off	64C	O-3	O-3	Gee, T.E., VC
Med Lab Sp	01H20	E-5		
Vet Anim Sp	91T20	E-4	E-5	Joyner, J.M.
Vet Anim Sp	91T20	E-3	E-4	Lee, Daniel F
Vet Anim Sp	91T10	E-3	E-4	Graf, James P
Hlth Tech/ Anm Res Asst	00699	GS-7	GS-7	Revels, J.E.
Anm Caretaker	07706	WG-3	WG-1	Burton, A.D.
Chemist	01311	GS-11	GS-11	Rauls, D.
Microbiologist	00403	GS-11	GS-11	Frederick, R.
Chemist	01320	GS-9	GS-9	Sandison, S.W.
Chemist	01320	GS-9		
Med Lab Tech	00645	GS-7	GS-7	Manna, B.S.
Med Lab Tech	00645	GS-7	GS-7	Teasley, C.E.
Editorial Asst	01087	GS-7	GS-7	Casteel, P.J.

EXPENDITURES

	FY76	FY77&7T	FY78
Personnel (Civilian)	89,914	148,153	118,995
Consumable Supplies	20,471	56,831	35,923
MEDCASE Equipment	49,739	48,324	33,169
Capital Equipment		-	-
TDY		3,485	2,805
Contracts, Services, Printing and reproduction		4,327	3,053
TOTAL	160,123	261,120	193,945

PROGRESS

The Clinical Investigations Service entered FY78 with 46 ongoing protocols. Thirty protocols were submitted for a total of 76 sponsored studies. Three protocols were completed and nine were terminated. Sixty-four protocols are ongoing to FY79.

The FDA inspected the Service for a week in July 1978 specifically reviewing in an exhaustive fashion protocol 77/04. The investigation encompassed all aspects of IND studies as they are conducted by DOD in general and in particular WBAMC.

TDY for minimal continuing education and mission-essential training was granted, but the Service provided no TDY for investigators to present findings at professional meetings. The moratorium on minor equipment purchases continued. Our consumable supply budget was reduced 31% from FY77. Coupled with an estimate of 7% inflation, we approximated our purchasing power loss at 36%. Preliminary funding prognostications for FY79 indicate little or no change from FY78.

As stated in the last report, and as anticipated, manpower was a significant problem in FY78. Of 108 authorized civilian man-months only 91 were filled, due primarily to budget constraints. This situation was compounded by the fact that all the positions involved were the most skilled - i.e. the GS-11 Microbiologist slot was unfilled all year, the GS-11 Chemist slot was unfilled three months, and the GS-11 Technologists slot was reclassified by CPO to a GS-9 Chemist and was unfilled three months. These slots are all being filled with a full staff expected for the first time in 15 months by 1 Nov 79. The Services only military laboratory technician and the sole RIA technician resigned in September 78, causing a delay in all protocols involving radioimmunoassay. Another 01H20 is expected in November. With his arrival, authorized strength will finally be realized and the Service enters the new year with a renewed spirit and sense of vigor. We feel we have assembled a talented and compatible group and sincerely hope the necessity of stabilization to achieve maximal productivity will be recognized.

During this fiscal year WBAMC authors had 28 articles or presentations published or accepted and submitted another 28.

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Normal Values of Serum Triiodothyronine (T3) as Determined by Radioimmunoassay in Various Clinical Euthyroid States

WORK UNIT NO: 75/07

PRINCIPAL INVESTIGATOR: LTC L.L. Penney, MD; Douglas Daniels, DAC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Determine normal values of T3 for: (a) Pregnancy during all three trimesters. (b) Females taking oral contraceptives. (c) Euthyroid Hashimoto's Disease. (d) Other thyroiditides.

TECHNICAL APPROACH

Serum samples will be obtained from patients during 1st, 2nd, and 3d trimester of pregnancy; females on oral contraceptives for at least three months; euthyroid patients with Hashimoto's thyroiditis before treatment with thyroid hormone and after treatment with Synthroid; patients with thyroiditis (subacute). Clinical histories will be obtained and the clinical thyroid state will be determined. The serum samples obtained will be evaluated by radioimmunoassay. Determination of the inclusion into the proposed categories will be from clinical diagnosis, clinically determined thyroid state and appropriate laboratory studies.

CONSUMBALE SUPPLIES

None

PROGRESS

Papers have been published in Clinical Nuclear Medicine reporting studies of T3 values in pregnancy and in patients with chronic renal failure on dialysis. Studies in other euthyroid states are ongoing. New principal investigators have assumed this study which was temporarily suspended due to funding constraints.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Isolation and Purification of Choline Phosphotransferase

WORK UNIT NO: 75/30

PRINCIPAL INVESTIGATOR: LTC L.L. Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To develop a method for the isolation of choline phosphotransferase from lung tissue and correlate respiratory distress with the presence and specific activity of this enzyme.

TECHNICAL APPROACH

Microsomal and lysosomal fractions of lung tissue will be subjected to standardized enzyme purification techniques. Cofactor effects will be studied in order to access possible prophylaxis development in cases of respiratory distress.

CONSUMABLE SUPPLIES

None

PROGRESS

This protocol has been temporarily suspended but will be resumed when the budget allows.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Study of Immune Response to Experimental Infection with *Brucella melitensis*

WORK UNIT NO: 76/21

PRINCIPAL INVESTIGATOR: Steve Raymond, DAC

ASSOCIATE INVESTIGATORS: MAJ E. Young MD, CPT N Sass PhD, K. Erke PhD

OBJECTIVES

The object of this study is to evaluate the possible correlation between development of delayed-type hypersensitivity (DTH) and development of cell-mediated immunity (CMI) to bacterial endotoxins as shown in migration inhibition factor (MIF) and lymphocyte transformation studies.

TECHNICAL APPROACH

This will be accomplished by experimental infection of guinea pigs with a specific endotoxin antigen derived from the cell walls of *Brucella melitensis* by fractionation methods. Upon subsequent infection, the experimental animals will be tested for production of MIF by standard methods as well as lymphocyte transformation studies using a RIA technique.

CONSUMABLE SUPPLIES

None

PROGRESS

The principal investigator resigned as did all the associate investigators. The data obtained has yet to be published.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: In Vivo Effect of Mitogenic Proteins on Granulopoiesis Following Bone Marrow Suppression

WORK UNIT NO: 77/17

PRINCIPAL INVESTIGATOR: Roman Kutsky, DAC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To ascertain physiological functions of nucleoprotein factor (NPF) as relates to its mitogenic activity and the acceleration of granulopoietic recovery in drug-induced agranulocytic mice.

TECHNICAL APPROACH

Mice will be made agranulocytic using either BCNU or vinblastine sulfate. Nucleoprotein factor will be administered on a daily regimen for six days. CBC's and blood smears will be taken serially for ten days following the end of treatment to ascertain the effects of nucleoprotein factor on the recovery of bone marrow cells.

CONSUMABLE SUPPLIES

$1,200

PROGRESS

No data was published prior to resignation of the principal investigator.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Variables in the Measurement and Calculation of MTF

WORK UNIT NO: 78/09

PRINCIPAL INVESTIGATOR: CPT A.R. Benedetto

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To assess exhaustively the impact of asymmetric line source response functions on determination of modulation transfer function.

TECHNICAL APPROACH

Asymmetric line source response functions whose kurtosis and skewness are known will be used to calculate modulation transfer fuction (MTF). The resulting MTF curves will be analyzed to determine what degree of asymmetry is acceptable for gamma camera quality control.

CONSUMABLE SUPPLIES

$100

PROGRESS

The computer program has been conceptualized and will be run in early FY79.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Theoretical and Applied Techniques in Gamma Camera Uniformity Quality Control

WORK UNIT NO: 78/21

PRINCIPAL INVESTIGATOR: Cpt A.R. Benedetto

ASSOCIATE INVESTIGATORS: LTC W.F. Kendall

OBJECTIVES

To develop the theoretical, mathematical basis for defining the separation distance between a gamma camera and a point source for which exposure variations across the face of the gamma camera are reduced to a statistically insignificant level.

TECHNICAL APPROACH

A computer program will be used to calculate the exposure rate at each location on a grid imposed on the face of standard and large crystal gamma cameras for varying separation distances between the point source and the camera. The effect of off-axis alignment of the source will also be evaluated. Experimental confirmation of the computer results will be obtained, using transmission densitometry to measure exposure variations.

CONSUMABLE SUPPLIES

$100

PROGRESS

Coordination for use of the necessary computer program has been accomplished. The required computer runs will be made early in FY79, followed closely by experimental verification.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Significance Study of meta and para metabolites of Catecholamine Compounds in the Rat

WORK UNIT NO: 78/28

PRINCIPAL INVESTIGATOR: MAJ M.E. Sellers, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To study the significance of meta and para substituted isomers of catecholamine metabolites such as m- and p-tyramine and m- and p-phenylacetic acids by noting changes in isomer quantitation after selective inhibition of the normal metabolic pathway.

TECHNICAL APPROACH

Weanling male Sprague-Dawley rats will be divided into test and control groups Test animals will be injected with various regimens of catecholamine enzyme inhibitors as well as exogenous L-DOPA. Catecholamines and their acid metabolites will be determined by GC, GCMS, TLC, etc. As many meta- and para-isomers will be identified, separated, and quantitated as is possible from brain, liver, and urine extracts. The data will be compiled to ascertain whether metabolic inhibition of normal pathways changes the ratios of meta- and para- metabolites and to try to investigate the significance of these changes if they occur.

CONSUMABLE SUPPLIES

None

PROGRESS

This is a new project awaiting funding.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Quantitative and Qualitative Phenolic Acid Changes in Rats Treated with Catecholamine Pathway Inhibitors

WORK UNIT NO: 78/29

PRINCIPAL INVESTIGATOR: MAJ M.E. Sellers, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Acid metabolites of L-DOPA, i.e., homovanillic acid (HVA), dihydroxyphenylacetic acid (DOPAC), Vanilmandelic acid (VMA), p-hydroxyphenylacetic acid, m-hydroxyphenylacetic acid, and p-hydroxymandelic acid will be qualitatively measured in urine of rats pretreated with monoamine oxidase inhibitors, and B hydroxylase inhibitors, then treated with radioactive (^{14}C) L-DOPA. The purpose of this study is to determine the effect of catecholamine pathway inhibitors on end metabolism acids.

TECHNICAL APPROACH

Weanling rats will be divided into test and control groups. Test animals will be subjected to various regimens of catecholamine pathway inhibitors such as B hydroxylase, monoamineoxidase, and decarboxylase inhibitors. Endogenous catecholamine metabolite acids will be measured in urine and compared to control animals. Exogenously administered radioactively (^{14}C) labeled L-DOPA will be given to both test and control animals and again acid metabolites will be measured in rats urine and compared to control animals. Urinary catecholamine acids will be measured by current techniques including gas chromatography, thin layer chromatography, etc. Scintillation counts will be performed on each acid fraction. Determinations and conclusions will be made from comparing endogenous and exogenously labeled metabolites by paying careful attention to changes in specific activity and quantitation changes after exogenous L-DOPA injections. Catecholamines may also have to be determined in order to study feedback inhibition and metabolic pathway shunt studies.

CONSUMABLE SUPPLIES

None

PROGRESS

This is a new project awaiting funding.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Minor Amine Metabolites of L-DOPA

WORK UNIT NO: 78/30

PRINCIPAL INVESTIGATOR: MAJ M.E. Sellers, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Weanling male rats will be injected with altered L-DOPA. Metabolism will be studied in the rat model.

TECHNICAL APPROACH

Forty male weanling Sprague-Dawley rats will be divided into four groups. The ten animal control group will be fed normal rat TEKLAD diet. Thirty animal test groups will have methionine supplement either by intubation or mixed with the TEKLAD pellets. The animals will be kept on this diet for ten days. Test animals will be further broken down into three groups of ten animals. Animals will be sacrificed at intervals starting at 2 - 24 hours after L-DOPA injection. Urine will be collected during this time. Brain, liver, and urine will be extracted for N- and O-methylated amines. They will be quantitatively and qualitatively determined by GC, GCMS, TLD, LC, etc.

CONSUMABLE SUPPLIES

None

PROGRESS

This is a new project awaiting funding.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: An Analysis of Ameloblastic Fibro-odontoma

WORK UNIT NO: 77/20

PRINCIPAL INVESTIGATOR: COL George J Tsagaris, DC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The goals of this research study are to report upon and analyze cases of ameloblastic fibro-odontoma and to correlate these findings with those of earlier investigators in an attempt to clarify the misunderstanding concerning this particular odontogenic tumor.

TECHNICAL APPROACH

A retrospective analysis of 77 cases referred to the Oral Pathology Department of the Armed Forces Institute of Pathology with reference to the clinical features, radiographic appearance and histologic characteristics of this entity.

CONSUMABLE SUPPLIES

None

PROGRESS

No data was published prior to resignation of the principal investigator.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Analysis of the Histologic Soft and Bony Tissue Effect of Terra Contril Healing Dental Extraction

WORK UNIT NO: 78/17

PRINCIPAL INVESTIGATOR: MAJ B.J. Klinger, DC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To study the histologic soft and bony tissue response to Terra-Cortril (Tetracycline - 30mg. and Hydrocortisone - 10 mg./gm).

TECHNICAL APPROACH

Using a dog model for surgical removal of selected mandibular teeth and placement of Terra-Cortril in one side only. The opposite side is to act as the control. The animals are to be sacrificed at predetermined intervals, the mandibles resected and microscopic examination of the extraction sites.

CONSUMABLE SUPPLIES

$400

PROGRESS

All animals have been sacrificed and presently the specimens are in the decalcification phase.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: ^{99m}Tc-Sn-DTPA Chelate in the Detection of Vesicoureteral Reflux

WORK UNIT NO: 75/24

PRINCIPAL INVESTIGATOR: MAJ A Hughes, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the usefulness of ^{99m}Tc-Sn-DTPA chelate as a renal imaging agent, and particularly in the demonstration of vesicoureteral reflux.

TECHNICAL APPROACH

Patients with known or suspected vesicoureteral reflux will be studied with 99mTc-Sn-DTPA. The results obtained will be compared with clinical findings, laboratory tests, and roentgenographic studies. Commercially available radiopharmaceutical Sn DTPA preparation kits will be employed. The kits will be supplied by Diagnostic Isotopes, Inc., 123 Pleasant Ave, Upper Saddle River NJ. These kits are supplied in sterilized and pyrogen-free form. Other suppliers will be sought only if their product appears to be far superior and only from those manufacturers who have filed an IND with the Food & Drug Administration. Several mCi of radiopertechnetate are followed for radiopharmaceutical preparation.

CONSUMABLE SUPPLIES

None

PROGRESS

Patient referrals have been infrequent but the study is continuing with a new principal investigator.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Myocardial Perfusion Scanning with Radioactive Particles

WORK UNIT NO: 76/14

PRINCIPAL INVESTIGATOR: MAJ A Hughes, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To demonstrate myocardial perfusion at the capillary level as an aid in differentiating those patients who are likely to benefit from coronary artery surgery. The injection of radioactive particles in each coronary artery will demonstrate runoff perfusion. This will provide supplemental information to determine candidates for coronary artery surgical procedures.

TECHNICAL APPROACH

Tc^{99m} microspheres and I-131 macroaggregated albumin will be injected into the left and right coronary artery respectively at the time of cardiac catheterization. Imaging will be performed with a gamma camera and the images will be studied for areas of decreased perfusion.

CONSUMABLE SUPPLIES

None

PROGRESS

This study is still suspended pending completion of the new cardiac catheterization facilities and appropriate staffing.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Thallium-201 Chloride for Diagnosis of Myocardial Ischemia and/or Myocardial Infarction

WORK UNIT NO: 76/15

PRINCIPAL INVESTIGATOR: COL M.L. Nusynowitz, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate the clinical efficacy of Thallium-201 Chloride in delineating areas of infarcted myocardium with regard to presence, extent, and healing and to delineate areas of myocardial ischemia under resting and/or exercise conditions.

TECHNICAL APPROACH

Patients with suspected myocardial infarction or ischemia will be injected with Thallium 201-Chloride. This material, an analog of potassium is concentrated in well perfused normal myocardium and is not taken up by ischemic myocardia. Images will be obtained to evaluate presence, size, and changes in hypoperfused myocardium under resting or exercise conditions as an aid to the clinical management of these patients.

CONSUMABLE SUPPLIES

None

PROGRESS

More than 200 patients have been studied to date. Thallium 201-Chloride appers to be an excellent agent for diagnosing cardiac ischemia, especially when stress/resting imaging is used. No data have been published by WBAMC. The drug is now approved by the FDA and in view of the NDA status the study has been discontinued.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Effect of a Broad Spectrum Antibiotic on the Course of Viral URI

WORK UNIT NO: 76/23

PRINCIPAL INVESTIGATOR: LTC R.E. Morrison, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine in a controlled double-blind study the effect of an antibiotic on the clinical course of acute viral upper respiratory tract infections with particular attention to any beneficial or deleterious effects of the treatment with respect to secondary bacterial complications.

TECHNICAL APPROACH

Patients admitted to the Acute Respiratory Distress (ARD) Ward without obvious bacterial infections were to be divided into two random groups. One group to receive tetracycline HCL, the other a placebo. The physician taking care of the patients, and the patients themselves, would not know whether they were receiving drug or placebo. The code would be held by the Pharmacy Service. The incidence of complications, in particular, secondary bacterial infections; the total length of fever; the general well-being; length of hospital stay; incidence of adverse drug reaction; and the total cost of treatment would be compared between the two groups.

CONSUMABLE SUPPLIES

None

PROGRESS

Staffing shortages have also caused suspension of this study. Another attempt to institute it with the next URI season is anticipated.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Diagnostic Adrenal Scanning with ^{131}I (NP59)

WORK UNIT NO: 76/33

PRINCIPAL INVESTIGATOR: MAJ A Hughes, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The purpose of this study is to determine the usefulness of ^{131}I-NP59 in scanning of the adrenal glands. It will be employed for the following purposes: (a) As a screening test for detection of primary aldosterone tumor, Cushing's disease, adrenal cortical adenoma, or pheochromocytoma. (b) Imaging of adrenals in patients who require adrenal venography and are allergic to contrast media. (c) Detection of unilateral adrenocortical hypofunction: calcification, metastatic carcinoma, post-venography infarction, etc. (d) Detection of functioning adrenal remnant after adrenalectomy for Cushing's dyndrome (e) Aid in assessment of adrenocortical steroid therapy.

TECHNICAL APPROACH

Patients with clinical evidence of adrenal disease will be studied upon referral from the Endocrine Service. Adrenal imaging will be performed after injection of the material to assess the presence or absence of visualization of the adrenal glands, their size and response to suppression therapy.

CONSUMABLE SUPPLIES

None

PROGRESS

A total of eight patients have been studied to date. NP59 appears to be a satisfactory agent for adrenal imaging.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Liver Amylase: Fact or Fiction

WORK UNIT NO: 77/07

PRINCIPAL INVESTIGATOR: CPT L M Lehrner, MD

ASSOCIATE INVESTIGATORS: MAJ C M Lund, MD, LTC J S Gunther, MD

OBJECTIVES

The two objectives are: (1) to determine if human liver contains an α-amylase other than that contributed by "trapped" blood, (2) to determine if there is a detectable alteration in serum and/or urine total and amylase activity and/or amylase isozyme patterns in patients with liver disease.

TECHNICAL APPROACH

Routine laboratory examinations will be performed prior to each peritoneoscopy procedure. Depending on the clinical indications one or more liver biopsies will be obtained. A 5 mm core of liver tissue from each biopsy will be subjected to special assay, and accordingly the existence of liver amylase and alterations in serum and/or urine total amylase activity and/or amylase isozyme patterns in patients with histologically proven liver disease will be definitely proven or disproven.

CONSUMABLE SUPPLIES

None

PROGRESS

The principal investigator has been on extended TDY. Completion of the study awaits his return.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Efficacy of Sucralfate in the Treatment of Gastric Ulcer

WORK UNIT NO: 77/08

PRINCIPAL INVESTIGATOR: COL J.L. Pitcher, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate the efficacy of Sucralfate in the endoscopically measured healing of benign gastric ulcer.

TECHNICAL APPROACH

Patients with benign uncomplicated gastric ulcer will be treated with Sucralfate tablets for a maximum period of six weeks. Endoscopy will be performed at 0, 14, 28, and 56 days.

CONSUMABLE SUPPLIES

None

PROGRESS

None

STATUS: Investigator has retired and the project has been terminated.

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Radionuclide Angiocardiography Evaluation of Cardiopulmonary Function Using a Mobile Dual Cardiac Probe

WORK UNIT NO: 77/16

PRINCIPAL INVESTIGATOR: MAJ Robert Sonnemaker, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To assess the clinical usefulness of a mobile dual cardiac probe in the assessment and serial evaluation of cardiopulmonary funjtion in patients with acute, chronic or potential cardiopulmonary compromise.

TECHNICAL APPROACH

Patients undergoing cardiac evaluation for a wide variety of clinical problems were studied to determine left ventricular ejection fraction, pulmonary transit time, cardiac output, stroke volume, end-diastolic volume and pulmonary blood volume at bedside.

CONSUMABLE SUPPLIES AND CONTRACTUAL SERVICES

$4,000

PROGRESS

The mobile dual cardiac probe was used to evaluate cardiac function in approximately 150 patients, including normals, persons with documented coronary artery disease (CAD) persons undergoing drug therapy optimization, and one case of restrictive pericarditis. Handgrip stress was found to be much better predictor of CAD than either rest or bicycle stress, and probe data agreed very well with ventriculography in predicting ejection fraction and other parameters of inotropy. Because of the low radiation dose to the patient probe radiocardiography should soon find a complementary role in nuclear medicine for measurement of left ventricular reserve and for therapeutic drug intervention monitoring. Several publications and presentations have been submitted or accepted as shown in that section of this report.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Differentiation of Restrictive from Obstructive Lung Disease by Comparing Parameters of Forced Expiratory Flow

WORK UNIT NO: 77/22

PRINCIPAL INVESTIGATOR: COL R C Zurek MD: MAJ C R Beechler MD

ASSOCIATE INVESTIGATORS: MAJ W N Schmidt-Nowara MD

OBJECTIVES

To evaluate the necessity of performing static lung volumes in light of possible predictive value of the vital capacity and the forced expiratory volume at one second-vital capacity ratio.

TECHNICAL APPROACH

Data from patients who have received complete pulmonary function studies and on whom morphometric data have been gathered will be retrospectively analyzed to determine the predictive value of the vital capacity and the forced expiratory volume at one second-vital capacity ratio in the diagnosis of restrictive lung disease. Computerized data correlation will be performed at the University of New Mexico Medical School by Dr. Schmidt-Nowara

CONSUMABLE SUPPLIES

None

PROGRESS

All the investigators have retired or resigned. No reply to the annual request for detail sheet information was received.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Effect of Catecholamines and Antagonists on Insulin Dependent Glucose Uptake by the Bladder of Bufo Marinus

WORK UNIT NO: 77/27

PRINCIPAL INVESTIGATOR: MAJ Gerald Kidd, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate the mechanism of action of insulin on glucose transport across the toad bladder.

TECHNICAL APPROACH

The toad bladder epithelium appears to be an analog of the distal tubule collecting duct complex of the mammalian kidney. The effects of alpha and beta adrenergic blocking drugs on glucose transport in this system will be studied.

CONSUMABLE SUPPLIES

None

PROGRESS

The principal investigator on this study has changed. It will be resumed when funding is appropriate.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Quantitative Assessment of Gastric Emptying: A Comparison of the Saline Load, Barium-Burgermeal and Radionucleotide Methods

WORK UNIT NO: 78/01

PRINCIPAL INVESTIGATOR: MAJ J Floyd, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine which of the three methods above most accurately reflects the state of gastric emptying.

TECHNICAL APPROACH

The experimental subjects will be drawn from inpatients on the Gastroenterology Service. The first group will be composed of 20 consecutive patients who have endoscopic evidence of gastric outlet compromise due to peptic ulcer disease. The second group will act as control and be composed of patients with other disease processes who have been endoscoped and have normal gastric outlets. The second group will not include those disease states known to alter gastric motility (e.g. diabetes mellitus), nor will it include patients who have been on long term therapy with drugs that are known to alter gastric motility (e.g. anticholinergics).

CONSUMABLE SUPPLIES

This study was withdrawn by the principal investigator following several delays in approval by OTSG.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Effect of Temperature of the Test Meal on Gastric Emptying Time

WORK UNIT NO: 78/02

PRINCIPAL INVESTIGATOR: MAJ J Floyd MD, MAJ C.M. Lund, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate the effect of temperature of a test meal of 500cc saline on the gastric emptying time (GET) of that meal.

TECHNICAL APPROACH

The patient population for this study will be volunteers obtained through the Gastroenterology Clinic. Ten (10) normal subjects will be studied. Patients who are under 18, pregnant, or lactating will not be done. Studies on women of childbearing age will be done during the first ten (10) days following the onset of menses. Gastric emptying will be measured by the method of Chaudhuri utilizing Tc-99m DTPA [5]. GET will be measured three times in each subject; in each case the saline/Tc-99m DTPA will vary from "cold" (4°C) to "warm" (24°C), to "hot" (42°C). The test will be done on three consecutive mornings following an overnight fast. The order in which the temperature varies will be randomized.

CONSUMABLE SUPPLIES

None

PROGRESS

This study was only recently approved by OTSG and is preliminary.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Comparison of Cellular Metabolic Indices with Thyroid Dysfunction and Therapy

WORK UNIT NO: 78/06

PRINCIPAL INVESTIGATOR: CPT R E Rychly, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To clarify the relationship and clinical usefulness of systolic time intervals as an index of cardiac output and myocardial contractility, O_2 consumption at rest and at steady state exercise, 2,3-diphosphoglycerate (2,3-DPG), measurements in hyperthyroid, euthyroid and hypothyroid patients and to evaluate the possible use of these parameters in monitoring therapeutic interventions.

TECHNICAL APPROACH

Prior to initiation of therapy, hypothyroid and hyperthyroid patients will be screened for factors influencing 2,3-DPG levels . The patients will then undergo testing of hematocrit, hemoglobin, 2,3-DPG, PaO2, PaCO2, pH, bicarbonate, serum CO2, O2 consumption at rest and at exercise steady state, and systolic time intervals at rest. Hyperthyroid patients will be tested prior to therapy, after one week of propanolol therapy, and at time of achieving a clinical and thyroid function euthyroid state by means of I131 therapy and/or prophylthiouracil or methaimazole. Hypothyroid patients will be tested prior to therapy and at time of achieving a clinical and thyroid function euthyroid state by means of I131 therapy and/or prophylthiouracil or methaimazole. Hypothyroid patients will be tested prior to therapy and at time of achieving clinical and thyroid function euthyroid state by means of levothyroxine therapy. Euthyroid goiter/nodule patients will be tested prior to therapy and at a therapeutic steady state approximately 2 months after initiation of suppression therapy with leveothyroxine. Factor analysis will be applied to clinical indices, thyroid function tests, 2,3-DPG, systolic time intervals and resting and exercise steady state O2 consumption with correlations being made to thyroid dysfunction state and therapeutic measures utilized.

CONSUMABLE SUPPLIES

$200

PROGRESS

Sample collection is completed. Chemical analysis and data reduction is in progress.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Acid Aspiration Prophylaxis with Cimetidine, Glycopyrrolate, and Antacids

WORK UNIT NO: 78/08

PRINCIPAL INVESTIGATOR: MAJ R E Rychly, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

This study will determine the relative effectiveness of three different preoperative premedication protocols in reducing the risk of acid aspiration before, during and after routine surgical procedures.

TECHNICAL APPRAOCH

The effects of premedication prior to surgery on gastric juice volume and pH will be evaluated in 200 patients undergoing elective nongastric surgical procedures under general anesthesia requiring intubation. Patients taking medications that alter gastric secretion or who have had a history of gastric surgery will be excluded. All patients will be NPO from 2300 the day before surgery. The patients will be randomly assigned to four treatment groups. The data to be analyzed will consist of age, weight, sex, type of premedication, type of surgery, type of anesthesia, length of surgery, observed aspiration, and pH and calculated gastric secretion volume of intubation and extubation collections.

CONSUMABLE SUPPLIES-

$200

PROGRESS

This study was recently approved. Patients will soon be entered. The principal investigator has changed.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Minoxidil as an Anti-hypertensive in Patients Refractory to Available Medications

WORK UNIT NO: 78/13

PRINCIPAL INVESTIGATOR: CPT L.M. Lehrner, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The objective of this protocol is to test the hypothesis that minoxidil is an effective alternative treatment for patients whose blood pressure is refractory to available drugs or who have experienced unacceptable side effects from them and whose situation is life-threatening. Another purpose is to document clinical experience with minoxidil in a manner that will provide a basis for extrapolation of the results to the specified hypertensive population.

TECHNICAL APPROACH

Patients with severe hypertension, unresponsive to conventional medication and in a life threatening situation will be placed on a regimen of Minoxidil. The ultimate purpose is to control refractory blood pressure problems such as sustained severe, accelerating, or malignant hypertension. Very thorough recordkeeping will be maintained documenting unresponsiveness to conventional treatment and responsiveness to Minoxidil.

CONSUMABLE SUPPLIES

None

PROGRESS

This is a new study with only three patients entered to date.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Evaluation of a Simple Device for Measuring Pulmonary Transit Time and its Value as a Predictor of Congestive Heart Failure in Acute Myocarcial Infarction

WORK UNIT NO: 78/18

PRINCIPAL INVESTIGATOR: MAJ David Albers, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The purpose of this study is to assess the clinical utility of a simple device for measuring pulmonary transit time in patients with acute myocardial infarction.

TECHNICAL APPROACH

All patients admitted to the coronary care unit at William Beaumont Army Medical Center, with a diagnosis of possible acute myocardial infarction will be entered into the study. Two hundred patients with myocardial infarct will be studied. A radiation detector will be positioned over the heart as determined by clinical examination. The radiopharmaceutical will be injected intravenously through an arm vein or through a pre-existing catheter if already in place. The radiopharmaceutical will be "flushed" into the central circulation with 20cc normal saline. The cardiopulmonary transit during the first pass through the heart and lungs will be monitored and recorded by an instrument. The radiopharmaceutical agent for this project will be Tc-99m pertechnetate, a radiopharmaceutical approved for vascular flow studies. The dose will be 3-600 uCi, a dose far less than utilized for any other routine procedure with this agent. Anticipated number of persons to be studied is approximately 60 per month, of which approximately 15 will represent true myocardial infarction. Periodic evaluation of results will be made in six month intervals to evaluate utility of information in terms of patient care, physician knowledge, and medical training.

CONSUMABLE SUPPLIES

None

PROGRESS

This is a new study awaiting OTSG approval.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Evaluation of Exercise Ejection Phase Indices in the Diagnosis of Coronary Artery Disease

WORK UNIT NO: 78/19

PRINCIPAL INVESTIGATOR: MAJ D. Albers, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The purpose of this study is to evaluate the diagnostic accuracy, sensitivity, and specificity, of changes in systolic ejection rate with hand grip stress as measured by radionuclide techniques when applied to patients with coronary artery disease.

TECHNICAL APPROACH

Patients undergoing routine coronary angiography for established indications will be studied. Written consent will be obtained. Left ventricular ejection fractions and systolic ejection rates will be obtained at rest and during the termination of the period of isometric handgrip exercise. The patient will be injected with 20 mCi of Tc-Human Serum or an approved radiopharmaceutical for cardiac imaging. Ejection Fraction and systolic ejection rates will be measured at rest and during stress in a modified 45° LAO projection period. In addition a resting study will be obtained in a 30° RAO projection for completion of the study and maximum information yield to the attending physician. Data will be processed with a dedicated nuclear medicine computer planned for acquisition . Approximately twelve patients will be studied monthly.

CONSUMABLE SUPPLIES

None

PROGRESS

This is a new study awaiting approval from OTSG.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Comparison of Left and Right Ventricular Function Response to Stress in Patients with Coronary Artery Disease

WORK UNIT NO: 78/20

PRINCIPAL INVESTIGATOR: MAJ D.G. Albers, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The goal of this study is to establish the functional reserve of the right ventricle in patients with coronary artery disease and normals, and to investigate the association of right coronary artery disease and right ventricular dysfunction.

TECHNICAL APPROACH

Patients will be limited to those having recently undergone coronary artery catheterization for established indications. A minimum of five and a maximum of ten patients with no demonstrable coronary artery obstructions will be evaluated in order to establish normal controls. Thirty patients with varying degrees of coronary artery disease will be entered into this study. The patients will be injected with 20 mCi Tc-99m human serum albumin (an approved radiopharmaceutical for cardiac imaging). The patients will be imaged in a supine position with the gamma camera detector head positioned in a modified 45 degree LAO projection. Data acquisition will require approximately two minutes for reliable determination of biventricular ejection fraction by a dedicated nuclear medicine computer. Patients will be required to sustain a handgrip of 25% maximum voluntary contraction using a JAMAR hand dynamometer for a period of six minutes. During the final two minutes a second acquisition of data would be performed and processed for measurement of stress ejection fraction. Results at rest and stress right and left ventricular ejection fractions would be related to findings by contrast angiography. Radiopharmaceuticals will not be administered to pregnant or lactating females or persons under 18 years of age. Anticipated number of persons to be studied is approximately 15 per month.

CONSUMABLE SUPPLIES

None

PROGRESS

This is a new project awaiting approval from SGO.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Separation and Identification of CPK Isoenzymes by Radioimmunoassay Technique

WORK UNIT NO: 78/31

PRINCIPAL INVESTIGATOR: MAJ A.D. Hughes, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The purpose of this study is to develop a routine method for measuring CPK isoenzyme levels with emphasis on the MB fraction using RIA techniques.

TECHNICAL APPROACH

Individual isoenzymes of CPK obtained from commercial sources will be injected into rabbits to elicit specific antibody responses. The analysis for CPK would be performed by classical RIA techniques. CPK would be tagged and reacted in varying concentrations with the individual antibodies produced and harvested from the rabbits. Standard concentration curves and cross-reactivities would be established to determine RIA specificity. From the standard curves, unknown CPK concentrations in serum will be determined. It would then be possible to correlate values for the MB fraction in the normal and infarcted populations.

CONSUMABLE SUPPLIES

None

PROGRESS

This is a new study which has not yet commenced.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Umbilical Cord Lactate, Pyruvate, Betahydroxy Butyrate, pCO_2, pO_2, and pH Value in Normal and Abnormal Pregnancies

WORK UNIT NO: 74/01

PRINCIPAL INVESTIGATOR: COL A. Killam MD, LTC W Daniel MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To study the effect of labor on normal pregnancies and pregnancies complicated by placental insufficiency.

TECHNICAL APPROACH

Maternal amniotic fluid, venous, umbilical arterial and umbilical venous blood samples will be studied for the above levels. The results will be correlated with neonatal outcome and morbidity.

CONSUMABLE SUPPLIES

None

PROGRESS

Although this project has been suspended a prolonged time it is still considered worthwhile and will be conducted if conditions permit.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Maternal and Fetal Plasma Levels of Steroid Hormones in Normal and Pathological Pregnancies During Labor

WORK UNIT NO. 74/16

PRINCIPAL INVESTIGATOR: COL A Killam MD, LTC LL Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if a rapid assay of steroid hormones would be of clinical value if drawn at the onset of labor from maternal vein or fetal scalp.

TECHNICAL APPROACH

Women in labor with a high risk for fetal distress from placental insufficiency will be included as samples upon admission to Labor and Delivery. The radioimmunoassay for estriol is being modified by eliminating some steps and increasing the temperature during incubation.

CONSUMABLE SUPPLIES

$800

PROGRESS

This study has been continued to include comparisons of plasma cortisol levels with estriol levels. Less than 10 patients have been entered and only a portion of the specimens have been analyzed.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Comparison of Clinical and Laboratory Measurements of Gestational Age to the Actual Gestational Age as Determined by Last Ovulation

WORK UNIT NO: 76/20

PRINCIPAL INVESTIGATOR: COL David Boyce, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To test the reliability of clinical and laboratory methods of gestational age assessment by comparing the assessments to true gestational age as determined by basal body temperature curves defining last ovulation.

TECHNICAL APPROACH

Patients volunteering to record basal body temperatures prior to conception will be monitored throughout their pregnancy by serial sonography and serum estriols. The neonate will be evaluated for gestational age both in blinded and unblinded studies.

CONSUMABLE SUPPLIES

None

PROGRESS

The study is still in the very early stages. It is presently felt that at least three years will be needed to collect enough data to be significant.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE:Estriol Production Rate Studies in Pregnant Women

WORK UNIT NO:76/29

PRINCIPAL INVESTIGATOR:LTC LL Penney MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Determination of estriol production rates in normal pregnant women and correlation in abnormal gestations with the clinical outcome.

TECHNICAL APPROACH

Estriol production rates will be estimated by the infusion of deuterated estriol into these women followed by subsequent serum sampling. A measurement of the amount of deuteroestriol present in extracted estriol samples relative to the total amount of estriol extracted would indicate the rate of endogenous estriol synthesized by the patient.

CONSUMABLE SUPPLIES

None

PROGRESS

Samples from one patient have been submitted to the collaborating institute, the University of Colorado, for analysis. The University cannot assist us with any patients until they receive renewal of their funding. Although several months have elapsed the protocol will be kept open in anticipation of further cooperation.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Correlation of Amniotic Fluid Cortisol and the Free Estriol Surge in Maternal Plasma

WORK UNIT NO: 76/34

PRINCIPAL INVESTIGATOR: LTC LL Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To confirm the amniotic fluid cortisol levels at varying gestational ages. To correlate these levels with the maternal free estriol surge and the amniotic fluid L/S ratio and attempt to determine if the cortisol increase is also nonlinear and, if so, if it precedes or follows the free estriol surge.

TECHNICAL APPROACH

The amniotic fluid cortisol concentration and L/S ratios on each specimen submitted will be determined, as will plasma free estriol and cortisol when each amniocentesis is performed. The indications for amniocentesis will be based on currently accepted clinical criteria and the decision for the procedure will be made by attending and resident staff managing the patient. The analyses will be done by radioimmunoassay and TLC as presently performed in the RIA laboratories. The data will be subjected to regression analysis and appropriate rank correlation.

CONSUMABLE SUPPLIES

$800

PROGRESS

Sixty-two study specimens were analyzed and the data presented at the Armed Forces District Meeting of the American College of Obstetrics and Gynecology in October 1977. Further analysis of a total of 109 samples is in progress, but it appears no significant cortisol "surge" in amniotic fluid will be demonstrable.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Correlation of Choline Phosphotransferase Activity in Human Amniotic Fluid and Neonatal Nasopharyngeal Aspirates

WORK UNIT NO: 76/35

PRINCIPAL INVESTIGATOR: MAJ R Heath MD, COL A Killam MD

ASSOCIATE INVESTIGATORS: LTC L L Penney, MD

OBJECTIVES

To construct normograms of the activity of choline phosphotransferase in human amniotic fluid with respect to gestational age and activity of the enzyme in neonatal nasopharyngeal secretions at 6 hour intervals from birth. These levels will be related to the occurrence of idiopathic respiratory distress syndrome in the neonate. The ultimate objective is to determine whether this enzyme activity is a better predictor of idiopathic respiratory distress syndrome than the currently used lecithin/sphingomyelin ratio.

TECHNICAL APPROACH

Concurrent with otherwise medically indicated amniocentesis, 10 milliliters of amniotic fluid will be obtained and analyzed for choline phosphotransferase and phosphatidate phosphohydrolase activities. A normogram of enzyme levels with respect to gestational age will be constructed. These levels will then be correlated with the occurrence of idiopathic respiratory distress syndrome to see indeed if one or both are better predictors of the syndrome. Additionally, routine nasopharyngeal suction material will be collected at 6-hour intervals on neonates and analyzed for this enzyme activity. Levels of activity will be compared to the course of the disease in hopes of developing an objective technique for differentiating idiopathic respiratory distress syndrome from other causes of respiratory distress in the neonate.

CONSUMABLE SUPPLIES

Amniotic fluid levels in uncomplicated pregnancies have been reported at the Armed Forces District of the American College Obstetrics and Gynecology meeting. A paper has been published in Pediatric Research. Work is progressing on nasopharyngeal and tracheal aspirates as well as on animal models previously included in Protocol 74/23.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Ultrastructure Investigation of Prostaglandin and their Precursors in the Human Fetal Chorioamnionic Membrane

WORK UNIT NO: 77/02

PRINCIPAL INVESTIGATOR: MAJ W C Daniell

ASSOCIATE INVESTIGATORS: B.E.F. Reimann

OBJECTIVES

To determine the subcellular location of prostaglandins and precursors in fetal amniochorionic membranes.

TECHNICAL APPROACH

Ultrastructure of fetal membranes have been observed.

CONSUMABLE SUPPLIES

$400

PROGRESS

We have had difficulty obtaining a good water soluble embedding media so that lipids could be retained in tissue without use of osmium for fixation. At the present we are attempting to react antibodies and peroxidase in thin sections of membrane prior to embedding of tissue and thereby circumvent this problem. Awaiting arrival of chemicals for use in indirect antibody labeling.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Prevention of Post-Cesarean Section Infections

WORK UNIT NO: 77/03

PRINCIPAL INVESTIGATOR: COL A Killam MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To see if postoperative morbidity can be prevented with prophylactic antibiotic therapy.

TECHNICAL APPROACH

Placebo and two treatment regimens will be given in randomized double blinded fashion. Postoperative febrile morbidity will be compared within the two groups.

CONSUMABLE SUPPLIES

None

PROGRESS

Final approval was never obtained from the HSRRB. The original principal investigator underwent a PCS and the current investigator, awaiting approval, has reached retirement and elects not to continue.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Inhibition of Premature Labor with Terbutaline

WORK UNIT NO: 77/04

PRINCIPAL INVESTIGATOR: MAJ T. Howard, MD, COL A Killam MD

ASSOCIATE INVESTIGATORS: LTC LL Penney MD

OBJECTIVES

To study inhibitory effects of Terbutaline on premature labor.

TECHNICAL APPROACH

Patients with no contraindicating condition, such as ruptured BOW, intrauterine sepsis, or abruptio placenta will be treated for premature labor with either Terbutaline or a placebo. After admission to the Labor and Delivery Suite, the following procedures will be initiated:

a. Infusion of either a Terbutaline or placebo loading dose of 0.5 mg IV diluted with normal saline by the use of an infusion pump over a 50 to 60 minute interval. This loading dose may be repeated up to a maximum of 3 times per 24 hours as needed to abolish uterine activity.

b. Following the loading dose, the Terbutaline or the placebo will be given subcutaneously at a rate of 0.25 mg every 2-4 hours as needed for a 24-hour period.

c. Patients will then be maintained on oral Terbutaline, 2.5 mg every 2-4 hours, or oral placebo as previously discussed, until fetal maturity is proven or suspected or patient delivers. On-going assessment of fetal maturity will include serial ultrasound exams and may include amniocentesis for L/S ratio determination to assess fetal pulmonary maturity. Labor will be inhibited until the patient delivers or reaches a point where she is felt to represent a gestational age of 36 weeks or an estimated fetal weight of 5 pounds or demonstrates an L/S ratio of 2:1 or greater. These dosage regimens were determined from manufacturer's recommended dosage schedules and from previous studies using betamimetic agents for inhibition of labor.

CONSUMABLE SUPPLIES

None

PROGRESS

After 28 patients the code was broken and no statistical difference was present. Coding has been re-established and the study will continue.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Study to Determine the Ability of Amniotic Fluid to Inhibit Growth of E. Coli

WORK UNIT NO: 77/06

PRINCIPAL INVESTIGATOR: COL David Boyce, MD

ASSOCIATE INVESTIGATORS: MAJ M Sellers PhD, COL A. Killam MD

OBJECTIVES

The growth and/or inhibition of a laboratory strain of E. Coli in amniotic fluid as well as certain controlled media is to be monitored by a technique using C14 tagged glucose in the various culture media and monitored by the amount of $^{14}CO_2$ eluted as measured in a liquid scintillation counter. Maternal and cord blood serum zinc levels will be determined as well as the zinc and phosphate ratios of the amniotic fluid. An attempt will be made to correlate the inhibitory or noninhibitory effect of amniotic fluid on the E. Coli as well as the Zinc and zinc/phosphate ratios to this inhibitory effect to neonatal sepsis.

CONSUMABLE SUPPLIES

$800

PROGRESS

The methodology has resulted in one presentation and one manuscript submitted for publication. Clinical evaluation is preliminary.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Effect of Prostaglandin Synthesis Inhibitors on Uterine Blood Flow

WORK UNIT NO: 77/19

PRINCIPAL INVESTIGATOR: MAJ W C Daniell MD

ASSOCIATE INVESTIGATORS: B.E.F. Reimann, DAC, LTC LL Penney MD

OBJECTIVES

To study the effect of prostaglandin synthesis inhibitors by direct flow-pressure measurements in both iliac artery and iliac vein in ewes.

TECHNICAL APPROACH

Pregnant and nonpregnant sheep or dogs will have blood flow monitors implanted around the two uterine arteries and catheters placed in the femoral artery and vein. A variety of substances will be infused to determine their effect on uterine blood flow, including arachidonic acids, prostaglandin synthesis intermediates, prostaglandins, known blockers of prostaglandin synthesis, and drugs of unknown efficacy in blocking prostaglandin synthesis.

CONSUMABLE SUPPLIES

$600

PROGRESS

Preliminary data indicate no change in uterine blood flow. A manuscript has been submitted for publication. Evaluation of ibuprofen is anticipated.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Efficacy Study of (15S)-15-methyl Prostaglandin F2a (tham) (U-32,921E) for Abortifacient Activity by IM, Administration in Cases of Failed Abortion by Other Means

WORK UNIT NO: 77/23

PRINCIPAL INVESTIGATOR: COL W.N. Otterson MD

ASSOCIATE INVESTIGATORS: COL D Boyce MD, CPT R George MD

OBJECTIVES

To determine the efficacy of (15S)-15-methyl Prostaglandin F2a (tham) as an abortifacient by IM administration for failed second trimester abortion following intra-amniotic injection of Prostaglandin.

TECHNICAL APPROACH

Patients desiring second trimester abortion will be counselled and selected for this study following their signing of a voluntary agreement to participate in this study. Forty milligrams of Prostaglandin F2a will be injected intra-amniotically. If this method fails to accomplish the second trimester abortion within 24 hours, the intramuscular 15 methyl Prostaglandin F2a will be administered according to protocol. Hemagram, urinalysis, clotting studies and vital signs will be monitored prior to, during, and at the termination of the abortion.

CONSUMABLE SUPPLIES

None

PROGRESS

Twenty patients have been studied to date. A manuscript is in preparation.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: A Comparison of Phospholipid Levels and Choline Phosphotransferase (CPT) Activity in Amniotic Fluid and Newborn Trachael Fluid

WORK UNIT NO: 77/25

PRINCIPAL INVESTIGATOR: COL A Killam MD

ASSOCIATE INVESTIGATORS: LTC L L Penney MD, MAJ R Heath MD

OBJECTIVES

To determine if the level of phosphatidyl glycerol (PG) and phosphatidyl inositol (PI) or the activity of choline phosphotransferase could serve as an accurate index of lung maturity.

TECHNICAL APPROACH

Amniotic fluid, and neonatal gastric and pharyngeal fluids which are normally discarded, will be analyzed for phosphatidyl glycerol, phosphatidyl inositol, choline phosphotransferase, and magnesium. The levels measured will be correlated with the incidence and severity of neonatal respiratory stress and hyaline membrane disease.

CONSUMABLE SUPPLIES

$800

PROGRESS

Biochemical techniques for rapid separation of PG have proved to be difficult to reproduce. Further evaluation is in progress.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Fetal Movement as an Indicator of Fetal Well Being

WORK UNIT NO: 77/26

PRINCIPAL INVESTIGATOR: MAJ Walter Daniell MD

ASSOCIATE INVESTIGATORS: COL A Killam MD, MAJ T Howard MD

OBJECTIVES

To determine if quantitation of fetal movement is a reliable indicator of fetal well-being comparable to estriols and the oxytocin challenge test.

TECHNICAL APPROACH

Patients admitted to the Antepartum OB Ward who are being monitored by urine or serum estriol and oxytocin challenge tests will be asked to participate in this study. They will be instructed to count and record the number of fetal movements that they feel each hour between 0800 hours and 2200 hours. Changes noted in fetal movement will then be compared with changes in the estriols, the OCT, and the ultimate fetal outcome to determine if changes in the number of fetal movements is a predictor of intrauterine fetal distress that could be comparable to or better than present methods being used. Fetal movements counted each day will be compared to those counted each hour to determine if shorter time periods for counting fetal movements would be of value.

CONSUMABLE SUPPLIES

$400

PROGRESS

Approval from OTSG has recently been obtained and the study is just commencing.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Comparison of Usual Clinical and Laboratory Measurements of Gestational Age with Gestational Age Determined by Radioreceptor Assay (RRA) for HCG

WORK UNIT NO: 78/07

PRINCIPAL INVESTIGATOR: LTC LL Penney MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To confirm the accuracy of pregnancy dating within the first to fourth weeks following ovulation reported by others with the use of RRA for HCG. To correlate this data with other parameters of fetal age as an assessment of the accuracy of these teses which heretofore have relied on subjective, variable gestational age estimates (i.e. menstrual cycle length, LMP, etc.)

TECHNICAL APPROACH

The study will be run as an adjunct to protocol 76/20, with additional volunteers selected from the routine obstetrical clinic. The HCG values will be determined by commercially available RRA. These values will be available only to the principle investigator until the conclusion of the study, at which time the test, if justified, may be instituted as a routine study.

CONSUMABLE SUPPLIES

$1800

PROGRESS

The RRA assay has been clinically evaluated and is being instituted for routine use. The study as detailed above is awaiting OTSG approval.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: RhoGam Monitoring; Fetaldex versus Detection of Circulating Anti-Rho(D)

WORK UNIT NO: 78/10

PRINCIPAL INVESTIGATOR: COL A Killam MD, MAJ M Sellers MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare testing for anti-D antibody in the serum of Rh negative women receiving human anti-D gamma globulin for the prevention of Rh sensitization with the Fetaldex test for fetal RBC in maternal blood.

TECHNICAL APPROACH

Fetaldex tests and the standard test to determine if anti-D antibodies are present in the patient's blood 24 to 48 hours after the RhoGam will be done and the results compared. When possible Rh sensitization will be tested for at 6 to 9 months after delivery.

CONSUMABLE SUPPLIES

$200

PROGRESS

Approximately one half of anticipated samples have been collected.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Role of Prostaglandins and Prostaglandin Synthetase Inhibitors in Hemorrhagic Shock

WORK UNIT NO: 78/11

PRINCIPAL INVESTIGATOR: COL A Killam MD

ASSOCIATE INVESTIGATORS: LTC L L Penney MD

OBJECTIVES

To determine if prostaglanding levels are increased during hemorrhagic shock and if prostaglandin synthetase inhibitors improve or worsen an animal's condition in hemorrhagic shock.

TECHNICAL APPROACH

Hemorrhagic shock is induced in the standard method of Hardaway. Serial determinations of prostaglandins and the standard physiologic parameters. Some of the animals will be given a saline placebo, others will be given a prostaglandin synthetase inhibitor.

CONSUMABLE SUPPLIES

None

PROGRESS

Work was suspended temporarily because of a lack of funds to buy animals and supplies. Equipment to perform analysis of prostaglandins was purchased and the necessary biochemical analyses will be available in FY79.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Inhibition of the Vascular Effect of 17b-Estradiol with Actinomycin D

WORK UNIT NO:

PRINCIPAL INVESTIGATOR: LTC LL Penney MD

ASSOCIATE INVESTIGATORS: 78/26

OBJECTIVES

To determine if the vascular effect of 17β estradiol employs the same pathways as the growth promoting effect on the sex organs of rabbits.

TECHNICAL APPROACH

Actinomycin D will be given to rabbits in sufficient dosage to block the growth promoting effect of estradiol 17-beta, which is a potent vasodilator of the uterus as well as a potent growth promoter. If the vascular effect of estradiol-17-beta is not affected nearly as much as the growth promoting effect, this would suggest that the vascular effect does not rely on transcription. Thirty rabbits will be divided into five random groups, all will initially have their ovaries removed. A minimum of thirty days will be allowed to elapse before studying the animals. A femoral vein and artery and a carotid artery will be catheterized. Baseline uterine blood flow will be determined by infusing 10-15 μCi ^{141}Ce microspheres in the carotid catheter and sampling from the femoral artery. One μg/Kg of 17β estradiol with labeled uridine and amino acids will be given IV and the control animlas subdivided for study at hourly (or less if needed) intervals to determine onset of increased blood flow. An infusion of 30-40 μCi ^{51}Cr at these intervals will be used to calculate blood flow. All animals will then be sacrificed and aliquots of uterine tissue for RNA and protein quantitation and label incorporation will be analyzed. The microspheres per gram of uterine tissue and per organ will be determined. Subsequent repeat blood flow studies will be done at the earliest time at which control animals increased their uterine blood flow. These animals will receive actinomycin 8 mg/Kg, cycloheximide 4 mg/Kg, a combination of these two, or puromycin 200 mg/Kg 30 minutes prior to hormone administration.

CONSUMABLE SUPPLIES
$700

PROGRESS

The project is suspended pending further funding.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Distribution of Group B Streptococcus

WORK UNIT NO: 78/27

PRINCIPAL INVESTIGATOR: COL A Killam MD, MAJ R Heath MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine where Group B Streptococci are sequestered in the body of rabbits after intravenous infusion.

TECHNICAL APPROACH

Approximately 24 rabbits will be given Group B strep grown in media containing P^{32} phosphate to make the organisms radioactive. The rabbits will be sacrificed at 15 minutes, 1 hour, or at 12 hours after the injection. Half will be given liver organisms and half will receive killed organisms. The blood, lung, heart, liver, spleen, brain, bowel (jejunum), adrenal lymph nodes in the mesentery and para-aortic area and thigh muscle will be removed and a portion prepared for microscopic evaluation and autoradiography. The remainder of the organs will be counted in the liquid scintillation counter for radioactivity. The amount of radioactivity in the 15 minute group will be compared with the one hour and 12 hour groups to see where the majority of the organisms are sequestered immediately after infusion and to see if the radioactivity of the organisms is redistributed from its initial position in the body.

CONSUMABLE SUPPLIES

$1000

PROGRESS

Gross tissue uptake of live and killed organisms as well as autoradiography are being utilized. Only a few animals have been studied.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Molecular Etching

WORK UNIT NO: 70/111

PRINCIPAL INVESTIGATOR: B.E.F. Reimann, DAC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To obtain general information on the ultrastructure of biological membranes (in particular the erythrocyte membrane) and other cellular organs in order to discern their structural changes under varying experimental (and disease related) conditions and, for this reason, to develop techniques by which the biological material can be investigated in the least altered state employing methods such as freeze drying and ionic etching in conjunction with electron microscopy.

TECHNICAL APPROACH

The final goal is to subject lyophilized embedded biological material to a bombardment with accelerated ions or atoms and to reveal the obtained structures by electron microscopy. Presently the experiments are primarily concerned with osmotic pressures of erythrocytes employing freezing point depression osmometry and direct measurements with a Pfeffer's cell. A "critical point" drying chamber has been constructed.

CONSUMABLE SUPPLIES

$700

PROGRESS

Experiments in collaboration with members of the Department of Metal. and Materials Engineering, New Mexico Institute of Mining and Technology, Socorro, NM 87801, with two phylogenetically early, thermophilic (growth optimum 55°C) chemoautotrophic bacteria, Thiobacillus ferrooxidans and Caldariella sp. (corrosive to FeS_2 and $CuFeS_2$) have been made with special emphasis to their membrane structure and function. Two publications have resulted to date.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Chemotherapy of Cancer

WORK UNIT NO: 76/07

PRINCIPAL INVESTIGATOR: Dr. J. Swaney MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The association of WBAMC Pediatric Oncology and Hematology Service with the various members of the Southwest Cancer Chemotherapy Study Group, Pediatric Division (through M.D. Anderson Hospital and Tumor Institute), Acute Leukemia Group B, and with the Children's Hospital Oncology Center, Denver, Colorado, in conducting trials of chemotherapy in cancer will (1) obtain the necessary understanding of the cancer process; (2) determine effective therapeutic approaches; and (3) provide needed information to use in the care of children with malignant diseases. The association provides for probing of common knowledge and for better statistical evaluation of processes and results.

TECHNICAL APPROACH

Each protocol used by the various aforenamed groups goes through a rigorous process of review, revision, and evaluation prior to becoming activated for group usage. The flow of protocol from author through specific disease committee, statistician, committee headquarters, studies management board, Cancer Investigation Branch of the National Cancer Institute is the usual process. Data collected by each member is reviewed and analyzed by the individual data sent.

CONSUMABLE SUPPLIES

None

PROGRESS

The patients on the noted protocols continue as previously. The patients remain in continuous remission. The patient on Denver Children's AL#3 HR has discontinued chemotherapy and is presently NED.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Use of Elliott's B Solution, Sterile as Methotrexate Diluent for Intrathecal Use

WORK UNIT NO: 76/28

PRINCIPAL INVESTIGATOR: Dr. J Swaney MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The object of this study is to determine if the use of Elliott's B solution as diluent for intrathecal Methotrexate will reduce the evidence of side effects, i.e., headaches, fever, vomiting, etc.

TECHNICAL APPROACH

Patients are eligible for this study who are receiving intrathecal Methotrexate either as prophylaxis or for treatment of central nervous system leukemia. Stock Solutions of Methotrexate will be diluted to a concentration of 1 mg/cc with Elliott's B solution. The dose of Methotrexate shall be calculated at 12 mg/M^2 per dose with a maximum of 15 mg/M^2 per dose. The timing of the intrathecal injection shall be individually determined. Records shall be kept of patient status following injection as regards headache, fever, nausea, vomiting, etc. Response shall be determined by absence of side effects of their diminution if they had previously present. Possible CNS contamination from injection of foreign material may result in toxicity which may be evidenced by fever, headache, nausea, and/or vomiting following intrathecal injection of Methotrexate diluted with Elliott's B solution. Approximately ten patients per year will be treated on this protocol.

CONSUMABLE SUPPLIES

None

PROGRESS

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Comparison of Pneumatic Otoscopy and Impedance Tympanometry in the Followup of Otitis Media in Children

WORK UNIT NO: 76/37

PRINCIPAL INVESTIGATOR: LTC Richard M. Lampe MD

ASSOCIATE INVESTIGATORS: L Artalejo DAC

OBJECTIVES

To compare pneumatic otoscopy with impedance tympanometry in the followup of otitis media and to asess the efficacy of three medical regimens in the treatment of acute otitis media.

TECHNICAL APPROACH

In cross sectional studies, impedance tympanometry is a reliable screening method for the detection of middle ear fluid in the pediatric age group and compares favorably with pneumatic otoscopy in accurately detecting middle ear fluid. Impedance tympanometry offers an objective measurement of middle ear fluid and its sequential presence or absence following acute otitis media. Comparison of these two methods in the followup of middle ear effusion should demonstate the utility of impedance tympanometry in the followup of middle ear effusions.

CONSUMABLE SUPPLIES

None

PROGRESS

To date over 100 patients have been enrolled in the study and most of these have completed their participation. Due to the double blind nature of the study, the data have not been analyzed rigorously. However, it does appear that tympanometric readings have been in excellent agreement with the pneumatic otoscopy. If subsequent statistical analysis indicates that the correlation is indeed good, impedance tympanometry promises effective utilization of the technique in objectively evaluating the patient's progress then treated with varying drug regimens. Additionally, tympanometry in the hands of a skilled technician could release physicians from routine post-ear infection followup.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Detection of Bacterial Antigen in Body Fluid by Counterimmuno-electrophoresis

WORK UNIT NO: 77/05

PRINCIPAL INVESTIGATOR: LTC R Lampe MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare the presence of bacterial antigen in various body fluids detected by counterimmunoelectrophoresis (CIE) to standard bacteriologic methods of identification.

TECHNICAL APPROACH

Pediatric patients suspected of having a bacterial infection will have appropriate Gram stains and cultures performed. In addition, sera, urine, and the body fluid suspected of being infected will be studied using CIE with the following antisera: Pneumococcal antisera, Hemophilus influenza B antisera, Neisseria meningitides antisera and Staphylococcal antisera. Should a specific antigen be detected, this will be followed sequentially during the hospitalization. The withdrawal of body fluids for this study will only accompany clinically indicated procedures requiring fluid withdrawal for diagnostic purposes.

CONSUMABLE SUPPLIES

$200

PROGRESS

Over 200 clinical specimens (CSF, serum, urine, plural fluids, exudates) have been analyzed to date, with the specimens from 10 individual patients diagnosed as positive by CIE. Eight of the ten patients had bacteriologic cultures confirmatory of the CIE diagnosis of pneumococcus, H influenza B, or Streptococcus B. Bacteriologic cultures were negative in the other two patients. Strep A can be detected, but it has not appeard in any clinical specimens as yet. Not only is the CIE technique much more rapid (1 hour versus 24 hours for cultures), but it can detect the presence of antigen even after antibiotic therapy has caused cultures to become negative.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Zinc Levels in Maternal Infant Pairs

WORK UNIT NO: 77/10

PRINCIPAL INVESTIGATOR: COL A Killam, MC

ASSOCIATE INVESTIGATORS: LTC L L Penney, M

OBJECTIVES

To determine the zinc level in maternal-infant pairs and to see if there is a correlation with the incidence of infection.

TECHNICAL APPROACH

Zinc and phosphate concentrations in maternal and neonatal cord blood will be correlated with the incidence of neonatal sepsis in a blind retrospective study. The hypothesis of increasing zinc and phosphate levels in enhanced amniotic fluid bactericidal activity will be studied.

CONSUMABLE SUPPLIES

$500

PROGRESS

Nearly 1000 samples have been analyzed. Statistical correlation of the data is underway.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Investigation of the Effects of Diphenylhydantoin on Intellectual Functioning of Children

WORK UNIT NO: 77/13

PRINCIPAL INVESTIGATOR: LTC P F LoPiccolo MD

ASSOCIATE INVESTIGATORS: CPT Robert Hulsebus PhD

OBJECTIVES

To determine if Dilantin has any effect on intellectual functioning.

TECHNICAL APPROACH

To test children over the age of six years who have been placed on phenobarb or dilantin because of a new seizure disorder. To test children who have been on long term anticonvulsants to see if there has been any change in intellectual function. This can only be accomplished if children had educational and psychological evaluations before the onset of their seizure disorder. Testing is being accomplished in Psychology using the WISC-R. The first part of the study has gone slowly because we have had very few cases of new spontaneous seizure disorders in children over the age of 6 years.

CONSUMABLE SUPPLIES

None

PROGRESS

Due to the low incidence of spontaneous seizure disorders in the study population, only two patients have been admitted to the first portion of the study. The one child who has completed the study exhibited interesting, unexplained findings. A number of patients have been admitted to the second portion of the study, and testing has been done. We are in the process of evaluating this data.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Infant Parent Bonding and Its Relationship to the Healthy Resolution of Grief

WORK UNIT NO: 77/18

PRINCIPAL INVESTIGATOR: Vivian Sheliga LT, MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate our current inpatient and outpatient nursery services and to increase our help to families who experience the death of a newborn. We were particularly interested in how absence of "normal" bonding affects the grief reaction.

TECHNICAL APPROACH

Eighteen families were interviewed, half in hospital, half in homes. Two interviewers of the three on the team saw each family. Interviews were geared to a specific set of questions and all were taped when permission was given by family. Family previously had been asked to complete a brief questionnaire containing some of the same questions as interview.

CONSUMABLE SUPPLIES

None

PROGRESS

Many factors have been delineated as contributing to the prolongation of parental grief following the death of a newborn, with most of the factors identifiable as areas which more sensitive hospital personnel could help alleviate. Data are currently awaiting analysis; but already some of the preliminary findings are being incorporated by our social workers into routine operational guidelines.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Breast Feeding Survey

WORK UNIT NO: 77/21

PRINCIPAL INVESTIGATOR: CPT Jackson ANC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Evaluate effectiveness of current breast feeding teaching program at this hospital. Determine breast feeding population and reasons for decision to do so.

TECHNICAL APPROACH

Mothers visiting the Well Baby Clinic will be administered a questionnaire on several successive visits to determine the number of breast feeding mothers, non-breast feeding mothers and/or discontinued breast feeding mothers. Data will be analyzed attempting to identify factors which encourage or discourage mothers from breast feeding.

CONSUMABLE SUPPLIES

None

PROGRESS

Due to staffing problems and a backlog of patients being seen in the Well Baby Clinic, proper procedure for administration of questionnaire was not being followed. Rather than continue to haphazardly conduct the survey and obtain results of no validity, the administration of the survey has been suspended. The forms have been kept for use at a later date. At present all that has been done is to collect a small sampling of responses, the results of which would be insignificant in themselves.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Cervical Intra-Epithelial Neoplasia in Adolescents

WORK UNIT NO: 78/12

PRINCIPAL INVESTIGATOR: MAJ Schydlower WBAMC

ASSOCIATE INVESTIGATORS: COL P Patterson, TAMC

OBJECTIVES

Determine incidence of CIN in adolescence.

TECHNICAL APPROACH

Survey of military dependent adolescent patients.

CONSUMABLE SUPPLIES

None

PROGRESS

Presented at the Tri-Service Pediatric Meeting, San Francisco, CA, Mar 78 and in preparation for publication.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Maintenance of Patency of the Ductus Arteriosus in Congenital Cardiac Lesion

WORK UNIT NO: 78/14

PRINCIPAL INVESTIGATOR: MAJ Wm Pearl MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To maintain patency of the ductus areteriosus in infants with congenital heart disease, by infusing prostaglandin until diagnostic studies are completed and surgery can be arranged.

TECHNICAL APPROACH

Prostaglandin E is the only nonsurgical treatment available for treatment of certain congenital heart defects such as maintaining patency of the ductus arteriosus until cardiac abnormalities in newborn infants can be surgically corrected. In infants in whom blood is flowing through the ductus from the aorta to the pulmonary artery, a catheter will be placed through the umbilical artery to the first part of the descending aorta, at or just above the ductus. Prostaglandin E_1 will be infused continually into this region at the rate of 0.1 micrograms per kilogram per minute. In infants in whom blood flow is passing through the ductus from the pulmonary artery to the aorta, a catheter will be placed in the pulmonary artery just beyond the ductus arteriosus, and the Prostaglandin E_1 will be infused at the rate of 0.1 micrograms per killogram per minute. In the event that the major artery cannot be catheterized, the infusion will be given into a large vein, and the investigator will be asked to observe the infant closely for any systemic effects. The infusion will be continued until surgery can be performed; this will usually be in a matter of hours. If the infusion is to be continued for more than seven days, the investigator should contact the monitor.

CONSUMABLE SUPPLIES

None

PROGRESS

Final approval was 5 July 1978. The drug has not yet been used.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Penicillin Alone vs Ampicillin and Gentamicin in the Treatment of Group B Streptococcal Sepsis

WORK UNIT NO: 78/15

PRINCIPAL INVESTIGATOR: MAJ R Heath MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the in vivo and in vitro killing rates of these antibiotics.

TECHNICAL APPROACH

Scintillation counting will be used for in vitro studies
Serial blood cultures will be used for in vivo studies with a rabbit model

CONSUMABLE SUPPLIES

$1300

PROGRESS

The in vitro aspect of the project is just now beginning. Technical problems have been eliminated. The in vivo aspect of the project has been approximately one fourth completed.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Efficacy of Intravenous and/or Intraventricular Antibiotic Therapy of Gram Negative Meningitis

WORK UNIT NO: 78/16

PRINCIPAL INVESTIGATOR: MAJ R Heath MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine which of the above methods of antibiotic administration results in the more rapid sterilization of infected ventricular fluid.

TECHNICAL APPROACH

Dogs will have E. coli instilled directly into their ventricles. Antibiotics will then be given intravenously or intramuscularly + intraventricularly, or intraventricularly alone, and serial culturing done for bacterial growth.

CONSUMABLE SUPPLIES

$200

PROGRESS

Work is progressing on the technical aspects of this study. Only one animal has been run thus far. We are awaiting further funding.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Efficacy of Active Immunization to Group B Streptococcal (GBS) Organisms in Preventing GBS Sepsis

WORK UNIT NO: 78/22

PRINCIPAL INVESTIGATOR: MAJ R E Heath MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if active immunity will prevent acquisition of disease and/or prevent and/or blunt the clinical parameters of sepsis.

TECHNICAL APPROACH

A rabbit model is being used in this study. Rabbits are immunized with GBS until they have a "+" CIE to GBS antigen. Once a "+" titer is demonstrated, the animals are injected with both live and killed organisms. CBC's, blood gases, and temperatures are followed closely. If death occurs, histological examination of tissue will be performed.

CONSUMABLE SUPPLIES

$500

PROGRESS

The model works very well, and the project is approximately one-third complete.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Detection of Toxin by the Group B Streptococcal (GBS) Organism

WORK UNIT NO: 78/23

PRINCIPAL INVESTIGATOR: MAJ R E Heath MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if the GBS organism has evidence of producing a toxin.

TECHNICAL APPROACH

Live and killed organisms will be injected into rabbits. CBS's, blood gases, and temperatures will be followed closely. Necropsy specimens will be histologically reviewed.

CONSUMABLE SUPPLIES

$500

PROGRESS

We have demonstrated similar changes in all parameters with both live and killed organisms indicating a high probability of toxin production by GBS. Isolation and purification studies are beginning.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Antibiotic Prophylaxis for Recurrent Otitis Media: Comparison of Sulfasoxizole, Erythromycin, and Placebo

WORK UNIT NO: 78/25

PRINCIPAL INVESTIGATOR: LTC R M Lampe MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare the effect of chronic administration of oral sulfasoxizole, erythromycin or placebo has upon the number of ear infections in children with a history of recurrent otitis media.

TECHNICAL APPROACH

Children under the age of six years who, upon review of their outpatient chart, have a documented history of four or more ear infections in the preceding twelve months will be considered eligible for the study. Children with previous history of PE tubes, cleft palate or immune disease will be excluded. After informed parental consent, the children will be placed on either sulfasoxizole 25 mgm/Kg/dose bid, erythromycin 10 mgm/Kg/dose bid, or placebo for a three-month period. During this time the patient will be followed monthly with impedance tympanometry and physical examination. Any new ear infections during this period will be treated with systemic antibiotics for ten days. During the second and third three-month period an alternate drug will be used. Each patient will be followed for nine months and will serve as his or her own control (Three months on Sulfasoxizole, 3 months on placebo, 3 months on erythromycin) in random order. At the conslusion of the study, the frequency of ear infections in children receiving placebo will be compared to those receiving sulfasoxizole or erythromycin.

CONSUMABLE SUPPLIES

None

PROGRESS

This new study has not yet been approved by OTSG

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Detection of Toxin by the Group B Streptococcal (GBS) Organism

WORK UNIT NO: 78/23

PRINCIPAL INVESTIGATOR: MAJ R E Heath MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if the GBS organism has evidence of producing a toxin.

TECHNICAL APPROACH

Live and killed organisms will be injected into rabbits. CBS's, blood gases, and temperatures will be followed closely. Necropsy specimens will be histologically reviewed.

CONSUMABLE SUPPLIES

$500

PROGRESS

We have demonstrated similar changes in all parameters with both live and killed organisms indicating a high probability of toxin production by GBS. Isolation and purification studies are beginning.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Assessment of Psychological Involvement in Patients Presenting with Back Problems.

WORK UNIT NO: 75/29

PRINCIPAL INVESTIGATOR: MAJ F H Rath, Jr

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To improve psychological assessment procedures using the MMPI with patients presenting with low back problems and better define those MMPI profiles reflecting premorbid personality dispositions which contraindicate medical/surgical intervention of low back pain syndromes.

TECHNICAL APPROACH

All outpatients in the Orthopedic Clinic presenting with low back pain which meet the criteria will be requested by the attending physician to complete the MMPI, until a sample size of 500 completed MMPI profiles are obtained. This should take approximately 12 months (the present rate of such patients is estimated at 30-50 per month). All in-patients on Orthopedic wards scheduled for either conservative treatment of low back problems or surgery (spinal fusion or dissectomy) will be administered the MMPI.

CONSUMABLE SUPPLIES

None

PROGRESS

The principal investigator has been reassigned. Any publications will be reported in subsequent years.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Infant Auditory Discrimination of Parents and Strangers

WORK UNIT NO: 77/12

PRINCIPAL INVESTIGATOR: Robert C. Huslebus, PhD, CPT MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The purpose of this research was to determine the extent to which very young infants are able to discriminate parents from strangers of the same sex; the present protocol involved comparison between fathers and male strangers.

TECHNICAL APPROACH

Parents are to be contacted within 1-2 days of birth and the planned research will be briefly described. Those who express interest in the study will be contacted approximately one week later and will be given a consent form. For each comparison (father's vs male stranger, and mother vs father) the reaction of 12- to 15 infants between 1 and 2 weeks of age will be compared.

CONSUMABLE SUPPLIES

None

PROGRESS

There were results from 20 infants which met the criteria of sufficient crying and of sufficient pausing while the adults were speaking to the infants. The major comparison of interest was the extent to which infants would pause from crying more readily to their father's voices than to a male stranger's voice. (Earlier published research revealed that infants discriminated their mother's voices from female stranger's voices and paused significantly sooner when their mothers spoke.) Two scorers worked independently and simultaneously to transcribe on an event recorder the pattern of cries and pauses emitted by each infant and to each adult. The percent agreement as to which adult the criterion pause occured first was calculated; in 23 of 24 cases, there was agreement - for a 95% rate of agreement. The latencies to criterion pauses for father and stranger were compared by means of t tests for paired comparisons. The results were as follows: = 2.925, p .01, a highly significant difference in favor of the fathers. Thus, the infants paused significantly sooner when their fathers spoke to them, supporting the conclusion that infants with an average age of 2 weeks can and do differentiate their father's voices from strangers' voices. This finding is consistent with the aforementioned results reported with mothers and their infants. Together these studies shed new light on the as yet not fully understood period of early infancy and the beginning of social attachment. These data have been submitted for publication.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Effect of Instructional Pretraining and Type of Treatment on the Acquisition of Assertive Behavior

WORK UNIT NO: 78/04

PRINCIPAL INVESTIGATOR: Edward O. Crandell, 1LT,MSC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The purpose of the study is to compare the effectiveness of two methods of psychotherapy (behavioral and insight-oriented) used in conjunction with instructional retraining on development of assertive behaviors.

TECHNICAL APPROACH

A total of 50 volunteer subjects will be selected from among the patient population of the Psychology Service of William Beaumont Army Medical Center in El Paso, Texas. All subjects will be assigned to one of five groups. The purpose of these groups will be to aid each subject in his/her ability to behave assertively and to determine which of the five methods to be used is most effective in teaching this skill. The procedures to be followed and qualifications of the therapists to be used are described in detail in the originally submitted protocol.

CONSUMABLE SUPPLIES

None

PROGRESS

The hypothesis that the combination of instructional pretraining and behavior therapy would result in significantly higher scores on the behavioral and self-report measures was not supported. The independent variable which contributed to higher negative assertion scores was the type of treatment received. Subjects receiving behavior therapy made significantly more negative assertive statements on the videotaped measure than subjects who received insight-oriented therapy or instructional pretraining only. Further research will be instituted to examine the need for training in positive assertion and the present study will be replicated using a no-treatment and no-pretraining control group.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Post Traumatic Hepatic Dysfunction Study

WORK UNIT NO: 76/08

PRINCIPAL INVESTIGATOR: MAJ Hartong MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To ascertain the etiology and pathophysiology of patients admitted to the Trauma Center who develop post-traumatic hepatic dysfunction.

TECHNICAL APPROACH

Liver chemistries are performed on a scheduled basis on patients admitted with criteria developed for the study which basically consists of severe shock and multiple injuries other than liver. Liver biopsies are done on those individuals who exhibit chemical evidence of hepatic dysfunction.

CONSUMABLE SUPPLIES

None

PROGRESS

None reported. The investigator has departed.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Development of a Computerized Trauma Registry

WORK UNIT NO: 76/09

PRINCIPAL INVESTIGATOR: MAJ Dumke MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To develop a computerized trauma registry for data recall on all patients admitted to the Trauma Center.

TECHNICAL APPROACH

A coding system was developed which has enabled identification of injury, mechanism of injury, diagnostic and therapeutic procedures employed on all patients admitted to the Trauma Center. The numbering system developed is similar to, but not identical to that used in the ICDA-8.

CONSUMABLE SUPPLIES

None

PROGRESS

The Trauma Registry Secretary position was vacant from May 77 to Jun 78, during which time the Trauma Registry was not kept up to date. Since the filling of this vacancy the registry has been coded from May 77 to Jun 78.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Investigation of the Etiology and Pathophysiology of Post-Traumatic Hepatic Dysfunction

WORK UNIT NO: 76/13

PRINCIPAL INVESTIGATOR: MAJ Hartong MD

ASSOCIATE INVESTIGATORS: CPT R S Dixon VC, MAJ J Greene MD

OBJECTIVES

To define the etiology and pathophysiology of post-traumatic hepatic dysfunction.

TECHNICAL APPROACH

Twenty-five laboratory bred beagles were utilized in the project and broken into various groups for study. A shock/trauma model was developed and utilized in this project. Liver function tests, blood gases, tissue pO2, and pH were measured in all animals. Sequential liver biopsies were performed.

CONSUMABLE SUPPLIES

None

PROGRESS

No progress was reported. All the original investigators have resigned or have been reassigned.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: An Investigation of the Effect of Supplemental Oxygen on Chemically Induced Fat Embolization

WORK UNIT NO: 76/24

PRINCIPAL INVESTIGATOR: CPT Foret MD

ASSOCIATE INVESTIGATORS: CPT Hill MD

OBJECTIVES

To determine whether or not supplemental oxygen prevents or lessens the potentially lethal effects of chemically induced fat embolization in dogs.

TECHNICAL APPROACH

Clinical observations as well as lung scans are generally accepted as criteria for determination of the presence of fat embolism syndrome. In this study laboratory parameters and lung scans are obtained for a 5-day period in beagles following injection of oleic acid. This data is collected from dogs supported on either room air or supplemental oxygen.

CONSUMABLE SUPPLIES

None

PROGRESS

Animal testing was suspended temporarily in order to evaluate preliminary work for possible improvements in technique, including discontinuance of oleic acid for embolization.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Early Detection of Fatigue Fracture by Bone Scanning with Tc-99 Bone Scan Agents

WORK UNIT NO: 76/31

PRINCIPAL INVESTIGATOR: COL D.A. Vichick MD

ASSOCIATE INVESTIGATORS: COL T J Scully MD
MAJ H A Snowdy MD

OBJECTIVES

To demonstrate if bone scans can detect fatigue fractures and/or stress reactions in bone in military personnel.

TECHNICAL APPROACH

Patients with suspected stress fractures of bone are given bone scans on a "stat" or "ASAP" basis - usually the day after being seen by the orthopaedic physician.

CONSUMABLE SUPPLIES

None

PROGRESS

Part I of the project was investigating the clinical efficacy of bone scans to detect fatigue fractures or stress fractures. This concept was proven. Also the project found that bone scans would detect stress fractures two to four weeks before x-rays would confirm their presence. As a result the bone scan was found to be a very helpful diagnostic tool for the military orthopaedic surgeon. The bone scan would allow early confirmation of a potentially devastating process in military personnel. This was particularly helpful in stress fractures of the hip. This finding was of major importance to the orthopaedic community nationwide. Subsequently a preliminary report was given to the Society of Military Orthopaedic Surgeons in Washington, D.C. in November 1976. Locally a report was given to the New Mexico Orthopaedic Association in December 1976. At the conclusion of the study two reports were given to national professional societies. Final reports were given to the Western Orthopaedic Association in October 1977 and to a national meeting of nuclear medicine physicians in El Paso in the Spring of 1977. A written final report was published in October 1977, J Bone and Joint Surgery, which is the definitive national and international orthopaedic journal. At the present time Part II of the study is to be continued by the Orthopaedic Service. Part II is a study of the actual prevention of stress fractures in military basic trainees. COL Scully, Asst C, Orthopaedics, has instituted changes in the actual basic training cycle to prevent stress fractures. The number of stress fractures has decreased significantly since that program was introudced. The conclusion of the project will be publication or presentation of the results of the Part II prevention program.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Proposal for Joint Study by Orthopedic Service, Dept of Clinics and Radiology

WORK UNIT NO: 76/32

PRINCIPAL INVESTIGATOR: MAJ Ewart MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare the clinical entity of low back pain with the presence of radiographic anomalies of the lumbo-sacral spine.

TECHNICAL APPROACH

Group analysis in a prospective fashion taking into account high risk categories. Personnel undergoing separation physicals (retirement, etc) will be assessed radiographically for the presence of lumbosacral anomalies. This evaluation will be correlated with previous history and consultations for low back pain.

CONSUMABLE SUPPLIES

None

PROGRESS

Material was presented in a paper to the Society of Military Orthopedic Surgeons, Wash DC, Nov 76. An updated report is similarly scheduled to be given at the same meeting this year. It is of great interest that most anomalies occur in the same relative numbers in both the symptomatic and asymptomatic.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Pathophysiology and Treatment of Hemorrhagic and Traumatic Shock

WORK UNIT NO: 77/24

PRINCIPAL INVESTIGATOR: MAJ Dumke MD

ASSOCIATE INVESTIGATORS: Dr. R M Hardaway III, CPT T Gee VC

OBJECTIVES

To study the pathophysiology and treatment of hemorrhagic and traumatic shock and the effect of vasodilation, steroids and fibrinolysin on these types of shock.

TECHNICAL APPROACH

Disseminated Intravascular Coagulation (DIC) and fatality have been shown to require the presence of slow capillary flow (shock) and the presence of a thromboplastic material in the blood stream. It is proposed to test the efficacy of phenoxybenzamine (an alpha blocking agent), steroids, and fibrinolysin in the prevention of DIC following traumatic shock.

CONSUMABLE SUPPLIES

$8,700

PROGRESS

Sixty animals have been studied to date. One manuscript has been submitted for publication. Portions of the experiment must be repeated as it was retrospectively discovered that some of the control animals were diseased.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: National Intraocular Lens Implantation Study

WORK UNIT NO: 78/03'

PRINCIPAL INVESTIGATOR: COL S M Galas

ASSOCIATE INVESTIGATORS: MAJ T W Doucet

OBJECTIVES

To participate in the study of clinical results of implantations of intraocular lenses organized by the Intraocular Lens Manufacturer's Association in response to directives of the Ophthalmic Classification Panel, FDA.

TECHNICAL APPROACH

An intraocular lens is a prosthetic replacement for the eye's crystalline lens. It is placed in the eye at the time of cataract surgery, where it is fixated by a variety of means, with the intention that it remain permanently and correct the large refractive error remaining after conventional cataract surgery.

CONSUMABLE SUPPLIES

$100

PROGRESS

From 22 Nov 77 through 3 Oct 78 a total of 25 cataract removal surgery with implantation of intraocular lens have been performed. All patients have been followed as outpatients as required by FDA. The SOP, as presented to the Clinical Investigations Committee, has been followed. There have been no undue complications except for one patient whose cornea has decompensated and will require corneal transplant; however, the patient continues to do well. The patient requiring corneal transplant will undergo surgery in the near future. Decompensation of the cornea, secondary to intraocular implant, is a recognized complication because of the loss of endothelial cells during routine cataract surgery. There were no technical or surgical complications associated with this case, and the patient had 20/20 visiion following surgery. The cornea decompensated approximately 7 months following surgery.

STATUS: Ongoing

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INVESTIGATORS

INVESTIGATORS (contd)

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