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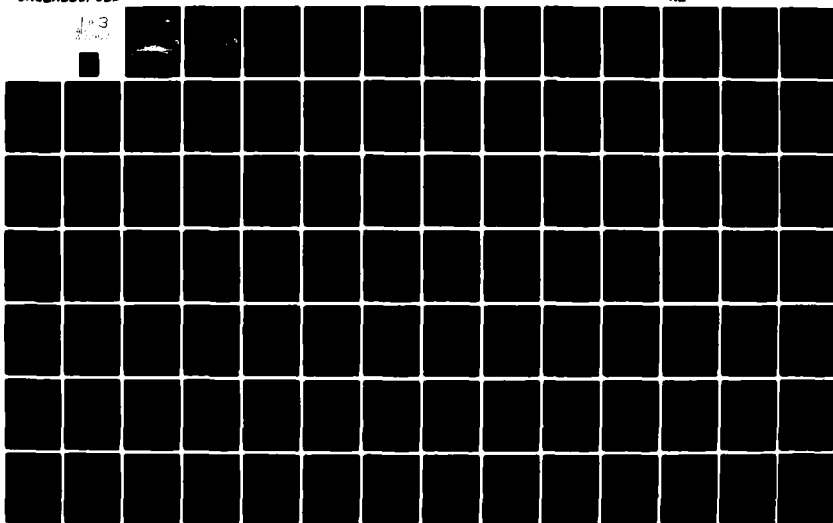
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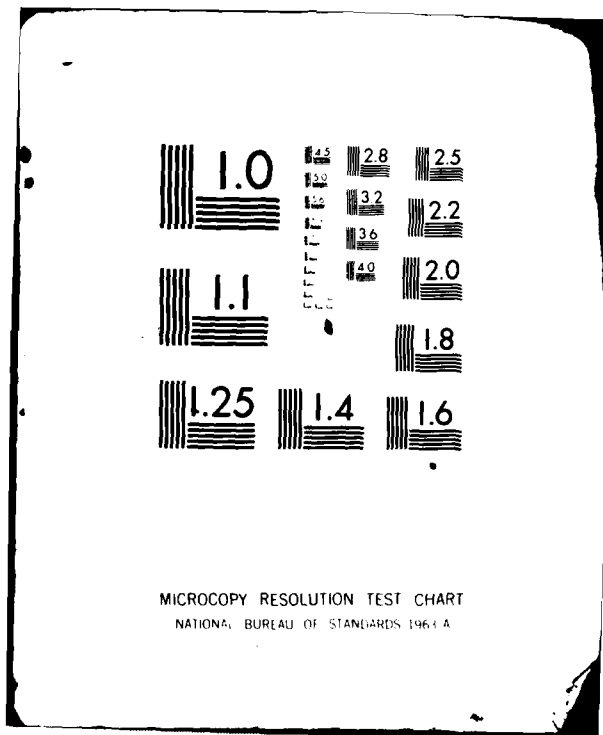
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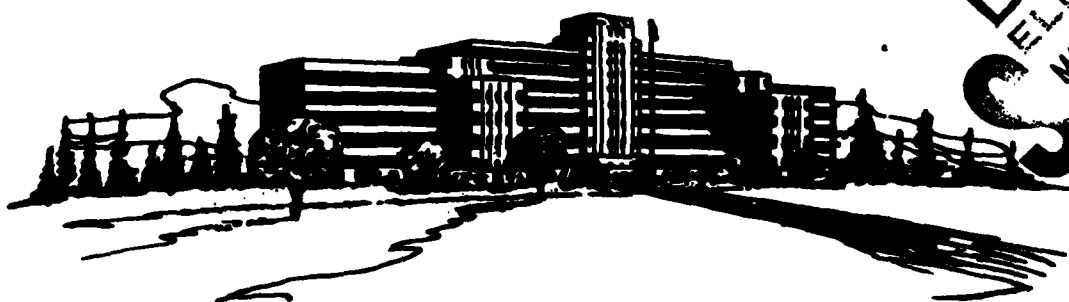
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Laboratory
Report No. 17



CLINICAL INVESTIGATION PROGRAM ANNUAL PROGRESS REPORT

30 September 1981



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DEPARTMENT OF CLINICAL INVESTIGATION

Fitzsimons Army Medical Center
Aurora, Colorado 80045

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Block 19. Key Words

publications, presentations of research data (at national, international and regional science meetings)
post graduate educational programs
protocol training and support programs
protocol registration
protocol status (ongoing, completed, terminated)
technological base (personnel and equipment)
experimental design (statistical tools, etc.)

Block 20. Abstract

Management of Clinical Investigation Protocols and Reports, Use of Volunteers as subjects of research and AR 40-38, as amended, Department of Clinical Investigation, policies and procedures, to insure the medical well-being, preservation of rights and dignity of human subjects who participated in these investigations.

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DEPARTMENT OF CLINICAL INVESTIGATION

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CLINICAL INVESTIGATION PROGRAM

ANNUAL PROGRESS REPORT

30 SEPTEMBER 1981

CLINICAL INVESTIGATIONS (U)

FITZSIMONS ARMY MEDICAL CENTER

AURORA, COLORADO 80045

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FOREWORD

This report identifies the research activities conducted by Fitzsimons Army Medical Center investigators through protocols approved by the Institutional Review Committee and registered with the Department of Clinical Investigation during Fiscal Year 1981 along with other known presentations and publications by FAMC professional staff.

The research protocols described in this report were conducted under the provisions of AR 40-38, as amended, Clinical Investigation Program, AR 40-7, Use of Investigational Drugs in Humans, AR 70-25, Use of Volunteers as Subjects of Research, and HSC Reg. 40-23, as amended, Management of Clinical Investigation Protocols and Reports, to insure the medical safety, well being, preservation of rights and dignity of human subjects who participated in these investigations.

In conducting the research described in this report, the investigator(s) adhered to AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs and the "Guide for Laboratory Animal Facilities and Care," as promulgated by the Committee or the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

The Department of Clinical Investigation is especially grateful to BRIGADIER GENERAL William R. Dwyre, MC, Commanding General of Fitzsimons Army Medical Center, his professional and administrative staff, and to the Commanding Officers and staffs of other supporting activities for the cooperation and assistance provided this Department of Clinical Investigation in our efforts to accomplish our mission. Finally, I would like to recognize the outstanding work, dedication, and wholehearted corroboration of my entire staff. I would especially like to thank my Proto/Ed Asst., Ms. Val McGrill and Mrs. Nancy Moran, Secy, without whose assistance and support this report would not have been possible.



DONALD G. CORBY, M.D.
COL, MC
Chief, Department of Clinical Investigation

UNIT SUMMARY

UNIT SUMMARY

Clinical Investigation Program, FAMC

Clinical Investigation efforts by FAMC personnel in FY 81 culminated in the publication of 108 articles and 154 presentations and lectures at national, international, and regional scientific meetings. As of 30 September 1981, there were 148 research protocols on the DCI register. Of these, 92 projects were ongoing and 54 were new registrations.

Objectives:

To encourage the performance of clinically-oriented investigation by personnel assigned to the Fitzsimons Army Medical Center (FAMC). To aid in the planning, development, support, and execution of experimental clinical studies, both in patients and by directly related laboratory work, into the clinical problems of significant concern in the health care of members of the military community. To provide physician experience in research and investigative procedures by furnishing a highly educated and trained staff of specialists, laboratory facilities, administrative services and funding for: supplies, equipment, consultants, publications and reprints. To achieve continuous improvement in the quality of patient care by providing an atmosphere of inquiry, maintaining high professional standing and accreditation of advanced health programs.

The Clinical Investigation Program differs from Medical Research and Development in that the emphasis is on the health care problems existing in our patient populations, i.e.; active duty, retired, and dependents and not solely on medical problems affecting combat readiness and the fighting strength. It is, by its nature, an integral part of the triad of patient care and medicine. It promotes and supports the finest ideals and traditions of Military Medicine and enhances the vitality of the teaching programs which in turn elevates the standard of medical care. The research program operates on the premise that all approved protocols will be supported to the fullest extent allowed by current funding. This concept allows for a larger number of physicians and ancillary personnel to participate in research rather than as in the grant system used elsewhere. This means that virtually every investigator is given a chance to pursue his research without having to compete for funds with "established" names in the field.

Technical Approach

This support, direction and management is carried out under the aegis of AR 40-38, as amended, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; AR 70-25, Use of Volunteers as Subjects in Research; AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs; HSC Reg 40-23, Management of

Clinical Investigation Protocols and Reports, as amended. This Department provides guidance, assistance, and coordinates the FAMC program with higher headquarters and other facilities.

Manpower: Current authorized strength is outlined.

<u>Description</u>	<u>Grade</u>	<u>MOS</u>	<u>Br</u>	<u>Auth</u>	<u>Actual</u>	<u>Name</u>
C, Dept of Clin Invest	06	60P9B	MC	1	1	Corby
C, Micro Svc	05	68A00	MS	1	1	Engelkirk
Lab Resources Mgr	04	68F00	MS	1	1	Quigg
C, Biochem Svc	03	68C00	MS	1	1	Zolock
C, Immunol Svc	03	68A00	MS	1	1	Whiteaker
C, Surg Rsch Labs Svc	03	68J00	MS	1	1	Harbell
Veterinarian	03	68F00	VC	1	1	Smith
NCOIC	E7	92B4R		1	1	Underhill
Sr, Med Lab NCO	E7	92B4R		1	1	Engle
Sr. O.R. SP	E6	91D3R		1	1	Smith, N.
Bio Sci Asst	E5	01H20		0	1	Kramer
Bio Sci Asst	E5	01H20		1	1	Kessens
Bio Sci Asst	E6	01H20		1	1	Chadwick
Bio Sci Asst	E5	01H20		1	1	Jones
Bio Sci Asst	E4	01H20		1	1	Nicholson
Vet SP	E6	91T3R		1	1	Alford
Supv Res Chem	13	1320 GS		1	1	O'Barr

<u>Description</u>	<u>Grade</u>	<u>MOS</u>	<u>Br</u>	<u>Auth</u>	<u>Actual</u>	<u>Name</u>
Microbiologist	11	0403 GS		2	2	Lima Paine
Microbiologist	09	0403 GS		5	4	Morse Nelson Feuerstein Rothla f
Med Technologist	09	0644 GS		1	1	Rush
	07	0644 GS		1	1	George
Med Technician	07	0645 GS		2	2	Hakes Ramirez
Research Chemist	09	1320 GS		4	3	Noble Swanson Waldrup
Bio Lab Tech (animal)	08	0404 GS		1	1	Jones
	09	0404 GS		1	1	Mercill
Ed Asst	06	0318 GS		1	1	McCrill
Animal Caretaker	05	7706 WG		2	2	Beltran Hitchcock
Clerk-steno	05	0318 GS		1	1	Moran

	FY 79	FY 80	FY 81
Civilian Pay	381,352	434,911	474,832
Travel	5,584	5,240	7,629
Supplies	179,883	189,998	222,999
Equipment	108,165	104,311	153,912
Contracts	16,397	18,598	23,540
Other (Military)	349,116	345,859	417,320

PROGRESS

Immunology Service

With the arrival of the new Titertek Multiskan plate reader, feasibility studies have begun on ELISA technique for quantitating anti-platelet antibodies.

Biochemistry Service

The development of a blocking antibody assay in the Biochemistry Service, specifically directed towards allergins of regional interest, has provided the Department of Allergy with a powerful tool for the evaluation of immunotherapy. Since its availability, this assay has been utilized routinely in clinical situations and presumably has raised the level of patient care.

Surgical Research Laboratories Service

Acquisition of a new VR-12 physiologic monitor for SRLS has made it possible for monitoring during both normal and special surgeries such as open heart. It is now feasible to conduct protocols such as the PCP study, where the necessity to determine physiological changes are an integral part of the protocol.

The installation of a reconditioned 600 MA X-ray Unit, from the hospital, complete with research fluoroscopic capabilities, is scheduled to be completed in the 2nd quarter of FY 82. This acquisition will result in a significant increase in our radiographic diagnostic and research capabilities.

The SRLS has established a prolific stable athymic Balb/C Nude Mouse Colony consisting of approximately 300 animals used in establishment and varification of human tumor cell lines and studies in chemotherapy directed against human tumors.

Additional significant improvements include: a new hydraulic animal table to lift and weigh animals; the creation of positive pressure clean rooms for tumor tissue culture and nude mouse colony rooms; new ladies' and mens' shower and changing facilities; and an enclosed area for the housing of sheep, goats and other livestock.

Construction on the new \$838,000 Animal Housing Facility will begin in FY 82.

Microbiology Service

During FY 81, counterimmunoelectrophoresis (CIE) and enzyme-linked immunosorbent assay (ELISA) technology was introduced and was utilized in five new protocols. CIE has been used to detect bacterial

Progress - continued

Antigens in clinical specimens (urine and CSF) from FAMC and a procedure has been developed for the detection of Clostridium difficile toxin in fecal specimens.

An ELISA procedure has been developed for the detection of Respiratory Syncytial Virus (RSV) in nasal secretions and urine, and an ELISA procedure is being developed for the detection of anti-RSV antibodies.

Axenic cultures of Giardia lamblia were established using either bovine or rabbit serum in the culture medium. Sonicated Giardia lamblia trophozoites have been utilized to stimulate the production of anti-Giardia lamblia antibodies in rabbits and these antibodies have been evaluated via gel diffusion, CIE, and immunoelectrophoresis (IEP) procedures. Preliminary experiments have been initiated to evaluate Giardia/rabbit host cell interactions at the ultrastructural level.

An ultramicrotome, glass knife maker, and a variety of electron microscopic supplies and reagents have been procured. Planning is in progress for the purchase of a new electron microscope with TEM, STEM, and SEM capabilities.

A ten week (ten hour) course entitled "Introduction to Biological Transmission Electron Microscopy" was taught by LTC Engelkirk. Approximately 20 DCI and other FAMC personnel attended the course.

A feasibility study of a new transport medium for mycobacterial specimens has been completed, utilizing clinical specimens from National Jewish Hospital, Denver, CO. A manuscript entitled "Isolation of Mycobacteria from Undecontaminated Specimens with Selective 7H10 Medium" was published in the January 1981 issue of the Journal of Clinical Microbiology.

Funding

The OMA costs have not been itemized by protocol number because it is not feasible or practical to do so.

MEDCASE items purchased for protocols and general laboratory use are listed as follows:

<u>ITEM</u>	<u>COST</u>
VR12 Psychologic Monitor	\$27,165.00
Nuaire 408-624 Laminar Flow Biological Safety Cabinet	4,148.00
Nuaire 408-424 Laminar Flow	3,310.75
Tri-carb Oxidizer Mdl 306	16,739.00
Nuaire 407-624 Laminar Flow	4,607.00
Ultra Microtome LKB	29,335.50
Titer multiskan	10,300.00
Heinike HN2 Glassware Washer	7,765.00
6 Channel Gilson Recorder	4,272.00
Eagle 2022 Steam Sterilizer	19,293.60
Heinike Glassware Washer W612E00	11,295.00
Hewlett Packard Strip Chart Recorder	3,275.00
Hem-O-Scan Oxygen Disassociation Analyzer	9,967.50

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PRESENTATIONS

DEPARTMENT OF MEDICINE

Allergy Service

Bunker-Soler, A.L. and Leavengood, D.: The Effect of Corticosteroids on Theophylline Metabolism. Presented: 37th Annual Congress, American College of Allergists, Washington, D.C., 4-8 April 1981.(C)

Dantzler, B.S.: The Effect of Positive and Negative Air Ions on Bronchial Asthma. Presented: 33rd Annual Pulmonary Disease Symposium, Carl W. Temple Symposium, FAMC, Aurora, CO, 20-21 January 1981.(C)

Dantzler, B.S., Martin, B. and Nelson, H.S.: The Effect of Positive (+) and Negative (-) Air Ions on Bronchial Asthma. Presented: 37th Annual Meeting, American Academy of Allergy, San Francisco, CA, 9-11 March 1981.(C)

Danziger, R.E.: Effects of Aspirin on Platelet Aggregation and Arachidonic Acid Metabolism in ASA-Sensitive Asthmatics. Presented: 33rd Annual Pulmonary Disease Symposium, Carl W. Temple Symposium, FAMC, Aurora, CO, 20-21 January 1981. (C)

Danziger, R.E., Gilham, R., O'Barr, P.T. and Nelson, H.S.: The Effects of Aspirin (ASA) on Platelet Aggregation and Arachidonic Acid (AA) Metabolism in ASA-Sensitive (AS) Asthmatics. Presented: 37th Annual Congress, American College of Allergists, Washington, D.C., 4-8 April 1981. (C)

Fortner, B.R., Dantzler, B.S., Tipton, W.R. and Nelson, H.S.: Frequency of Immunotherapy. Presented: 37th Annual Congress, The American College of Allergists, Washington, D.C., 4-8 April 1981.(C)

Fortner, B.R.: Influence of Frequency of Immunotherapy on Skin Tests and Immunologic Parameters. Presented: 33rd Annual Pulmonary Disease Symposium, Carl W. Temple Symposium, FAMC, Aurora, CO, 20-21 January 1981. (C)

Fortner, B.R.: The Effect of Ascorbic Acid on Cutaneous and Nasal Response to Histamine and Allergens. Presented: 33rd Annual Pulmonary Disease Symposium, Carl W. Temple Symposium, FAMC, Aurora, CO, 20-21 January 1981.(C)

Fortner, B.R., Dantzler, F., Rabinowitz, P. and Nelson, H.S.: The Effect of Ascorbic Acid on Cutaneous and Nasal Response to Histamine and Allergen. Presented: 37th Annual Meeting, American Academy of Allergy, San Francisco, CA, 9-11 March 1981.(C)

Mansfield, L.E.: Immunoglobulin Levels and Oral Beta-adrenergic Therapy in Patients with Bronchial Asthma. Presented: 33rd Annual Pulmonary Disease Symposium, Carl W. Temple Symposium, FAMC, Aurora, CO, 20-21 January 1981.(C)

(C) Direct result of approved registered protocol.

Allergy Service - continued

Mansfield, L.E. and Nelson, H.S.: The Effect of Beta Adrenergic Agents and Prednisone on Serum Immunoglobulins and Complement Levels of Asthmatic Patients. Presented: 37th Annual Congress, American College of Allergists, Washington, D.C., 4-8 April 1981. (C)

Martin, B.G.: Allergen Content of House Dust. Presented: 33rd Annual Pulmonary Disease Symposium, Carl W. Temple Symposium, FAMC, Aurora, CO, 20-21 January 1981. (C)

Martin, B.G. and Nelson, H.S.: The Cross-allergenicity of Bahia Grass. Presented: 37th Annual Congress, American College of Allergists, Washington, D.C., 4-8 April 1981. (C)

Nelson, H.S.: Evaluation of Sensitivity, Reproducibility, Reliability of Different Methods in Skin Testing---Prick, Scratch, Intracutaneous, Multiple Punctures, etc. Presented: 37th Annual Congress, The American College of Allergists, Washington, D.C., 4-8 April 1981.

Nelson, H.S.: Immunotherapy in Allergic Disease. Presented: Allergy Update 1981, Walt Disney World, Orlando, FL, 24-27 January 1981.

Nelson, H.S.: Re-administration of Drugs to Patients with a History of a Previous Adverse Reaction. Presented: Annual Meeting, Oklahoma State Medical Society, Shangri-La Resort, Afton, OK, 7-10 May 1981.

Smith, J.A.: Experience with Troleandomycin in the Treatment of Bronchial Asthma. Presented: 33rd Annual Pulmonary Disease Symposium, Carl W. Temple Symposium, FAMC, Aurora, CO, 20-21 January 1981. (C)

Smith, J.A., Mansfield, L.E. and Nelson, H.S.: Troleandomycin (TAO) in the Outpatient Management of Severe Asthma. Presented: 37th Annual Meeting, American Academy of Allergy, San Francisco, CA, 9-11 March 1981. (C)

Tipton, W.R.: Experience with Daily Immunotherapy in 59 Allergic Patients. Presented: 33rd Annual Pulmonary Disease Symposium, Carl W. Temple Symposium, FAMC, Aurora, CO, 20-21 January 1981. (C)

Cardiology Service

Cookman, J.J., Davis, R.C., Williams, T.H.: Right Parasternal Two-dimensional Echocardiography in Disease of the Aortic Root. Presented: Association of Army Cardiology Meeting, Brooke Army Medical Center, San Antonio, TX, May 1981.

Trnka, K.E., Davis, R.C., Williams, T.H.: Ejection Fraction; Correlation with R Wave Amplitude. Presented: Association of Army Cardiology Meeting, Brooke Army Medical Center, San Antonio, TX, May 1981.

(C) Direct result of approved registered protocol.

Dermatology Service

Aeling, J.L.: Doctor My Hair is Falling Out. Presented: Fifth Army Medical Conference, FAMC, Aurora, CO, February 1981.

Grimwood, R.: Dermatitis Herpetiformis Localized to the Scrotum. Presented: Annual Meeting of the American Academy of Dermatology, New York, NY, December 1980.

May, D.L.: Lumps and Bumps That I Have Known. Presented: Regional Nurse Clinician Meeting, Colorado Springs, CO, 2 June 1981.

May, D.L.: Phakomatosis. Presented: Fifth Army Medical Rounds, FAMC, Aurora, CO, February, 1981.

May, D.L.: Ringworm and Other Annular Lesions. Presented: Regional Nurse Clinician Meeting, Colorado Springs, CO, 2 June 1981.

Patterson, J.W.: Bowenoid Papulosis. Presented: Clinicopathologic Conference, Sixth Annual Uniformed Services Seminar, National Naval Medical Center, Bethesda, MD, May 1981.

Patterson, J.W.: Bowenoid Papulosis with Particular Emphasis on the Clinicopathologic Features, Ultrastructure Studies, Etiology and Biology. Presented: Annual Meeting, Dermatopathology Club, Chicago, IL, 1 March 1981.

Patterson, J.W.: Cutaneous Manifestations of Gastrointestinal Disease. Presented: Fifth Army Medical Rounds, FAMC, Aurora, CO, February 1981.

Endocrinology Service

Georgitis, W.T.: Resolution of Recurrent Thyroid Cysts with Tetracycline Instillation. Presented: Military Endocrinologists' Meeting, Endocrine Society, Cincinnati, Ohio, 16 June 1981.

Hofeldt, F.D.: Blood Glucose Control: Is It Worth It? Presented: Recent Advances in Diabetic Management, Sponsored by Colorado Affiliate ADA, Denver, CO, 15 October 1980.

Hofeldt, F.D.: Moderator, Afternoon Session Colorado Diabetes Institute, Vail Seminar Center, Vail, CO, 2 March 1981.

Hofeldt, F.D.: Postmenopausal Osteoporosis. Presented: Third Regional Conference in Internal Medicine, FAMC, Aurora, CO, 11-13 February 1981.

Kidd, G.S.: Review of Pituitary Tumors. Presented: U.S. Army Regional Short Course in Internal Medicine. FAMC, Aurora, CO, February 1981.

(C) Direct result of approved registered protocol.

Gastroenterology Service

Brewer, T.G., Dunn, M.A., Berry, W.R. and Harmon, J.W.: Urea Synthesis Reflects Hepatic Mass in Rats. Presented: American Association for the Study of Liver Diseases, 31st Annual Meeting, Chicago, IL, 7 November 1980.

Hematology-Oncology Service

Zaloznik, A.J.: CML Experience at FAMC. Presented: Walter Reed Army Hematology-Oncology Meeting, Washington, D.C., February 1981.

Zaloznik, A.J.: CML Experience at FAMC. Presented: Rose Medical Center, Aurora, CO, May 1981.

Zaloznik, A.J.: TCN Intrapleural Instillation in Pleural Effusions. Presented: Walter Reed Army Hematology-Oncology Meeting, Washington, D.C., February 1981. (C)

Pulmonary Disease Service

Jones, P.: High Frequency Positive Pressure Ventilation. Presented: Carl E. Tempel Pulmonary Symposium, Denver, CO, January 1981.

Kindig, N.B.: $DLCO_{SS}$ Correction Using $PACO$ Back Pressure Predicted from Venous Blood. Presented: Carl E. Tempel Pulmonary Symposium, Denver, CO, January 1981. (C)

Perry, M.E.: Simplified Room Air $A-a O_2$ D Calculation. Presented: Carl E. Tempel Pulmonary Symposium, Denver, CO, January 1981. (C)

DEPARTMENT OF CLINICAL INVESTIGATION

Bobitt, J.R., Ford, C.L., Hayslip, C.C. and Damato, J.J.: Amniotic Fluid Infections in Premature Patients as Determined by Transabdominal Amniocentesis. Presented: 29th Annual Meeting of the American College of Obstetricians and Gynecologists, Las Vegas, Nevada, April 1981. (C)

Damato, J.J., Rothlauf, M.V., Collins, M.T., and McClatchy, J.K.: Detection of Mycobacteria Using Radiometric and Standard Plate Procedures. Poster presented: Annual Meeting of the American Society for Microbiology, Dallas, TX, March 1981. (C)

Damato, J.J., Rothlauf, M.V., Collins, M.T., and McClatchy, J.K.: Detection of Mycobacteria Using Radiometric and Standard Plate Procedures. Presented: Spring Meeting, Rocky Mountain Branch-American Society for Microbiology, Greeley, Colorado, April, 1981. (C)

(C) Direct result of approved registered protocol.

Department of Clinical Investigation - continued

Decker, W.J., Corby, D.G., Hilburn, R.E., Lynch, R.E.: Adsorption of Solvents by Activated Charcoal, Polymers, and Mineral Sorbents. Presented: Clinical Toxicology '81, Salt Lake City, Utah, August 1981. (C)

Decker, W.J., Corby, D.G., Shafik, H.M., Hilburn, R.E.: Sequestration of Iron by Magnesium Oxide. Presented: Clinical Toxicology '81, Salt Lake City, Utah, August 1981.(C)

Todd, J.K., Todd, N.S., Damato, J.J., and Todd, W.A.: Diagnosis and Treatment of Purulent Nasopharyngitis-A Double-Blind, Two-Drug Evaluation. Presented: Joint Meeting of the Society for Pediatric Research and American Pediatric Society, San Francisco, CA, April 1981.(C)

DEPARTMENT OF NURSING

DiGirol, M.T.: A Comparison of Consultation to the Pediatric Automated Military Outpatient: Systems Specialist (PAMOSIST) by the Pediatric Nurse Specialist and Physician in Fifty-two Patients. Presented: Phyllis J. Verhonick Research Symposium, Academy of Health Sciences, San Antonio, TX, 2 June 1981.

Ellis, C.: Ethics of Newborn ICU. Presented: Chautauqua Colorado Nurses' Association, Vail, CO, 11-12 July 1981.

Ellis, C.: High Risk Pregnancy. Presented: Chautauqua Colorado Nurses' Association, Vail, CO, 11-12 July 1981.

Ellis, C. and Turner, B.S.: The Incidence of Bacterial and/or Viral Infection in Premature Infants Following Initiation of a Sibling Visitation Policy in a NICU. Presented: Phyllis J. Verhonick Research Symposium, Academy of Health Sciences, San Antonio, TX, 2 June 1981.(C)

Krimball, C.J.: A Unique Educational Outreach Program for Nurses Working in Outlying Referring Hospitals. Presented: Sixth Annual Conference of District VIII of American Academy of Pediatrics, 4 June 1981.

DEPARTMENT OF OB-GYN

Hayslip, C.C.: Amniotic Fluid Infection in Patients with Premature Labor and Intact Membranes, as Detected by Amniocentesis. Presented: AFD-ACOG Meeting, Orlando, FL, October 1980.(C)

Howard, F.M.: A Case Report of Ovarian Serous Cystadenocarcinoma Presenting with Psammoma Bodies in the Cervical Smear. Presented: AFD-ACOG Meeting, Orlando, FL, October 1980.

(C) Direct result of approved registered protocol.

Department of OB-GYN - continued

Howard, F.M.: The Relationship of Paracervical Block Bradycardia to the Technique of Administration. Presented: AFD-COG Meeting, Orlando, FL, October 1980.

Lundblad, E.G.: Maternal/Infant Bonding in Primates. Presented: AFD-ACOG Meeting, Orlando, FL, October 1980.

Mancuso, J.J.: The Effect of Suction Drainage on Postop C-Section Infectious Morbidity. Presented: AFD-ACOG Meeting, Orlando, FL, October 1980. (C)

Phillips, G.L., Jr.: Visceral Recurrence of Adenocarcinoma of the Endometrium. Presented: Society of Gynecologic Oncologists, Marco Island, FL, January 1981.

Phillips, G.L., Jr.: Vulvar Melanoma: A Microstaging Study. Presented: Western Association of Gynecologic Oncology, Napa, CA, May 1981.

Shirts, S.R.: Prospective Study of the Effect of Unopposed Exogenous Estrogen in Postmenopausal Women: A Preliminary Report. Presented: AFD-ACOG Meeting, Orlando, FL, October 1980. (C)

DEPARTMENT OF PEDIATRICS

Allen, W.R., Brouhard, B.H., Lynch, R.E.: The Proximal Tubular Effect of *Diazoxide*. Presented: Fifth International Pediatric Nephrology Symposium, Philadelphia, PA, October 1980.

Allen, W.R., Lynch, R.E.: Proximal Tubular Effect of *Diazoxide* on the Dog. Presented: Tri Service's MTN, San Antonio, TX (Bruton Award), 1981.

Allen, W.R., Travis, L.B., Cavallo, T.: Immunodeposits in Minimal Change Nephrotic Syndrome: Clinical Relevance. Presented: Society for Pediatric Research, San Antonio, TX, 1981.

Bryant, M.: Apnea, Sudden Infant Death, Acute Respiratory Failure in Children, X-ray Diagnosis of Pulmonary Disease. Presented: Visiting Consultant Pulmonary Disease, Department of Pediatrics, William Beaumont Army Medical Center, El Paso, TX, 17-18 April 1981.

Bryant, M.: Medical Consultant, Symposium on Reye's Syndrome - a Nursing Perspective. Presented: Pathophysiology and Medical Management, April 1981.

(C) Direct result of approved registered protocol.

Department of Pediatrics - continued

Frank, C.G., Weisman, L.E., Golden, S. and Merenstein, G.B.: Relationship of Patent Ductus Arteriosus in Neonatal Necrotizing Enterocolitis. Presented: Sixth Annual Conference on Perinatal/Neonatal Medicine District VIII, Coeur D'Alene, Idaho, June 1981.

Gumbiner, C., Shih, J., Gillette, P.: Atrial Flutter in Children. Presented: Association of Army Cardiologists, San Antonio, TX, May 1981.

Herrera, A., Weisman, L.E. and Merenstein, G.B.: Relationship of Polycythemia, Exchange Transfusions, and Umbilical Venous Catheters with Neonatal Necrotizing Enterocolitis. Presented: Sixth Annual Conference on Perinatal/Neonatal Medicine District VIII, Coeur D'Alene, Idaho, June 1981.

Merenstein, G.B.: Colorado Perinatal Care Council: A Model for Perinatal Planning. Presented: Sixth Annual Conference on Perinatal/Neonatal Medicine District VIII, Coeur D'Alene, Idaho, June 1981.

Merenstein, G.B.: The Spectrum of Group B-Beta Hemolytic Streptococcus Infection in the Neonate. Presented: Sixteenth Annual Uniformed Services Pediatric Seminar, San Antonio, TX, February 1981.

Merenstein, G.B.: Neonatal Transport: Experience at Fitzsimons Army Medical Center. Presented: Sixteenth Annual Uniformed Services Pediatric Seminar, San Antonio, TX, March 1981.

Merenstein, G.B.: The Spectrum of Group B-Beta Hemolytic Streptococcus Infection in the Neonate. Presented: Memorial Hospital, Colorado Springs, CO, February 1981. (C)

Mosijczuk, A.D.: Workshop on Iron Deficiency. University of Colorado Pediatric Hematology/Oncology Seminar, Aspen, CO, 23-27 February 1981.

Pierce, J.R. and Merenstein, G.B.: Results of Agonal Blood and Spinal Fluid Cultures in an Intensive Care Nursery. Presented: Sixth Annual Conference on Perinatal/Neonatal Medicine District VIII, Coeur D'Alene, Idaho, June 1981.

Sanders, J.M.: Planning a Successful Adolescent Program. Presented: Denver Conference on Adolescence, Denver, Colorado, March 1981.

Sanders, J.M.: Teens, Booze and Pot: What Can or Should be Done? Presented: Denver Children's Hospital Sponsored Controversies in Pediatrics Series, Denver, CO, June 1981.

(C) Direct result of approved registered protocol.

Department of Pediatrics - continued

Sanders, J.M.: The Teenager in the Military Family. Presented: Plenary Session Speaker, Uniformed Services Pediatric Seminar, San Antonio, TX, March 1981.

Sanders, J.M.: Vaginitis and Sexually Transmitted Disease, Approach to the Adolescent and Dysmenorrhea and Amenorrhea. Presented: Member of Faculty at a three day seminar sponsored by the University of Tennessee Health Sciences Center, Gatlinberg, Tennessee, June 1981.

Stalker, H.P., Gumbiner, C.H., Pierce, J.R., and Merenstein, G.B.: Significance of Absent SV₁ in Healthy, Term Infants at 5,280 Feet. Presented: Sixth Annual Conference on Perinatal/Neonatal Medicine District VIII, Coeur D'Alene, Idaho, June 1981. (C)

Steenbarger, J.R. and Merenstein, G.B.: Perinatal Relapsing Fever. Presented: Sixth Annual Conference on Perinatal/Neonatal Medicine District VIII, Coeur D'Alene, Idaho, June 1981.

Steenbarger, J.R. and Pierce, J.R.: Congenital Tick-borne Relapsing Fever: Report of a Case with First Documentation of Transplacental Transmission. Presented: 1981 Birth Defects Conference sponsored by March of Dimes, San Diego, CA, June 1981.

Weisman, L.E.: Human Colostral T-Lymphocytes. Presented: Aspen Conference on Perinatal Research, Aspen, CO, July 1981. (C)

Weisman, L.E., Brown, G., Rangel, F., and Merenstein, G.B.: Mitogen Induced Lymphoproliferative Response in Human Colostrum T-Lymphocytes are Hyporeactive. Presented: Western Society for Pediatric Research, Carmel, CA, February 1981. (C)

Weisman, L.E., Cagle, N., Mathis, R., and Merenstein, G.B.: Clinical Estimation of Liver Size in Normal Neonates. Presented: Sixth Annual Conference on Perinatal/Neonatal Medicine District VIII, Coeur D'Alene, Idaho, June 1981.

Weisman, L.E., Golden, S., Todd, W.A., and Merenstein, G.B.: Failure of Oral Antibiotic Therapy to Eliminate Epidemic *Klebsiella Pneumoniae* Colonization and Disease in an NICU. Presented: Sixth Annual Conference on Perinatal/Neonatal Medicine District VIII, Coeur D'Alene, Idaho, June 1981.

Weisman, L.E. and Merenstein, G.B.: Relationship of Polycythemia, Exchange Transfusion and Umbilical Venous Catheters with Neonatal Necrotizing Enterocolitis. Presented: Society of Pediatric Research, San Francisco, CA, April 1981.

(C) Direct result of approved registered protocol.

Department of Pediatrics - continued

Weisman, L.E., Smazal, S.F., and Shirts, S.: Comparative Analysis of Fetal Gestational Age and Size Assessment Methods. Presented: Aspen Conference on Military Perinatal Research, Aspen, CO, July 1981. (C)

Wells, D.W.: Early Sexual Experience and Teenage Pregnancy. Presented: Denver Conference on Adolescence, Denver, CO, March 1981.

DEPARTMENT OF RADIOLOGY

Campbell, J.C.: Cushings Syndrome in Infancy. Presented: John Caffey Society Meeting, Carmel, CA, 16 March 1981.

Campbell, J.C.: Diagnostic Imaging in Pediatric Oncology. Presented: Annual Course in Pediatric Disease, Aspen, CO, 9-11 August 1981.

Campbell, J.C.: Emergency Room Pediatric Radiology. Presented: University of Colorado Family Practice Review Course, Denver, CO, 23 February 1981.

Campbell, J.C.: Esophageal Foreign Bodies in Children. Presented: Pediatric Radiology Post Graduate Course, Vail, CO, 23 February 1981.

Campbell, J.C.: Melorheostosis. Presented: John Caffey Society Meeting, Carmel, CA, 18 March 1981.

Campbell, J.C.: Neonatal Cranial Ultrasonography. Presented: Eastern Radiology Society Meeting, Mid Pines, North Carolina, 27 April 1981.

Campbell, J.C.: Non-operative Removal of Esophageal Foreign Bodies. Presented: Society for Pediatric Radiology, San Francisco, CA, 22 March 1981.

Campbell, J.C.: Exhibit: Pediatric Radiology Case of the Day. Presented: Rocky Mountain Radiological Society Meeting, Denver, CO, 19-22 August 1981.

Everhart, F.R.: Preoperative Embolization of Meningiomas. Presented: Western Neuroradiologic Society Meeting, San Diego, CA, 16 October 1980.

Hopper, K.D., Ghaed, N.: CT and Sonographic Diagnosis of Rectus Sheath Hematoma. Presented: Rocky Mountain Radiologic Society, Denver, CO, August 1981.

Smazal, F.C.: Growth-adjusted Sonographic Age Determination. Presented: Rocky Mountain Radiologic Society, Denver, CO, August 1981. (C)

Williams, B.D.: Sonographic Diagnosis of Plexiform Neurofibromatosis of the Bladder. Presented: Rocky Mountain Radiological Society Meeting, Denver, CO, August 1981.

(C) Direct result of approved registered protocol.

DEPARTMENT OF SURGERY

Anesthesia and Operative Service

Bernier, B.: Comparative Cardiovascular Hemodynamics of Isoflurane. Presented: Denver General Hospital, Annual Anesthesia Update, Denver, CO, May 1981.

Bernier, B.: Pharmacology and Physical Characteristics of Isoflurane. Presented: Colorado Association of Nurse Anesthetists, Annual Meeting, Denver, CO, March 1981.

General Surgery Service

Ferraris, V.A.: Oral Cholecystography and Ultrasonography in Diagnosis of Acute Cholecystitis. Presented: William Beaumont Symposium, El Paso, TX, March 1981.

Ophthalmology Service

Cottingham, A.J., Jr.: Corneal and External Disease. Presented: Letterman Army Medical Center, Presidio of San Francisco, CA, March 1981.

Cottingham, A.J., Jr.: Fungal Corneal Ulcers, Bacterial Corneal Ulcers Endophthalmitis. Presented: University of Colorado, Boulder, CO December 1980.

Cottingham, A.J., Jr.: Ocular Trauma. Presented: Gary P. Wratten Symposium. San Antonio, TX, April 1981.

Cottingham, A.J., Jr.: Residual Astigmatism Following Keratoplasty. Presented: American Academy of Ophthalmology, Chicago, IL, November 1980.(C)

Cottingham, A.J., Jr.: Residual Astigmatism Following Keratoplasty. Presented: Biennial Walter Reed Ophthalmology Postgraduate, Baltimore, MD, April 1981.(C)

Steahly, L.P.: Primary vs Secondary Vitrectomy in Severe Ocular Trauma. Presented: John Hopkins University, Baltimore, MD, April 1981.

Steahly, L.P.: Vitreous Lecture Series (8). Presented: University of Colorado Health Sciences Center, Denver, CO, May and June 1981. The eight lectures presented are as follows: Argon laser photocoagulation in diabetic retinopathy; Diabetic retinopathy; Retinal detachment; Retinal detachment using vitrectomy techniques; Vitreous anatomy; Vitrectomy and ocular trauma; Vitrectomy in diabetic retinopathy; and Vitreous physiology/biochemistry.

(C) Direct result of approved registered protocol.

Department of Surgery - continued

Orthopedic Service

Coville, F.V.: Joint Infection. Presented: Ninth Annual Symposium of Children's Orthopedics. Presented: Fitzsimons Army Medical Center, Aurora, CO, January 1981.

Coville, F.V.: Lower Extremity Bracing. Presented: Symposium on Spinal Upper and Lower Extremity Orthotics and Prosthetics, Fitzsimons Army Medical Center, Aurora, CO, May 1981.

Eversmann, W.W.: The Radiographic Evaluation of Vascular Lesions of the Upper Extremity. Presented: Raymond M. Curtis Hand Surgery Seminar, Walter Reed Army Medical Center, Washington, D.C., October 1980.

Eversmann, W.W.: Congenital Hand Deformity. Presented: Ninth Annual Symposium of Children's Orthopedics, Fitzsimons Army Medical Center, Aurora, CO, January 1981.

Eversmann, W.W.: Symposium on Nerve Entrapment in the Upper Extremity. Presented: American Society for Surgery of the Hand 26th Annual Meeting, Las Vegas, Nevada, February 1981.

Eversmann, W.W.: Extensor Tendon Injuries in the Hand. Presented: U.S. Army Gorgas Hospital, Republic of Panama, April 1981.

Eversmann, W.W.: Compression Neuropathies of the Upper Extremity. Presented: U.S. Army Gorgas Hospital, Republic of Panama, April 1981.

Eversmann, W.W.: Infections of the Hand. Presented: U.S. Army Gorgas Hospital, Republic of Panama, April 1981.

Eversmann, W.W.: Congenital Deformities of the Hand. Presented: U.S. Army Gorgas Hospital, Republic of Panama, April 1981.

Eversmann, W.W.: Evaluation of Injuries of the Hand. Presented: U.S. Army Gorgas Hospital, Republic of Panama, April 1981.

Eversmann, W.W.: Radiographic Evaluation of Upper Extremity Lesions. Presented: University of Panama, Republic of Panama, April 1981.

Eversmann, W.W.: Compression Neuropathies of the Upper Extremity. Presented: University of Miami School of Medicine, Department of Orthopedics and Rehabilitation, Miami, Florida, April 1981.

Eversmann, W.W.: Compression Neuropathies of the Ulnar Nerve. Presented: University of Colorado Health Sciences Center Hand Surgery Seminar, Denver, CO, May 1981.

(C) Direct result of approved registered protocol.

Orthopedic Service - continued

Eversmann, W.W.: Evaluation of the Above Knee Prosthesis. Presented: Symposium on Spinal, Upper and Lower Extremity Orthotics and Prosthetics, Fitzsimons Army Medical Center, Aurora, CO, May 1981.

Eversmann, W.W.: Radiographic Evaluation of Upper Extremity Lesions. Presented: Rocky Mountain Chapter Western Orthopedic Association Scientific Meeting, Steamboat Springs, CO, June 1981.

Eversmann, W.W.: Extensor Tendon Injuries in the Hand. Presented: International Symposium of Hand Surgery, Keystone, CO, July 1981.

Eversmann, W.W.: Fingertip Injuries. Presented: University of Colorado Orthopedic Practice for the Family Practitioner, Aspen, CO, August 1981.

Eversmann, W.W.: Soft Tissue Problems of the Hand. Presented: University of Colorado Orthopedic Practice for the Family Practitioner, Aspen, CO, August 1981.

Eversmann, W.W.: Fractures of the Forearm and Wrist. Presented: University of Colorado Orthopedic Practice for the Family Practitioner, Aspen, CO, August 1981.

Fry, T.G.: The Antibiotic Treatment of the Acute Hemotogenous Osteomyelitis in Children. Presented: Symposium Denver Children's Hospital, Denver, CO, April 1981.

Glancy, G.L.: Overuse Syndromes. Presented: Ninth Annual Symposium of Children's Orthopedics, Fitzsimons Army Medical Center, Aurora, CO, January 1981.

Glancy, G.L.: Foot Deformities in Children. Presented: American Orthopedic Foot Society, Ind. Annual Meeting, Las Vegas, Nevada, February 1981.

Glancy, G.L.: X-rays and the TLSO. Presented: Symposium on Spinal, Upper and Lower Extremity Orthotics and Prosthetics, Fitzsimons Army Medical Center, Aurora, CO, May 1981.

Goldberg, B.: Fractures of the Cervical Spine in Children. Presented: Ninth Annual Symposium of Children's Orthopedics, Fitzsimons Army Medical Center, Aurora, CO, January 1981.

Goldberg, B.: Treatment of Low Back Pain and Spinal Stenosis. Presented: Low Back Pain Symposium, Fitzsimons Army Medical Center, Aurora, CO, March 1981.

Goldberg, B.: Treatment of the Failed Back. Presented: Low Back Pain Symposium, Fitzsimons Army Medical Center, Aurora, CO, March 1981.

(C) Direct result of approved registered protocol.

Orthopedic Service - continued

Goldberg, B.: Treatment of Low Back Pain. Presented: St. Joseph's Hospital, Denver, CO, April 1981.

Goldberg, B.: Time Frame for Fitting the Juvenile Amputee. Presented: Symposium on Spinal Upper and Lower Extremity Orthotics and Prosthetics, Fitzsimons Army Medical Center, Aurora, CO, May 1981.

Goldberg, B.: Treatment of Low Back Pain. Presented: University of Colorado Family Practice Symposium, Estes Park, CO, June 1981.

Goldberg, B.: Treatment of Spine Fractures. Presented: University of Colorado Family Practice Symposium, Estes Park, CO, June 1981.

Goldberg, B.: Corns, Bunions and Nails. Presented: University of Colorado Orthopedic Practice for the Family Practitioner, Aspen, CO, August 1981.

Goldberg, B.: Common Dislocations. Presented: University of Colorado Orthopedic Practice for the Family Practitioner, Aspen, CO, August 1981.

Hopkinson, W.J.: Treatment of Ulnar Palsy by Neurolysis. Presented: Society of Military Orthopedic Surgeons Meeting, San Antonio, TX, November 1981.

Otolaryngology Service

Hasbrouck, J.M.: Prospects and Procedures for the Remediation of Auditory Processing Disorders. Presented: Conference on Auditory Processing: A Multi-discipline Approach, Denver, CO, March 1981.

Scharfenaker, S.K. and Hasbrouck, J.M.: The Speech Characteristics of Children Post Reye's Syndrome. Presented: Joint Annual Meeting of National Reye's Syndrome Foundation and American Reye's Syndrome Foundation, Vail, CO, June 1981. (C)

Woody, E.A.: The Role of C-T Scanning in Pre-operative Assessment of Congenital Choanal Atresia: A Preliminary Report. Presented: Pacific Coast Oto-Ophthalmological Society, Salt Lake City, UT, 8 June 1981.

Plastic Surgery Service

Rich, J.D.: Breast Reconstruction Utilizing Flap Transposition. Refinements in Lateral Wedge Mastopexy. Current Concepts in Facial Reanimation. Presented: Rocky Mountain Association of Plastic and Reconstructive Surgeons, Bozeman, Montana, February 1981.

(C) Direct result of approved registered protocol.

Department of Surgery - continued

Thoracic Surgery Service

Clarke, J.S.: Repair of Acquired Tracheoesophageal Fistulae - a New Approach. Presented: Gary Wratten Symposium at Brooke Army Medical Center, San Antonio, TX, April 1981.

Walker, O.M.: Chest Trauma. Presented: Fort Carson Army Hospital, Fort Carson, Colorado, 29 April 1981.

Walker, O.M., Pauling, F.W.: The Intraaortic Balloon Pump: An Analysis of Six Years' Experience at Fitzsimons Army Medical Center. Presented: Brooke Army Medical Center, San Antonio, TX, May 1981.

Urology Service

Fauver, H.E.: Unilateral Absence of the Vas - A Useful Clinical Sign. Presented: 28th Annual Kimbrough Urological Seminar, San Francisco, CA, November 1980.

Horne, D.W.: Acute Bleomycin Toxicity. Presented: 28th Annual Kimbrough Urological Seminar, San Francisco, CA, November 1980.

Vaccaro, J.A.: Microscopic Vasovasostomy - The Fitzsimons Experience. Presented: 28th Annual Kimbrough Urological Seminar, San Francisco, CA, November 1980. (C)

(C) Direct result of approved registered protocol.

EXPLANATION of ANNUAL PROGRESS REPORT DETAIL SHEETS

- (1) DATE: Fiscal Year ending date.
- (2) PROTOCOL NO: FAMC Work Unit Number of the study.
- (3) STATUS: Indicates if the study is Ongoing, Completed or Terminated.
- (4) TITLE: Project title of the study.
- (5) START DATE: The date the study started.
- (6) ESTIMATED COMPLETION DATE: The projected completion date of the study.
- (7) PRINCIPAL INVESTIGATOR(s): List of all Principal Investigator(s)
involved in the study.
- (8) FACILITY: Fitzsimons Army Medical Center
- (9) DEPARTMENT/SECTION: Department or Service the protocol originated from.
- (10) ASSOCIATE INVESTIGATOR(s): List of all Associate Investigator(s)
involved in the study.
- (11) KEY WORDS: Key words pertaining to the particular area of research
involved in the study.
- (12) ACCUMULATIVE MEDCASE COST: See Unit Summary Sheet - Funding.
- (13) ESTIMATED ACCUMULATIVE OMA COST: See Unit Summary Sheet - Funding
- (14) PERIODIC REVIEW RESULTS: Date of the continuing review by the
Institution Review Committee.
- (15) STUDY OBJECTIVE: A summary of objectives to be accomplished during
the study.
- (16) TECHNICAL APPROACH: A brief summary of the technical approach to be taken
during the study.
- (17) PROGRESS: A summary of prior and current progress since inception of
of the study.

The Continuation Sheets are used as extensions for (1) - (17) and as an accumulative listing for Publications and Presentations that are a direct result from the study.

The Detail Sheets were submitted in final form by the Principal Investigators and have not been edited.

DETAIL SUMMARY SHEETS

MEDICINE

029

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 73/135 (3) Status: on-going
(4) Title:

Active Antigens in House Dust

(5) Start Date: 1973	(6) Est Comp Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: Lyndon E. Mansfield, MD, LTC, MC Bruce Martin, MD, CPT, MC, USAF
(11) Key Words: House dust	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 6/81 Review Results: Ongoing	

(15) Study Objective:

to determine to what degree the reactivity of commercial house dust extract is related to its content of recognized allergens such as animal dander and mite products.

(16) Technical Approach:

Use of pooled house dust allergic serum and RAST inhibition employing allergen disks manufactured in the allergy research laboratory.

(17) Progress:

Additional RAST inhibition studies were performed during this year, and it is likely that no further laboratory work will be required under this protocol. One publication has been submitted to the Journal of Allergy and Clinical Immunology. A second abstract is under preparation for presentation at a national medical meeting this winter.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 73/135

SERVICE Allergy-Immunology

DEPARTMENT Medicine

1. Mansfield, LE, Nelson, HS: Allergens of Commercial House Dust Extracts (Abst.) Journal of Allergy and Clinical Immunology 63:212;1979.

PRESENTATIONS for FY 81 Annual Progress Report

1. Mansfield, L.E.: Allergens of Commercial House Dust Extracts. Presented: Annual Meeting, Academy of Allergy, New Orleans, LA, 25 March 1979.
2. Martin, Bruce: Analysis of the Allergens of Commercial House Dust. Presented: Annual Allergy-Immunology Pulmonary Symposium, Fitzsimons Army Medical Center, Aurora, CO, 21 January 1981.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 74/101 (3) Status: Completed
(4) Title: Immuno-chemical Evaluation of Myeloproliferative and Plasmaproliferative Diseases.

(5) Start Date: 1 Jul 74	(6) Est Comp Date: Oct 81
(7) Principal Investigator: Nicholas J. DiBella, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Hematology	(10) Assoc Investigators: G.L. Brown, Ph.D., COL, MSC R. S. Whiteaker, Ph.D., CPT, MSC
(11) Key Words: immunodiagnosis myeloproliferative plasmaproliferative	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
	(14) Date of Review: 1/81 Review Results: Ongoing

(15) Study Objective: To determine whether there are any alterations of serum protein profiles in myeloproliferative and plasmaproliferative disease. To determine whether there are any alterations of serum protein profiles and lymphocyte transformation in myeloproliferative and plasmaproliferative diseases.

(16) Technical Approach: This is in-depth immunologic evaluation of patients with myeloproliferative and plasmaproliferative disorders.

(17) Progress: One patient with myeloproliferative and 13 with plasmaproliferative disorders were studied immunologically. I) Myeloproliferative Disorders: Results recorded were as follows: no monoclonal gammopathies; serum immunoglobulin levels within normal limits; lymphocyte transformation to PHA was suppressed. II) Plasmaproliferative Disorders: results recorded were as follows: five subjects studied had IgG monoclonal gammopathies with evidence of free light chains in the serum. Two patients were found to have elevated serum IgM levels with monoclonal gammopathies, differentiated as IgM type.

SERVICE Hematology-OncologyDEPARTMENT of Medicine

- (1) Brown, G.L., DiBella, N.J., and Corby, D.G.: IgE-IgM Kappa Gammopathy Associated with Lymphocytic Lymphoma. Federation Proceedings 35:438, 1976.
- (2) Brown, G.L., Corby, D.G., DiBella, N., and Lima, J.: IgE-IgM Gammopathy Associated with Lymphocytic Lymphoma: Immunologic Considerations. Mil Med 142:921, 1977.
- (3) DiBella, N.J., and Brown, G.L.: Immunologic Dysfunction in the Myeloproliferative Disorders. Cancer 42:149, 1978.

PRESENTATIONS:

- (1) DiBella, N.J., and Brown, G.L.: Cellular and Humoral Immunity in the Myeloproliferative Disorders. Presented: Annual Joint Meeting of the American College of Physicians and American Society of Internal Medicine, Colorado Regional Meeting, Colorado Springs, CO, January 15, 1976.
- (2) Brown, G.L., DiBella, N.J., and Corby, D.G.: IgE-IgM Kappa Gammopathy Associated with Lymphocytic Lymphoma. Presented: FASER, Anaheim, CA, April 12, 1976.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81		(2) Prot No.: 74/110	(3) Status: Ongoing
(4) Title: Reactive Hypoglycemia: An Analysis of Glucose-Insulin-Glucagon Interrelationships and Counter Hormonal Regulatory Factors			
(5) Start Date: FY71		(6) Est Comp Date: Indefinite	
(7) Principal Investigator: Fred D. Hofeldt, MD, COL, MC		(8) Facility: FAMC	
(9) Dept/Sec: Medicine/Endocrine		(10) Assoc Investigators: Gerald S. Kidd, LTC, MC David Zolock, MAJ, MS T.P. O'Barr, Ph.D., DAC Leonard B. Sanders, MD, MAJ, MC, WBAMC Annelie Shackelford, MT, DAC	
(11) Key Words: reactive hypoglycemia glucose tolerance counter-regulatory hormones		(12) Accumulative MEDCASE:*	
(13) Est Accumulative OMA Cost:*		(14) Date of Review: 11/80 Review Results: Ongoing	

*Refer to Unit Summary Sheet of this report.

(15) Study Objective: The objectives of the hypoglycemic study is to continue to investigate in our large clinic population the glucose-insulin-glucagon and prolactin interrelationships and the response of counter-regulatory hormones to hypoglycemic stress. This project is a continuation of the previous project initiated in 1969 at the University of California Medical Center, Moffatt Hospital, San Francisco, California.

(16) Technical Approach: The clinical research protocol involves evaluation of control subjects and hypoglycemic patients to assess the interrelationships of beta cell and alpha cell responsiveness to oral and intravenous glucose administration. Based upon findings in controls and patients with disease states, a classification system has been proposed. The data have allowed for an understanding of the basic pathophysiology of reactive hypoglycemia disorders. The clinical studies are being conducted in the Department of Medicine, Endocrine Clinic, with the assistance of an assigned GS-5 Med Tech to perform blood sampling and assist during the testing. During the glucose tolerance test the patient has an indwelling catheter for frequent sampling of blood glucose, and is continually monitored by a cardiac monitor system and blood glucoses are assessed by the Ames Reflectance Meter immediately after sampling. After glucose administration, blood insulins, glucagons, growth hormones, prolactins and cortisols are sampled and values are determined by a sensitive radioimmunoassay. The procedure is designed to provide a minimum of patient inconvenience in the performance of these well standardized procedures. Many normal individuals experience a low blood sugar state sometime after glucose administration, the clinical significance of a low blood glucose state is observed by recording appropriate adrenergic symptoms at the nadir of the glucose and determining if

(16) Technical Approach (cont)

there is a counter hormonal responsiveness to defend the stress of a low blood glucose state. This approach allows strict definition of bona fide reactive hypoglycemia and clearly distinguishes it from the benign low blood glucose states.

(17) Progress: This study continues as an active endocrine protocol with recruitment of 10 to 15 new patients per year for evaluation and study of bonafide hypoglycemia. The patients currently studied in this protocol have the data stored on the MISO computers at FAMC, and William Beaumont Army Medical Center. The data analysis will be conducted by MAJ Leonard R. Sanders at WBAMC. The study is an active and continued endocrine research protocol. It is hoped that by enlisting the active participation of Department of Clinical Investigation staff that a gastric inhibitory polypeptide assay could be established to determine if alterations in this hormonal substance can be implicated in the hyperinsulinism seen in some of the disorders of reactive hypoglycemia.

SERVICE EndocrineDEPARTMENT Medicine

- (1) Abrams, R., Hofeldt, F.D., Adler, R., O'Barr, T.P., and Morse, P.: Late Reactive Hypoglycemia in Hypothyroidism. (Submitted for review to American Journal of Medical Sciences.)
- (2) Charles, M.A., Hofeldt, F.D., Dodson, L.E., Shackelford, A., Waldeck, N., Bunker, D., Coggins, J.T., and Eichner, H.: Comparison of Glucose Tolerance Tests and Mixed Meals in Patients With Idiopathic Reactive Hypoglycemia: Absence of Hypoglycemia After Mixed Meals. Diabetes 30: 465-470, 1981.
- (3) Sanders, L.R., Hofeldt, F.D., Kirk, M., and Levin, J.: Food Abuse as a Cause of Reactive Hypoglycemia. (Submitted to Southern Medical Journal).
- (4) Hofeldt, F.D.: Transitional Low Blood Glucose States. Rocky Mountain Medical Journal 76:30-34, 1979.
- (5) McCowen, K.D., Adler, R.A., O'Barr, T.P., and Hofeldt, F.D.: Clinical Implications of Flat Oral Glucose Tolerance Test. Military Medicine 144:177-179, 1979.

PRESENTATIONS:

- (1) Hofeldt, F.D.: Reactive Hypoglycemia: Update 1980. Presented: Endocrine Grand Rounds, University of Colorado Health Sciences Center, Denver, CO, 16 January 1980.
- (2) Sanders, L.R.: Reactive Hypoglycemia. Presented: Grand Rounds, University of Colorado Medical Center, Denver, CO, 13 March 1979.
- (3) Sanders, L.R.: Reactive Hypoglycemia. Presented: Medical Grand Rounds, Denver General Hospital, Denver, CO, 15 March 1979.
- (4) Sanders, L.R.: Reactive Hypoglycemia. Presented: Endocrine Grand Rounds, University of Colorado Medical Center, Denver, CO, 11 April 1979.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 75/107 (3) Status: completed
(4) Title: A Comparison of the Results of Hyposensitization with Aqueous Grass Extract and Alluminum Precipitated Aqueous Extracted Grass Extract in the Treatment of Patients with Allergic Symptoms Due to Grass Allergy

(5) Start Date: 1975	(6) Est Comp Date: 1980
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators:
(11) Key Words: allergy immunotherapy	none

(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 2/81
*Refer to Unit Summary Sheet of this report.		Review Results: Ongoing

(15) Study Objective:
to compare the immunologic response to long-term immunotherapy with aqueous and aluminum precipitated allergy extracts.

(16) Technical approach:
Monitoring the clinical tolerants for the extracts drawing blood twice annually over a period of four years and measuring the immune response by both specific IgE and IgG antibody assays.

(17) Progress: completed

SERVICE Allergy-Immunology

DEPARTMENT Medicine

1. Nelson, H.S.: A Three-year Comparison of Immunotherapy with Alum Precipitated and Glycero-saline Grass Extracts. (Abst) Annals of Allergy 42:123, 1979.
2. Nelson, H.S.: Long-term Immunotherapy with Aqueous and Alum Precipitated Grass Extracts. Annals of Allergy 45:333, 1980.

PRESENTATIONS for FY 81 Annual Progress Report

1. Nelson, H.S.: A Three-year Comparison of Immunotherapy with Alum Precipitated and Glycero-saline Grass Extracts. Presented: Annual Meeting of American College of Allergists, San Francisco, CA, 29 Jan 79.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 75/116 (3) Status: terminated
(4) Title: Fractionation of Kochia Pollen with Isolation of Kochia Pollen Allergens

(5) Start Date: 1975	(6) Est Comp Date: unknown
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators:
(11) Key Words: purified kochia allergens	T.P. O'Barr, PhD, DAC
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 12/80 Review Results: Ongoing	

(15) Study Objective:
to extract raw Kochia pollen and purify the principle allergens through chemical fractionation.

(16) Technical Approach:
The study will employ multiple methods of separation of proteins with investigation of allergenic activity of the fractions by RAST assay.

(17) Progress: There has been no activity on this protocol since the transfer of the original principal investigator. It should, therefore, be terminated.

PUBLICATIONS AND PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 76/102 (3) Status: Ongoing
(4) Title: Anti-neoplastic Therapy with Methyl CCNU (NSC95441)/1-(2-Chloroethyl)-3-(4-Methyl Cyclohexyl) - 1-Nitrosourea

(5) Start Date: 1976	(6) Est Comp Date: 1982
(7) Principal Investigator: N.J. DiBella, M.D., COL, MC	(8) Facility: FAMC FAMC
(9) Dept/Sec: Hem/Onc	(10) Assoc Investigators:
(11) Key Words: Chemotherapy, CA of colon	
(12) Accumulative MEDCASE: * *Refer to Unit Summary Sheet of this report.	(13) Est Accumulative OMA Cost: * (14) Date of Review: 10/80 Review Results: Ongoing

(15) Study Objective:
To test the efficacy of methyl CCNU in metastatic or recurrent CA of the colon.

(16) Technical Approach:
Clinical study.

(17) Progress:
One patient was begun on this agent in combination with 5-FU. He has had only one cycle of therapy which he has tolerated without ill-effects, but it is too early to determine response at this time.

Publications and Presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 76/116 (3) Status: Ongoing
(4) Title:
The Effect of Dexamethasone on Gonadotropins in Post-menopausal Women

(5) Start Date: 1976	(6) Est Comp Date: 1982
(7) Principal Investigator: Michael Bornemann, MD, LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Endocrine Service	(10) Assoc Investigators: William J. Georgitis, MD, MAJ, MC Gary L. Treece, MD, LTC, MC Fred D. Hofeldt, MD, COL, MC
(11) Key Words: women post-menopausal Dexamethasone gonadotropins	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
	(14) Date of Review: 12/80 Review Results: Ongoing

(15) Study Objective: To clarify the mechanisms whereby glucocorticoids may interfere with gonadotropin secretion or release in post-menopausal women. This is of interest because of the high frequency of gonadal dysfunction in both male and female patients with endogenous as well as exogenous Cushing's syndrome.

(16) Technical Approach: Patient population to be studied are healthy, post-menopausal women on no medication. A post-menopausal woman will be defined as any woman with elevated pl-sma gonadotropin levels as a result of physiological ovarian failure or prior surgical extirpation of the ovaries. A baseline 0800 plasma FSH, LH, cortisol and prolactin level will be drawn on two consecutive days prior to the subjects taking 2 mg qid po of Dexamethasone on three consecutive days. A.M. FSH, LH, cortisol and prolactin levels will be obtained daily during the Dexamethasone treatment. In order to define the site of the anticipated Dexamethasone suppression of the gonadotropins a GNRH infusion test will be performed by giving a single IV bolus of 100 ug of GNRH on the day prior to, and on the third day of Dexamethasone treatment. Blood for FSH, LH, cortisol and prolactin will be drawn at -15, 0, 15, 30, 45, 60, 90 and 120 minutes after GNRH injection.

(17) Progress: As reported in the Research Project Resume of 30 Sep 77, seven post-menopausal females have been studied. Saline placebo injections prior to the GNRH injection failed to alter hormone levels in three subjects. The basal levels and the response to GNRH for prolactin, FSH and LH was not significantly altered by Dexamethasone in five patients. An unanticipated new observation was that GNRH stimulated prolactin release in post-menopausal subjects with the time of the peak response being delayed by Dexamethasone. Such a response by prolactin to GNRH has been reported recently in pre-menopausal women with secondary amenorrhea, but heretofore has not been reported for post-menopausal women. The protocol is currently being considered for modification for studying of patients before and after estrogen therapy to determine if the observed rise in prolactin is related to estrogen status.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 76/116SERVICE EndocrineDEPARTMENT Medicine

- (1) Treece, G., Dodson, L.E., and Hofeldt, F.D.: Effect of GNRH on Post-Menopausal Gonadotropins and Prolactin Levels: Influence of Short-term Glucocorticoid Administration. Program and Abstracts, 61st Annual Meeting of the Endocrine Society, Anaheim, CA 1979.

PRESENTATIONS:

- (1) Treece, G., Dodson, L.E., and Hofeldt, F.D.: Effect of GNRH on Post-Menopausal Gonadotropins and Prolactin Levels: Influence of Short-Term Glucocorticoid Administration. Presented: 61st Annual Meeting of the Endocrine Society, Anaheim, CA, 1979.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 77/103 (3) Status: completed
(4) Title: Comparison of the Clinical and Immunological Response of Pre-seasonal and Co-seasonal Versus Post Seasonal Initiation of Allergy Immunotherapy.

(5) Start Date: 1977	(6) Est Comp Date: 1981
(7) Principal Investigator: Bryant Fortner, MD, MAJ, MC	(8) Facility: FAMC
(9) Dept/Sec: Med/Allergy-Imm	(10) Assoc Investigators:
(11) Key Words: frequency of immunotherapy	William R. Tipton, MD, COL, MC
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 1/81 Review Results: Ongoing	

(15) Study Objective:

This study was altered somewhat in the protocol in order to gain more clinically meaningful data. In a double-blind, crossover, patients received immunotherapy to ragweed either on a weekly schedule or a monthly schedule with a crossover at two months. This was accomplished during the nonpollen season.

16. Technical Approach:

Immunological approaches including specific IgE (RAST), titrated skin test, blocking antibody (IgG), nasal provocation titrations, and conjunctival challenge were done on patients during a double-blind, crossover during four months of nonpollenating season to determine the efficacy of the immunotherapy related to the frequency of the injections. Weekly injections were compared with monthly injections.

17. Progress:

The results of this study were presented at the Annual Meeting of the American College of Allergists and are scheduled for publication in September, 1981, in the Annals of Allergy.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 77/103

SERVICE Allergy-Immunology

DEPARTMENT Medicine

1. Fortner, B.R., Dantzler, B.S., Tipton, W.R. and Nelson, H.S.: The Effect of the Frequency of Immunotherapy on Skin Tests and Immunologic Parameters. *Annals of Allergy*, September 1981.

PRESENTATIONS for FY 81 Annual Progress Report

1. Fortner, B.R., Dantzler, B.S., Tipton, W.R., and Nelson, H.S.: Frequency of Immunotherapy. Presented: 37th Annual Congress of American College of Allergists, Washington, D.C., 6 April 1981.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 77/106 (3) Status: Completed
(4) Title: The Effect of Chronic Nonimmunologically Mediated Bronchial
Constriction of Bronchial Smooth Muscle

(5) Start Date: 1977	(6) Est Comp Date: Completed September 1981
(7) Principal Investigator: David L. Pittman	(8) Facility: FAMC

(9) Dept/Sec: All-Imm. & Pathology	(10) Assoc Investigators: Lyndon E. Mansfield
(11) Key Words: Bronchial smooth muscle	

(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 7/81 Review Results: Completed
*Refer to Unit Summary Sheet of this report.		

(15) Study Objective:
To determine if the hyperactivity or constriction of the bronchial smooth muscle in asthmatic patients is the cause of the bronchial smooth muscle hypertrophy found in the asthmatic lung, and secondly, to determine if bronchodilators as presently used have any protective effect against this hypertrophy.

(16) *Technical Approach:
Guinea pigs were subjected to nonantigen mediated bronchoconstriction from the age of weaning to sexual maturity. The animals were then sacrificed, and bronchial muscle examined.

(17) *Progress:
The technical portion of the project is completed. It is being prepared for publication and is in final draft.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 77/114 (3) Status: Terminated
(4) Title:
Effect of Propranolol in Patients with Reactive Hypoglycemia

(5) Start Date: FY78	(6) Est Comp Date: FY81
(7) Principal Investigator: Gary L. Treece, MD, LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Endocrine Service	(10) Assoc Investigators: Fred D. Hofeldt, MD, COL, MC Annelie Shackelford, MT, DAC
(11) Key Words: propranolol reactive hypoglycemia	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 9/81 Review Results: Ongoing	

(15) Study Objective: To investigate the therapeutic efficacy of chronic oral propranolol (Inderal) administration on the symptoms and metabolic defects of patients with postabsorptive (reactive) hypoglycemia.

(16) Technical Approach: The subjects will be those with persistent symptomatology despite prior drug or dietary therapy for any of the forms of reactive hypoglycemia. A baseline 5-hr oral glucose tolerance test (GTT) using 100 grams of glucose and a 3-day 150 gram carbohydrate preparatory diet will be obtained. A dietary, drug and symptom history will also be recorded in the form of a questionnaire. Propranolol (160 mg qd po) or placebo will then be administered double blindly for one month. A repeat 5-hr GTT will be performed and a second questionnaire obtained at the end of the month. For a second month, the laterante drug is administered and another 5-hr GTT and questionnaire obtained. The effect of glucose, insulin, glucagon, growth hormone, cortisol and prolactin levels during the 5-hr GTT will be compared.

(17) Progress: No patients have been studied in this protocol since it has been in effect at Fitzsimons Army Medical Center. It has subsequently been discussed with the endocrine staff and the interest no longer is present for continuation of the protocol and the protocol should be considered terminated with no patients entering in the study.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/102 (3) Status: on-going
(4) Title: The Development of Specific and Cross Sensitivity in the
Tracheal Tissue of Guinea Pigs treated with Isoproterenol and Aminophylline

(5) Start Date: 1978	(6) Est Comp Date: 1982
(7) Principal Investigator: William Ronald Tipton, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: William P. Andrade, MD, LTC, MC Pinkus Goldberg, MD, CPT, MC Edward Squire, MD, MAJ, MC
(11) Key Words: subsensitivity beta agonist guinea pig trachea	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 4/81	Review Results: Ongoing

(15) Study Objective:

This study is designed to measure the development of the subsensitivity to two drugs, Isoproterenol and Theophylline, by examining both their dilating response on histamine contracted tracheal tissue and ability to increase levels of cyclic-AMP in tracheal tissue and parenchymal lung tissue.

16. Technical Approach:

Guinea pig tracheal and peripheral lung strips will be analyzed for cyclic nucleotide levels, metabolites of arachidonic acid and physiologic response to various mediators employing a continuous flow tissue bath system. The equipment for this study is presently available at Fitzsimons Army Medical Center.

17. Progress:

The equipment has just been assembled at FAMC and a few trial runs have been conducted to test the equipment and to train the personnel in the technique. Further drug studies are about to begin.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 78/102

SERVICE Allergy-Immunology

DEPARTMENT Medicine

1. Tipton WR, Nelson HS, Souhrada JF, Morris HG, Jacobson KW: Dynamics of Isoproterenol Subsensitivity in Guinea Pig Airway Smooth Muscle. Lung 159:199;1981.

PRESENTATIONS for FY 81 Annual Progress Report

1. Tipton WR, Jacobson R, Nelson HS, Morris H, Souhrada J: Dynamics and Mechanism of Guinea Pig Trachea Subsensitivity to Isoproterenol. Presented at 31st Annual Pulmonary Disease Symposium, Fitzsimons Army Medical Center, Aurora, CO, September, 1978.
2. Tipton WR, Jacobson K, Nelson HS, Morris H, Souhrada J: Dynamics and Mechanism of Guinea Pig Trachea Subsensitivity to Isoproterenol, presented at The American Thoracic Society, Las Vegas, Nevada, May, 1979.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/106 (3) Status: Completed
(4) Title: Evaluation of the Effects of the Frequency of Pollen
Allergen Injections

(5) Start Date: 1978	(6) Est Comp Date:
(7) Principal Investigator: Bryant R. Fortner, MD, MAJ, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: Brian S. Dantzler, MD, MAJ, MC WR Tipton, MD, COL, MC HS Nelson, MD, COL, MC
(11) Key Words: hyposensitization injections pollen ragweed immunotherapy	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 5/81 Review Results: Completed	

(15) Study Objective:

The object was to study patients who had recently reached maintenance immunotherapy levels and determine whether their sensitivity and immunologic response to the immunotherapy varied with whether injections were given at weekly or monthly periods.

16. Technical Approach:

All patients received weekly injections; however, in a double-blind manner the antigen being studied was administered either weekly or monthly. Immunologic sensitivity was measured by skin test, nasal challenge, ocular challenge and immunologic response by RAST and blocking antibody titers.

17. Progress:

The results of this study were presented at the Annual Meeting of the American College of Allergists and were published in the Annals of Allergy in September, 1981. The references are contained in the annual progress report of protocol 77/103 of which this was a revision.

Publications and Presentations: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/107 (3) Status: ongoing
(4) Title: An Evaluation of the Efficacy of Animal Dander Allergy
Immunotherapy in Perennial Rhinitis

(5) Start Date: y. 1979	(6) Est Comp Date: 1 June 1982
(7) Principal Investigator: H.S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Med/Allergy-Imm	(10) Assoc Investigators: Alvin J. Aubry, MD, LTC, MC Gary Carpenter, MD, MAJ, MC Paul Rabinowitz, MD, CPT, MC Bryant R. Fortner, MD, MAJ, MC
(11) Key Words: animal dander skin test antibody titers	(13) Est Accumulative OMA Cost: * none
(12) Accumulative MEDCASE: * none	(14) Date of Review: 6/81 Review Results: Ongoing

(15) Study Objective:

To evaluate the response to immunotherapy with commercial cat and dog extracts in patients with marked skin test reactivity to these antigens and their response in their perennial symptoms.

16. Technical Approach:

Patients markedly sensitive to dog or cat dander extract and having perennial symptoms are randomly placed on either dog or cat dander or placebo extracts for a period of at least one year. During this period of time the tissue threshold is measured by periodic titrated skin tests and titrated nasal challenges and the immunologic response is measured by specific RAST and blocking antibody titers.

17. Progress:

Patient evaluation has been completed under this protocol. Laboratory evaluation of IgE and specific blocking antibodies has been completed. The material has been submitted for presentation at a national meeting.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81		(2) Prot No.: 78/113		(3) Status: Ongoing	
(4) Title: Effects of Salicylic Acid on Fatty Acid Oxidation in Rat Skeletal Muscle Mitochondria					
(5) Start Date: 4 January 1979			(6) Est Comp Date: June 1982		
(7) Principal Investigator: Robert E. Jones, MAJ, MC			(8) Facility: FAMC		
(9) Dept/Sec: Medicine/Endocrine			(10) Assoc Investigators:		
(11) Key Words: salicylic acid mitochondrial fatty acid long chain fatty acid:CoASH ligase (AMP)			Gerald S. Kidd, LTC, MC David T. Zolock, MAJ, MS Fred D. Hofeldt, MD, COL, MC		
(12) Accumulative MEDCASE:*		(13) Est Accumulative OMA Cost:*		(14) Date of Review:	
*Refer to Unit Summary Sheet of this report.				10/80 Review Results: Ongoing	

(15) Study Objective: The principal objective of this protocol is to determine the mechanism of salicylate-induced stimulation of fatty acid oxidation by studying the effects of salicylic acid and other compounds on the activation step of fatty acid oxidation, fatty acid: CoASH ligase (AMP) (E.C.6.2.1.3).

(16) Technical Approach: Rat skeletal muscle mitochondria are isolated from the quadriceps femoris muscle group. Ligase activity is determined using a radio-ligand millipore filter procedure. Salicylic acid, phosphate and NaF are co-incubated with substrates for the ligase reaction. Statistical analysis is performed with a paired t test on individual data points or an unpaired t test on the slopes of the lines generated by double-reciprocal plots.

(17) Progress: Salicylic acid enhances the rate of fatty acid:CoASH ligase by lowering the Michaelis constant (K_m) of palmitic acid from 0.0030 mM in controls to 0.0019 mM ($p < 0.001$) without effecting the maximal velocity of the reaction. Dose response curves for salicylate are hyperbolic with maximal stimulation (40% over controls) occurring at concentrations of 0.05 mM or greater. At half saturating concentrations of palmitate (preliminary studies), phosphate (5 mM) and NaF (25 mM) both stimulate the ligase reaction by approximately 50% ($p < 0.005$). The effects of salicylic acid and phosphate are not additive which

suggests a possible common mechanism of action whereas the trend of the salicylate and fluoride data suggest that fluoride inhibits ligase stimulation by salicylate. These observations are compatible with the possibility that salicylic acid may indirectly enhance the ligase reaction by facilitating the rate of pyrophosphorolysis (e.g., inorganic pyrophosphatase). Additionally, the fluoride enhancement of the ligase enzyme may imply the presence of an additional controlling factor for mitochondrial fatty acid activation such as a fluoride-sensitive protein kinase. Further studies aimed at clarifying these interactions are being planned.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 78/113SERVICE EndocrinologyDEPARTMENT Medicine

- (1) Jones, R.E., Askew, E.W., Hecker, A.L., and Hofeldt, F.D.: Salicylic Acid Stimulation of Palmitic Acid Oxidation by Rat Skeletal Muscle Mitochondria. *Biochim. Biophys. Acta.* 666:120-126, 1981.
- (2) Jones, R.E., and Hofeldt, F.D.: Stimulation of Mitochondrial Long Chain Fatty Acid:CoASH Ligase (AMP) by Salicylic Acid. *J. Colorado-Wyoming Acad. Sci.* (In press).

PRESENTATIONS for FY 81 Annual Progress Report

- (1) Jones, R.E.: Salicylic Acid Stimulation of Palmitic Acid Oxidation by Rat Skeletal Muscle Mitochondria. Presented: Hugh Mahon Lecture-ship Awards, FAMC, June 1980.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78-114 (3) Status: Ongoing
(4) Title: Treatment of Systemic Scleroderma with Minoxidil (U-1858)

(5) Start Date: Jun 79	(6) Est Comp Date: Feb 82
(7) Principal Investigator: STEVEN R. BAILEY, MD, CPT, MC	(8) Facility: FAMC
(9) Dept/Sec: Dermatology, DOM	(10) Assoc Investigators: JAMES MCCOY, MD, LTC, MC JOHN L. AELING, MD, COL, MC, RET ROBERT G. CLAYPOOL, MD, COL, MC JAMES THOMPSON, MAJ, MC
(11) Key Words: Systemic Scleroderma/Minoxidil	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 10/80 Review Results: Ongoing	

- (15) Study Objective: Minoxidil, a potent vasoactive medication, is being administered systemically to assess its potential in the therapy of systemic scleroderma and associated Raynaud's phenomena.
- (16) Technical Approach: Consenting patients with systemic scleroderma are entered into this twelve month double-blind cross-over study, using Minoxidil at increasing dosage increments. The patients are followed at bi-weekly and monthly intervals with hospital admission upon entrance, at cross-over and at the end of the study for detailed physical examination and laboratory evaluation.
- (17) Progress: The first patient was entered in June 1979 and since that time, ten patients have been entered, one of whom was withdrawn because she did not meet protocol criteria. Since that time, all nine patients have either completed protocol or were dropped from the protocol but continued on Minoxidil with the consent of FDA. One patient died while on the protocol however, our determination, that of an indepth evaluation at the University of Kansas Medical Center and that of the FDA is that this was not related to the Minoxidil. At this time, all patients have had subjective improvement on Minoxidil and there has been objective improvement as assessed by range of motion and improvement in the cutaneous manifestations in four patients. Publications at this time are pending extensive computer analysis of our objective data.

Publications and Presentations: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/116 (3) Status: on-going
(4) Title: The Effect of Positive and Negative Air Ions on Pulmonary
Functions in Patients with Bronchial Asthma

(5) Start Date: 1978	(6) Est Comp Date: indefinite
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: Brian Dantzler, MD, MAJ, MC Bruce Martin, MD, CAPT, MC, USAF
(11) Key Words: small air ions	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 10/80 Review Results: Ongoing	

(15) Study Objective:

To evaluate the short-term response of patients with bronchial asthma to an increase in the ambient concentration of positive or negative air ions.

16. Technical Approach:

Patients with bronchial asthma whose clinical condition was stable will be exposed on two consecutive days for periods of six hours to either an increased concentration of positive or negative small air ions. The response will be monitored by pulmonary function studies.

17. Progress:

Nine patients were studied. The results were presented as noted on the accompanying sheets and are currently being prepared for publication.

PUBLICATIONS for FY 81 Annual Progress Report: none

PRESENTATIONS for FY 81 Annual Progress Report

Proto No. 78/116

SERVICE Allergy-Immunology

DEPARTMENT Medicine

Dantzler BS, The Effect of Positive and Negative Air Ions on Bronchial Asthma, 33rd Annual Pulmonary Symposium, Fitzsimons Army Medical Center, Aurora, CO, 20 Jan 81.

Dantzler BS, Martin B, Nelson, HS. The Effect of Positive and Negative Air Ions on Bronchial Asthma, 37th Annual Meeting American Academy of Allergy, San Francisco, CA, 9 March 81.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/117 (3) Status: on-going
(4) Title: The Effect of Parasitic Infestation on Immediate Skin Test Reactions

(5) Start Date: 1980	(6) Est Comp Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: LE Mansfield, MD, LTC Praphan Phanupahak, MD, PhD
(11) Key Words: IgE parasites	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 10/80 Review Results: Ongoing	

(15) Study Objective:

To determine whether antiparasite antibodies of the IgE class present in high concentrations in patients with infestations are able to saturate receptors in the mast cells and in so doing block mast cell sensitization by IgE antibody directed toward inhaled allergen.

16. Technical Approach:

Evidence for mast cell IgE receptor saturation will be sought by comparing the direct immediate wheal and flare skin test to circulating levels of IgE specific for the same allergen. The clinical portion of this study will be performed in Thailand by Dr. Phanuphak. The laboratory portion will be performed at Fitzsimons.

17. Progress:

The clinical portion of this study is currently being performed in Thailand.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/118 (3) Status: Ongoing
(4) Title: A Precision Measurement of Anatomic Deadspace Using Multiple
Inert Gas Analysis, Comparison with Fowler's Technique and Application

(5) Start Date: September, 1978	(6) Est Comp Date: 1982
(7) Principal Investigator: Michael E. Perry, LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Pulmonary	(10) Assoc Investigators: Neal B. Kindig, PhD
(11) Key Words: Deadspace Steady state diffusion	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 10/80 Review Results: Ongoing	

(15) Study Objective:
To experimentally confirm a proposed new procedure for anatomic deadspace measurements which has important advantages over conventional techniques.

(16) *Technical Approach: Deadspace measurements are first performed using the technique of Fowler, with careful attention to insure a constant inspiratory volume and expiratory air flow. This is followed by the multiple inert gas technique whereby two breaths of specific mixtures of argon, neon, and nitrogen are inhaled in a two breath sequence and the exhaled gas from each sequence analyzed on a gas chromatograph. From changes in concentration of the inert gases deadspace is deduced.

(17) *Progress: The portion of the study for normal volunteers has been completed, and the data published. The next phase of the study using the patients with obstructive lung disease is planned for the near future.

SERVICE PulmonaryDEPARTMENT Medicine

- (1) Kindig, N.B., Martin, B., Morgan, E., Filley, G.F.: Ventilation Variations at Constant Load Exercise. Federation Proceedings 38:1050, 1979.
- (2) Kindig, N.B., Zimmerer, R.W., Hazlett, D.R.: Automation and Profile; Computer Simulation. Clinical Engineering, 6:68-69, 1978.
- (3) Hazlett, D.R., Zimmerer, R.W., Kindig, N.B.: Ultrasound in Tissue Characterization. Medical Instrumentation 11:24, 1979.
- (4) Kindig, N.B., Editor: Proceedings of the 16th Annual Rocky Mountain Bioengineering Symposium and 16th International ISA Biomedical Sciences Instrumentation Symposium. Biomedical Sciences Instrumentation, 15, Instrument Society of America, Pittsburg, 1979.
- (5) Kindig, N.B., Perry, M.E., Filley, G.F.: Gas-Mixing Deadspace: Measurement with Tracer Gases Unbound. (Abst) Max Planck Institute for Experimental Medicine, July 1980.
- (6) Kindig, N.B., Perry, M.E., Filley, G.F.: Gas-Mixing Deadspace Measurement with Paired Tracers. Prog. Resp. Res. 6:31-32 (Karger, Basel 1981).

SERVICE Pulmonary

DEPARTMENT Medicine

- (1) Kindig, N.B.: Physiologic Deadspace; Influence of Pattern of Breathing.
Presented: 32nd Annual Pulmonary Symposium, FAMC, Aurora, CO, September, 1979.
- (2) Kindig, N.B., Perry, M.E., Filley, G.F.: Gas-Mixing Deadspace: Measurement with Tracer Gases. Presented: The Symposium on Gas Exchange Function of Normal and Disease Lungs, Max Planck Institute for Experimental Medicine, Goettingen, Germany, July 9-11, 1980.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/119 (3) Status: on-going
(4) Title: The Effect of Aspirin on Platelet Aggregation in Aspirin
Sensitive Asthmatics

(5) Start Date: 1978	(6) Est Comp Date: indefinite
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: RA Gillham, MD, LTC, MC, USAF RE Danziger, MD, CDR, USN PT O'Barr, PhD, DAC
(11) Key Words: aspirin sensitivity platelet aggregation	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 10/80	Review Results: Ongoing

(15) Study Objective:

To determine whether the intolerance to aspirin and other related substances manifested by some patients with bronchial asthma could be diagnosed by an in vitro test.

16. Technical Approach:

The plan is to utilize the platelet aggregation assay and the thromboxane assay to compare the response of platelets from patients with aspirin sensitivity and control patients.

17. Progress:

The patient study portion of the protocol is completed. The results are presently being analyzed and prepared for submission.

PUBLICATIONS for FY 81 Annual Progress Report: none

PRESENTATIONS for FY 81 Annual Progress Report

Proto No. 78/119

SERVICE Allergy-Immunology

DEPARTMENT Medicine

1. Danziger RE, Effects of Aspirin on Platelet Aggregation and Arachidonic Metabolism in Aspirin Sensitivit Asthmatics, 33rd Annual Pulmonary Disease Symposium, Fitzsimons Army Medical Center, Aurora, CO, January, 1981.
2. Danziger RE, Gillham R, O'Barr PT, Nelson HS, The Effects of Aspirin on Platelet Aggregation and Arachidonic Acid Metabolism in Aspirin Sensitive Asthmatics, 37th Annual Congress American College of Allergists, Washington, DC, 6 Apr 81.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/121 (3) Status: ongoing
(4) Title: The Determination of Cross Allergenicity between Western
Grass Pollens and Common Northern Grass Pollens.

(5) Start Date: 1978	(6) Est Comp Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm.	(10) Assoc Investigators:
(11) Key Words: grass pollen and cross allergenicity	BG Martin, MD, MAJ, MC, USAF
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 12/80 Review Results: Ongoing	

(15) Study Objective:
To study the cross allergenicity of extracts of common western prairie
grasses and to compare them to the already well-studied northern pasture
grasses and Bermuda grass.

16. Technical Approach:

The approach is to employ a pooled allergic serum and RAST inhibitions with
allergen disks manufactured in the allergy research laboratory at Fitzsimons
and a variety of commercial allergy extracts.

17. Progress:

Further RAST inhibition studies were performed during this year, particularly
to delineate the relationship of Bahia grass to the grasses previously
investigated.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 78/121

SERVICE Allergy-Immunology

DEPARTMENT Medicine

1. Martin BG, Manfield LE, Nelson HS: Patterns of Cross Allergenicity among Grasses (abstr) Journal Allergy-Clinical Immunology 65:229;1980.

PRESENTATIONS for FY 81 Annual Progress Report

1. Martin BG: Patterns of Cross Allergenicity among Grasses, presented at the annual meeting of the American Academy of Allergy, Atlanta, Georgia, 20 Feb 1980.
2. Martin BG, Nelson HS, Cross Allergenicity of Bahia Grass, presented at the 37th Annual Congress, American College of Allergists, Washington, DC, 6 Apr 81.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78-122 (3) Status: Terminated
(4) Title:

Effects of Dietary Fructose in Diabetes Mellitus

(5) Start Date: FY78	(6) Est Comp Date: FY81
(7) Principal Investigator: Fred D. Hofeldt, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Endocrine	(10) Assoc Investigators: Phyllis A. Crapo, UCHSC, Denver, CO Jerrold M. Olefsky, MD, UCHSC, Denver, CO Orville G. Kolterman, MD, UCHSC, Denver, CO Jon Insel, MD, UCHSC, Denver, CO
(11) Key Words: fructose diabetes mellitus	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
	(14) Date of Review: 12/80 Review Results: Ongoing

(15) Study Objective: To assess the post prandial response of simple carbohydrates (fructose, glucose and sucrose) and natural cooked foods (cake and ice cream) which are prepared with either sucrose or fructose. The aim of this study is to determine if fructose, a natural occurring nutrient, can substitute as an artificial sweetener in diabetic patients. The plasma glucose insulin responses to the various test meals will be assessed to determine which substance is the most diabetogenic. Fructose plays an unimportant role in carbohydrate metabolism; its use as a food sweetener might have therapeutic value in the management of the large diabetic population.

(16) Technical Approach: Three groups of subjects will be studied to include: 1) chemical diabetics; 2) adult onset, non-ketotic diabetics with significant fasting hyperglycemia (plasma glucose levels greater than 140 mg% on three different occasions) and 3) age and weight matched diabetic control patients. These patients will undergo acute studies where their hormonal responses will be determined by glucose, sucrose and fructose, and chronic studies where the patient will be fed diets containing mixed test meals of various starches containing calories of fructose or sucrose, and glucose. Postprandial hormonal responsiveness again will be measured. Each of the diets will be fed for a period of 3 weeks. At the end of this time the postprandial plasma glucose, insulin and glucagon responses will be determined following the ingestion of 50 grams of glucose, sucrose and fructose (as described above). Likewise, each patient's tolerance will be tested with a standard glucose to tolerance test before and after the 3 weeks of the chronic dietary period. The influence of diet on triglyceride metabolism will be determined by the measurement of VLDL-TG production rate and fasting triglyceride levels, before and after the dietary period.

(12) Progress: Only 2 patients from Fitzsimons Army Medical Center were included in the study. The data from the study is being completed and compiled at this time in consideration for publication in a journal. It is hoped that fructose can be shown to serve as an adequate food additive for diabetic patients inasmuch as it does not contribute to greatly elevated glucose levels and in normal controls does not elicit a significant insulin discharge. The protocol is terminated and results are being compiled for publication.

Publications and Presentations: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/123 (3) Status: Ongoing
(4) Title: A Comparison of the Zimmerer and Dubois Techniques of Airway Resistance Measurements by Body Plethysmography

(5) Start Date: January, 1979	(6) Est Comp Date: December, 1982
(7) Principal Investigator: Michael E. Perry, LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Pulmonary	(10) Assoc Investigators: Robert W. Zimmerer, PhD Robert J. Browning, BS
(11) Key Words: Alveolar pressure Airway resistance Body plethysmography	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 1/81 Review Results: Ongoing	

(15) Study Objective: To compare a clinically untried measurement of airway resistance with a standard technique.

(16) *Technical Approach: Forced expiratory maneuvers are performed with the subject seated in a constant volume body plethysmograph, while plethysmograph pressure and airflow are monitored and recorded with a DEC PDP11/10 computer. With this information and the previously determined FRC of the patient, alveolar pressure is calculated throughout the expiratory maneuver. Pressure flow relationships are then related to the patient's maximal expiratory flow volume loop.

(17) *Progress: Since the last report and the several publications and presentations which arose from this protocol, further work has been delayed because of other department commitments. However, it is the full intent of the principal and associate investigator to continue with this protocol once other priorities have been fulfilled.

SERVICE PulmonaryDEPARTMENT Medicine

- (1) Perry, M.E., Zimmerer, R.W., Browning, R.J.: Non-Invasive Alveolar Pressure/Flow Pattern Determination by Computerized Plethysmography (Abstract) Symposium on Computers in Critical Care in Pulmonary Medicine, Page 47, June 1980.
- (2) Perry, M.E., Zimmerer, R.W., Nelson, R.A., Browning, R.J.: Non-Invasive Determination of Alveolar Pressure-Flow Relationship (Abstract) American Review of Respiratory Disease, Volume 121, Page 389, April 1980.
- (3) Zimmerer, R.W., Perry, M.E., Browning, R.J.: Expiratory Pressure/Flow Assessment by Plethysmography (Abstract) AAMI 15th Annual Meeting, Page 246, April 1980.

PRESENTATIONS:

- (1) Perry, M.E., Zimmerer, R.W., Browning, R.J.: Non-Invasive Alveolar Pressure/Flow Pattern Determination by Computerized Plethysmography, presented at the annual Computers in Critical Care and Pulmonary Medicine, Lund, Sweden, June 3-6, 1980.
- (2) Zimmerer, R.W., Perry, M.E., Browning, R.J.: Expiratory Pressure/Flow Assessment by Plethysmography, presented at the AAMI 15th Annual Meeting, San Francisco, April 13-17, 1980.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/124 (3) Status: Ongoing
(4) Title: A Self Consistent Method of Single Breath DLCO Measurement

(5) Start Date: September, 1978	(6) Est Comp Date: December, 1982
(7) Principal Investigator: Michael E. Perry, LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Pulmonary	(10) Assoc Investigators: Neal B. Kindig, PhD Robert J. Browning, BS
(11) Key Words: Single breath diffusion Alveolar gas Breathing patterns	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 1/81 Review Results: Ongoing	
(15) Study Objective: To experimentally confirm a proposed new method of DLCO measurement.	

(16) *Technical Approach: Data will be sampled during the single breath DLCO determination at various breath holding times and at various exhaled lung volumes. Data will be analyzed online by computer which will correct for volume averaging and effective breath holding time. If the theoretical approach as outlined in the original protocol is selfconsistent, the calculated diffusion capacity should remain constant regardless of breathing pattern or gas collection timing.

(17) *Progress: For the past year this instrument has been completely assembled and the computer program has been completed and is now operating. There were several long unanticipated delays because of equipment failure and program debugging, but at this time we are about to start the actual collection of data. We fully anticipate this protocol being completed within fiscal year 82.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 78/124

SERVICE Pulmonary

DEPARTMENT Medicine

- (1) Kindig, N.B., Hazlett, D.R., Filley, G.F.: "Timing and Volume Averaging in Single Breath DLCO Measurement". The Physiologist, 21:64, 1978.

PRESENTATIONS for FY 81 Annual Progress Report

- (1) Zimmerer, R.W.: Simulated Diffusion Testing. Presented: 32nd Annual Pulmonary Symposium, FAMC, Aurora, CO, September 1979.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/101 (3) Status: Terminated
(4) Title:

The Relationship of Granuloma Annulare (GA) to Diabetes Mellitus (DM)

(5) Start Date: Mar 79	(6) Est Comp Date: Terminated 81
(7) Principal Investigator: Gene E. Graff, DO, MAJ, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Endocrine	(10) Assoc Investigators: Bernard F. Davies, MD, MAJ, MC John L. Aeling, MD, COL, MC Fred D. Hofeldt, MD, COL, MC D. M. Strong, MD, WRAMC George L. Brown, PhD, COL, MSC
(11) Key Words: granuloma annulare (GA) Diabetes mellitus (DM) HLA typing	(13) Est Accumulative OMA Cost:*
(12) Accumulative MEDCASE:*	(14) Date of Review: 5/81 Review Results: Ongoing

*Refer to Unit Summary Sheet of this report.

- (15) Study Objective: To determine if an association exists between GA and DM by special laboratory procedures, including HLA typing.
- (16) Technical Approach: Patients with biopsy proven GA are studied for concurrent DM historically, and following oral and intravenous glucose challenge. HLA typing is also done. Baseline studies to include: complete physical exam, CBC, sedimentation rate, SMA-18, triglycerides, cholesterol, HDL, 2-hour pc blood glucose, TSH, T3, T4, T3 resin uptake, and an EKG, if indicated. Parameters monitored following glucose challenge include: serum insulin, glucose, glucagon, growth hormone and cortisol.
- (17) Progress: The study is now complete with the study of twenty patients with granuloma annulare. At the present time, the data is being compiled and it is anticipated that one or two, perhaps three, publications may result from the data obtained in this study. The association of diabetes to granuloma annulare is seen in a variable spectrum of carbohydrate abnormalities from frank diabetes to idiopathic hypoglycemia in normal carbohydrate tolerance. Final hormonal analysis may clarify a more precise association, the results of which are pending.

PUBLICATIONS and PRESENTATIONS: none

DEPARTMENT OF CLINICAL INVESTIGATION
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ANALYSIS REPORT

Form 10-74, App. 1-75

(Printed Name of Project)

(1) Date: 10 SEP 81 (2) Proj No.: 74-100 (3) Version: 1.0
(4) Title: An Evaluation of Combined H1 and H2 Receptor blocking Agents
in the Treatment of Seasonal Allergic Rhinitis

(5) Start Date: 1979	(6) Est Comp Date: 1981
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm.	(10) Assoc Investigators: GB Carpenter, MD, MAJ, MC A Barker Coley, MD, MAJ, MC
(11) Key Words: histamine receptor blocking agents	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
(14) Date of Review: 7/81	
Review Results: Ongoing	

Refer to Unit Summary Sheet of this report.

(15) Study Objective:

to determine whether the addition of a blocker of the H2 receptor would provide greater symptomatic relief in patients with allergic rhinitis than was provided by an H1 blocking agent alone.

(16) Technical Approach:

A double blind, crossover study was performed during the weed season of 1979. In this study patients continuously received an H1 blocker (Chlorpheniramine) and alternately for two week periods received either a placebo or cimetidine, an H2 blocker. Patients recorded symptoms twice daily throughout the weed season.

(17) Progress:

The clinical study was performed during the weed season of 1979. The data is still in preparation for final publication.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 79/103

SERVICE Allergy-Immunology

DEPARTMENT Medicine

1. Carpenter, G.B., Bunker, A.L., and Nelson, H.S.: An Evaluation of Combined H1 and H2 Antagonists in the Treatment of Seasonal Allergic Rhinitis. (Abst) Journal of Allergy and Clinical Immunology 65:187, 1980.

PRESENTATIONS for FY 81 Annual Progress Report

1. Carpenter, G.B.: An Evaluation of Combined H1 and H2 Antagonists in the Treatment of Seasonal Allergic Rhinitis. Presented: Annual Meeting of the American Academy of Allergy, Atlanta, Georgia, 18 February 1980.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/104 (3) Status: Terminated
(4) Title:
Vindesine in the Treatment of Cancer

(5) Start Date: Spet 79	(6) Est Comp Date: Closed
(7) Principal Investigator: Nicholas J. DiBella, M.D., COL., MC	(8) Facility: FAMC FAMC
(9) Dept/Sec: Hem/Onc	(10) Assoc Investigators:
(11) Key Words: None	
(12) Accumulative MEDCASE: *	(13) Est Accumulative OMA Cost: *
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 9/81 Review Results: Ongoing	

(15) Study Objective:
As previously stated

(16) Technical Approach:
Clinical Study

(17) Progress:
See last years report. Patient with lymphoma remains in complete remission.
No further patients have been placed on study.

Publications and Presentations: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/105 (3) Status: Ongoing
(4) Title: Breathing Pattern Effects on Steady State DLCO Measurement.

(5) Start Date: November, 1979	(6) Est Comp Date: December, 1982
(7) Principal Investigator: Michael E. Perry, LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Pulmonary (11) Key Words: Disease Steady state DLCO Breathing pattern	(10) Assoc Investigators: Neal B. Kindig, PhD
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 10/80 Review Results: Ongoing	

(15) Study Objective:

To experimentally confirm theoretically determined corrections for breathing patterns during steady state diffusion studies.

(16) *Technical Approach: Breathing patterns - various breathing patterns including inspiratory and expiratory breath holds will be performed while the subject performs during the standard steady state diffusion measurement. If our approach is correct, mathematical corrections for breathing pattern will result in a constant value for diffusion capacity.

(17) *Progress: The computer program for sampling and analyzing the breathing pattern has been written and is at this point ready for use. This protocol will be completed in concert with protocol No. 78/124 (A Self Consistent Method of Single Breath DLCO Measurement), and an attempt will be made to show the essential equivalence of these two different methods.

PUBLICATIONS: none

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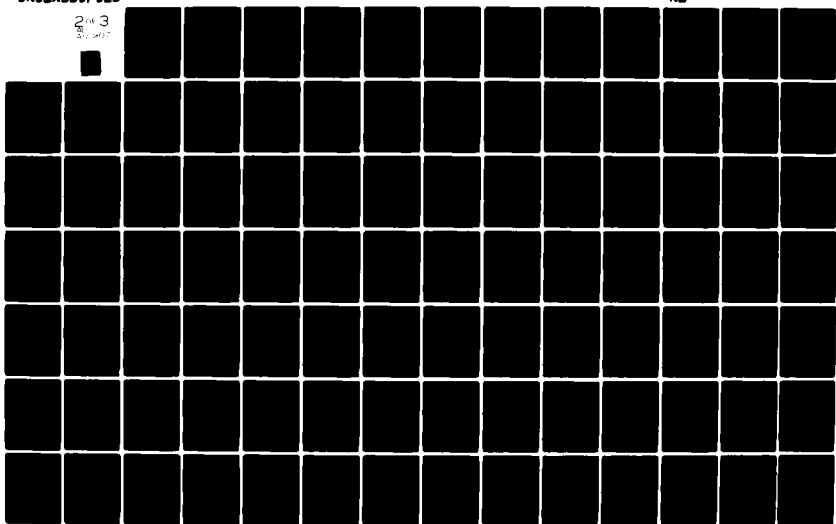
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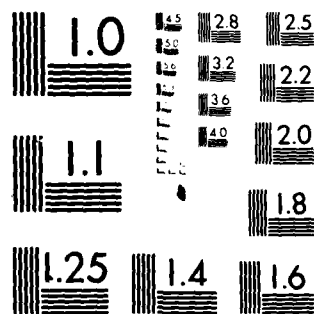
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PRESENTATIONS for FY 81 Annual Progress Report

Proto No. 79/105

SERVICE Pulmonary

DEPARTMENT Medicine

- (1) Kindig, N.B.: $D_{LCO_{SS}}$ correction using $PaCO$ back pressure predicted from venous blood. Presented: Carl E. Tempel Pulmonary Symposium, Denver, Colorado, January, 1981.
- (2) Perry, M.E.: Simplified room air $(A-a)O_2$ D calculation. Presented: Carl E. Tempel Pulmonary Symposium, Denver, Colorado, January, 1981.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/106 (3) Status: Ongoing
(4) Title: Measurement of Lung Compliance Utilizing Pulmonary Capillary
Wedge Pressures.

(5) Start Date: January, 1979	(6) Est Comp Date: December, 1982
(7) Principal Investigator: Michael E. Perry, LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Pulmonary	(10) Assoc Investigators: Robert Zimmerer, PhD
(11) Key Words: Wedge pressure	

(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 10/80
*Refer to Unit Summary Sheet of this report.		Review Results: Ongoing

(15) Study Objective:
Validation of lung compliance measurement using pulmonary capillary wedge
pressure by simultaneous comparison with esophageal pressure.

- (16) *Technical Approach: Simultaneous measurements of intrathoracic
pressure via Swan Ganz intraesophageal balloon, inhaled lung volumes, and
airway pressures will be monitored with a specially designed computerized
recording instrument and correlations between these measurements sought.
- (17) *Progress: Because of delay in arrival of certain key parts which
were not delivered until August, 1981, completion of this project has been
delayed. The special instrument is still under construction and the protocol
will begin after construction is completed.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/107 (3) Status: Ongoing

(4) Title:

The Effects of Fructose on Reactive Hypoglycemia

(5) Start Date: 1979	(6) Est Comp Date: undetermined
(7) Principal Investigator: Fred D. Hofeldt, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Endocrine	(10) Assoc Investigators: Jerrold Olefsky, MD, UCHSC Phyllis Crapo, UCHSC John Scarlet, MD, UCHSC
(11) Key Words: fructose reactive hypoglycemia	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
(14) Date of Review: 3/81 Review Results: Ongoing	

*Refer to Unit Summary Sheet of this report.

(15) Study Objective: The objective of this study is to determine whether patients with reactive hypoglycemia will experience alterations in their glucose, insulin and counter-regulatory hormones following testing of glucose, fructose solutions and fructose meals. Patients with bonafide reactive hypoglycemia previously identified as having this disorder at Fitzsimons Army Medical Center will be further studied under Clinical Research Unit.

(16) Technical Approach: Patients with standard dietary intake will undergo the glucose tolerance test with measurements of insulin, glucagon and counter-regulatory hormones in response to either glucose, sucrose or fructose as a test solution or meal. Glucose clamp study to determine insulin sensitivity will be performed in an adipose tissue biopsy for measurement of in vit insulin sensitivity in insolated adipose sites. It will be performed on subject.

(17) Progress: Approximately seven patients have entered the protocol, and a preliminary publication of the results of dietary testing in these patients is currently in press for publication. These preliminary results show that patients uniformly demonstrated all the criteria of reactive hypoglycemia in response to glucose administration, but this was seldom seen with sucrose cake and never seen with fructose solution. One patient had reactive hypo-

glycemia to a fructose cake. An unexpected observation consisted of the presence of biochemical hypoglycemia without hypothalamic cortisol response in patients that were asymptomatic or symptomatic when studied with sucrose. Sucrose is a glucose-fructose mixture and it may well be that the fructose provides intercellular nutrient for hypothalamic stress and ameliorates the hormonal response to the stress of hypoglycemia. The physiologic data in regards to insulin receptor number of this group of patients is currently pending further data analysis. Additional patients will be studied in regards to these physiologic studies.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/108 (3) Status: on-going
(4) Title: The Effect of Beta Adrenergic Bronchodilators on Serum Immuno-
globulin-G Levels

(5) Start Date: 1981	(6) Est Comp Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm.	(10) Assoc Investigators: William Vinson, MD, COL, MC Paul Rabinowitz, MD, CPT, MC
(11) Key Words: immunoglobulin bronchodilators bronchial asthma	
(12) Accumulative MEDCASE: * *Refer to Unit Summary Sheet of this report.	(13) Est Accumulative OMA Cost: * (14) Date of Review: 1/81 Review Results: Ongoing

(15) Study Objective:

To determine whether chronic administration of beta adrenergic agonists depressed serum levels of immunoglobulin-G.

16. Technical Approach:

To study the immunoglobulin-G levels of patients with bronchial asthma prior to their beginning therapy with beta agonists and periodically while they continue on the drugs.

17. Progress:

Patient study under this protocol has begun but no data is yet available.

PUBLICATIONS and PRESENTATIONS none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/109 (3) Status: Ongoing
(4) Title: Control of Nausea and Vomiting with Delta-9-tetrahydro-cannabinol
(THC) Combined with Standard Antiemetics (A Phase II Study)

(5) Start Date: June 1980	(6) Est Comp Date: Approximately Jan 1982
(7) Principal Investigator: Nicholas J. DiBella, M.D., COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Hematology	(10) Assoc Investigators: Richard A. Artim, M.D., MAJ, USAF, MC
(11) Key Words: Chemotherapy, nausea and vomiting control	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 2/81 Review Results: Ongoing	

(15) Study Objective:

- 1) To determine if THC has a useful antiemetic effect when added to standard antiemetic regimen.
- 2) To determine if the antiemetic effect is additive or potentiating.
- 3) To determine if THC reduces nausea and vomiting in those patients who do not respond to standard antiemetics.

(16) Technical Approach:
Clinical study

(17) Progress:

Thirty nine (39) patients have been entered on this protocol, approximately 15 have been double blinded. Our goal is to obtain 20 double blinded patients. A total of 4 patients have been removed from the study due to side effects, generally mental status changes. This represents only 10% of the total patients with good to excellent control of nausea and vomiting.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/110 (3) Status: on-going
(4) Title: Evaluation of Local Anesthetic Skin Testing and Progressive Challenge in Patients with a History of an Adverse Reaction to Local Anesthetic

(5) Start Date: 1979	(6) Est Comp Date: indefinite
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators:
(11) Key Words: local anesthetic adverse drug reaction	multiple
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 1/81 Review Results: Ongoing	

(15) Study Objective:

To confirm the safety and usefulness of the progressive challenge in a large number of patients with histories of previous suspected adverse reactions to local anesthetics.

16. Technical Approach:

Patients with a history of an adverse reaction to local anesthetics will undergo progressive challenge with these drugs as has been practiced over the last eight years in the Fitzsimons Allergy Clinic. The historical data and results of challenge will be accumulated for future correlations.

17. Progress:

Patients are being studied under this protocol at several installations.

PUBLICATIONS and PRESENTATIONS: one

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/111 (3) Status: on-going
(4) Title: A Comparison of the Development of Sensitivity to Penicillin
in Normal and Atopic Individuals

(5) Start Date: 1980	(6) Est Comp Date: 1983
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm.	(10) Assoc Investigators:
(11) Key Words: penicillin allergy	
(12) Accumulative MEDCASE: *	(13) Est Accumulative OMA Cost: *
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 2/81 Review Results: Ongoing	

(15) Study Objective:

To determine the frequency with which normal and atopic individuals develop positive immediate wheal and flare skin test to penicillin following a course of therapy with the drug.

16. Technical Approach:

Children scheduled to receive a course of penicillin therapy will be skin tested prior to receiving the course of therapy to both penicillin and several pollen allergens. They will return for follow-up skin testing several weeks after completing the course of therapy. Data will be analyzed in terms of the frequency with which patients have unexpected positive skin test to Penicillin that they develop positive skin test following a course of therapy and the relation of this to the evidence of allergy as demonstrated by positive skin test to inhalant allergens.

17. Progress:

It has not been possible thus far to effectively recruit patients for this protocol at Fitzsimons Army Medical Center. It is possible the protocol will be reactivated at a later time.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/112 (3) Status: Ongoing
(4) Title: Use of Sodium Salt of Allopurinol to Control Hyperuricemia in
Patients with No Therapeutic Alternative. A Pilot Study.

(5) Start Date: March 1980	(6) Est Comp Date: 1983
(7) Principal Investigator: N.J. DiBELLA, M.D., COL, MC	(8) Facility: FAMC FAMC
(9) Dept/Sec: HEM/ONC	(10) Assoc Investigators:
(11) Key Words: Hyperuricemia, allopurinol	Michael Langin, CPT, MSC
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 3/81 Review Results: Ongoing	

(15) Study Objective:

To determine a parenteral form of allopurinol to control hyperuricemia when the patient is unable to take the tablet form (commercially available).

(16) Technical Approach:
Clinical study.

(17) Progress:

A second patient has been treated successfully with I.V. Allopurinol with no ill-effects and with control of hyperuricemia.

Publications and Presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/114 (3) Status: Terminated
(4) Title: Vindesine and Cis-platinum in the Treatment of Unresectable
Carcinoma of the Lung.

(5) Start Date: June 1980	(6) Est Comp Date: Closed
(7) Principal Investigator: N.J. DiBella, M.D., COL., MC	(8) Facility: FAMC
(9) Dept/Sec: Hem/Onc	(10) Assoc Investigators:
(11) Key Words: CA lung, chemotherapy	

(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 6/81 Review Results: Ongoing
*Refer to Unit Summary Sheet of this report.		

(15) Study Objective:
To test the efficacy of these drugs in two different schedules in advanced
CA of the lung.

(16) Technical Approach:
Clinical Study.

(17) Progress:
No further patients have been placed on this study and this study has
been terminated.

Publications and Presentations: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/118 (3) Status: ~~Terminated~~
(4) Title: Treatment of Severe Erythema Multiforme with Systemic Steroids

(5) Start Date: 1979	(6) Est Comp Date: Dec 81
(7) Principal Investigator: Dennis C. Polley, CPT, MC	(8) Facility: FAMC
(9) Dept/Sec: Med/Dermatology	(10) Assoc Investigators: Dennis L. May, LTC, MC John L. Aeling, COL, MC
(11) Key Words: erythema multiforme Stevens-Johnson steroids	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 8/81 Review Results: Ongoing	

- (15) Study Objective:
To determine if systemic steroids are useful in the treatment of severe erythema multiforme.
- (16) Technical Approach:
Patients with severe erythema multiforme will be admitted as an inpatient and randomized to placebo or prednisone treated groups and treated for three weeks. Various parameters, including photographs of lesions, duration of fever, duration of arthralgias and complications secondary to systemic steroids will be followed.
- (17) Progress:
Since the inception of the protocol, one patient has been entered and completed the protocol. The protocol was given to the Dermatology Services at Walter Reed Army Medical Center, Letterman Army Medical Center, and Brooke Army Medical Center, and has been approved at Brooke Army Medical Center.

Due to the inability to enroll more patients in this protocol, it is recommended that this protocol be discontinued.

Publications and Presentations: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/119 (3) Status: Terminated
(4) Title: Captopril For Refractory Hypertension

(5) Start Date: 1979	(6) Est Comp Date: 1982
(7) Principal Investigator: Lawrence G. Smith, M.D., CPT, M.C.	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Nephrology	(10) Assoc Investigators: None
(11) Key Words: Captopril Hypertension	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 10/80 Review Results: Terminated	

(15) Study Objective:

To test the use of Captopril in patients with severe hypertension, refractory to standard medication therapy.

(16) *Technical Approach:

The patient qualifying for study has hypertension medications tapered, is placed on increasing doses of Captopril to a maximum dose of 400 mg./day. In a set sequence, beta blockade, diuretics, and vasodilators are added to the regimen until no more tension is achieved. The patient is monitored for all potential side effects.

17) *Progress:

The patient has received Captopril since the initiation of the protocol and his blood pressure has not returned to the normotensive range, but it has been under better control than under any prior medication regimen. The Principal Investigator has departed this station, therefore, this protocol has been terminated.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/100 (3) Status: terminated
(4) Title: Further Studies on the Reflex Mechanism of Bronchoconstriction in Dogs with Esophagitis. The Effects after Therapeutic Healing of the Esophageal Lesions.

(5) Start Date: 8 Dec 80	(6) Est Comp Date: 1 Apr 81
(7) Principal Investigator: Harry Spaulding, Jr, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm.	(10) Assoc Investigators: Nigel Smith, SP6, Technician Richard E. Danziger, MD, CDR, USN Joseph S. Rice, MD, MAJ, MC
(11) Key Words: reflex mechanism in bronchoconstriction	
(12) Accumulative MEDCASE: *	(13) Est Accumulative OMA Cost: *
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 2/81 Review Results: Ongoing	

(15) Study Objective:

To determine if the previously demonstrated reflex-mediated bronchoconstriction secondary to stimulation of the lower inflamed esophagus can be ablated by treatment and resolution of the chemical esophagitis.

16. Technical Approach:

A recent protocol demonstrated bronchoconstriction in a group of dogs who had a chemical esophagitis. This study is designed to firm up this earlier investigation after healing of the lesion. Pulmonary function studies will be done pre- and post esophagitis and confirmed with biopsy.

17. Progress:

All investigators involved in this protocol have left Fitzsimons Army Medical Center. Progress if any is unknown.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/102 (3) Status: Ongoing
(4) Title: Study of Coagulation Parameters Prior To and Following
Intravenous Injection of Radiographic Contrast Media.

(5) Start Date: 20 March 1979 (6) Est Comp Date: 1 December 1982
(7) Principal Investigator: (8) Facility: FAMC
STEPHEN G. OSWALD, D.O., CPT., MC

(9) Dept/Sec: Dept. of Hem/Onc (10) Assoc Investigators:
(11) Key Words: Radiographic contrast media,
Hypercoagulation DAVOR A. LUKETIC, CPT, MC
JUDY BARBER (A.S.C.P.)
PATRICIA RUSH (A.S.C.P.)

(12) Accumulative MEDCASE: * (13) Est Accumulative (14) Date of Review:
OMA Cost: * 4/81
*Refer to Unit Summary Sheet of this report. Review Results:
Ongoing

(15) Study Objective:

To determine if coagulation parameters which have been associated with hypercoagulable states are altered by injection of contrast media.

(16) *Technical Approach:

Prior to the administration of radiographic contrast media, baseline coagulation parameters are drawn. Twenty-four (24) hours following contrast injection repeat studies are drawn and compared with the baseline results, i.e., each patient serves as his own control.

(17) *Progress:

At present more than 20 patients have been studied. Thus far there has been no significant coagulation abnormalities from the baseline studies.

Publications and Presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/103 (3) Status: Ongoing
(4) Title: Etoposide (VP-16-213) Single Agent Chemotherapy in Small Cell Lung Cancer Patients Refractory to First Line Chemotherapy

(5) Start Date: June 1980	(6) Est Comp Date: 1982
(7) Principal Investigator: N.J. DiBella, M.D., COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Hem/Onc	(10) Assoc Investigators:
(11) Key Words: Chemotherapy protocol Small cell lung cancer	Michael Langin
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 6/81 Review Results: Ongoing	

(15) Study Objective:
To test the efficacy of VP-16-213 in patients with recurrent or metastatic small cell CA of the lung.

(16) Technical Approach:
Clinical study.

(17) Progress:
One additional patient has been placed on this drug during the last year. She failed to respond and was taken off the drug because of progressive disease. No serious toxicities were observed.

Publications and Presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/104 (3) Status: Ongoing
(4) Title: Etoposide, (VP-16-213) Combined with Cyclophosphamide plus Vincristine Compared to both Doxorubicin plus Cyclophosphamide plus Vincristine and Cyclophosphamide plus Vincristine of Small Cell Lung Cancer.

(5) Start Date: June 1980	(6) Est Comp Date: 1983
(7) Principal Investigator: N.J. DiBella, M.D., COL, MC	(8) Facility: FAMC FAMC
(9) Dept/Sec: Hem/Onc	(10) Assoc Investigators:
(11) Key Words: Small cell CA, chemotherapy	
(12) Accumulative MEDCASE: *	(13) Est Accumulative OMA Cost: *
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 6/81 Review Results: Ongoing	

(15) Study Objective:

To compare the response, duration of response and survival of small cell lung cancer patients initially treated with either (a) Etoposide (VP-16-213) plus Vincristine plus Cyclophosphamide or (b) Doxorubicin plus Cyclophosphamide or (c) Cyclophosphamide plus Vincristine.

To compare the qualitative and quantitative toxicities of the above 3 regimens.

(16) Technical Approach:
Clinical study.

(17) Progress:
Ongoing. No patients have been entered onto this study.

Publications and Presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/105 (3) Status: Terminated
(4) Title: Dibromodulcitol in Stage IV Metastatic Malignant Melanoma

(5) Start Date: June 1980	(6) Est Comp Date: Terminated 1981
(7) Principal Investigator: N.J. DiBella, M.D., COL., MC	(8) Facility: FAMC FAMC
(9) Dept/Sec: Hem/Onc	(10) Assoc Investigators: MICHAEL LANGIN, CPT, MSC
(11) Key Words: Melanoma, chemotherapy	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 6/81 Review Results: Ongoing	

(15) Study Objective:

To determine the efficacy, duration of response and toxicity of
DBD in melanoma.

(16) Technical Approach:
Clinical Study.

(17) Progress:
No patients have been entered and the study has been closed.

Publications and Presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/107 (3) Status: on-going
(4) Title: Cross Allergenicity among Grasses Determined by Tissue
Threshold Changes

(5) Start Date: 1980	(6) Est Comp Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: BG Martin, MD, CAPT, MC, USAF R Renard, MD, CPT, MC D Leavengood, MD, CAPT, MC, USAF
(11) Key Words: immunotherapy cross allergenicity	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 7/81 Review Results: Ongoing	

(15) Study Objective:

To determine if the cross allergenicity of the western grasses demonstrated by RAST inhibition can be confirmed in vivo using the tissue threshold technique.

16. Technical Approach:

Patient with broad reactivity to grasses who are beginning immunotherapy will have titrated sensitivity to the various grasses determined. Separate groups will then receive immunotherapy either with all the grasses to which they are sensitive or only Timothy or Bermuda. It will be determined whether therapy with only Timothy and Bermuda suppresses cutaneous sensitivity to the entire group of grasses as well as does immunotherapy with all of the individual grass allergens.

17. Progress:

No further patients are being enrolled under this study. All patients will have completed their one year of immunotherapy and have been reassessed by late October, 1981. The material will then be analyzed for presentation and publication.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/108 (3) Status: Ongoing
(4) Title: Topical Cocaine for the Relief of Stomatitis in Patients with
Malignancies: A Double-Blind Study.

(5) Start Date: October 1980	(6) Est Comp Date: 1981
(7) Principal Investigator: N.J. DiBella, M.D., COL., MC	(8) Facility: FAMC FAMC
(9) Dept/Sec: Hem/Onc	(10) Assoc Investigators:
(11) Key Words: Chemotherapy, Cocaine	Richard A. Artim, M.D., MAJ., USAF, MC

(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 9/81
*Refer to Unit Summary Sheet of this report.		Review Results: Ongoing

- (15) Study Objective:
- To determine whether topical cocaine is better than Viscous Xylocaine in the treatment of stomatitis.
 - To determine which concentration of cocaine affords optimal relief and the fewest side effects in the treatment of stomatitis.

(16) Technical Approach:
Clinical study - Three different concentrations of cocaine combined with Viscous Xylocaine will be tested against Viscous Xylocaine alone in the relief of pain due to stomatitis.

(17) Progress:
Six patients have been entered into this study. Transient benefit was noted in two patients. No significant toxicity was observed.

Publications and Presentations: None.

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(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/109 (3) Status: Ongoing
(4) Title:

Insulin Post-Receptor Physiology

(5) Start Date: September 1980 (6) Est Comp Date: September 1982

(7) Principal Investigator: (8) Facility: FAMC

Robert E. Jones, MD, MAJ, MC

(9) Dept/Sec: Endocrinology Svc (10) Assoc Investigators:

(11) Key Words: Gerald S. Kidd, LTC, MC
Fred D. Hofeldt, COL, MC
David T. Zolock, MAJ, MS
insulin receptor
post receptor defect
insulin action

(12) Accumulative MEDCASE:*(13) Est Accumulative (14) Date of Review:
OMA Cost:*

*Refer to Unit Summary Sheet of this report.

9/81
Review Results:
Ongoing

(15) Study Objective: The medical objective of this study is to study the receptor physiology and biochemistry to define membrane and/or intracellular mechanisms of Insulin resistance.

(16) Technical Approach: Establish the methodology for measuring glucose uptake in target tissue. The erythrocyte is the tissue that has been chosen for the experimental assessment of insulin post-receptor action. Previous work has been conducted in the erythrocyte to show changes in membrane receptors in relationship to physiologic insulin concentrations. In this study, H3-2-dioxyglucose, a non-metabolizable glucose analog, which is transported and trapped in a fashion similar to glucose will be used as a marker of glucose uptake in the red cell. Various ambient fatty acid concentrations in the incubation mixture will be used to determine the influence of fatty acids on receptor glucose transport.

(17) Progress: Preliminary studies and establishing the assay are currently in progress in the Department of Clinical Investigation Research Laboratory. Inasmuch as the assay has not yet been established, critical studies in regards to experimental design have not been conducted.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/110 (3) Status: completed
(4) Title: The Effect of Ascorbic Acid on the Cutaneous and Nasal
Response to Histamine and Antigen

(5) Start Date: 1980	(6) Est Comp Date: complete
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: Bryant Fortner, MD, MAJ, MC Richard Danziger, MD, CDR, MC, USN Paul Rabinowitz, MD, CPT, MC
(11) Key Words: ascorbic acid histamine	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 9/81 Review Results: Completed	

(15) Study Objective:

To determine whether pharmacologic doses of ascorbic acid can decrease the response to either histamine or other mast cell mediators released by allergen injection.

16. Technical Approach:

Patients were skin tested to allergen to which they were sensitive, morphine sulfate, a nonspecific mast cell degranulator, and histamine while on a low ascorbic acid diet and receiving in a double-blind manner either ascorbic acid or placebo.

17. Progress:

Eight patients were studied under the protocol. The results have been presented a national meeting and have been submitted for publication.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 80/110

SERVICE Allergy-Immunology

DEPARTMENT Medicine

1. Fortner B, Danziger R, Rabinowitz P, Nelson HS: The Effect of Ascorbic Acid on Cutaneous and Nasal Response to Histamine and Allergen (abstr) Journal Allergy Clinical Immunology 67:48;Jan, 1981 (supplement).

PRESENTATIONS for FY 81 Annual Progress Report

1. Fortner BR, The Effect of Ascorbic Acid on Cutaneous and Nasal Response to Histamine and Allergens, 33rd Annual Pulmonary Disease Symposium, Fitzsimons Army Medical Center, Aurora, CO, January, 1981.
2. Fortner BR, Danziger RE, Rabinowitz P, Nelson H, The Effect of Ascorbic Acid on Cutaneous and Nasal Response to Histamine and Allergen, 17th Annual Meeting American Academy of Allergy, San Francisco, CA, March, 1981.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/111 (3) Status: completed
(4) Title: Effect of Corticosteroids on Theophylline Metabolism

(5) Start Date: 1980	(6) Est Comp Date: 1981
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm.	(10) Assoc Investigators: A Bunker-Soler, MD, MAJ, MC D Leavengood, MD, CAPT, MC, USAF
(11) Key Words: corticosteroids theophylline metabolism	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 9/81	Review Results: Ongoing

(15) Study Objective:

To determine whether high-dose corticosteroids interfere with the metabolism of theophylline.

16. Technical Approach:

Subjects were stabilized on long-acting, oral theophylline and then received either placebo, two doses of hydrocortisone four hours apart or two doses of methylprednisolone four hours apart with measurement of serum theophylline level for eight hours.

17. Progress;

Six patients were studied, and since the results were entirely negative, this number was considered to be adequate. The results have been reported and are being prepared for publication.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 80/111

SERVICE Allergy-Immunology Svc

DEPARTMENT Medicine

1. Bunker-Soler, A.L., Leavengood, D.C., Nelson, H.S.: The Effects of Corticosteroids on Theophylline Metabolism. (Abst) Annals of Allergy 47:133, 1981.

PRESENTATIONS for FY 81 Annual Progress Report

1. Bunker-Soler, A., Leavengood, D.: The Effect of Corticosteroids on Theophylline Metabolism. Presented: 37th Annual Congress of American College of Allergists, Washington, D.C., April 1981.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/112 (3) Status: on-going
(4) Title: The Effect of Troleandomycin and Methylprednisolone Alone
and in Combination on Bronchial Sensitivity to Methacholine

(5) Start Date: 1981	(6) Est Comp Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm.	(10) Assoc Investigators: RL Renard, MD, CPT, MC WP Andrade, MD, LTC, MC
(11) Key Words: troleandomycin methacholine sensitivity	
(12) Accumulative MEDCASE: *	(13) Est Accumulative OMA Cost: *
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 9/81 Review Results: Ongoing	

(15) Study Objective:

To attempt to demonstrate under carefully controlled conditions that Troleandomycin either by itself or in conjunction with Methylprednisolone decreases the hypersensitivity to inhaled Methacholine present in patients with allergic rhinitis and mild asthma.

16. Technical Approach:

Patients with demonstrated Methacholine sensitivity but not requiring chronic bronchodilator administration will be studied in a double-blind manner with Methacholine sensitivity measured following placebo, methylprednisolone alone, troleandomycin alone or the combination of troleandomycin and methylprednisolone.

17. Progress;

Seven subjects have been studied under the protocol, an eighth is currently being studied, and it is hoped that two more can be studied within the near future. It is hoped to submit an abstract based on this study to the meetings in early 1982.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/113 (3) Status: on going
(4) Title: The Effect of Spontaneous Variation in Ambient Small Ion
Concentrations on Pulmonary Function in Patients with Bronchial Asthma

(5) Start Date: 1980	(6) Est Comp Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: R Danziger, MD, CDR, MC, USN C Wagner, MD, LCDR, MC, USN
(11) Key Words: small air ions	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 9/81 Review Results: Ongoing	

(15) Study Objective:

To monitor pulmonary function in a group of patients with bronchial asthma in order to determine whether there is a deleterious effect of changes in concentration of small air ions which occurs spontaneously preceding the arrival of weather fronts.

16. Technical Approach:

Ambient concentrations of small air ions are to be monitored three times daily and at approximately the same three times a group of patients with bronchial asthma will record their pulmonary function employing a Mini-Wright Peak Flow Meter. Weather information will be obtained from public sources.

17. Progress;

A preliminary study was done during the winter of 1980-81 and was negative. However, 1980-81 winter was marked by an unusual absence of typical storm fronts. It is, therefore, intended to repeat this study during the winter of 1981-82.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. (C))

(Detail Summary Sheet)

(4) Date: 30 SEP 81 (2) Proj No.: 860142 (3) Status: Completed
 (4) Title: The Effect of Troleandomycin and Methylprednisolone Alone and in Combination on Bronchial Sensitivity to Methacholine between Patients with Cancer and Medical Personnel.

(5) Start Date: 1981-1980	(6) End Comp Date: 1981-1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC N. J. DiBella, M.D., COL, MC	(8) Facility: FAMC FAMC
(9) Dept/Spec Medicine/Allergy-Imm.	(10) Assoc Investigators: RL Renard, MD, CPT, MC WP Andrade, MD, LTC, MC Wayne D. Lewis, MA, ABD
(11) Key Words: troleandomycin social aspects of malignancy methacholine sensitivity	
(12) Accumulative Response: **	(13) Est Accumulative OMACost:**
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 9/89/81	Review Results: Ongoing

(15) Study Objectives:

To attempt to demonstrate under a carefully controlled and procedural characteristics Troleandomycin either by itself or in conjunction with methylprednisolone decreases the hypersensitivity to inhaled Methacholine present in patients with allergic rhinitis and mild asthma communication patterns between physicians and patients upon patient satisfaction with clinical and nonclinical

16. Technical Aspects of treatment.

Patients with demonstrated Methacholine sensitivity but not requiring chronic bronchodilator administration will be studied in a double-blind manner with Methacholine sensitivity measured following placebo, methylprednisolone alone or the combination of troleandomycin and methylprednisolone.

17. Progress;

Seven subjects have been studied under the protocol, an eighth is currently being studied and data is hoped and the data is being analyzed approximately four physicians hoped to submit data and 25-40 patients in this study to the meetings in early 1982.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/115 (3) Status: Ongoing
(4) Title: Evaluation of Amiodarone for the Therapy of Cardiac Arrhythmias

(5) Start Date: 1980	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Richard C. Davis, Jr., LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Cardiology	(10) Assoc Investigators:
(11) Key Words: amiodarone cardiac arrhythmias	none
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 9/81 Review Results: Ongoing	

(15) Study Objective: To control symptomatic cardiac arrhythmias which have not been responsive to the conventional and accepted forms of treatment or whose control is dependent upon the use of a drug which has been shown to be harmful to or in other ways not tolerated by the individual.

(16) Technical Approach: After patient selection, baseline laboratory results as outlined in the protocol will be obtained. After initiation of therapy, the patient will be followed regularly by the principal investigator with frequent Holter monitors to assess the efficacy of the drug and other laboratory tests and examination to warn of potential toxicity.

(17) Progress: At this point, only the original patient is on protocol. No other candidates have been entered into the protocol. The patient continues without ventricular ectopy or further episodes of "sudden death". Her maintenance dose of amiodarone has been decreased to 200 mg p.o. daily because of increasing corneal deposits.

Publications and Presentations: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/116 (3) Status: Terminated
(4) Title: Prevention of Gonadal Damage in Men treated with Combination
Chemotherapy/Radiotherapy for Hodgkin's Disease and Non-Hodgkin's Lymphomas

(5) Start Date: Aug 80	(6) Est Comp Date: 1981
(7) Principal Investigator: N.J. DiBella, M.D., COL., MC	(8) Facility: FAMC FAMC
(9) Dept/Sec: Hem/Onc	(10) Assoc Investigators:
(11) Key Words: Fertility, chemotherapy	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 11/80 Review Results: Ongoing	

(15) Study Objective:

To attempt to prevent permanent infertility and alterations in normal sexual function caused by combination chemotherapy in the treatment of Hodgkin's Disease or Non-Hodgkin's lymphoma.

(16) Technical Approach:

Clinical pathologic study.

(17) Progress:

No patient has ever been placed on this study. The study chairman from Walter Reed Army Medical Center had decided to close the study.

Publications and Presentations: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/117 (3) Status: on-going
(4) Title: Correlation of Clinical Signs and Symptoms with Assays of
Circulating Immune Complexes (CIC)

(5) Start Date: approx. Oct. 1980	(6) Est Comp Date: Oct. 1982
(7) Principal Investigator: William R. Tipton, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: R. Stephen Whiteaker, PhD, CPT, MSC Vasundhara Iyengar, MD, MAJ, MC David Thomas, MD, CPT, MC
(11) Key Words: immune complexes CIQ laboratory assays	
(12) Accumulative MEDCASE: *	(13) Est Accumulative OMA Cost: *
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 11/81 Review Results: Ongoing	

(15) Study Objective:

The purpose of this study is to determine the relative sensitivity of several laboratory assays for immune complexes in patients with suspected immune complex disorders.

16. Technical Approach:

Patients in whom serum is submitted for antinuclear antibodies will have a standard clinical evaluation and their serum will be examined by a standardized battery of four assays for circulating immune complexes. Correlations will then be made to determine which of the assays best reflects clinical disease.

17. Progress:

The immunology laboratory is continuing to perfect the assay for circulating immune complexes. The clinical data and specimens are being stored from the patients involved in the study, and it is anticipated the lab will commence the actual work on the patients' sera in the immediate future.

Publications and Presentations: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/118 (3) Status: Ongoing

(4) Title:

5-Azacytidine in the Treatment of Acute Nonlymphocytic Leukemia

(5) Start Date: 1 Oct 1980

(6) Est Comp Date: Indefinite

(7) Principal Investigator:

(8) Facility: FAMC

Arlene J. Zaloznik, M.D., MAJ, MC

(9) Dept/Sec: Hematology-Oncology

(10) Assoc Investigators:

(11) Key Words:

Nicholas J. DiBella, M.D., COL, MC

5-Azacytidine

Acute nonlymphocytic leukemia

(12) Accumulative MEDCASE: *

(13) Est Accumulative

(14) Date of Review:

OMA Cost: *

12/80

*Refer to Unit Summary Sheet of this report.

Review Results:

Ongoing

(15) Study of Interest:

(15) Study Objective: To determine the efficacy of 5-Azacytidine in patients with acute nonlymphocytic leukemia who have relapsed after conventional chemotherapy.

(15) Technical Approach:

(16) Technical Approach:

Patients with biopsy proven acute nonlymphocytic leukemia who have failed conventional modes of therapy are given 5-Azacytidine 200 mg/M²/day in four divided doses, each to infuse over six hours for five days. A bone marrow aspiration and biopsy is performed ten days after the completion of therapy. If the patient is not in a complete remission then the course of therapy is repeated until the patient is in complete remission or declines any further therapy.

(17) Progress:

Three patients have thus far been registered on the protocol, all three had acute myelogenous leukemia and had failed conventional therapy consisting of Daunomycin, 5-Azacytidine and 6-Thioguanine. One patient had no response, the other two patients had a partial response after two courses of 5-Azacytidine; however all three patients have expired from their underlying leukemia. At the present time there are no patients who are with acute leukemia who are currently eligible for this protocol. However, as 5-Azacytidine is an acceptable salvage protocol for patients who have failed previous forms of chemotherapy for acute leukemia, the drug will continue to be offered to those patients who meet the eligibility of requirements of this protocol.

PUBLICATION and PRESENTATIONS: none

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/119 (3) Status: on going
(4) Title: Assessment of the Development of Alpha Adrenergic Subsen-
sitivity with Chronic Ingestion of Oral Decongestant Agents

(5) Start Date: 1981	(6) Est Comp Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm.	(10) Assoc Investigators: Pinkus Goldberg, MD, CPT, MC Paul Rabinowitz, MD, CPT, MC
(11) Key Words: alpha adrenergic subsensitivity	
(12) Accumulative MEDCASE: * *Refer to Unit Summary Sheet of this report.	(13) Est Accumulative OMA Cost: * (14) Date of Review: 12/80 Review Results: Ongoing

(15) Study Objective:

To determine whether chronic administration of oral nasal decongestants which are alpha adrenergic agonists induce a state of alpha adrenergic subsensitivity.

16. Technical Approach:

Response to nasal decongestants will be assessed by their ability to modulate the nasal airway resistance increase with instillation of histamine. Alpha adrenergic reactivity will be measured by the ability of neosinephrine to prolong the zeon washout time from the skin and the response in the cold pressor test. These responses will be studied before and after two weeks of chronic administration of the nasal decongestant medication.

17. Progress:

Approximately six patients have been studied under this protocol. Enrollment of subjects should be completed by the fall of 1981.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81		(2) Prot No.: 80-120	(3) Status: Ongoing
(4) Title: Evaluation of Carbohydrate Metabolism in Thyrotoxicosis: Investigations Into the Frequency, Type and Mechanisms of Carbohydrate Intolerance.			
(5) Start Date: April 1981		(6) Est Comp Date: April 1983	
(7) Principal Investigator: Gerald S. Kidd, MD, LTC, MC		(8) Facility: FAMC	
(9) Dept/Sec: Medicine/Endocrinology		(10) Assoc Investigators: T. P. O'Barr, Ph.D. Fred D. Hofeldt, MD, COL, MC	
(11) Key Words: carbohydrate intolerance thyrotoxicosis			
(12) Accumulative MEDCASE:*		(13) Est Accumulative OMA Cost:*	(14) Date of Review: 3/81 Review Results: Ongoing
*Refer to Unit Summary Sheet of this report.			

(15) Study Objective: The first objective of the study is to determine the frequency and reversibility of carbohydrate intolerance in thyrotoxicosis and to determine the importance of gut factors by doing oral and intravenous glucose tolerance tests. The second objective is to study the mechanisms of carbohydrate intolerance. This objective will be approached by measuring glucose, insulin, glucagon and free fatty acids, basally and after oral or intravenous glucose and by measuring the responses to exogenous insulin.

(16) Technical Approach: Ten non-diabetic patients who are taking no medications, are less than age 45, are less than 120% of ideal body weight, will be studied while thyrotoxic and after recovery. Each patient will have an oral and an intravenous glucose tolerance test. Each patient will have an insulin tolerance test basally and following glucose infusion.

(17) Considerable time has been spent in preparing and improving laboratory assays to be used in the study. A precise and reproducible assay has been developed for the measurement of free fatty acids in serum. Great difficulty has been encountered in the measurement of plasma glucagon. The original assay was too insensitive. Recent improvements have been made. As yet, no patients have been studied because of the above assay problems.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 4Q-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81			(2) Prot No.: 80-121			(3) Status: Ongoing		
(4) Title: An Evaluation of Pituitary and Thyroid Hormonal Responses to a 4-Hour Continuous and a Bolus Intravenous Infusion of TRH as a Useful Test of Thyroidal Functional Reserve								
(5) Start Date: March 1981				(6) Est Comp Date: July 1983				
(7) Principal Investigator: Michael Bornemann, MD, LTC, MC				(8) Facility: FAMC				
(9) Dept/Sec: Endocrine Service				(10) Assoc Investigators: Gerald S. Kidd, MD, LTC, MC Fred D. Hofeldt, MD, COL, MC William J. Georgitis, MD, MAJ, MC				
(11) Key Words: thyroid functional pituitary reserve thyroidal axis TRH infusion								
(12) Accumulative MEDCASE:*				(13) Est Accumulative OMA Cost:*		(14) Date of Review: 4/81 Review Results: Ongoing		
*Refer to Unit Summary Sheet of this report.								

(15) Study Objective:

The objective of this study is to determine if the diagnosis of mild or subclinical hypothyroidism can be more clearly established by some integrated parameter reflecting both the pituitary and thyroidal reserve responses to intravenous thyrotropin releasing hormone.

(16) Technical Approach:

Three groups of subjects will be evaluated in this protocol. Group 1 will consist of normal control patients; Group 2 will consist of patients with mild hypothyroidism diagnosed by an elevated TSH level but normal thyroid hormone levels; Group 3 will consist of patients from the Thyroid Clinic with high-normal TSH values and normal thyroid function tests, but who are clinical suspects of having mild hypothyroidism. The patients will undergo two TRH infusion tests in a random manner consisting of conventional bolus administration of 500 ug of TRH solution and the constant infusion of TRH over a 4-hour period with 500 ug of TRH diluted in normal saline and diffused at a rate of 2 ug per minute over the 4 hours using a Harvard infusion pump. The TSH values in the various groups of patients will be determined and statistically analyzed for differences between the groups.

(17) Progress:

Because of the late acceptance of the protocol for study at Fitzsimons Army Medical Center, the primary investigator has subsequently been assigned to Brooke Army Medical Center and the study will require completion at FAMC with a new principal investigator, LTC Michael Bornemann. The study will be ongoing over the next two years.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 80-121

SERVICE Endocrinology

DEPARTMENT Medicine

None.

PRESENTATIONS for FY 81 Annual Progress Report

None.

DEPARTMENT OF CLINICAL INVESTIGATION
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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/ 100 (3) Status: Ongoing
(4) Title:

EVALUATION OF THIAZIDE USE AND CHOLELITHIASIS

(5) Start Date: 3 March 1981	(6) Est Comp Date: 3 March 1983
(7) Principal Investigator: Steve R. Parker, M.D. Gregory J. DeWerd, M.D. Stanley F. Smazal, M.D.	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Cardiology	(10) Assoc Investigators: Bob Kazenoff, M.D. Thomas Brewer, M.D. Nasser Ghaed, M.D.
(11) Key Words: Cholelithiasis Thiazides	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 3/81 Review Results: Ongoing	

(15) Study Objective:

A. To objectively evaluate the reported association between thiazide use and gallbladder disease. B. To evaluate the dose-response relation of the duration of thiazide usage to cholelithiasis. C. To evaluate a possible relationship between other antihypertensives and gallbladder disease.

(16) Technical Approach:

Approximately 300 total patients (divided into three groups of 100 each) will be evaluated. One group is designated the control group, a second group is designated the hypertensive control group, and the third group is comprised of hypertensive patients on thiazides. All patients in the above three groups are evaluated by ultrasound for the detection of cholelithiasis.

(17) Progress:

To date, 82 patients have been included in the study with 46 patients falling into the thiazide group, 28 into the control group, and 8 into the hypertensive control group. In order to prevent investigator bias, prospective data has not yet been tabulated and will not be tabulated until each group contains enough patients for valid statistical analysis.

PUBLICATIONS and PRESENTATIONS: none

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(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81-101 (3) Status: Ongoing
(4) Title: Development and evaluation of rapid immunologic procedures for the diagnosis of giardiasis.

(5) Start Date: 5 May 1981	(6) Est Comp Date: March 1983
(7) Principal Investigator: Thomas G. Brewer, et al.	(8) Facility: FAMC
(9) Dept/Sec: Gastroent./DCI	(10) Assoc Investigators:
(11) Key Words: Diarrhea, giardiasis, <u>Giardia lamblia</u>	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 81/101 Review Results: Ongoing	

(15) Study Objective: To develop immunodiagnostic procedures for rapid detection of Giardia lamblia antigen in fecal and duodenal aspirate specimens and the detection of anti-Giardia antibodies in the serum of giardiasis patients. To evaluate the efficacy of these tests for rapid diagnosis of giardiasis in a select patient population.

(16) Technical approach: We have not deviated from the technical approach described in detail in the protocol.

(17) Progress: Objectives of Phases I and II as described in the protocol have been accomplished; namely, in vitro cultivation of Giardia lamblia and production of anti-Giardia serum in rabbits. Two separate cultures are being maintained; one in medium containing bovine serum; one in medium containing rabbit serum. Giardia trophozoites are harvested weekly from tube cultures. Phase III has been initiated: to date, gel diffusion, immunoelectrophoresis and counterimmuno-electrophoresis procedures using sonicated trophozoite antigen and rabbit anti-serum have been performed with success. Under Phase IV, paired sera and preserved fecal specimens have been collected from 20 giardiasis patients.

PUBLICATIONS and PRESENTATIONS: none

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(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/102 (3) Status: Ongoing
(4) Title: Treatment of Herpes Zoster with High versus Low Dose
Systemic Steroids.

(5) Start Date: 1 Jul 1981	(6) Est Comp Date: 1 Jul 1983
(7) Principal Investigator: Stephen W. Eubanks, M.D., Cpt, MC	(8) Facility: FAMC
(9) Dept/Sec: Dermatology/ D.O.M.	(10) Assoc Investigators: Dennis L. May, M.D., LTC, MC
(11) Key Words: Herpes Zoster Steroids	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: April 1981 Review Results: Ongoing	

(15) Study Objective:

The primary objective is to determine if high dose Prednisone (80 mg per day) is more effective than moderate dose oral Prednisone (40 mg per day) in the prevention of post-herpetic neuralgia, secondary to herpes zoster.

(16) Technical Approach: A double blind study compares high versus medium dose oral Prednisone in the prevention of post herpetic neuralgia. Subjective testing and objective evaluation of nerve damage using a histamine flare test is utilized. Patients are followed on days 3, 7, 14, 21 and 60.

(17) Progress: Only four patients have been entered into the study. One patient dropped out prior to starting the Prednisone, secondary to fears of side-effects. The three patients to complete the study have had resolution of their herpes zoster, with no post-herpetic neuralgia to date.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/103 (3) Status: Terminated
(4) Title: Cardiovascular Response to Isometric Stress Before and
After Circuit Weight Training

(5) Start Date: May 1980	(6) Est Comp Date: Indefinite
(7) Principal Investigator: John T. Svinarich, CPT, MC	(8) Facility: FAMC
(9) Dept/Sec: Med/Cardio	(10) Assoc Investigators: Steven Bailey, CPT, MC
(11) Key Words: echocardiogram cardiac scan weight training	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 6/81 Review Results: Ongoing	

(15) Study Objective: To assess cardiovascular adaptations to circuit weight training and to evaluate the response to isometric stress before and after weight training.

(16) Technical Approach: Patients will be recruited to participate in a 10 week course of circuit weight training. They will be evaluated before and after the 10 week course of training. Patients will be supervised to insure a uniform method of training and exercise schedule. Patient responses will be compared to obtain statistical evaluation.

(17) Progress: This study has been terminated because adequate echocardiograms and cardiac scans could not be achieved on the first three patients which were enrolled. This was related to technical limitations of the equipment available to us.

Publications and Presentations: none

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(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/104 (3) Status: on-going
(4) Title: The Incidence of Host Defence Deficiency in Patients
Presenting with Frequent or Prolonged Infections

(5) Start Date: to be determined		/ by the Immunology Sec., Clinical Inves. Svc.	
(7) Principal Investigator: William R. Tipton, MD, COL, MC		(6) Est Comp Date: 4-5 yrs.	
(9) Dept/Sec: Medicine/Allergy-Imm		(8) Facility: FAMC	
(11) Key Words: immunodeficiency infection laboratory tests		(10) Assoc Investigators: Harold S. Nelson, MD, COL, MC R. Stephen Whitaeker, CPT, MSC Joseph Lima, BAC Fellows, Allergy-Immunology Service	
(12) Accumulative MEDCASE: *	(13) Est Accumulative OMA Cost: *	(14) Date of Review: 7/81 Review Results: Ongoing	

*Refer to Unit Summary Sheet of this report.

(15) Study Objective:

To determine the cost effectiveness of performing various laboratory evaluations of immune responsiveness in patients presenting with frequent or prolonged infections.

16. Technical Approach:

Patients who are referred for this protocol will have a standardized clinical evaluation by the Fellows in the Allergy-Immunology Service and then will have a standard battery of tests performed to evaluate their immune status and phagocytic function. On the basis of the clinical history certain laboratory tests will be determined to have been clinically indicated, subsequently the yield from the routine battery of tests will be compared to the yield from those tests which were thought to have been clinically indicated.

17. Progress: Work has not yet begun on this protocol.

Publications and Presentations: none

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(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/105 (3) Status: on-going
(4) Title: Measurement of the Effects of Specific IgG on the Levels
of Specific IgE as Measured by the Radioallergosorbent Test

(5) Start Date: July, 1981	(6) Est Comp Date: March, 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: T. O'Bara, PhD, DAC R. Ledoux
(11) Key Words: RAST Blocking antibody	
(12) Accumulative MEDCASE: *	(13) Est Accumulative OMA Cost: *
(14) Date of Review: 7/81 Review Results: Ongoing	

*Refer to Unit Summary Sheet of this report.

(15) Study Objective:

To determine whether IgG blocking antibodies generated by allergy immuno-therapy significantly interfere with the determination of specific IgE by the radioallergosorbent test.

16. Technical Approach:

Sera with and without levels of blocking antibody will be studied before and after adsorption with staphylococcus protein A. The parameters measured will be total IgG and IgE and antigen specific RAST and blocking antibody.

17. Progress:

Laboratory work on the protocol is reaching its final stages.

PUBLICATIONS and PRESENTATIONS: none

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(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/106 (3) Status: on-going
(4) Title: Clinical Effectiveness and Development of Subsensitivy
with Chronic Administration of Atropine Methonitrate

(5) Start Date: 1981	(6) Est Comp Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators:
(11) Key Words: atropine subsensitivity	Allergy-Immunol Svc Fellows, DOM
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 7/81 Review Results: Ongoing	

(15) Study Objective:

To determine the effect of chronic administration on the bronchodilator response to atropine.

16. Technical Approach:

The efficacy will be determined by a double-blind placebo atropine comparison, each of one week's duration monitored by home measurement of pulmonary function. In addition, the acute response to atropine inhalation will be monitored prior to and following the week of chronic atropine administration.

17. Progress:

No studies have been undertaken under this protocol.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/107 (3) Status: on-going
(4) Title: Relation of Distance and Direction on the Effect of One
Immediate Wheal and Flare Skin Test Upon Another.

(5) Start Date: 1981	(6) Est Comp Date: December, 1981
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: WR Tipton, MD, COL, MC W Vinson, MD, COL, MC D McBride, MD, MAJ, MC
(11) Key Words: false positive skin tests	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 7/81 Review Results: Ongoing	

(15) Study Objective:

To determine the extent to which a positive immediate wheal and flare skin test can influence the response to a nearby skin test.

16. Technical Approach:

A skin test giving a large positive prick test reaction will be repeated on the back surrounded in varying directions and at varying distances by prick tests to an antigen which previously gave a negative response. The occurrence of false positive skin tests will be monitored.

17. Progress:

Patient studies under this protocol have now been completed. The data has been submitted for presentation.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/108 (3) Status: on-going
(4) Title: Development and Class Specificity of Tolerance to Antihistamine
Drugs

(5) Start Date: 1981	(6) Est Comp Date: 1983
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: Allergy-Immunol Fellows, DOM
(11) Key Words: Antihistamine subsensitivity	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 7/81 Review Results: Ongoing	

(15) Study Objective:

To re-examine the development of subsensitivity to the anti-H1 effects of commonly employed antihistamine preparations and to determine whether the tolerance is related to the chemical structure of the H1 antagonist or applies equally to all H1 antagonists regardless of chemical structure.

16. Technical Approach:

The ability of antihistamines to suppress histamine skin tests will be measured prior to and during the course of prolonged antihistamine therapy.

17. Progress:

No studies have been undertaken under this protocol.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/109 (3) Status: Ongoing
(4) Title: Southwestern Oncology Group Collaborative Studies

(5) Start Date:	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Nicholas J. DiBella, M.D., COL., MC	(8) Facility: FAMC FAMC
(9) Dept/Sec: Hem/Onc	(10) Assoc Investigators:
(11) Key Words: Chemotherapy	
(12) Accumulative MEDCASE: *	(13) Est Accumulative OMA Cost: *
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 2/81	Review Results: Ongoing

(15) Study Objective:

Variable according to protocols involved. FAMC currently participating in 29 protocols.

(16) Clinical Approach &

(17) Progress:

Four patients have been entered into these protocols to date. One patient was placed on 7924 for limited disease small cell carcinoma and remains clinically in remission; he has had no significant toxicity from the therapy. A second patient has been placed on protocol 7827 which is an adjuvant therapy protocol for metastatic breast cancer. She has tolerated the oophorectomy and adjuvant chemotherapy except for moderately severe side effects from the chemotherapy, as expected.

A third patient has been placed on Protocol 7727 involving chemotherapy for metastatic melanoma. She has completed her first cycle of chemotherapy and has tolerated it well to date; that is, there is no evidence of response at this point.

A fourth patient has been placed on protocol 8027 which is a Natural History protocol for patients with pathological Stage T-1 N-0 M-0 positive estrogen receptors in the primary tumor; no treatment is involved here and she is being followed in the clinic.

Publications and presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/110 (3) Status: on-going
(4) Title: Lability of Blocking Antibody during Allergy Immunotherapy.

(5) Start Date: 1981	(6) Est Comp Date: 1982
(7) Principal Investigator: Harold S. Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm.	(10) Assoc Investigators: TP O'Barr, PhD, DAC C Wagner, MD, LCDR, MC, USN
(11) Key Words: blocking antibody lability	
(12) Accumulative MEDCASE: * *Refer to Unit Summary Sheet of this report.	(13) Est Accumulative OMA Cost: * (14) Date of Review: 7/81 Review Results: Ongoing

(15) Study Objective:

To follow a group of patients through a course of allergy immunotherapy with the objective of determined the duration of the rise in specific IgG following an injection of allergy extract at different intervals following the commencement of treatment.

16. Technical Approach:

The response over a one month period of time will be measured to a single injection of allergy extract in patients just reaching maintenance doses and in patients who have been on maintenance injections for several years.

17. Progress:

Patient study is underway and should be completed within one month.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/111 (3) Status: on-going
(4) Title: Comparative Effect of Major Corticosteroids on Lymphocyte Blastogenesis and Assessment of the Corticosteroid Sparing Effect of Troleandomycin

(5) Start Date: July, 1981	(6) Est Comp Date: Dec. 1981
(7) Principal Investigator: James S. Brown, MD, MAJ, MC	(8) Facility: FAMC
(9) Dept/Sec: Medicine/Allergy-Imm	(10) Assoc Investigators: William P. Andrade, MD, LTC, MC William R. Tipton, MD, COL, MC R. Stephen Whiteaker, CPT, MSC
(11) Key Words: corticosteroids lymphocyte blastogenesis dosage of steroids	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 7/81 Review Results: Ongoing	

(15) Study Objective:

To determine if various classes of corticosteroids differ in the magnitude of suppression of lymphocyte blastogenesis and to ascertain the effect of Troleandomycin in combination with these corticosteroids on lymphocyte blastogenesis.

16. Technical Approach:

This is an in vitro study using normal lymphocyte populations for blastogenesis as triggered by mitogens and measured by incorporation of tritiated thymidine.

17. Progress:

The necessary preservative-free drugs have been obtained and the immunology laboratory has begun preliminary studies.

Publications and Presentations: none

SURGERY

DEPARTMENT OF CLINICAL INVESTIGATION
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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 71-202 (3) Status: Ongoing
(4) Title:

Evaluation of Peripheral Nerve Injuries at FAMC

(5) Start Date: 1971	(6) Est Comp Date: indef
(7) Principal Investigator: William W. Eversmann, Jr., COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Ortho Svc	(10) Assoc Investigators: Bertram Goldberg, COL, MC
(11) Key Words: Neurorrhaphy, peripheral nerve	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 7/81 Review Results: Ongoing	

(15) Study Objective:

To establish a pattern of peripheral nerve repair and recovery following injuries to peripheral nerves and in most cases following neurorrhaphy of multiple peripheral nerves.

(16) Technical Approach: Detailed questionnaire follow-up of patients with peripheral nerve injuries who have undergone repair are followed by detailed outpatient physical examination and evaluation supplemented by the questionnaires. The questionnaires are divided into specific detailed questions and customized for the level and type of nerve injury.

(17) Progress: During FY 1981 we have continued the ongoing clinical data mostly by questionnaires supplemented with an occasional outpatient visit and continue to accumulate data from this important nerve injury evaluation. It is important to realize at this time that all patients are being invited back to FAMC for detailed peripheral nerve study and many of them are accepting this invitation which enables us to accumulate more accurate and more detailed data.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 73/219 (3) Status: Ongoing
(4) Title:

Treatment of Urinary Tract Trauma in the Laboratory Animal

(5) Start Date: May 1973	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Major Daniel W. Horne, MC	(8) Facility: FAMC
(9) Dept/Sec: Surgery-Urology Svc	(10) Assoc Investigators: Captain John H. Mani, M.D., MC LCMDR William Shipton, M.D., MC Lt Colonel Michael Norris, M.D., MC Colonel Edward G. Buck, M.D., MC Colonel Howard E. Fauver, M.D., MC
(11) Key Words: Trauma-Renal transplantation	(12) Accumulative MEDCASE: * (13) Est Accumulative OMA Cost: *
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 6/81 Review Results: Ongoing	

(15) Study Objective: Investigation of and comparison of various modes of treatment of urological trauma with emphasis on newer surgical techniques to include renal vascular repair, bench surgery and autotransplantation.

(16) Technical Approach: Various techniques of vascular reanastomosis and autotransplantation will be performed. This will be followed by IVPs 2-4 weeks postoperatively to ascertain success or failure.

(17) Progress: Continuing experimentation with various techniques of autotransplantation is being performed. Unfortunately due to personnel shortages we were unable to utilize this protocol as extensively as desired. It is anticipated with full staffing in the coming fiscal year, the protocol will enjoy increased utilization and several techniques to prolong warm ischemia time will be explored.

SERVICE UrologyDEPARTMENT of Surgery

- (1) Levisay, G.L.: Renal Autotransplantation in the Dog. Proc of the Kimbrough Urolo Sem, January 1974.
- (2) Jackson, J.E.: Renal Autotransplantation with Partial Nephrectomy in the Dog. Proc of the South Central Sect, AUA, Denver, CO, 15-19 September 1974.
- (3) Page, M.E.: Renal Autotransplantation with Venal Caval Occlusion. Proc of the Kimbrough Urolo Sem, Seattle, WA, 5 October 1975.

PRESENTATIONS:

- (1) Levisay, G.L.: Renal Autotransplantation in the Dog. Presented: Kimbrough Urological Seminar, Washington, D.C., January 1974.
- (2) Levisay, G.L.: Renal Autotransplantation in the Dog. Presented: South Central Section Meeting of the AUA, Denver, CO, September 1974.
- (3) Jackson, J.E.: Renal Autotransplantation with Partial Nephrectomy in the Dog. Presented: South Central Section of the AUA, Denver, CO, 15-19 September 1974.
- (4) Jackson, J.E.: Renal Autotransplantation with Partial Nephrectomy in the Dog. Presented: Kimbrough Urological Seminar, San Antonio, TX, 14-19 November 1974.
- (5) Page, M.E.: Renal Autotransplantation with Vena Caval Occlusion. Seattle, Washington, October 1975.
- (6) Page, M.E. and Weigel, J.W.: Exhibit-renal Transplantation with Proximal Vena Caval. Presented: South Central Section Meeting in Urology, September 1975.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

- (1) Date: 30 SEP 81 (2) Prot No.: 76/203 (3) Status: Ongoing
(4) Title: Screening Program for Military Children at High Risk for Hearing Loss

(5) Start Date: 17 Oct 76	(6) Est Comp Date: Undefined
(7) Principal Investigator: Susan T. Slibeck, M.S., DAC	(8) Facility: FAMC
(9) Dept/Sec: Surgery/Otolaryngology	(10) Assoc Investigators: None
(11) Key Words: Parent Interview Chart Review High Risk Registry	(13) Est Accumulative OMA Cost:*
(12) Accumulative MEDCASE:*	(14) Date of Review: 1/81 Review Results: Ongoing

*Refer to Unit Summary Sheet of this report.

- (15) Study Objective: To screen infants and children for information indicating high risk for hearing loss so that early identification and treatment can be enhanced.
- (16) *Technical Approach: Trained Red Cross volunteers will screen the medical and family histories of all newborns, pediatric ward patients (0-6) years of age), and one-year old Well Baby Clinic patients through parent interviews and medical chart reviews. The investigator will review the gathered data for indications of high risk for hearing loss and designate children as AT RISK or NOT AT RISK. Parents of AT RISK children will be notified by a letter suggesting that they arrange an Audiology evaluation for their child. Tested AT RISK children will be followed and treated appropriately.
- (17) *Progress: Of all the AT RISK children followed with this protocol, 12.68% were found to have some degree of hearing impairment. All of these losses were identified before the children were three and one-half years of age.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 76/203

None

PRESENTATIONS:

- (1) Slibeck, Susan T.: High Risk Factors for Hearing Loss. Presented:
Pediatric Department, Fort Carson, CO, December 1976.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 77/204 (3) Status: Ongoing

(4) Title:
The Anatomical and Physiological Development of the Flexor Tendon
Sheaths in the Human Fetus.

(5) Start Date: Sep 79

(6) Est Comp Date: indef.

(7) Principal Investigator:
William W. Eversmann, Jr., COL, MC

(8) Facility: FAMC

(9) Dept/Sec: Ortho Svc

(10) Assoc Investigators:

(11) Key Words:

Flexor Anatomical Development
Flexor Tendon

none

(12) Accumulative MEDCASL:*(13) Est Accumulative
OMA Cost:*

(14) Date of Review:
12/80

*Refer to Unit Summary Sheet of this report.

Review Results:
Ongoing

(15) Study Objective: The objective of this study is to detail the anatomical development embryologically of the flexor tendon sheaths of the human fetus to 20 weeks of age and to correlate this development with biochemical changes within the flexor muscle mass which are indicative of developing contractility.

(16) Technical Approach: Collection of human fetal specimens to 20 weeks of age gestation and combined anatomical and correlative biochemical studies of the flexor muscle mass.

(17) Progress: Because of the limitations of funding and therefore the collection of specimens imposed by the congress of the United States this study is being converted to the use of another primate mammal probably the marmoset. The complete conversion of this study to the study of the marmoset flexor tendon is dependent upon pilot studies which are now being undertaken on the dissection of the flexor tendon sheaths.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/200 (3) Status: Ongoing
(4) Title:

Anastomosis of the Dog Vas Deferens Using Microsurgical Technique

(5) Start Date: April 1978	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Colonel Howard E. Fauver, M.D., MC	(8) Facility: FAMC
(9) Dept/Sec: Surgery/Urology	(10) Assoc Investigators: Col Edward G. Buck, M.D., MC Maj Daniel W. Horne, M.D., MC LTC Michael Morris, M.D., MC Cpt John H. Earl, M.D., MC LCol William Shipton, M.D., MC
(11) Key Words: Microsurgery-vasovasostomy	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 4/81	Review Results: Ongoing

(15) Study Objective: To master the microsurgical anastomosis of the vas deferens.

(16) Technical Approach: Standard bilateral vasectomy performed on mongrel male dogs. Three weeks later a two layer microsurgical anastomosis using 10-0 nylon is completed. Three weeks later the dog is sacrificed and bilateral vasograms completed.

(17) Progress: Twenty-one vasovasostomies were performed using a variety of suture and microsurgical techniques. This protocol continues to be an invaluable and irreplaceable tool for teaching of residents and staff in the techniques of microsurgery. In addition, this year it was utilized to instruct physicians from outlying hospitals in the technique.

Continuing experimentation with various sutures and microsurgical technique is being performed. Since it is felt that a minimum of thirty hours of microscope time is essential before this procedure can be performed in human subjects, this current protocol represents the only practical way in which experience can be gained.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 78/200

SERVICE Urology

DEPARTMENT Surgery

1. Vaccaro, J.A.: Microscopic Vasovasostomy: The Fitzsimons Experience. Kimbrough Urological Proceedings Vol. 14, 1980.

PRESENTATIONS for FY 81 Annual Progress Report

1. Vaccaro, J.A.: Microscopic Vasovasostomy: The Fitzsimons Experience. Kimbrough Urological Seminar, San Diego, CA, November 1980.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/201 (3) Status: Ongoing
(4) Title:

Clinical Study for Intraocular Lenses

(5) Start Date: September 1976	(6) Est Comp Date: Unknown
(7) Principal Investigator: Andrew J. Cottingham, Jr., M.D.	(8) Facility: FAMC
(9) Dept/Sec:	(10) Assoc Investigators: Richard A. Manson, M.D., COL, MC Lance P. Steahly, M.D., LTC, MC Craig A. Peterson, M.D., CPT, MC Thomas H. Mader, M.D., Major, MC (cont'd)
(11) Key Words: Cataract Intraocular Lens Pseudophakos	(12) Accumulative MEDCASE:*(13) Est Accumulative OMA Cost:*
(14) Date of Review: 4/81 Review Results: Ongoing	

*Refer to Unit Summary Sheet of this report.

(15) Study Objective:

- 1). To determine postoperative visual acuity of patients receiving an intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens.
- 2). To describe the occurrence and time course of postoperative ocular complications and adverse reactions both for intraocular lens implant subjects and for control subjects.
- 3). To compare the occurrence of adverse reactions and ocular complications in the implant group and in the control group, in order to delineate any significant differences.
- 4). To describe the occurrence of postoperative lens complications for the implant group, and their relationship to ocular complications.
- 5). To identify subgroups within the implant study population that are at "high risk" of particular complications as compared to the control group.

(16) Technical Approach:

After didactic courses, observations, laboratory practice and assistance with an experienced implant surgeon, a surgeon who can perform an accomplished cataract extraction, is then allowed to perform intraocular lens surgery under proper tutorage. Postoperative examinations include: pachymetry, keratometry, and specular microscopy. Contraindications to surgery include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, and inadequately controlled glaucoma, Fuch's endothelial dystrophy, and a history of previous retinal detachments or uveitis.

- (10) William G. Carey, M.D., CPT, MC
Ronald R. Holweger, M.D., CPT, MC
William S. Hill, M.D., CPT, MC

(17) Progress:

Due to the initial 25 implants between September 1976 and February 1978 the implantation of intraocular lenses at FAMC was expanded. We now have implanted over 300 intraocular lenses.

As a result of the past five years experience, we have evolved better guidelines for patient selection, better surgical techniques and improved guidance for postoperative care. Our study includes tabulation of operative complications, postoperative complications, visual results, endothelial cell loss, corneal thickness changes, changes in corneal astigmatism, and residual refractive error.

The results of every ophthalmologist implanting intraocular lenses in the United States additionally compiled by computer in Washington, D.C. by the FDA, our results are a small part of this overall study. Final data from this massive study is to be completed in the future. As a result of this study many intraocular lenses have been taken off the protocol due to their proven safety. These devices need only be registered when implanted at this time.

SERVICE OphthalmologyDEPARTMENT Dept of Surgery

- (1) Cottingham, Jr., A.J.: The Initial Fifty Intraocular Lens Implantations in an Ophthalmology Residency Training Program. Submitted for publication to the American Journal of Ophthalmology.

PRESENTATIONS for FY 81 Annual Progress Report

- (1) Cottingham, Jr., A.J.: Keratoplasty. Presented: Optometry Meeting, FAMC, October 1978.
- (2) Cottingham, Jr., A.J.: Endophthalmitis - Cause and Treatment. Presented: University of Colorado Health Sciences Center, January 1979.
- (3) Cottingham, Jr., A.J.: Corneal Keratomycoses. Presented: University of Colorado Health Sciences Center, January 1979.
- (4) Cottingham, Jr., A.J.: Bacterial Corneal Ulcers. Presented: University of Colorado Health Sciences Center, January 1979.
- (5) Cottingham, Jr., A.J.: The Use of Vitrectomy Instrumentation in Anterior Segment Reconstruction. Presented: Scheie Institute Trauma Symposia, Philadelphia, Pennsylvania, September 1979.
- (6) Cottingham, Jr., A.J.: An Analysis of the Initial Twenty-Five Intraocular Lens Implantations in an Ophthalmology Residency Training Program. Presented: 7th Biennial, Walter Reed Ophthalmology Post Graduate Course and Alumni Meeting, April 1978.
- (7) Cottingham, Jr., A.J.: An Analysis of the Initial Twenty-Five Intraocular Lens Implantations in an Ophthalmology Training Program. Presented: Bascom Palmer Eye Institute Annual Resident Alumni Meeting, June 1978.
- (8) Cottingham, Jr., A.J.: Residual Astigmatism - Postoperative Keratoplasty. Presented: American Academy of Ophthalmology, Chicago, Illinois, 7 November 1980.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/202 (3) Status: Terminated
(4) Title: Evaluation of the Nitroblue Tetrazolium Test (NBT) in Pyogenic Arthritis Using Synovial Fluid

(5) Start Date: Sep 79	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Robert M. Campbell, Jr., CPT, MC	(8) Facility: FAMC
(9) Dept/Sec: Surgery/Orthopedic	(10) Assoc Investigators: Thomas G. Fry, III, CPT, MC
(11) Key Words: NBT test pyogenic arthritis	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 12/80 Review Results: ongoing	

- (15) Study Objective:
To correlate the NBT test performed on synovial fluid with culture proven pyogenic arthritis in the knee joint.
- (16) Technical Approach:
The coordinated effort to evaluate the use of NBT test to predict pyogenic arthritis of the knee joint and correlation of this test with proven bi-culture pyogenic arthritis.
- (17) Progress:
This protocol has been terminated due to PCS of the Principal Investigator.

Publications and Presentations: none

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/201 (3) Status: Ongoing
(4) Title:

Platelet Function in Disease States.

(5) Start Date: 7 Aug 79	(6) Est Comp Date: June 82	
(7) Principal Investigator: Victor Ferraris, M.D., Ph.D.	(8) Facility: FAMC Aurora, CO. 80045	
(9) Dept/Sec: POS/Gen Surg Svc	(10) Assoc Investigators:	
(11) Key Wcrds: Prostaglandins Thromboxane Arachidonic Acid Prostacyclin Platelets	T. P. O'Barr E. Swanson D. Corby J. B. Smith	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 8/81 Review Results: Ongoing
*Refer to Unit Summary Sheet of this report.		

15. Study Objective:

- a. To develop and assess methods of measuring in vitro platelet function.
- b. To investigate the importance of arachinodonic acid (AA) metabolism in platelet function.
- c. To use the TXB₂ radioimmunoassay to measure platelet survival.
- d. To use the above described tests of platelet function to screen patients with various clinical illnesses for disturbed platelet function. (Contd Incl 1).
- e. To investigate in vivo platelet function using an animal model and the above described platelet function tests.
- f. To propose and test new clinical therapeutic modalities to treat disease of altered platelet function. These modalities will be based on the results obtained from pursuing objectives a, b, c, d, and e.

16. Technical Approach:

To use tests of platelet function to screen surgical patients for platelet related abnormalities.

17. Progress:

A radioimmunoassay for thromboxane B_2 (TxB_2) has been developed.

Since ASA irreversibly inhibits platelet arachidonic acid metabolism, the serum TxB_2 level, an indicator of arachidonate metabolism, is decreased in patients² who have taken ASA (Figure 1).

Sixteen patients undergoing unplanned or emergency operations have been screened for evidence of ASA effect on platelet by measuring serum thromboxane B_2 levels. Four patients admitted taking ASA less than 48 hours prior to operation. Measurement of serum TxB_2 levels confirmed ASA effect in the serum of these patients. Two patients were found to have decreased TxB_2 levels in serum, but did not recall taking ASA prior to operation. Thus, six of sixteen patients had evidence of prior ASA ingestion.

Parameters of perioperative bleeding were monitored in all patients. These parameters included measured blood loss at operation, fall in preoperative hematocrit by the fourth postoperative day, need for perioperative transfusion, excessive drainage from operative drains or the presence of wound hematoma. There was no difference in these parameters when patients with evidence of ASA effect were compared to patients who had not taken ASA prior to emergency operation.

These preliminary results suggest that ASA use is common prior to emergency operation and that the ingestion of ASA prior to emergency operation is not associated with increased bleeding complications.

Patients undergoing emergency operation are continuing to be screened for evidence of ASA-effect and for evidence of abnormal bleeding complications.

SERVICE General Surgery Service

DEPARTMENT of Surgery

- (1) Eiseman, B.:
Prognosis of Surgical Disease:
W. B. Saunders Company, 1980

The following chapters were contributed by our staff doctors:

Carcinoma of the Oral Cavity by Richard M. Hirata, M. D.

Reflux Esophagitis by Ross S. Davies, M. D.

Varicose Veins by Lewis Mologne, M. D.

- (2) Ferraris, V.A., and Sube, Janis:
Retrospective Study of the Surgical Management of Reflux Esophagitis Surgery,
Obstetrics and Gynecology, 1980 (in Press).

PRESENTATIONS for FY 81 Annual Progress Report (3rd Part of Detail Summary Sheet)

SERVICE General Surgery

DEPARTMENT of Surgery

- (1) Ferraris, V. A., Sube, Janis:
Retrospective Study of the Surgical Management of Reflux Esophagitis,
Presented:
William Beaumont Army Medical Center, El Paso, Texas, March, 1980.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/200 (3) Status: Ongoing

(4) Title:
Hearing Loss In Hypothyroidism

(5) Start Date: 1980 (6) Est Comp Date: June 1983

(7) Principal Investigator:
Marc Sachs, CPT, MC (8) Facility: FAMC

(9) Dept/Sec: Surgery/Otolaryngology (10) Assoc Investigators:

(11) Key Words:
hearing loss
hypothyroidism COL John Kolmer
COL Fred Hofeldt
MAJ Don Bender

(12) Accumulative MEDCASE: * (13) Est Accumulative OMA Cost: * (14) Date of Review:
10/80

*Refer to Unit Summary Sheet of this report.

Review Results:
Ongoing

(15) Study Objective: The objectives are to determine if there is a relationship of hearing loss to hypothyroidism, the locus of this effect, and the potential reversability of this effect.

(16) Technical Approach: Newly diagnosed hypothyroid patients are given a routine hearing evaluation, tympanograms, and a BSER. They are then restudied four weeks after beginning therapy, and again at least twelve weeks later.

(17) Progress: Twelve patients are currently being studied. The percentage of these patients having hearing loss is about 40% (from all causes). Two patients actually presented with hearing loss to the ENT Clinic and were later diagnosed as being hypothyroid. At present not enough data is present to comment on reversability.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81		(2) Prot No.: 80-201	(3) Status: Ongoing
(4) Title: Comparison of Cardiac Output and Left Ventricular Stroke Work Before and After Standard Anesthesia Induction of Patients Undergoing Surgical Correction of Combined Mitral Valve Disease and Coronary Artery Disease.			
(5) Start Date: 1 Oct 80		(6) Est Comp Date: 30 Sep 85	
(7) Principal Investigator: LTC Barre S. Bernier, MC		(8) Facility: FAMC	
(9) Dept/Sec: Anes & Op Svc, D/Surg		(10) Assoc Investigators:	
(11) Key Words: Fentanyl, Cardio-vascular Anesthesia, Coronary Artery Disease, Mitral Valvular Disease, Open Heart Surgery		Refer to Continuation Sheet	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 10/80	
*Refer to Unit Summary Sheet of this report.		Review Results: Ongoing	

- (15) Study Objective: To determine the presence or absence of significant statistical difference of left ventricular work as affected by conventional cardiac anesthesia techniques.
- (16) Technical Approach: Real-time data is obtained from pulmonary artery and radial artery catheters using transistor-generated analog data. Portable digital microprocessor provides all second generation data analysis. Cardiac anesthesia uses routine technique.
- (17) Progress: Two patients with combined pathology allowing protocol entry have presented in the first twelve months of this study. This patient data represents four percent of minimum subject-patient population.

(10) ASSOCIATE INVESTIGATORS:

COL Stephen Sitter, MC, Anes and Oper Svc
MAJ Jack Hempling, MC, Anes and Oper Svc
COL Robbie Cooper, ANC, CRNA
LTC Arthur Hertel, ANC, CRNA
LTC Richard Lenig, ANC, CRNA
LTC Francis Moriarty, ANC, CRNA
MAJ Edward Oswald, ANC, CRNA
MAJ Daniel Debban, ANC, CRNA
CPT Raymond Martin, ANC, CRNA
CPT Timothy Scott, ANC, CRNA
MRS Linda Brennan, CRNA, DAC
MRS Vivian Lucas, CRNA, DAC
MR Eugene Pennington, CRNA, DAC

1981-1982 - New
Investigators

LTC William J. Reynolds, MC, Anes and Oper Svc
MAJ Jonathan H. Chang, MC, Anes and Oper Svc
MAJ Thomas W. Muller, MC, Anes and Oper Svc
COL Konstantine Kalandros, ANC, CRNA
LTC Raymond Golden, ANC, CRNA
MAJ David Bohner, ANC, CRNA
MAJ Donald Newton, ANC, CRNA
CPT Yvonne Boles, ANC, CRNA
CPT Brenda Galeas, ANC, CRNA
CPT Frederick Masters, ANC, CRNA
MR Ronald Rabe, CRNA, DAC
MS Rosemarie Perillo, CRNA, DAC
MRS Sharon Heiss, CRNA, DAC

Deleted Investigators -
due to military reassignment
or resignation

COL Stephen Sitter, MC
MAJ Jack Hempling, MC
COL Robbie Cooper, ANC, CRNA
LTC Arthur Hertel, ANC, CRNA
MAJ Edward Oswald, ANC, CRNA
MAJ Daniel Debban, ANC, CRNA
CPT Raymond Martin, ANC, CRNA
CPT Timothy Scott, ANC, CRNA
MRS Linda Brennan, CRNA, DAC

PUBLICATIONS and PRESENTATIONS; none

DEPARTMENT OF CLINICAL INVESTIGATION
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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/200 (3) Status: Ongoing
(4) Title: Biomechanical and Anatomical Characterization of Unstable
Burst Fractures of the Thoracolumbar Spine and an Evaluation of Surgical
Approaches for Stabilization and Decompression.

(5) Start Date: Apr 81	(6) Est Comp Date: Nov 82
(7) Principal Investigator: LTC George G. Richardson, Jr., MC	(8) Facility: FAMC
(9) Dept/Sec: Ortho Svc	(10) Assoc Investigators: Dr. Ghaed Dr. Lowe Mr. Jatko
(11) Key Words: Spine Fractures	

(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 3/81 Review Results: Ongoing
*Refer to Unit Summary Sheet of this report.		

(15) Study Objective: To create bursting injuries in the thoracolumbar spine in cadaver material and thereafter describe the biomechanics and anatomy of those burst fractures involving gross anterior bursting with involvement of the posterior complex resulting in characteristic fracture fragments which impinge on the spinal canal. These will be characterized by axial tomography and radiographic examination as well as anatomic dissection.

(16) Technical Approach: To develop a model through a study of several phases which will arrive at a final phase to develop surgical approaches for stabilization and decompression. Hopefully the data obtained will provide clearer indication for one-stage anterior and posterior approaches.

(17) Progress: Equipment is now being ordered and upon receipt the progress of the study will continue.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/201 (3) Status: Completed
(4) Title: The Speech Characteristics of Children Post Reye's Syndrome

(5) Start Date: 5 May 1981	(6) Est Comp Date: 17 June 1981
(7) Principal Investigator: Sarah Scharfenaker	(8) Facility: FAMC
(9) Dept/Sec: Surgery/Speech Path.	(10) Assoc Investigators: Jon M. Hasbrouck, Ph.D.
(11) Key Words: children speech Reye's Syndrome	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 5/81 Review Results: Ongoing	

(15) Study Objective: To identify and compare the speech characteristics of children post-Reye's Syndrome. Also to identify any relationship that may exist between the extent and type of brainstem damage sustained as a result of Reye's Syndrome and speech production.

(16) Technical Approach: The approach involved selecting 5 children age 7-17 years who were 3 to 9 years post Reye's Syndrome. Case history data relative to the course of Reye's Syndrome was obtained by parental interview and perusal of medical records. Information obtained included: age of onset, most severe stage and duration of most severe stage, related disorders, and behavioral, speech, hearing, language, and auditory perceptual and intellectual status pre-, post-Reye's Syndrome and currently. Patient speech characteristics were obtained including: respiration, voice, articulation, and oral peripheral structure and function.

(17) Progress: In the results, the 5 subjects were divided into two groups. Group 1 consisted of 2 subjects who reached Stage 3 to 4 for 24 to 48 hours. Both subjects were within normal limits for speech production abilities directly post-Reye's Syndrome and remain so at this time. Only one of the subjects suffered from any neurological, behavioral, or psychological sequelae. These included hyperactivity, restlessness, decreased attention span, irritability, mood swings, severe headaches,

and seizures. Group 2 consisted of 3 subjects. The most severe stage reached for this group ranged from Stage 4 to Stage 4 1/2, with the duration ranging from 2 to 42 days. The non-speech sequelae, existing directly post-Reye's Syndrome and presently to a milder degree, commonly shared by this group consisted of decreased visual acuity and reduced intelligence. The present speech production characteristics common to Group 2 are multiple articulation errors at both the word and conversation level and mild to moderately severe dysarthria. Based on the small population sampled, it appears that the occurrence and severity of speech production disorders is related to the severity of the stage reached and duration of brain dysfunction at that stage. The subjects who reached the more severe stages of Reye's Syndrome and remained there for 2 to 42 days showed increased number and severity of speech production disorders. It was also found that all children in need of speech of therapy benefited from therapy.

PUBLICATIONS:

1. Scharfenaker, S.K. and Hasbrouck, J.M.: The Speech Characteristics of Children Post-Reye's Syndrome. Journal of the National Reye's Syndrome Foundation, In Press.

PRESENTATIONS:

1. Scharfenaker, S.K. and Hasbrouck, J.M.: The Speech Characteristics of Children Post-Reye's Syndrome. Presented: Joint Annual Meeting of the National Reye's Syndrome Foundation and the American Reye's Syndrome Association, Vail, Colorado, June 1981.

CLINICAL INVESTIGATION

DEPARTMENT OF CLINICAL INVESTIGATION
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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 72/302 (3) Status: Ongoing
(4) Title: Comparison of Metabolic and Functional Changes in Defects
of Platelet Function

(5) Start Date: 1972	(6) Est Comp Date: 1983
(7) Principal Investigator: Donald G. Corby, M.D., Colonel, MC	(8) Facility: FAMC
(9) Dept/Sec: Clinical Investi.	(10) Assoc Investigators: Thomas P. O'Barr, Ph.D., DAC
(11) Key Words: cyclic nucleotides, platelet function, prostaglandins, prostacyclins	
(12) Accumulative MEDCASE:*(13) Est Accumulative OMC Case:*	(14) Date of Review: 11/80 Review Result: Ongoing

*Refer to Unit Summary Sheet of this Report.

(15) Study Objective:

To correlate biochemical and functional parameters to gain a better understanding of the pathophysiology of the disorders of platelet function.

(16) Technical Approach:

Subjects: In most part, this study will deal with the further investigation of the platelet "defect" found in the normal newborn infant. However, since the techniques of studying the biochemical aspects of platelet function developed in previous studies permit the thorough evaluation of qualitative platelet disorders in older children and adults, the protocol is also intended to cover the diagnostic evaluation of patients with functional platelet syndromes associated with the "hemorrhagic state".

Blood Collection: Samples of cord blood will be taken from the umbilical vein as follows: Immediately after delivery, the umbilical cord will be clamped and an 18 gauge disposable needle will be inserted into the umbilical vein. Blood will be drawn into a plastic syringe and immediately transferred to a plastic centrifuge tube containing either (1) 10% by volume of 0.1 M buffered citrate anticoagulant or (2) a purple-topped tube containing EDTA. Samples from the mother which will serve as controls will be taken either prior to or at the time of delivery using a two-syringe technique where a butterfly-type needle is inserted into the antecubital vein. A small amount of blood (0.5-1 ml) is drawn into this syringe at this time;

(16) Technical Approach - continued

then a second syringe containing the appropriate anticoagulant is connected to the end of the butterfly needle and the desired sample is drawn directly into this syringe, mixed well by inversion, and transferred to a plastic centrifuge tube. Samples from patients or normal adult volunteers will be collected in the same manner when needed.

Platelet Function Studies:

When indicated clinically, platelet counts, bleeding times, platelet adhesion, and platelet aggregation in response to ADP, collagen, epinephrine, or ristocetin will be performed in the Coagulation Section, Department of Pathology or the Biochemistry Service, Department of Clinical Investigation.

Biochemical Studies:

Assessment of the content and release of the content of the platelet's sub-cellular storage organelles (alpha and dense granules) and evaluation of the platelet membrane will include, but not be limited to the following:

- a) content and release of adenine nucleotides and serotonin in the dense granules.
- b) assessment of cyclooxygenase activity by measuring Thromboxane₂ and malondialdehyde formation.
- c) electron microscopy and mepacrine staining of dense granules.
- d) content of platelet factor 4 and B-thromboglobulin activity in the alpha granules.
- e) production of platelet-derived growth factor by ³H-thymidine incorporation in 3T3 mouse fibroblasts by platelet lysates.
- f) measurement of secreted acid hydrolases (B-glucuronidase, B-galactosidase, and membrane P-nitrophenyl phosphatase) activities.
- g) membrane glycoprotein and phospholipid content.
- h) release of arachidonate from membrane phospholipids by phospholipase C and diglyceride lipase.
- i) mobilization of Ca⁺⁺.
- j) other studies as they become available.

Other studies to be conducted include the measurements of ADP receptors and alpha-adrenergic receptors, adhesion of platelets to deendothelialized rabbit aortic subendothelium and prostacyclin activity in umbilical veins.

Procedures already available in the Biochemistry Service, Department of Clinical Investigation, are designated by an asterisk. Other procedures are readily available in the literature and will be developed as needed.

Statistical Analysis:

Differences between the platelets of new infants and their mothers will be compared using the unpaired Student's t-test. Clinically oriented studies will be performed and compared with normal adult volunteers as controls.

17. Progress:

During the past fiscal year, work on this protocol has centered in three main areas:

(1) The evaluation of membrane glycoprotein in platelets of newborn infants. Although all studies are not complete, newborn platelets appear to qualitatively and quantitatively have no apparent significant abnormalities in the composition of membrane glycoproteins.

(2) The development of assays for phospholipase $A_2 + C$ activity.

(3) The assessment of the effect of lipogenase derived metabolites of arachidonic acid on newborn platelet function.

DEPARTMENT of Clinical Investigation

- (1) Corby, D.G., Shigeta, F.H., Greene, H.L., and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDI): Reversal with Total Parenteral Alimentation (TPA). (Abst.) Clin. Res. 21:304, 1973.
- (2) Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P., and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. (Abst., P. 107), III Congress, International Society on Thrombosis Hemostasis (Vienna, Austria), June 1973.
- (3) Corby, D.G., (Intr. by Wm. E. Hathaway): Mechanism of Platelet Dysfunction in Newborn Infants. J. Ped. Res., Vol. 8, No. 4, April 1974.
- (4) Corby, D.G., Preston, K.A., O'Barr, T.P.: Adverse Effect of Gel Filtration on the Function of Human Platelets. Proceedings of the Society for Experimental Biology and Medicine, 146:96-98, 1974.
- (5) Corby, D.G., Putnam, C.W., Greene, H.L.: Impaired Platelet Function in Glucose-6-Phosphatase Deficiency. The J. Ped., 85:71-76, July 1974.
- (6) Corby, D.G., and Zuck, T.F.: Newborn Platelet Dysfunction: A Storage Pool and Release Defect. Thrombosis and Haemostasis, 36:200-207, 1976.
- (7) Corby, D.G., Goad, W.C., Barber, J., and O'Barr, T.P.: Evaluation of Cyclo-Oxygenase Pathway in Platelets of the Newborn, Thrombosis and Haemostasis (Stuttgart), 38:35, 1977 (Abstract).
- (8) Corby, D.G., O'Barr, T.P.: Decrease in α -Adrenergic Binding Sites in Newborn Platelets: Cause of Abnormal Response to Epinephrine? Blood, 52:161, 1978.
- (9) Corby, D.G.: Aspirin in Pregnancy: Maternal and Fetal Effects. Pediatrics, 62:930, 1978.
- (10) Corby, D.G., O'Barr, T.P.: Decreased Alpha-Adrenergic Receptors in Newborn Platelets: Cause of Abnormal Response to Epinephrine. Dev Pharmacol & Ther, 2:215-225, 1981.
- (11) Corby, D.G., O'Barr, T.P.: Neonatal Platelet Function: A Membrane-Related Phenomenon. Haemostasis, 10(4):177-232, 1981.

Publications for FY 81 Annual Progress Report (72/302) - continued

- (12) Corby, D.G., O'Barr, T.P.: Newborn Platelet Function. Chapter in Book "Acquired Bleeding Disorders in Childhood". Masson Publ, pages 31-37, 1981.

Presentations:

- (1) Corby, D.G., Shigeta, F.H., Greene, H.L., and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDI): Reversal with Total Parenteral Alimentation (TPA). Presented: Western Society for Pediatric Research, Carmel, California, February 1973.
- (2) Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P., and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. Presented: III Congress, International Society on Thrombosis and Hemostasis, Vienna, Austria, June 1973.
- (3) Corby, D.G.: Mechanism of Platelet Dysfunction in Newborn Infants, Society for Pediatric Research, APS-SPR, Washington, D.C., May 1974.
- (4) Corby, D.G., Goad, W.C., Barber, J., and O'Barr, T.P.: Evaluation of Cyclo-Oxygenase Pathway in Platelets of the Newborn. Presented: VIth International Congress on Thrombosis and Haemostasis, Philadelphia, Pennsylvania, June 1977.
- (5) Corby, D.G. and O'Barr, T.P.: Decreased - Adrenergic Receptors in Newborn Platelets: Cause of Abnormal Response to Epinephrine? Presented: VIIth Congress International Society of Thrombosis and Haemostasis, London, England, 1979.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 76/301 (3) Status: Completed
(4) Title: Pancreatic Islet Transplantation in Diabetic Animals

(5) Start Date: 1976	(6) Est Comp Date: 1982
(7) Principal Investigator: David T. Zolock, MAJ, MSC	(8) Facility: FAMC
(9) Dept/Sec: Clinical Investi.	(10) Assoc Investigators: Donald G. Corby, MD, COL, MC
(11) Key Words: diabetic, pancreatic islets transplantation	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 10/80	Review Results: Completed

(15) Study Objective: Information derived from islet transplantation experiments indicates that diabetes mellitus can be effectively treated in animals. For this treatment approach to become practical in humans it appears obligatory to achieve effective animal allograft islet transplants. This goal has not been realized and thus the current protocol directly attempts to perform allogenic islet transplantation in diabetic animals.

(16) Technical Approach: Pancreatic islets are isolated and purified from donor strain rats and under various conditions are transplanted to Lewis recipient rats. The assessment of transplantation success is made by measurement of daily urine volumes and 24 hr urine glucose excretion in addition to serum glucose values.

(17) Progress: Islet transplants in experimental diabetic rats have been approximately 95% successful for isographs and unsuccessful for allographs. Cryopreservation in a glycerol medium and subsequent transplantation of the rat islets were only partially successful. The conditions for the cryopreservation steps were not completely acceptable since most of the islets were destroyed in the process. The process of removing the glycerol from the thawed islet preparation before transplantation destroyed more islets. Recently, procedures for successful cryogenic preservation with DMSO and subsequent transplantation were published by another laboratory.

SERVICE Biochemistry

DEPARTMENT of Clinical Investigation

1. Charles, A., Noble, S., Ownbey, J., Brown, G.L., and O'Barr, T.P.: Mechanisms of Islet Allograft Rejection. (Abst.) Journal of the American Diabetes Association, 1979.
2. Charles, M.A.: Islet Allograft Transplantation in Diabetic Rats. Diabetes 26, 1978.

PRESENTATIONS:

1. Charles, M.A.: Islet Allograft Transplantation in Diabetic Rats. Presented: American Diabetes Association National Meeting, 1978.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 77/300 (3) Status: Ongoing
(4) Title: Immunologic Disorders in Children and Adults: I. Correlation of Immune Functions in the Immunodeficiency State. II. Correlation of Immune Functions of Leukemia and other Childhood Malignancies.

(5) Start Date: 1 Oct 77	(6) Est Comp Date: Open ended
(7) Principal Investigator: R. Stephen Whiteaker, CPT, MSC	(8) Facility: FAMC
(9) Dept/Sec: Clinical Investi.	(10) Assoc Investigators: Donald G. Corby, MD, COL, MC
(11) Key Words: immunologic disorders	

(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 4/81 Review Results: Ongoing
*Refer to Unit Summary Sheet of this report.		

(15) Study Objective: Existing specialized immuno-chemical procedures will be consolidated into a registered protocol for use, on a consultative basis, by the hospital staff.

(16) Technical Approach: A clinical laboratory immunology consultation service has been established. Main emphasis is performance and evaluation of specialized immuno-chemical tests, for training house-staff personnel and consultative support of hospital. The major areas of studies include humoral and cellular immunity and leukocyte function evaluation. Patients are selected on the basis of severity of recurrent infections, clinical immunodeficiency state, lack of response to medical management and availability of clinical investigation service for laboratory evaluations for patient care.

(17) Progress: A total of 146 patients were evaluated on a consultative basis for immunologic disorders. During this period eight physician housestaff personnel were also trained in laboratory clinical immunology procedures. Patients studied: 32 in the area of serum protein gammopathies, 39 in the area of cell mediated function and 75 in the area of combined humoral-cellular function. Subjects with indicated major findings were as follows: 1) Humoral immunologic disorders-serum protein profile evaluations: 9 cryoglobulinemias, 38 serum protein gammopathies, 26 immunoglobulin disorders (heavy and light chain and benign spike), 7 hypogammaglobulinemias, 18 hypergammaglobulinemias,

(17) continued-

5 complement abnormalities; 11) Cellular immunologic disorders - 104 lymphocyte transformations, of these 17, 6, and 2 patients were recorded suppressed to PHA, PWM, and candida stimulations respectively, 110T-lymphocyte enumerations with 17 patients recorded as low T-lymphocyte percentages, 77B-lymphocyte enumerations with 0 patients recorded as abnormal, 19 NBT evaluations with 6 patients recorded as abnormal and 8 neutrophil chemotactic studies with 2 patients recorded as abnormal.

PUBLICATIONS: none

PRESENTATIONS:

1. Brown, G.L. and Heggers, J.: Medical Mycology: Assessment of bacteriologic and serologic parameters of clinically-important mycoses normal and immunologic comprised host. Presented: American Medical Technologist Educational Seminars, Denver, CO, July 1979.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/303 (3) Status: Ongoing
(4) Title: Evaluation of Humic Substances as Potential Gastrointestinal
Decontaminants in the Emergency Management of the Poisoned Patient.

(5) Start Date: 1978	(6) Est Comp Date: 1983
(7) Principal Investigator: Donald G. Corby, M.D. Colonel, MC	(8) Facility: FAMC
(9) Dept/Sec: Clin. Investigation	(10) Assoc Investigators: T.P. O'Barr, Ph.D., DAC Walter J. Decker, Ph.D. (Texas Med Br) R.L. Wershaw Ronald L. Malcolm
(11) Key Words: humic acid, gastrointestinal decontamination, poisons	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review 12/80 Review Result: Ongoing	

(15) Study Objective:
To prepare and evaluate in vitro the ability of humic substances to
bind a large variety of potentially toxic drugs and household poisons.

(16) Technical Approach:
Humic acid will be extracted from highly organic soil from Florida
through acid-base extractions and then lyophilized. After obtain-
ing a low ash product in vitro studies will be performed to deter-
mine the relative complexing or adsorptive activities of these
substances to amphetamine, primaquine, chlorpheniramine, colchicine,
dephenylhydantoin, aspirin, probenecid, quinacrine, chlor-
promazine, meprobamate, chloroquine, quinidine, quinine, ferrous sulfate,
iodine phenal, methylsalicylate, 2,4-D(20%), malathion (50%), DDT,
N-methyl carbamate, basic acid (3%), d-propoxyphene hydrochloride,
mineral acids, sodium and potassium hydroxide, sodium metasilicate,
and talbutanide.

(17) Progress:
Humic acid has been purified to an ash content of less than 0.3%.
Humic acid precipitates out of solution at a pH above 6. Using gel
filtration on sephadex 6-25 at pH3, humic acid binds 600 ugFe⁺⁺/mg.

(17) Progress - continued

Instead, in vitro tests using 200g rats orally closed with a LD₅₀ of 2gFe++/Kg in 0.7 ml followed 30 min later by 1g humic acid/ 50 Kg in 0.7 ml at pH5 showed no difference in LD as compared to control rats given no humic acid. Further tests such as equilibrium dialysis are being conducted in order to determine the optimum conditions for binding of iron and other harmful drugs to humic acid.

Publications and Presentations: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81			(2) Prot No.: 78/304			(3) Status: Ongoing		
(4) Title: Treatment of Iron-deficiency Anemia 1: Comparison of Hematologic Parameters following Treatment with Carbonyl Iron of Ferrous Sulfate In Wistar Rats.								
(5) Start Date: 1978						(6) Est Comp Date: 1981		
(7) Principal Investigator: Donald G. Corby, M.D. Colonel, MC						(8) Facility: FAMC		
(9) Dept/Sec: Clin. Investigation						(10) Assoc Investigators: Walter J. Decker, Ph.D., Tx.Med.Br. Penelope R. Giese, SSG, B.S. Lawrence E. Jones, DAC Troy Engle, SFC		
(11) Key Words: Iron-deficiency anemia, carbonyl iron, ferrous sulfate, hematocrit values								
(12) Accumulative MEDCASE:*			(13) Est Accumulative OMA Cost:*			(14) Date of Review: 12/80		
*Refer to Unit Summary Sheet of this report.						Review Results: Ongoing		

(15) Study Objective:
To evaluate carbonyl iron in the treatment of experimentally induced iron deficiency in the rat.

(16) Technical Approach:
This will be a comparative study of hematocrit values using an animal model. In addition, this study will evaluate CBC indices, serum iron, unsaturated iron-binding capacity, free erythrocyte protoporphyrin levels, ferritin levels, and stainable bone marrow iron. This experiment will be conducted in three phases in which the first two phases will be identical due to time, space, and personnel limitations to minimize temporal changes.

(17) Progress:
Study is in progress. No data is yet available for analysis.

Publications and Presentations: none

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(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/300 (3) Status: Ongoing
(4) Title: A Study of the Hormone-dependent Growth of Human Mammary Tumors In Vitro

(5) Start Date: 1979	(6) Est Comp Date: indefinite
(7) Principal Investigator: John W. Harbell, Ph.D., CPT, MSC	(8) Facility: FAMC
(9) Dept/Sec: DCI, SRL	(10) Assoc Investigators: Donald Mercill, B.S., DAC SP 5 Norman Jones, B.S.
(11) Key Words: breast tumors organ culture	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 3/81 Review Results: Ongoing	

(15) Study Objective: To examine the hormone requirements for the growth of human mammary tumors using explant organ culture.

(16) Technical Approach: Tissue samples are obtained from biopsy or mastectomy specimens. Each sample is cut into many small pieces and distributed, for culture, in a battery of hormone combinations. Replicate samples from each hormone combination are subjected to the appropriate radiolabelled precursor to determine DNA, RNA, and protein synthesis. Histology and macromolecular synthesis measure response.

(17) Progress: To date, over 50 samples of normal, hyperplastic and malignant human breast tissue have been studied. The interaction of insulin with ovarian and pituitary hormones has been the major thrust thus far. As expected from rodent studies, normal human mammary epithelium required insulin to undergo maximum proliferation when stimulated by other mammatrophic hormones. However, even malignant epithelium which was apparently insensitive to the other mammatrophic hormones also showed a marked insulin dependence. Due to the small number of human carcinomas available, corollary experiments with rodent tissue were completed to characterize the biochemistry of this dependence. Normal, benign, and malignant murine mammary epithelia were studied.

(17) continued -

Each required insulin while only the normal and benign required ovarian and pituitary hormones. Assessment of DNA, RNA, and protein synthesis as well as glucose utilization demonstrated that DNA synthesis was the most sensitive to the insulin concentration with the other parameters markedly less so. No progress on this protocol was made during 1981 as limited SRLS resources were reallocated to protocol 80/303 to support this protocol.

PUBLICATIONS for FY 81 ANNUAL PROGRESS REPORT

1. Harbell, J.W.: Insulin Action on Normal and Transformed GR/A Strain Mouse Mammary Tissues. (Abst.) Ann Tissue Cult Assoc, 1980.
2. Harbell, J.W.: Insulin Action on Normal and Transformed GR/A Strain Mouse Mammary Tissues. In Vitro 16(3):247, 1980.

PRESENTATIONS:

1. Harbell, J.W.: Insulin Action on Normal and Transformed GR/A Mouse Mammary Tissues. Presented: 31st Annual Meeting, Tissue Culture Association, St. Louis, MO, June 4, 1980.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/301 (3) Status: Ongoing
(4) Title: Basic Studies to Hasten Recovery from or Help Prevent
Bone Injury

(5) Start Date: 1979	(6) Est Comp Date: October 1983
(7) Principal Investigator: David T. Zolock, Ph.D., MAJ, MSC	(8) Facility: FAMC
(9) Dept/Sec: Clinical Investigation	(10) Assoc Investigators: Daniel D. Bikle, M.D., Ph.D. Veterans Administration Med. Ctr. San Francisco, CA
(11) Key Words: vitamin D, calcium, bone, intestine, calcium binding protein	
(12) Accumulative MEDCASE: *	(13) Est Accumulative OMA Cost: *
*Refer to Unit Summary Sheet of this report.	
	(14) Date of Review: 4/81 Review Results: Ongoing

(15) Study Objective: To reduce the incidence of fracture wounds and to reduce the time involved to heal fracture wounds by increasing the absorption and retention of calcium and phosphorus through nutritional and medical therapeutic improvements.

(16) Technical Approach: Since bone mineralization is indirectly regulated by intestinal absorption, the bone as well as the intestinal responses to various therapeutic measures, will be studied. In general the animal of choice will be chicks, which will be fed a vitamin D deficient diet containing 0.43% phosphorus for approximately three weeks.

(17) Progress: Rachitic chicks were administered various vitamin D metabolites in order to compare their mechanism of action on intestinal calcium transport, mucosal calcium accumulation, and calcium binding protein (CaBP). Intestinal calcium transports for 1,25,26-trihydroxycholecalciferol (1,24,25-THCC), and 1,25,26-trihydroxycholecalciferol (1,25,26-THC) were similar except the 1,25-DHCC treated chicks had a higher calcium transport and the duration of the effect was longer. Mucosal calcium accumulations for the three metabolites were essentially the same. The quantity of CaBP synthesis at the onset of synthesis was the same for the 1,24,25-THCC and 1,25-DHCC treated chicks. However, after the onset the 1,24,25-THCC group could only

(17) continued -

synthesize about a third as much as the 1,25-DHCC group. CaBP synthesis for the 1,25,26-THCC group was similar to the 1,24,25-THCC group except the onset time of synthesis was delayed. These results suggest the mechanisms for calcium transport and accumulation may be similar for all three metabolites but may be different for CaBP synthesis. A possible theory is two different receptor mechanisms with different metabolite specificities.

PUBLICATIONS for FY 81 ANNUAL PROGRESS REPORT

1. Zolock, David T., Morrissey, Robert L., and Bikle, Daniel D.: Meaning of Non-parallel 1,25(OH)₂D₃ Mediated Response Relationships in Intestine and Bone to Dose and Time in Vitamin D; Biochemical, Chemical and Clinical Aspects Related to Calcium Metabolism. Walter DeGruter, Inc., New York, 1979.
2. Bikle, D.D., Morrissey, R.L., Zolock, D.T. and Herman, R.H.: Stimulation of Chick Gut Alkaline Phosphatase Activity by Actinomycin D and 1,25-dihydroxyvitamin D₃: Evidence for Independent Mechanisms. J Lab Clin Med 94:88-94, 1979.
3. Bikle, D.D., Morrissey, R.L., and Zolock, D.T.: The Mechanism of Action of Vitamin D in the Intestine. Am J Clin Nutr 32: 2322-2338, 1979.
4. Morrissey, R.L., Zolock, D.T., Mellick, P.W. and Bikle, D.D.: Influence of Cycloheximide and 1,25-dihydroxyvitamin D₃ on Mitochondrial and Vesicle Mineralization in the Intestine. Cell Calcium 1:69-79, 1980.
5. Bikle, D.D., Askew, E.W., Zolock, D.T., Morrissey, R.H. and Herman, R.H.: Calcium Accumulation by Chick Intestinal Mitochondria: Regulation by Vitamin D₃ and 1,25-dihydroxyvitamin D₃. Biochem, Biophys Acta 598:561-574, 1980.
6. Bikle, D.D., Morrissey, R.L., Zolock, D.T. and Rasmussen, H.: The Intestinal Response to Vitamin D. Rev Physiol Biochem Pharmacol 89:63-142, 1981.

PRESENTATIONS for FY 81 ANNUAL PROGRESS REPORT

1. Zolock, D.T., Morrissey, R.L. and Bikle, D.D.: Meaning of Non-parallel 1,25 (OH)₂D₃ Mediated Response Relationships in Intestine and Bone to Dose and Time. Presented: Berlin (West) Germany, February 1979.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/304 (3) Status: Terminated
(4) Title: Quantitation of Steroid Hormone Receptors in Tissue
Sections Using Quantitative Autoradiography

(5) Start Date: 1979	(6) Est Comp Date: 1981
(7) Principal Investigator: John W. Harbell, Ph.D., CPT, MSC	(8) Facility: FAMC
(9) Dept/Sec: DCI, SRLS	(10) Assoc Investigators:
(11) Key Words: steroid receptors	none
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 4/80 Review Results: Terminated	

(15) Study Objective: To provide a means to quantify cellular steroid receptors (estrogen, progesterone and glucocorticoids) on a cell by cell basis in both normal and transformed tissue samples.

(16) Technical Approach: Viable tissue samples are pulse-labeled, in vitro, with ³H-labeled steroids, extensively washed with culture medium and quick frozen. Frozen sections are placed on emulsion-coated slides and exposed at -15C. Microscope quantitation of specific (total-background) silver grain number over the cell nucleus is used to indicate a responsive cell.

(17) The basic steroid autoradiography technique using in vitro steroid exposure is now available and is used: 1) to provide nuclear translocation controls for more rapid but nonquantitative fluorescent steroid receptor localizing techniques especially applicable for very small clinical samples and 2) to study steroid receptors in cells of the growing murine and human mammary end-buds and mesenchyme. Limited SRL personnel resources have precluded continuation of this protocol.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/306 (3) Status: Terminated
(4) Title: Adenohypophyseal-thyroid Interrelationships in Dehydration

(5) Start Date: June 1979	(6) Est Comp Date: December 1980
(7) Principal Investigator: W. Nicholas Glab, B.S., SP6	(8) Facility: FAMC
(9) Dept/Sec: DCI/SRL	(10) Assoc Investigators: John W. Harbell, Ph.D., CPT, MSC
(11) Key Words: adenohypophysis thyroid dehydration	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
	(14) Date of Review: 6/81 Review Results: Ongoing

(15) Study Objective: To examine the activity of the thyroid and thyroid stimulating hormone (TSH) producing cells of the anterior pituitary gland during dehydration, utilizing light and electron microscopy.

(16) Technical Approach: Sacrifice periods, totaling eight days, will include members of two groups of rats: controlled and water-deprived, and body weights and urine output monitored. Upon completion pituitary, thyroid and adrenals will be processed for light and electron microscopy. Cell morphology, counts of both TSH cell numbers, and secretion granule size versus number per cell will be evaluated.

(17) Progress: The animal phase has been completed and samples collected. Tissues are being evaluated, with preliminary results showing a decrease in thyroid cell height in dehydration. However, differences between treatment groups are not sufficiently large to warrant continued experimentation.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/300 (3) Status: Terminated
(4) Title: Evaluation of Laser Nephelometry for Detecting and Quantitating
Circulating Immune-complexes in Cancer Patients.

(5) Start Date: 1 Mar 80	(6) Est Comp Date: 1 Mar 82
(7) Principal Investigator: G. L. Brown, Ph.D., COL, MSC	(8) Facility: FAMC
(9) Dept/Sec: Clinical Investi.	(10) Assoc Investigators: N. J. DiBella, M.D., COL, MC W. C. Bourg, M.D., MAJ, MC
(11) Key Words: laser nephelometry circulating immune complexes cancer patients	
(12) Accumulative MEDCASE: *	(13) Est Accumulative OMA Cost: *
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 3/81 Review Results: Ongoing	

(15) Study Objective: To evaluate laser nephelometry as a means of efficient and rapid detection and quantitation of circulating immune complexes in cancer patients. To correlate the levels of circulating immune complexes with disease status.

(16) Technical Approach: The known ability of polyethylene glycol to precipitate immune complexes will be combined with the ability of laser nephelometry to detect small quantities of precipitates to produce a rapid, simple, efficient assay for detecting circulating immune complexes (CIC). This assay will then be used to quantitate the levels of CIC in the serum from cancer patients and determine the correlation between CIC levels and disease status.

(17) Progress: The assay conditions reported in the previous year's report improved the sensitivity of the assay by a factor of 10. However, day to day variability of the assay continued to be excessive in spite of extensive efforts to bring it within acceptable limits. Therefore, this protocol has been terminated.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80-301 (3) Status: Completed
(4) Title: Microbiological Research in Tuberculosis.

(5) Start Date: June 1980	(6) Est Comp Date: Completed
(7) Principal Investigator: J.J. Damato	(8) Facility: FAMC
(9) Dept/Sec: DCI	(10) Assoc Investigators: D.D. Paine J.K. McClatchy P.J. Kessens J.D. Hakes
(11) Key Words: Mycobacteria	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
	(14) Date of Review: 6/81 Review Results: Ongoing

(15) Study Objective: To evaluate and/or design new methods for improving diagnostic laboratory procedures in mycobacteriology and to maintain an in-depth data base and reference cultures on all patient isolates for future correlation with patient data, treatment results and laboratory quality control.

(16) Technical Approach:

- a. Evaluation and comparison of growth media.
- b. Urease testing using radiometric procedure.
- c. Niacin, nitrate and pyrazinamide testing using 7H10 Tween broth.
- d. Detection of mycobacteria using radiometric procedure.
- e. Rapid chromogenicity testing.

(17) Progress: A paper describing the isolation of mycobacteria from undecontaminated specimens using selective 7H10 medium has been published in the Journal of Clinical Microbiology. A paper describing urease testing of mycobacteria using radiometric procedures has been accepted, but not yet published, by the Journal of Clinical Microbiology. Other papers in various stages of completion involve detection of mycobacteria using radiometric procedures; niacin, nitrate and pyrazinamide testing using Middlebrook 7H10 Tween broth; rapid chromogenicity testing of mycobacteria; evaluation of S7H10 medium for direct susceptibility testing; isolation of casual isolates from undecontaminated medium; and growth temperature range of mycobacteria.

PUBLICATIONS for FY 81 Annual Progress Report

1. Damato, J.J., Collins, M.T., and McClatchy, J.K.: Urease testing of Mycobacteria with Bactec Radiometric Instrumentation. (Accepted for publication in J Clin Micro)
2. Rothlauf, M.V., Brown, G.L., and Blair, E.G.: Isolation of Mycobacteria from Undecontaminated Specimens with Selective 7H10 Medium. J Clin Micro 13:76-79, 1981.

PRESENTATIONS for FY 81 Annual Progress Report

1. Damato, J.J.: Biochemical Methods for Differentiating Mycobacteria. Presented: Colorado State University, Ft. Collins, CO, May 1980.
2. Damato, J.J., Rothlauf, M.V., Collins, M.T. and McClatchy, J.K.: Detection of Mycobacteria Using Radiometric and Standard Plate Procedures. Poster presented: Annual Meeting of the American Society for Microbiology, Dallas, Texas, March 1981.
3. Damato, J.J., Rothlauf, M.V., Collins, M.T., and McClatchy, J.K.: Detection of Mycobacteria Using Radiometric and Standard Plate Procedures. Presented: Spring Meeting, Rocky Mountain Branch - American Society for Microbiology, Greeley, Colorado, April 1981.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/302 (3) Status: Ongoing
(4) Title: Rapid detection of bacterial antigens in patient specimens using counterimmunoelectrophoresis (CIE).

(5) Start Date: 1 Jan 81	(6) Est Comp Date: 30 Apr 82
(7) Principal Investigator: P.L. Morse	(8) Facility: FAMC
(9) Dept/Sec: Micro Svc, DCI	(10) Assoc Investigators: D.D. Paine P.G. Engelkirk
(11) Key Words: Bacterial antigens, counterimmunoelectrophoresis	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: Review Results:	

(15) Study Objective:

To develop laboratory procedures using CIE which will detect bacterial antigens in patient specimens within a few hours of receipt.

(16) Technical Approach:

Using commercial antisera and published methodologies we developed the capability of performing CIE procedures for the detection of bacterial antigens in clinical specimens. We then evaluated these procedures as a rapid adjunct to the bacteriological procedures currently being used by the FAMC clinical microbiology laboratory for the diagnosis of bacterial diseases.

(17) Progress:

To date, 103 specimens from 73 patients have been studied under this protocol. Thirteen specimens from 8 patients have been positive; one was Group B Streptococcus, one was S. pneumoniae, and eleven were H. influenzae type b. Three of the patients with H. influenzae type b positive results were felt to be false positives. In certain newborns such false positive reactions represent a problem of unknown origin, and such a phenomenon has been confirmed by discussions with laboratory personnel at Children's Hospital in Denver. CIE results are difficult to correlate with routine culture results from the FAMC clinical microbiology laboratory because often dual specimens were not submitted, or specimens were submitted on different days. In several cases CIE detected antigens where culture results were negative. We are not aware of any instances where culture results were positive and CIE results were negative. To date, performance of CIE results at FAMC has saved the Dept of Pathology approximately \$3400.00.

(17) Technical Approach, cont.

A substudy involving 65 additional specimens was completed to evaluate the use of CIE in testing blood cultures. One positive specimen (Group B Streptococcus) was identified by both CIE and routine culture. CIE was found to be an unjustifiable expense when evaluating blood cultures.

PUBLICATIONS and PRESENTATIONS: none

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(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/303 (3) Status: Ongoing
(4) Title: Study of Sensitivity of Tumors to Chemotherapy

(5) Start Date: December 1980	(6) Est Comp Date: indefinite
(7) Principal Investigator: John W. Harbell, Ph.D., CPT, MSO	(8) Facility: FAMC
(9) Dept/Sec: DCI, SRLS	(10) Assoc Investigators: Donald Mercill, B.S., DAC SP5 Norman Jones
(11) Key Words: chemotherapy <u>in vitro</u> , <u>in vivo</u> tumor cell	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: i/81 Review Results: Ongoing	

(15) Study Objective: a) To perform in vitro chemotherapeutic sensitivity testing using tumor cell systems. b) To correlate in vitro chemotherapeutic sensitivity testing results with in vivo chemotherapeutic responses. c) To provide better patient care, i.e., better tumor cell kill, by using in vitro chemotherapeutic sensitivity testing.

(16) Technical Approach: Human tumor cell lines are established in monolayer culture. After purification and cell type varification, replicate cultures are subjected to physiological concentrations of chemotherapeutic agents. Efficacy is determined through measurement of macromolecular synthesis labeling index and cell loss. Correlations between in vitro parameters and patient responses are then established.

(17) Progress: To date 280 primary cultures from over 60 samples have been processed. From this group 20 patients are currently on the protocol though it is still premature to draw firm conclusions the amount of in vitro depression by given agents which predicts success in vivo.

PUBLICATIONS and PRESENTATIONS: none

DEPARTMENT OF CLINICAL INVESTIGATION
FITSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/300 (3) Status: Ongoing

(4) Title: Rapid detection of clostridial toxins using counter-immunoelectrophoresis (CIE).

(5) Start Date: 1 Mar 81	(6) Est Comp Date: Dec 82
(7) Principal Investigator: P.L. Morse I.J. Fritz	(8) Facility: FAMC
(9) Dept/Sec: Pathology/DCI	(10) Assoc Investigators: P.G. Engelkirk D.J. Wuerz D.D. Paine
(11) Key Words: Clostridial toxins, counterimmunoelectrophoresis	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: Review Results:	

(15) Study Objective:

To develop laboratory procedures using CIE to detect the presence of toxin produced in growing cultures of clostridial organisms. This technique could later be developed to detect toxins in patient specimens, such as serum and feces, and in food items.

(16) Technical Approach:

Procedures developed for detecting bacterial antigens using CIE were adapted for detecting clostridial toxins. It was found that changes in buffer molarity and pH and electrophoretic time were necessary. ATCC cultures of C. difficile, C. tetani, and C. botulinum were grown, and cell-free culture filtrates containing toxin were removed and partially purified for use as antigen. Commercially prepared anti-toxins were used as antibody.

(17) Progress:

The CIE procedure has been successful with both C. difficile and C. tetani culture filtrates. Both produce precipitate bands with 60 minutes of electrophoresis. Techniques for detecting C. botulinum have not yet been developed. One patient specimen from an individual suspected of having C. difficile was CIE tested with negative results. Microbial cultures failed to isolate the organism. An attempt is being made to locate additional patient specimens in the Denver area.

PUBLICATIONS and PRESENTATIONS: none

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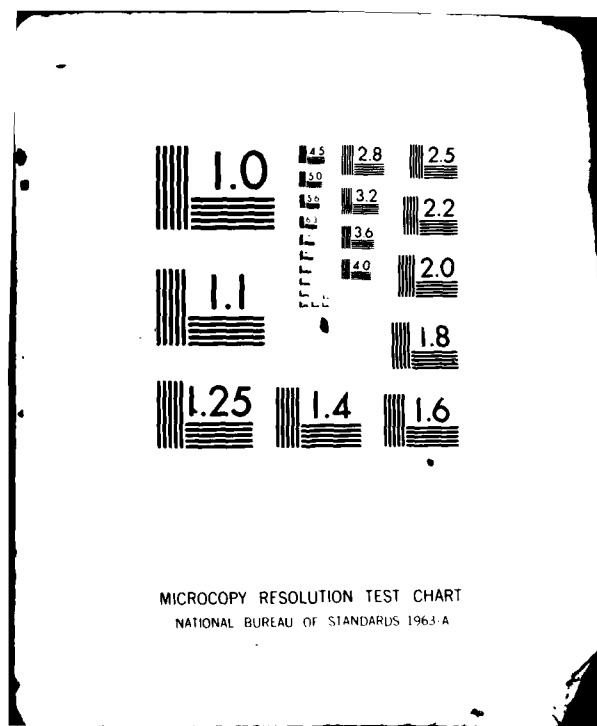
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DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81/301 (3) Status: Ongoing
(4) Title: Field trial of a transport medium for clinical specimens being sent to reference laboratories for processing for mycobacteria.

(5) Start Date: March 1981	(6) Est Comp Date: 1983
(7) Principal Investigator: M.V. Rothlauf S. Hayne M. Cho	(8) Facility: FAMC
(9) Dept/Sec: DCT	(10) Assoc Investigators: P.G. Engelkirk J.K. McClatchy
(11) Key Words: Mycobacteria, Transport medium, Holding medium.	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
(14) Date of Review: 3/81 Review Results: Ongoing	

*Refer to Unit Summary Sheet of this report.

(15) Study Objective: To develop and evaluate the use of a transport medium for clinical specimens being sent to reference laboratories for isolation of mycobacteria.

(16) Technical Approach: The initial phase of this investigation involved a controlled study of the holding medium using specimens from known positive patients (the specimens were kindly furnished by National Jewish Hospital-National Asthma Center). The second phase, which is still in progress, is a field trial of the holding medium involving specimens submitted to FAMC by Munson and Irwin Army Hospitals.

(17) Progress: The initial phase of this protocol utilizing the National Jewish Hospital specimens has been concluded. The study demonstrated that contamination was reduced or suppressed on those plates inoculated with specimens held one to six days in holding medium. There was an overall 100% correlation of mycobacteria isolation between specimens held in the holding medium and the controls. A variety of mycobacterial species were isolated. A review of the data from specimens received to date from Munson and Irwin Army Hospitals indicates that the average time from collection to processing of the specimen was 9 days, and as long as 21 days. The data reinforces the value of selective 7H11 medium as a primary medium for the isolation of mycobacteria. We have concluded that an additional control plate must be introduced to evaluate fully the effectiveness of the holding medium, and have taken necessary action to include such a control.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 81-301

SERVICE Microbiology

DEPARTMENT Clinical Investigation

None.

PRESENTATIONS for FY 81 Annual Progress Report

None.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81	(2) Prot No.: 81/302	(3) Status: Ongoing
(4) Title: Induction of Cerebellar Hypoplasia in Pups by Intrauterine Inoculation of Canine Parvovirus		

(5) Start Date: 15 Sep 81 (7) Principal Investigator: Cheryl K. Smith, DVM, CPT, VC Richard Kingston, DVM (9) Dept/Sec: (11) Key Words: canine parvovirus cerebellar hypoplasia	(6) Est Comp Date: 30 Jun 82 (8) Facility: FAMC (10) Assoc Investigators: John W. Harbell, Ph.D., CPT, MSC SP5 Leslie C. Kramer (12) Accumulative MEDCASE: * (13) Est Accumulative OMA Cost: * (14) Date of Review: 6/81 Review Results: Ongoing
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*Refer to Unit Summary Sheet of this report.

(15) Study Objective: To determine if canine parvovirus will induce cerebellar hypoplasia in puppies exposed in utero as the feline parvovirus does in kittens.

(16) Technical Approach: Six pregnant mongrel dogs will be anesthetized with Halothane Gas Anesthesia by mask induction. Laparotomy will be performed and a measured quantity of viral inoculum will be injected directly through the uterine wall into each fetus. Two of the dogs will serve as controls and their fetuses will be injected with physiologic saline when the pups are born. Several from each litter will be euthanitized with overdoses of halothane anesthesia. The brains will be collected in 10% formalin and reviewed by a veterinary pathologist for changes associated with parvovirally induced cerebellar hypoplasia.

(17) Progress: The virus is being established in tissue culture. The project has not yet been fully begun due to difficulty of obtaining pregnant dogs free of titers to parvovirus. The study is currently being revised to inject pups post-partum before ingestion of colostrum, since parvoviruses are known to induce cerebellar hypoplasia up to two to three weeks after birth in kittens. The first puppies are due to be born 23 November 1981 and will be injected with virus at that time.

PUBLICATIONS and PRESENTATIONS: none

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FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81		(2) Prot No.: 81/303	(3) Status: Ongoing
(4) Title: Use of Urinary Counterimmunoelectrophoresis (CIE) to Detect Occult Bacteremia in Young Children.			
(5) Start Date: November		(6) Est Comp Date: December 1982	
(7) Principal Investigator: P.L. Morse E.N. Squire		(8) Facility: FAMC	
(9) Dept/Sec: Pediatrics/DCI		(10) Assoc Investigators: P.G. Engelkirk B.J. Anders D. Moffitt	
(11) Key Words: Bacteremia, Counterimmunoelectrophoresis			
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review:	
*Refer to Unit Summary Sheet of this report.		Review Results:	

- (15) Study Objective:
To evaluate the sensitivity of CIE for early detection of bacteremia among children with high fever but no obvious etiology or treatable focus of infection, so that patients needing antibiotics and closest attention may be rapidly identified.
- (16) Technical Approach:
To utilize previously reported and standardized CIE procedures.
- (17) Progress:
FAMC IRC-approval for this protocol was granted on 3 March 1981, but HSC approval was also required. Notification of HSC approval was not received until 17 June 1981. Due to the late approval of this protocol and a dearth of clinical specimens, work on this protocol has not yet begun. It is anticipated that specimens will be obtained and tested when the Fall 1981 "disease season" begins.

PUBLICATIONS and PRESENTATIONS: none

DEPARTMENT OF CLINICAL INVESTIGATION
Surgical Research Laboratories Service

Training Support Summary

During the year, 93 students received training in suturing techniques. Sixty-two were students in the practical nurse (91C) course; nine were personnel assigned to Emergency Treatment Service, FAMC; six were from the U.S. Air Force Clinic, Lowry; three Pediatric Health Associates; and eight from the Aurora Technical Center. Training was conducted on 22 days, using 22 dogs, and consisted of a slide lecture and movie, introduction to the operating room, including aseptic technique, scrub, gowning and gloving, and hands-on experience in the dry and wet labs. Two hundred and sixty-four hours was expended by Surgical Research Labs personnel in providing this training.

A Chemical Casualty Course used six monkeys on two visits. Twenty hours was expended to train 68 personnel in nerve gas casualty procedures. This required 30 hours of support by Surgical Research Labs personnel.

General Surgery Service, Department of Surgery, used two dogs in training six surgeons in the use of staple guns. A total of 12 hours of training was received, requiring 16 hours of support by Surgical Research Labs personnel in pre-operative anesthetic induction, surgical preps, anesthesia monitoring, circulating and clean-up.

Inhalation Therapy Clinic, Pulmonary Disease Service, used three dogs in three visits to train 30 residents, interns, and two specialists in pulmonary procedures. A total of 24 hours was spent in training, requiring 27 hours of monitoring by Surgical Research Labs personnel.

Orthopedic Service, Department of Surgery, utilized 18 rabbits and seven rats in 29 visits to train one staff surgeon and eight residents in microvascular surgery using the operation microscope. A total of 116 hours was spent to accomplish this training, requiring 145 hours of support by Surgical Research Labs personnel in pre-operative anesthetic induction, surgical preps, anesthesia monitoring, post-operative recovery and angiography.

The Department of Pediatrics trained 12 nurses and medical students in the placement of endotracheal and chest tubes, using six cats in two visits of approximately three hours duration. Fifteen hours was required of Surgical Research Labs personnel in pre-operative anesthetic induction, surgical preps, anesthesia monitoring, and maintenance.

Thoracic Surgery Service, Department of Surgery, used two dogs in the training and evaluation of cardiopulmonary bypass methods. Two staff surgeons spent 24 hours in training, requiring 32 hours of support by Surgical Research Labs personnel in pre-operative anesthetic induction, surgical preps, anesthesia monitoring and pump operation.

DCI-SRLS Training Support Summary - continued

Urology Service, Department of Surgery, used eight rabbits in 15 visits for training in microvascular procedures. A total of 45 hours of training was received, requiring 60 hours of support by Surgical Research Labs personnel.

Under a Memorandum of Agreement, two high school seniors from Aurora Public Schools Technical Center received on-the-job vocational training; one as a veterinary aide and one as a clinical laboratory aide. A total of 353 hours of training was received, requiring 530 hours of instruction and supervision by personnel of the Surgical Research labs personnel.

Cost of Training

Suturing Techniques:	\$ 90.64/session	x 22 sessions	= \$1,994.08
Pediatric Nurses:	14.35/animal	x 6 cats	= 86.10
Rabbit Microsurgery:	79.19/session	x 26 sessions	= 2,058.94
Rat Microsurgery:	61.94/animal	x 7 rats	= 433.58
Thoracic Surgery:	143.75/animal	x 2 dogs	= 287.50
Staple Gun Exercises:	76.11/animal	x 2 dogs	= 152.22
Pulmonary Medicine:	4.00/animal	x 3 dogs	= 12.00
Chemical Casualty:	18.17/day	x 2 days	= 36.34
			<u>(\$5,042.59)</u>

OB-GYN

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/352 (3) Status: Completed

(4) Title: Amniotic fluid infection in premature labor patients with intact membranes; as determined by transabdominal amniocentesis

(5) Start Date: May 1979

(6) Est Comp Date: 30 April 1980

(7) Principal Investigator:

(8) Facility: FAMC

Clifford C. Hayslip, M.D., MAJ, MC

(9) Dept/Sec: OB/GYN

(10) Assoc Investigators:

(11) Key Words:

Amniotic fluid infection and premature labor

John R. Bobbitt, M.D., COL, MC

James D. Damato, MAJ, MSC

(12) Accumulative MEDCASE:*

(13) Est Accumulative

(14) Date of Review:

OMA Cost:*

8/81

*Refer to Unit Summary Sheet of this report.

Review Results:

Completed

(15) Study Objective:

To ascertain a relationship of subclinical or clinical amnionitis despite intact membranes as a cause of premature labor.

(16) *Technical Approach:

Patients admitted in premature labor between twenty and thirty-six weeks gestation were evaluated for other complications, causes and presence of intact membranes. After proper counseling and determining that the patient fit the study group, transabdominal amniocentesis was performed under direct ultrasound sterile technique. The fluid was studied for bacterial growth, white blood cell count and LDH values. The patients were then treated per treatment protocol for premature labor. Morbidity and mortality was then correlated with the fluid studies.

(17) *Progress:

The study has been completed. Thirty-one patients were studied. Seventy-five percent (8/31) showed amnionitis (positive culture) and 75% of the eight were subclinical. There was an increased morbidity in the infected group manifested by early delivery, low birth weight infants and prolonged hospital stay.

Prot No 78/352

Dept OB/GYN

PUBLICATIONS:

1. Hayslip, C.C., Bobitt, J.R., Damato, J.D.: Amniotic Fluid Infection Premature Labor Patients with Intact Membranes: As Determined by Transabdominal Amniocentesis. American Journal of Obstetrics and Gynecology, Vol. 140, No. 8, pp 947-952, 15 August 1981.

PRESENTATIONS:

1. Hayslip, C.C.: Amniotic Fluid Infection in Patients with Premature Labor and Intact Membranes, as Detected by Amniocentesis. Presented: AFD-ACOG Meeting, Orlando, FL, October 1980.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/353 (3) Status: Completed
(4) Title: Prenatal evaluation of quantitative cervical and vaginal cultures for the Group B Streptococcus and their relationship to maternal and neonatal morbidity and mortality.

(5) Start Date: 1978	(6) Est Comp Date: May 1981
(7) Principal Investigator: J.R. Bobitt, M.D., COL, MC	(8) Facility: FAMC
(9) Dept/Sec: OB/GYN	(10) Assoc Investigators: G.L. Brown, PHD, COL, MSC J.J. Damato, MAJ, MSC
(11) Key Words: Prenatal evaluation for Group B Streptococcus	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 12/80 Review Results: Completed	

(15) Study Objective:

To determine the incidence and clinical significance of Group B Streptococcus colonization in the cervix and vagina of prenatal women beyond 24 weeks gestation.

(16) *Technical Approach:

Antepartal vaginal cultures are collected by the clinical personnel in the Department of OB/GYN at weekly intervals and at delivery. Plates are streaked and growth quantitated by the Clinical Investigation Service, Department of Microbiology. Results are blinded. Mother newborn records are reviewed for infectious morbidity.

(17) *Progress:

The study was completed in March 1980 after approximately 700 patients had been studied. Maternal and neonatal clinical charts are currently being reviewed to establish infectious morbidity among the entire population. No data presently available for evaluation. Microbiologic cultures and antepartum evaluation completed. Compiling data ongoing.

PUBLICATIONS and PRESENTATIONS: none

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FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/350 (3) Status: Completed

(4) Title: A prospective study of endometrial changes with exogenous hormone therapy

(5) Start Date: June 1979 (6) Est Comp Date: 30 Sep 1981

(7) Principal Investigator: Steven R. Shirts, M.D., CPT, MC (8) Facility: FAMC

(9) Dept/Sec: OB/GYN

(10) Assoc Investigators: George E. Cothran, M.D., CPT, MC
(11) Key Words: Exogenous estrogen use in postmenopausal females

(12) Accumulative MEDCASE:*(13) Est Accumulative OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) Date of Review:

11/81

Review Results:

Ongoing

(15) Study Objective:

To determine by tissue diagnosis, the incidence of various forms of endometrial pathologic changes in women who use exogenous hormonal therapy in relief of perimenopausal and postmenopausal symptoms.

(16) *Technical Approach:

We do yearly endometrial sampling on unopposed postmenopausal estrogen users, either by in office endometrial biopsies or formal D&C. The rate of abnormal biopsy results will be tabulated.

(17) *Progress:

Preliminary report of results were tabulated and presented at the AFD-ACOG meeting October 1980 and published in Gynecological Oncology February 1981. The study was continued until 30 September 1981. Followup of those studied continues and final data will be compiled for a final paper which will hopefully afford greater number of patients studied.

Proto No 79/350

Dept OB/GYN

PUBLICATIONS:

1. Simsen, D.A., Shirts, S.R., Sims, J., Howard, F.M., Hill, J.M.:
Endometrial Findings in Asymptomatic Postmenopausal Women on
Exogenous Estrogen: A Preliminary Report. Gynecological Oncology,
Vol. 11, p. 56, February 1981.

PRESENTATIONS:

1. Shirts, S.R.: Prospective Study of the Effect of Unopposed Exogenous
Estrogen in Postmenopausal Women: A Preliminary Report. Presented:
AFD-ACOG Meeting, Orlando, FL, October 1980.

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81	(2) Prot No.: 80/350	(3) Status: Ongoing
(4) Title: GOG protocol/a collective and collaborative study on the management of gynecological malignancies. (See attached list for corrections)		

(5) Start Date: August 1980	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Francis J. Major, M.D.	(8) Facility: FAMC
(9) Dept/Sec: OB/GYN	(10) Assoc Investigators:
(11) Key Words: Treatment study of gynecological malignancies	George Phillips, M.D., LTC, MC Jay M. Hill, M.D., COL, MC

(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 9/81
*Refer to Unit Summary Sheet of this report.		Review Results: Ongoing

(15) Study Objective:

This clinical investigation is to participate in approved protocols of the gynecologic oncology group in the study of gynecological malignancies. The studies which the group engages in are primarily phase III studies comparing a proven method of primary or adjuvant treatment with a newer method of treatment in an attempt to improve response and survival in patients with gynecologic malignancies. Phase II studies are also conducted imploring experimental drugs. Entry of patients on a phase II study is permissible only when conventional methods of therapy or phase III study treatments have failed to show an improvement in the patients condition.

(16) *Technical Approach:

It is proposed that patients be entered on approved studies (see attached appendicies) for which they are eligible, following the patients signature being obtained on a form consent. Each protocol permits the removal of the patient from the study should there be progression of the disease, or should serious adverse effects occur. The study portion involves a combination of various approved drugs and/or adjuvant therapy with radiation or chemotherapy to standard surgical procedures. Any radiation therapy employed in these protocols is a standard accepted dose and field treatment and has received prior approval of the National Cancer Institute before incorporation in a study protocol. It is anticipated that between 12 and 15 patients will

(16) year will be entered from the Fitzsimons Army Medical Center on these protocols. There will be no financial impact on Fitzsimons Army Medical Center as all experimental drugs will be furnished free of charge and maintained in the Fitzsimons pharmacy by the oncology pharmacist. Patients with gynecologic malignancies eligible for protocol will be receiving the newest, most advanced treatment which is currently available.

(17) *Progress:

The GOG has recently received approval for continuation of its clinical studies through 1984. This approval was granted by the National Cancer Advisory Board and it is planned to continue these studies as long as the GOG is functional. It should be noted that different protocols require different periods of time to complete and the completion date is based, not on the availability of patients at Fitzsimons Army Medical Center, but the availability of patients throughout the entire GOG which consists of 20 member institutions throughout the United States. As protocols are closed to study the Clinical Investigation Service will be immediately notified of the termination of a study and as new protocols are activated they will be submitted in advance to the Clinical Investigation Service for review by the Human Use Committee at Fitzsimons Army Medical Center. (Please review the attached collective listing of protocols as to the ones closed and the ones ongoing. It will be noted that protocol #24 and #25 have been closed. It should also be noted that the address for the control of the study in Colorado has been changed to: Colorado Foundation for Medical Care, 1801 Gilpin, Denver, Colorado 80206.)

PUBLICATIONS and PRESENTATIONS; none

PEDIATRICS

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 75/401 (3) Status: Ongoing
(4) Title: Effect of Prophylactic Antibiotic Therapy on Gravid Group
B Beta Hemolytic Streptococcus Carriers

(5) Start Date: September 1975	(6) Est Comp Date: July 1983
(7) Principal Investigator: Gerald B. Merenstein, Col, MC	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn	(10) Assoc Investigators: John R. Pierce, LTC, MC
(11) Key Words: Group B Strep, Prophylactic Penicillin	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 1/81 Review Results: Ongoing	

(15) Study Objective:
To evaluate the use of prophylactic antibiotic therapy in antepartum
GBHS carriers with regard to colonization of the infant.

(16) *Technical Approach:
Gravid females are evaluated for the presence of Group BHS using
selective broth and are then considered candidates for prophylactic
antibiotics or control. The infants are evaluated for colonization
with GBHS.

(17) *Progress:
We are currently reviewing the literature and otherwise evaluating
methods of more rapidly identifying GBHS carriers. The rapid
identification will then permit random evaluation of preterm
deliveries. We hope to be able to enter preterm infants in the
study by early 1982.

SERVICE NewbornDEPARTMENT Pediatrics

1. Yost, C. C., Calcagno, J. V., Merenstein, G. B., Todd, W. A., Dashow, E. E., Brown, G. L., Tull, A. H. and Kile, D. E. Group B Beta Hemolytic Streptococcus: Improved Culture Detection and a Controlled Treatment Trial. Clinical Research 24, 186A, 1976.
2. Luzier, T. L., Merenstein, G. B., Todd, W. A., Yost, C. C., Brown, G. L. The Treatment of Gravid Females at Term Colonized with Group B Streptococcus A Randomized Controlled Study. Clinical Research 26, 200A, 1978.
3. Pierce, J. R., Merenstein, G. B. Streptococcal Sudden Unexpected Death Syndrome. Clin Res. 27, 128A, 1979.
4. Merenstein, G. B., Todd, W. A., Brown, G., Yost, C. C., Luzier, T. L. Group B Hemolytic Streptococcus: Randomized Controlled Treatment Study at Term. OB-GYN 55, 315-318, 1980.

SERVICE NewbornDEPARTMENT Pediatrics

1. Calcagno, J. V., Brown, G. L., Tull, A. H. et al. Evaluation of Three Collection-Transport Systems for the Isolation of Group B Streptococcus from PrePartum Women and Neonates. Presented: American Society for Microbiology, Atlantic City, N. J. 1976.
2. Luzier, T. L. The Treatment of Gravid Females at Term Colonized with Group B Beta Hemolytic Streptococcus: A Randomized Controlled Study. Presented: Military Section, American Academy of Pediatrics, New York, New York, November 1977.
3. Luzier, T. L. The Treatment of Gravid Females at Term Colonized with Group B Strep. Presented: Western Society for Pediatric Research, Carmel, California 2 February 1978.
4. Pierce, J. Streptococcal Sudden Unexpected Death Syndrome. Presented: Aspen Conference on Perinatal Research, Aspen, Colorado July 1978.
5. Pierce, J. Streptococcal Sudden Unexpected Death Syndrome. Presented: American Academy of Pediatrics, District VIII, Section on Perinatal Medicine. Park City, Utah, May 1980.
6. Merenstein, G. B. Th Prevention of Group B Streptococcal Colonization Presented: American Academy of Pediatrics District VIII, Section on Perinatal Medicine, Park City, Utah, May 1980.
7. Merenstein, G. B. The Spectrum of Group B Streptococcal Disease in the Newborn. Presented: Aspen Conference on Perinatal Medicine, July 1980.

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FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 75/402 (3) Status: Terminated

(4) Title: Early Digitalization in Premature Infants with Idiopathic Respiratory Distress (IRDS) Who Have Echocardiographic Evidence of Left Atrial Enlargement.

(5) Start Date: January, 1976

(6) Est Comp Date: 1981

(7) Principal Investigator:

(8) Facility: FAMC

*Gerald L. Way, M.D., MAJ, MC

(9) Dept/Sec: Pediatrics/Newborn

(10) Assoc Investigators:

(11) Key Words: Digitalization, infants, idiopathic respiratory distress, echocardiographic, left atrial enlargement

Gerald B. Merenstein, M.D., COL, MC
John R. Pierce, M.D., LTC, MC

(12) Accumulative MEDCASE:*

(13) Est Accumulative
OMA Cost:*

(14) Date of Review:
12/80

*Refer to Unit Summary Sheet of this report.

Review Results:
Ongoing

(15) Study Objective: To determine the usefulness of early digitalization in altering the progression of congestive heart failure and left-to-right shunting through the PDA in premature infants with IRDS.

(16) Technical Approach: Infants with RDS and left atrial aortic diameter ratio of greater than 1.0 by echocardiograph will be included in the two study groups. The two study groups will be Group A - infants who will be digitalized with 40 mcg/kg dose of digoxin and maintained at 10 mcg/kg/day. Group B - infants who will not receive digoxin unless they clinically demonstrate overt congestive heart failure. Echocardiogram will be repeated every other day throughout the respirator course, and subsequently only if abnormal findings remain. Additional echocardiograms will be obtained if the clinical situation deteriorates. Echocardiograms will be evaluated with coinciding arterial blood gases, chest x-rays, EKG's and laboratory data which will be done as needed for clinical management.

(17) Progress: No new patients have been added to this study during the past year. Review and evaluation of data accumulated prior to the death of the principal investigator has not produced meaningful results. We do not anticipate studying more patients.

Presentations and Publications: None.

*Deceased

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 77/402 (3) Status: Ongoing
(4) Title: Evaluation of Ventricular Function and Pulmonary Vascular
Resistance in Asphyxiated Infants.

(5) Start Date: December 1977	(6) Est Comp Date: Dec 1983
(7) Principal Investigator: Carl Gumbiner, Maj, MC	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn	(10) Assoc Investigators:
(11) Key Words: Newborn, Asphyxia, Heart	None
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 2/81	
Review Results: Ongoing	

(15) Study Objective:

To serially measure left ventricular function in newborns with asphyxia neonatorum.

(16) *Technical Approach:

All infants with the diagnosis of asphyxia neonatorum as defined by Apgar \leq 6 are candidates for this study. Study infants will be serially evaluated on days 0, 1, 2, 4, 6, 10 with echocardiograph.

(17) Other responsibilities have taken precedence over resumption of this study in the past year. Resumption is anticipated within CY 81 and, based on current nursery census, is expected to require 2 years for completion.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 77/403 (3) Status: Completed
 (4) Title: Determination of Pulmonary Vascular Resistance

(5) Start Date: March 1981	(6) Est Comp Date: July 1981
(7) Principal Investigator: H. Phillip STalker, Cpt, MC	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn	(10) Assoc Investigators: Carl H. Gumbiner, Maj, MC John R. Pierce, LTC, MC Gerald B. Merenstein, Col, MC
(11) Key Words: Newborn, Altitude, Electro- cardiogram	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
	(14) Date of Review: 2/81 Review Results: Ongoing

(15) Study Objective:
 To establish normal electrocardiographic values for neonates at
 5280 feet.

(16) *Technical Approach:
 One hundred normal newborns admitted to the Well Baby Nursery at FAMC
 were evaluated by scalar electrocardiography. Specific measurements
 included PR, QRS, PQT intervals P, QR, and S amplitudes.

(17) *Progress:
 The study has been completed. A paper has been presented and will be
 submitted for publication.

Publications: None

PRESENTATIONS for FY 81 Annual Progress Report

Proto No. 77/403

SERVICE Newborn

DEPARTMENT Pediatrics

Stalker, H. P., Gubminer, G. H., Pierce, J. R., Merenstein, G. B.
Significance of absent VS, in healthy, term infants at 5280 feet. Presented
at 6th Annual Conference on Perinatal/Neonatal Medicine, District VIII
American Academy of Pediatrics, Coeur D'Alene, Idaho, June 1981.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/402 (3) Status: Completed
(4) Title: The Influence of Body Positioning on Gastric Residuals in
Premature Infants

(5) Start Date: July 1978	(6) Est Comp Date: July 1981
(7) Principal Investigator: Barbara S. Turner, Maj, ANC	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn	(10) Assoc Investigators:
(11) Key Words: Body position, gastric residuals, premature infants	None
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 5/81 Review Results: Ongoing	

(15) Study Objective:

To compare the amount of gastric residuals in the premature infant's stomach three hours after feeding in relation to the body position of the infant.

(16) Technical Approach: Preamture infants requiring gavage feedings who were less than 35 weeks gestation were examined. Infants meeting outlined criteria were fed the same formula, at the same time and in the same manner as previously used. Gastric residuals were measured and recorded with body position. Positions used are right side, left side and stomach.

(17) Progress: Data collection began in July 1978. Data have been recorded on gastric residuals, body positions as well as the extraneous variables of gestational age, sex, race and type of formula. Data analysis is being done by the principal investigator who has left FAMC. Publication is being considered.

Publications and Presentations: NOne

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/403 (3) Status: Completed
(4) Title: The Influence of Body Positioning on Gastric Residuals in
Premature Infants Requiring Ventilatory Assistance

(5) Start Date: July 1978	(6) Est Comp Date: July 1981
(7) Principal Investigator: Barbara S. Turner, Maj, ANC	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn	(10) Assoc Investigators:
(11) Key Words: Gastric residuals, premature infants, body positioning	None
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 5/81 Review Results: Ongoing	

- (15) Study Objective:
To compare the amount of gastric residuals in the premature infant's stomach three hours after feeding in relation to the body position of the infant.
- (16) Technical Approach: Premature infants requiring ventilatory assistance and gavage feedings who were less than 35 weeks gestation were examined. Infants meeting outlined criteria were fed the same formula, at the same time, and in the same manner as previously used. Gastric residuals were measured and recorded with body position. Positions used are left side, right side and back.
- (17) Progress: Data collection began in July 1978. Data have been recorded on gastric residuals, body positions as well as the extraneous variables of gestational age, sex, race, and type of formula. Data analysis is being done by the principal investigator who has left FAMC. Publication is being considered.

Publications and presentations: None

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 Sep 81 (2) Prot No.: 79/400 (3) Status: Ongoing
(4) Title:

Effect of Adriamycin in Platelet Function

(5) Start Date: Nov/78	(6) Est Comp Date: 1982
(7) Principal Investigator: Askold D. Mosijczuk, M.D. COL, MC.	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics	(10) Assoc Investigators: T. Philip O'Barr, Ph.D., DAC Ellen Swanson, M.S., DAC
(11) Key Words: Effect of Adriamycin in Platelet Function	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 5/81 Review Results: Ongoing	

(15) Study Objective:
To determine and measure possible effect of adriamycin on platelet function.

(16) Technical Approach: Forty ml of blood are drawn from a healthy adult volunteer. The blood is centrifuged and PRP and PPP are drawn off. In a platelet aggregometer, 20 ml of adriamycin are added to the PRP in one cuvette, with the other cuvette with PRP serving as a control. After one minute, aggregating agents--ADP, Epinephrine, collagen--are added to each cuvette and the percent aggregation compared in the two samples. Aliquots of PRP are removed at certain times to measure the amount of tromboxane released.

(17) Progress:
None since last report of September 1980.

Publications and Presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/403 (3) Status: On going
(4) Title: Evaluation of Transcutaneous Oxygen Monitoring in the Acute Management of Infants with RDS.

(5) Start Date: January, 1980	(6) Est Comp Date: July, 1982
(7) Principal Investigator: Gerald B. Merenstein, M.D., COL, MC	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn	(10) Assoc Investigators: Howard Kilbride, M.D., LTC, MC C. Gilbert Frank, M.D., MAJ, MC
(11) Key Words: transcutaneous oxygen monitoring	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 10/80 Review Results: Ongoing	

(15) Study Objective:

To determine the efficacy of continuous transcutaneous PO₂ monitoring in the acute management of infants with RDS.

(16) Technical Approach:

Infants less than 34 weeks gestation with RDS will be assigned to 24 hours of continuous transcutaneous oxygen monitoring. They will have the data blinded in either the first or second 12 hours.

(17) Progress:

We have so far studied 20 infants with analysis of data. We project a need for 6-10 additional infants and anticipate completion by July, 1982.

Publications: None.

Presentation:

Kilbride, H. Transcutaneous oxygen monitoring. Presented: Aspen Conference on Perinatal Research, July, 1980. (Aspen, CO)

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/404 (3) Status: Ongoing
(4) Title: The Effect of Early Meconium Evacuation on Bilirubin Levels
in Breast-Fed and Formula-Fed Healthy Full-Term Infants.

(5) Start Date: February, 1981	(6) Est Comp Date: January, 1982
(7) Principal Investigator: Leonard E. Weisman, M.D., MAJ, MC	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn	(10) Assoc Investigators: Gerald B. Merenstein, M.D., COL, MC Marilyn Digirol, LTC, ANC Jan Collins, CPT, ANC
(11) Key Words: Bilirubin Meconium, Breast Fed, Bottle Fed	

(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 12/80 Review Results: Ongoing
*Refer to Unit Summary Sheet of this report.		

(15) Study Objective: To determine the effect of glycerine suppositories
on peak bilirubin levels in breast and formula fed infants.

To compare peak bilirubin levels in breast and formula fed full term
infants.

(16) Technical Approach: One hundred healthy full-term infants will be
randomly assigned to one of four groups including suppository or
control and breast or bottle fed.

Bilirubin will be measured serially by bilirubinometer.

(17) Progress: Seventy (70) babies have completed the study.

Publications & Presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/405 (3) Status: Ongoing

(4) Title: Assessment of Maternal Fever in the Immediate Prenatal Period as a Predictor of Perinatal Newborn Infections

(5) Start Date: January, 1982

(6) Est Comp Date: July, 1983

(7) Principal Investigator:
John R. Steenbarger, M.D.
LCDR, MC, USNR

(8) Facility: FAMC

(9) Dept/Sec: Pediatrics/Newborn

(10) Assoc Investigators:

(11) Key Words: Maternal fever,
re: perinatal infections

C. Gilbert Frank, M.D., MAJ, MC
Howard Kilbride, M.D., LTC, MC

(12) Accumulative MEDCASE:*

(13) Est Accumulative
OMA Cost:*

(14) Date of Review:

12/80

Review Results:

Ongoing

*Refer to Unit Summary Sheet of this report.

(15) Study Objective: To determine the incidence of serious perinatal infections in infants born to febrile mothers.

(16) Technical Approach: Mothers who are febrile within 24 hours of delivery as well as a matched control mother will have blood and placental cultures at the time of delivery. Each infant born to these study and control mothers will have peripheral blood, stool and umbilical cultures, CBC, platelet count, C-reactive protein all within 6 hours of birth. Each study infant will have a chest x-ray. The CBC and platelet count will be repeated at 24 hours

(17) Progress: Dr. John R. Steenbarger has become the principal investigator and will assume primary responsibility for the protocol. The technical approach is being re-evaluated, which may result in changes of a minor nature.

Presentations and Publications: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 Sep 81 (2) Prot No.: 79/406 (3) Status: Ongoing
(4) Title:

Intergroup Ewing's Sarcoma of Pelvic and Sacral Bones

(5) Start Date: 27 March 1980	(6) Est Comp Date: 1982
(7) Principal Investigator: Askold D. Mosijczuk, M.D. Col, MC.	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics	(10) Assoc Investigators: None
(11) Key Words: Intergroup Ewing's Sarcoma of Pelvic and Sacral Bones	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 5/81 Review Results: Ongoing	

(15) Study Objective:

1. Improve the survival of patients with localized Ewing's sarcoma of the pelvis and sacrum who have no evidence of metastases by using an intensive multimodal therapeutic approach.

2. Determine the effectiveness of high dose intermittent chemotherapy to prevent local recurrence of disease and/or metastases.

(16) Technical Approach:

Patients with Ewing's sarcoma of pelvic and sacral bones receive surgery, radiation and chemotherapy according to protocol guidelines and tumor survival and response are measured.

(17) Progress:

To date no FAMC patients have been entered in this study. Nationally, although the study is open, survival is poor in both treatment areas. A new protocol for treating Ewing's sarcoma of pelvic and sacral bones is being proposed.

Publications and Presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 Sep 81 (2) Prot No.: 79/407 (3) Status: Ongoing
(4) Title:

Intergroup Ewing's Sarcoma Plevic and Sacral Sites Excluded

(5) Start Date: 27 March 1980	(6) Est Comp Date: 1982
(7) Principal Investigator: Askold D. Mosijczuk, M.D. Col., MC.	(8) Facility: FAMC
(9) Dept/Sec: General Pediatrics	(10) Assoc Investigators: None
(11) Key Words: Intergroup Ewing's Sarcoma; Pelvic and Sacral Sites Ex- cluded	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
(14) Date of Review: 5/81 Review Results: Ongoing	

*Refer to Unit Summary Sheet of this report.

(15) Study Objective:

1. Improve the survival of patients with localized Ewing's sarcoma of bone who have no evidence of metastases at diagnosis with an intensive multi-modal therapeutic approach.
2. Determine the effectiveness of high dose intermittent chemotherapy as compared to moderate dose continuous chemotherapy to prevent local relapse and/or metastases.

(16) Technical Approach:

Patients with Ewing's sarcoma, except those involving pelvic and sacral bones, receive surgery, radiation, and chemotherapy according to protocol guidelines and tumor response and survival are measured.

(17) Progress:

To date, no FAMC patients have been entered on this study. Nationally, the study is progressing satisfactorily, with approximately a 60%, 3-year survival and no statistical difference among the three treatment areas.

Publications and Presentations: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 Sep 81 (2) Prot No.: 79/408 (3) Status: Ongoing
(4) Title:

Intergroup Rhabdomyosarcoma Study II

(5) Start Date: 27 March 1980	(6) Est Comp Date: 1982
(7) Principal Investigator: Askold D. Mosijczuk, M.D. Col. MC.	(8) Facility: FAMC
(9) Dept/Sec: pediatrics	(10) Assoc Investigators: None
(11) Key Words: Intergroup Rhabdomyosarcoma	

(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 5/81 Review Results: Ongoing
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*Refer to Unit Summary Sheet of this report.

(15) Study Objective:

The objectives of this study are to determine if cyclophosphamide can be dropped from the standard VAC regimen with radiation omitted without jeopardizing disease control and survival, and if so, if there would be less side effects without it, particularly testicular, ovarian and renal dysfunction in Clinical Group I Disease. In Clinical Group II Disease, it is to determine if repetitive courses of "pulse" VAC improve the duration of complete remission and survival beyond that which is now (cont'd)

(16) Technical Approach:

Patients with rhabdomyosarcoma received surgery, radiation, and chemotherapy according to protocol guidelines, and tumor response and survival is measured.

(17) Progress:

To date, two FAMC patients have been enrolled on this study. One patient with II-b disease involving upper extremity is in CR six months from diagnosis. The second patient, with a Stage III head and neck is in PR at four months from diagnosis. Nationally, no advantage is seen in group I and II disease between IRS-I and the current IRS-II. For stage III and IV patients, significant improvement is seen on IRS-II as compared to IRS-I.

(15) Cont'd:

achievable for microscopic residual disease with cyclic-sequential vincristine and dactinomycin, all patients receiving post-operative radiation to the tumor bed. In Clinical Group III and IV Disease, it is to determine if adriamycin, if given in pulse combination with vincristine and cyclophosphamide ("pulse" VADRC), improves the complete remission and survival beyond that now achievable with "pulse" VAC, all patients receiving radiation to the tumor bed and sites of metastases. It is also to determine if two years of repetitive pulse therapy is superior to the non-repetitive pulse regimens previously employed in IRS-1 for Groups III and IV disease (Regimens E and F). In the case of "Extremity Rhabdomyosarcoma Requiring Primary Amputation", it is to determine if two years of repetitive "pulse" VAC will improve the duration of remission and survival in patients subjected to primary major amputation for primary tumors localized in the extremity. In the case of "Rhabdomyosarcoma Localized in the Nasopharynx-Nasal Cavity, Middle Ear and Paranasal Sinus" the objective is to determine if the "prophylactic" local meningeal radiation with or without intrathecal chemotherapy can prevent direct meningeal extension of disease and improve the duration of remission and survival in these patients. In "Rhabdomyosarcoma localized to the Pelvis (vagina, uterus, bladder, prostate)" it is to determine if a primary chemotherapeutic and radiotherapeutic approach can avoid the disability associated with radical surgery without jeopardizing local disease control and survival. In "lymphatic involvement in Rhabdomyosarcoma" it is to determine what the frequency and significance is of regional lymph node involvement in relation to primary site of tumor origin. In relation to "Pathology" it is to determine the relationships between the special and undifferentiated cell types I and II (Ewing's tumor of soft tissue) and classical rhabdomyosarcomas in terms of biological behavior, ultrastructural features, and response to therapy.

Publications and Presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 Sep 81 (2) Prot No.: 79/409 (3) Status: Ongoing
(4) Title:
National Wilm's Tumor Study III

(5) Start Date: 27 March 1980	(6) Est Comp Date: 1982
(7) Principal Investigator: Askold D. Mosijczuk, M.D. Col. MC.	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics	(10) Assoc Investigators: None
(11) Key Words: National Wilm's Tumor Study	

(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 5/81 Review Results: Ongoing
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*Refer to Unit Summary Sheet of this report.

(15) Study Objective:

To gain a better understanding of the Wilm's tumor by gathering detailed information regarding gross and histologic morphology, and to correlate this information with treatment and clinical outcome. To refine methods of treatment according to staging, so as not to incur the adversities of unnecessary treatment in patients requiring minimal therapy. To test treatment hypotheses by randomized, prospective clinical trials according to stage and histologic grade of disease. To gather information regarding patients and their families, including patterns of cancer within families, in an attempt to identify children and families at high risk for cancer. To study the late consequences of successful treatment given for Wilm's tumor.

(16) Technical Approach:

Patients with Wilm's tumor receive treatment with surgery, radiation and chemotherapy according to protocol guidelines and then tumor response and survival are measured.

(17) Progress:

To date no patients from FAMC have been enrolled on study. Nationally, the study is progressing satisfactorily, but thus far no advantage between the regimens for any group of patients (by stage) is apparent.

Publications and Presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 Sep 81 (2) Prot No.: 79/410 (3) Status: Completed
(4) Title:
Non-Hodgkin's Lymphoma

(5) Start Date: 27 March 1980	(6) Est Comp Date: June 1981
(7) Principal Investigator: Askold D. Mosijczuk, M.D. Col, MC.	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics	(10) Assoc Investigators: None
(11) Key Words: Non-Hodgkin's Lymphoma	

(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 6/81
*Refer to Unit Summary Sheet of this report.		Review Results: Ongoing

(15) Study Objective:

To study the classification and biology of that group of childhood neoplasms included in the "Non-Hodgkin's Lymphomas." To compare the effectiveness of two combination chemotherapy programs in the control of all forms of childhood Non-Hodgkin's Lymphoma. Pulsed High Dose Cyclophosphamide, Moderate Dose Methotrexate, Vincristine and Prednisone (COMP). Regimen I. The Memorial Hospital LSA₂-L₂ Protocol (Modified). Regimen II. To determine for each of the two treatment regimens the effectiveness of standardized IT MTX without radiation for the control of occult CNS disease. To determine for each of the treatment regimens the effectiveness of standardized irradiation of bulk disease.

(16) Technical Approach:

Patients with non-Hodgkin's lymphoma receive one of two chemotherapeutic regimens as per protocol guidelines, and their survival and tumor response are measured.

(17) Progress: To date, two FAMC patients have been enrolled on study, and both are in CR at 16 months and 3 months from diagnosis (regimen 2). The previously reported advantage of LSA₂-L₂ for patients with lymphoblastic lymphoma and, conversely, the advantage of COMP (regimen 1) for all other types of childhood non-Hodgkin's lymphoma has been statistically substantiated in a larger number of patients in the past 12 months, and therefore, the question has been answered and the protocol is closed for new patient entries.

Publications and Presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/400 (3) Status: Ongoing
(4) Title: Evaluation of Lymphocyte Blast Transformation in Breast Milk and Peripheral Blood Lymphocytes.

(5) Start Date: 1 Apr 80	(6) Est Comp Date: 30 Sep 83
(7) Principal Investigator: Leonard E. Weisman, M.D., MAJ, MC	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Newborn	(10) Assoc Investigators: R. Stephen Whiteaker, Ph.D., CPT, MSC
(11) Key Words: Breast Milk, Lymphocyte, Blast Transformation	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 4/81	Review Results: Ongoing

(15) Study Objective: To obtain data on lymphocyte blast transformation of human breast milk lymphocytes and compare them to maternal post-partum peripheral blood lymphocytes.

(16) Technical Approach: Simultaneous breast milk and peripheral blood samples from post-partum subjects are evaluated for lymphocyte blast transformation using a microtechnique after: 1) utilizing various isolation procedures, or 2) utilizing various selected patient populations or 3) utilizing various laboratory storage conditions.

(17) Progress: a) Fifteen paired samples were collected from term uncomplicated post-partum women. Milk and blood lymphocytes were co-cultured in various concentrations with mitogen and lymphocyte blast transformation evaluated. b) Twelve paired samples were collected from term uncomplicated post-partum women for comparative evaluation of Active-rosetting. c) Six paired samples were collected from term uncomplicated post-partum women for comparative evaluation of lymphocyte blast transformation after Active-rosetting. d) Three paired samples were collected from term pre-eclampsia post-partum women for comparative evaluation of lymphocyte blast transformation. e) Three paired samples were collected from pre-term post-partum women for comparative evaluation of lymphocyte blast transformation.

f) Fifteen paired samples were collected from term uncomplicated post-partum women for comparative evaluation by monoclonal antibody labelling. g) Three paired samples were collected from term uncomplicated post-partum women for comparative evaluation of lymphocyte blast transformation to Rubella HI antigen. h) Three paired samples were collected from term uncomplicated post-partum women for comparative evaluation of lymphocyte blast transformation to mitogens and antigens. Similar evaluations were done just to mother's blood one month prior to delivery.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 80/400

SERVICE Newborn

DEPARTMENT Pediatrics

1. Weisman LE, Brown G, Rangel F, Merenstein GB: Mitogen Induced Lymphoproliferative Response in Human Colostrum T-Lymphocytes Are Hyporeactive. Clinical Research 29(1):124A, February, 1981 (abst).
2. Weisman LE, Brown G, Rangel F, Merenstein GB: In Vitro Comparison of Human Colostral and Maternal Peripheral Blood T-Lymphocytes. Pediatric Research 15(4): 977, 1981 (abst).

PRESENTATIONS for FY 81 Annual Progress Report

1. Weisman LE, Brown G, Rangel F, Merenstein GB: Mitogen Induced Lymphoproliferative Response In Human Colostrum T-Lymphocytes Are Hyporeactive. Immunology Section, Western Society for Pediatric Research, Carmel, California, 5 Feb 1981.
2. Weisman LE, Brown G, Rangel F, Merenstein GB: The Human Colostral T-Lymphocyte. The Aspen Conference on Perinatal Research, Aspen, Colorado, 23 Jul 1981.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/401 (3) Status: Ongoing
(4) Title: Investigation of Heparin Induced Platelet Aggregation
Secondary to Prostacyclin Interference in the Rabbit Model

(5) Start Date: <u>June 1980</u>	(6) Est Comp Date: <u>July 1981</u>
(7) Principal Investigator: <u>Larry G. Maden, Maj, USAF, MC</u>	(8) Facility: <u>FAMC</u>
(9) Dept/Sec: <u>Pediatrics/Newborn</u>	(10) Assoc Investigators: <u>John Harbell, PhD, Cpt, MSC</u> <u>Donald G. Corby, Col, MC, PhD</u> <u>Peter W. Blue, LTC, MC</u> <u>Gerald B. Merenstein, Col, MC</u>
(11) Key Words: <u>Heparin, Prostacyclin, Platelet Aggregation</u>	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: <u>6/81</u> Review Results: <u>Ongoing</u>	

(15) Study Objective:

To investigate heparin induced prostacyclin inhibition as manifested by increased platelet adhesion at the tip of an arterial catheter in a rabbit model.

(16) Technical Approach:

Four groups of rabbits will have arterial catheters placed and infused with varying concentrations of heparin. Platelets will be harvested from the animals labelled and reinfused. The rabbits will be scanned by a gamma counter at six and 24 hours. After euthanized 4 rabbits from each group will have an autocardialograph of the aorta. The remaining 2 rabbits in each group will have the aorta analyzed for prostacyclin and heparin at the catheter site.

(17) Progress:

All experiments have been completed. Data is being retrieved from computer storage and will be analyzed.

Publications and Presentations: None

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 Sep 81 (2) Prot No.: 80/402 (3) Status: Ongoing
(4) Title: Incidence of Latent Iron Deficiency

(5) Start Date: 20 June 1981	(6) Est Comp Date: Jan/82
(7) Principal Investigator: Stephen N. Nelson, MD., CPT, MC.	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Hem/Onc.	(10) Assoc Investigators: Askold D. Mosijczuk, MD, LTC, MC. William H. Parry, MD, COL, MC. LeRoy M. Graham, MD, CPT, MC.
(11) Key Words: Latent Iron Deficiency	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 2/81 Review Results: Ongoing	

(15) Study Objective:

To determine the incidence of latent iron deficiency in a population of children who present for routine physical examination.

(16) Technical Approach:

Ten cc's of venous blood was obtained from 270 random and nonrandom volunteers after informed consent. This blood was analysed for hemoglobin, hematocrit, red cell indices, serum iron, TIBC and serum ferritin. The number of patients with abnormal results will be compared to the total number of patients enrolled, yielding the incidence of latent iron deficiency as defined in this study.

(17) Progress: Although laboratory reporting of results remains far from complete, preliminary data suggest that the incidence of latent iron deficiency as defined in the study protocol is very low. Because much of the data remains pending, precise enumeration or statistical analysis is not possible at this time.

PUBLICATIONS and PRESENTATIONS: none

DEPARTMENT OF CLINICAL INVESTIGATION
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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81-400 (3) Status: Ongoing

(4) Title:

Phencyclidine (PCP) Removal by Hemoperfusion.

(5) Start Date: 1 March 1981	(6) Est Comp Date: 1 June 1982
(7) Principal Investigator: WILLIAM R. ALLEN, MD, LTC, MC.	(8) Facility: FAMC
(9) Dept/Sec: Pediatrics/Gen Ped	(10) Assoc Investigators: T. P. O'Barr, Ph.D D. G. Corby, M.D.
(11) Key Words: charcoal hemoperfusion phencyclidine (PCP)	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 2/81 Review Results: Ongoing	

(15) Study Objective:

Determine whether charcoal hemoperfusion removes adequate amounts of PCP to alter the course of clinical intoxication.

(16) Technical Approach: A single dose of PCP is given intravenously. Blood sampling is then done for pharmacodynamic data. In control experiments, blood and urine PCP levels are then monitored for six hours. In hemiperfusion experiments, blood and urine PCP levels are measured, including measurement of cartridge drug removal rates. Duration of coma and other behavior is monitored to detect changes brought about by hemoperfusion.

(17) Progress: In eight experiments, the model for study has been developed, and it has been demonstrated that cellulose-coated charcoal cartridges do not remove PCP. Additionally, pharmacodynamic data suggests that large amounts of the drug are distributed to other compartments than the plasma and, therefore, are not available for charcoal binding and removal.

PUBLICATIONS and PRESENTATIONS: none

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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81	(2) Prot No.: 81/401	(3) Status: <u>Ongoing</u>
(4) Title: Evaluation of Transcutaneous Oxygen Monitoring During Labor Puncture of the Neonate		

(5) Start Date: June 1981	(6) Est Comp Date: January 1982
(7) Principal Investigator: Leonard E. Weisman, Maj, MC	(8) Facility: FAMC
(9) Dept/Sec: <u>Pediatrics/Newborn</u>	(10) Assoc Investigators: John R. Steenbarger, LCDR, MC Gerald B. Merenstein, Col, MC
(11) Key Words: Transcutaneous Oxygen Lumbar Puncture Newborn	

(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 6/81 Review Results: Ongoing
*Refer to Unit Summary Sheet of this report.		

- (15) Study Objective:
To determine if the sick newborn becomes hypoxic during lumbar puncture. To determine if hypoxemia is position dependent.
- (16) Neonates less than 24 hours old requiring lumbar puncture were randomized, after parental permission was obtained, into four groups. A. On side, open transcutaneous oxygen monitor. B. On side, blinded transcutaneous oxygen monitor. C. Sitting, open. D. Sitting, blinded.
- (17) Data has been collected, analyzed, presented and accepted for publication. Additional patients are being evaluated to further delineate position effect.

PUBLICATIONS for FY 81 Annual Progress Report

Proto No. 81/401

SERVICE Newborn

DEPARTMENT Pediatrics

Weisman, L. E., Steenbarger, J. R., Merenstein, G. B. Oxygen tension changes during lumbar puncture of the neonate and mechanisms of action in symposium on continuous transcutaneous blood gas monitoring, Huch and Huch editors, M. Dekker Inc. New York in press.

PRESENTATIONS for FY 81 Annual Progress Report

Weisman, L.E., Steenbarger, J.R., Merenstein, G.B.: Oxygen tension changes during lumbar puncture of the neonate and mechanisms of action. Presented: Continuous Transcutaneous Blood Gas Monitoring Second International Symposium, Zurich, Switzerland, October, 1981.

DEPARTMENT OF CLINICAL INVESTIGATION
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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81	(2) Prot No.: 81-402	(3) Status: Ongoing
(4) Title: Diagnosis of Respiratory Syncytial Virus Infection in Infants by Enzyme-Linked Immunosorbent Assay		
(5) Start Date: 7 January 1981	(6) Est Comp Date: 1 June 1982	
(7) Principal Investigator: Donald R. Moffitt, M.D., MAJ, MC. Donald D. Paine	(8) Facility: FAMC	
(9) Dept/Sec: Pediatrics/Pulmonary	(10) Assoc Investigators:	
(11) Key Words: Disease ELISA RSV Infection	William H. Parry, MD, COL, MC. Paul G. Engelkirk, LTC, MSC.	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 6/81 Review Results: Ongoing
*Refer to Unit Summary Sheet of this report.		

(15) Study Objective:

1. Study Objective: Development of ELISA procedures for the detection of RSV antigen and RSV antibodies, using commercially available reagents, and determining the efficacy of these procedures for the diagnosis of RSV infections in infants.

(16) Technical Approach: This project has been approached first from the laboratory in developing reliable ELISA tests for use with clinical specimens. This has been done with commercial reagents and controls, and with human serum obtained from the Letterman Virology Laboratory. The clinical aspects of the protocol involves sampling nasal secretions, urine, and serum from infants with suspected RSV infection. Results of the ELISA assay will be compared with virus cultures and complement fixation serial conversion rates.

(17) Progress: The primary progress made on this protocol has been with the development of the assay in the laboratory. The assay for RSV antigen has been developed and is quite sensitive and specific when using commercially available test antigens. The use with clinical specimens has been markedly limited, since the protocol was not approved by HSC until this past summer. Progress with the ELISA detection of anti-RSV antibodies has been slower, owing to the non-availability of human anti-RSV serum. A few serum specimens were obtained from Letterman Army Hospital, and recent preliminary assays of this serum indicates that the ELISA in our laboratory will easily detect anti-RSV IGG antibodies at high serum dilutions. The collection of clinical specimens for assay in our laboratory will begin with RSV season this winter.

Publications and Presentations: none

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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81-403 (3) Status: Not Yet Begun
(4) Title: Use of Theophylline in Wheezing Associated Respiratory
Illness (WARI) in Young Children

(5) Start Date: Est. Nov/Dec. 1981	(6) Est Comp Date: Mar/Apr 1982
(7) Principal Investigator: Max V. Bryant, M.D., LTC, MC.	(8) Facility: FAMC
(9) Dept/Sec: Dept Pediatrics/Ped Pul	(10) Assoc Investigators: W. H. Perry, M.D., COL, MC.
(11) Key Words: Theophylline Use in Wheezing Associated Respiratory Illness	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 6/81 Review Results: Ongoing	

(15) Study Objective: To demonstrate effectiveness of intravenous Theophylline on the clinical course of children with a wheezing associated respiratory illness.

(16) Technical Approach: Those children three months to two years of age with a clinical diagnosis of a first episode of WARI severe enough to require hospitalization, and without other underlying disease, will be assessed clinically and by numerous laboratory parameters upon admission. Then, patients will be randomly assigned to a study or placebo group, and the study group will receive intravenous Theophylline in their standard dosages. Both during and at the end of the study, patients will be reassessed using the same clinical and laboratory parameters as at the inception of the study. Data will then be analyzed to determine if Theophylline is effective in WARI.

(17) Progress: This study depends on having Wheezing Associated Respiratory Illness present in the community at the time. Since this study was finally approved, there has been no such disease present, but we expect there to be multiple cases of WARI beginning in November/December, 1981. At this time, the study will begin and last approximately through the respiratory season, estimated to be March/April, 1982.

PUBLICATIONS and PRESENTATIONS: none

PATHOLOGY

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/450 (3) Status: Terminated
(4) Title: The Role of Complement Activation in the Pathogenesis of
Juvenile Onset Diabetes and its Subsequent Effects on the Coagulation Status
and Peripheral Vascular Complications in Diabetic Patients

(5) Start Date: Sep 79	(6) Est Comp Date: Sep 81
(7) Principal Investigator: Patricia L. Stranahan, M.D.	(8) Facility: FAMC
(9) Dept/Sec: Pathology	(10) Assoc Investigators: Paul Nakane, Ph.D. Judy Barber, MT (ASCP) Patricia Rush, MT (ASCP)
(11) Key Words: complement activation; juvenile onset diabetes; coagulation abnormalities, peripheral vascular com.	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
(14) Date of Review: 3/81 Review Results: ongoing	

*Refer to Unit Summary Sheet of this report.

(15) Study Objective:

Clq is present on human platelets. 1) It is known that Clq displaces collagen with respect to collagen dependent platelet aggregation.
2) It is also known that Clq specifically binds to Beta cell membranes.
3) The objective of this study is to compare the levels of Clq in normal patients with juvenile onset diabetes mellitus.

(16) Technical Approach:

We have developed a rocket immunoelectrophoresis procedure for quantitation of Clq. Previous methods used for determining Clq levels take up to 10 days. With our procedure, overnight results are obtained. Presently we are reporting our results in % of normal as we currently have no purified Clq to quantitate ug levels.

(17) Progress:

This protocol has been terminated due to PCS of the Principal Investigator.

Publications and Presentations: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 79/451 (3) Status: Terminated
(4) Title: Efficacy of Freeze Preservation of Platelets for Human Utilization-In Vitro and In Vivo Functional Capabilities after Freeze Preservation with Hydroxyethystarch (HES)

(5) Start Date: 30 Sep 80	(6) Est Comp Date: 30 Sep 81
(7) Principal Investigator: Patricia L. Stranahan, M.D.	(8) Facility: FAMC
(9) Dept/Sec: Pathology	(10) Assoc Investigators: Rick Martinez, MT (ASCP) Judy Barber, MT (ASCP)
(11) Key Words: freeze preservation of human platelets; platelets utilizing HES	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
(14) Date of Review: 6/81 Review Results: Ongoing	

*Refer to Unit Summary Sheet of this report.

(15) Study Objective:

To compare the differences between fresh platelets and freeze preserved (HES) platelets for use in thrombocytopenic leukemic patients.

(16) Technical Approach:

In the past six months, platelets have been frozen in HES and tested for in vitro function. These studies have been carried out both before freezing and after thawing. Suitable controls with room temperature incubation have also been studied.

(17) Progress:

This protocol has been terminated due to PCS of the Principal Investigator.

Publications and Presentations: none

PSYCHIATRY

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/500 (3) Status: Terminated
(4) Title: Health Expectancy Styles for Patients and Physicians and Their Perceptions of a Referral Process

(5) Start Date: July 1980	(6) Est Comp Date: Sep 81
(7) Principal Investigator: Robert R. Roland, CPT, MC	(8) Facility: FAMC
(9) Dept/Sec: Psychiatry	(10) Assoc Investigators:
(11) Key Words: health styles, patient/physician, perception of referral	Paul G. Longobardi, CPT, MC
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 5/81 Review Results: Ongoing	

(15) Study Objective:

The purpose of this study is to demonstrate that reliable similarities and differences between patients and their referring physicians in the degree to which their perceived health behavior is under one's control or as a result of luck, chance, or fate will affect the satisfaction of each with specific aspects of their interactions and contribute to differing numbers of referrals for psychological revolutions.

(16) Technical Approach:

Survey data compiled from both referring physician and subject patients will be compared and evaluated to establish any significant connections between health expectancy styles for these two groups and the referral process.

(17) Progress:

This study has been terminated due to insufficient availability of subjects to obtain enough data for analysis.

Publications and Presentations: none

RADIOLOGY

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 74/600 (3) Status: Ongoing
(4) Title: Bone Marrow Scintigraphy and Scintigraphic Localization of
Soft Tissue Tumors by Use of Indium-111 Chloride

(5) Start Date: 1974	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Peter W. Blue LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Nuclear Medicine Svc	(10) Assoc Investigators: Nasser Ghaed, COL, MC
(11) Key Words: Indium 111 Chloride Bone Marrow	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 6/81 Review Results: Ongoing	

(15) Study Objective:

Clinical evaluation of Indium-111 Chloride supplied by Medi-Physics, Inc. The evaluation of the agent is significant in that it represents a method of studying sites of erythropoiesis in bone marrow and allows scintigraphic localization of soft tissue tumors by non-invasive techniques. In selected patients, this affords clinical information which could not be obtained by other methods.

(16) *Technical Approach:

Up to 2mc of Indium-111 Chloride or proportionally less depending on body weight supplied by Medi-Physics, Inc. will be administered intravenously to patients referred to Nuclear Medicine Laboratory for either scintigraphic evaluation of sites of erythropoiesis in bone marrow or the presence of soft tissue tumors.

(17) *Progress:

No studies were performed during the previous year. It is anticipated that several of these studies will be done in the coming year.

PUBLICATIONS and PRESENTATIONS: none

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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 74/602 (3) Status: Ongoing
(4) Title: The Use of Indium 111 DTPA for the Study of Cerebrospinal Fluid Pathways.

(5) Start Date: 1974	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Peter W. Blue LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Nuclear Medicine Svc	(10) Assoc Investigators: Nasser Ghaed, COL, MC
(11) Key Words: Indium 111 DTPA Cerebrospinal Fluid	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 6/81	Review Results: Ongoing

(15) Study Objective:
Clinical evaluation of Indium 111 DTPA in aqueous ionic solution (pH 7 to 8) for study of cerebrospinal fluid pathways as supplied by Medi-Physics, Inc.

(16) *Technical Approach:
Evaluation of this agent represents a method of studying cerebrospinal fluid pathways in selected patients with a compound that will result in significantly less absorbed radiation doses to patients than the methods currently used. The incidence of side reactions, such as fever, headaches and mild meningitis, will probably be decreased in comparison to the compound presently used.

(17) *Progress:
7 studies using Indium 111 DTPA for evaluation of patients with cerebral spinal fluid pathways pathology have been done in the last year since 1 October 1980. The radiopharmaceutical proved adequate for the intended diagnostic purpose, and again no detectable side effects were observed.

PUBLICATIONS and PRESENTATIONS: none

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Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/600 (3) Status: Ongoing
(4) Title:
Tc-99m - PIPIDA for diagnosis of Hepatobiliary disease

(5) Start Date: 1980	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Peter W. Blue LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Nuclear Medicine Svc	(10) Assoc Investigators: Nasser Ghaed, COL, MC
(11) Key Words: Tc-99m-PIPIDA, diagnostic hepatobiliary, Diagnostic Is- otopes	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
(14) Date of Review: 9/81 Review Results: Ongoing	

*Refer to Unit Summary Sheet of this report.

(15) Study Objective:

To evaluate the clinical efficacy of Tc-99m-PIPIDA as a diagnostic hepatobiliary and gallbladder agent for Diagnostic Isotopes, Incorporated, Bloomfield, New Jersey, as an FDA Phase III study. Information concerning the efficacy will be furnished to Diagnostic Isotopes in support of the company's New Drug Application (NDA) on a cost recovery basis.

(16) *Technical Approach:

Each patient will be studied following a 6-8 hour period of fasting when possible. Following intravenous administration of the Tc-99m-PIPIDA sequential scintiphotos will be obtained at 5 minute intervals for up to 1 hour following injection.

(17) *Progress:

42 studies using 99m-Tc-PIPIDA for evaluation of patients with possible biliary disease were performed since 1 Oct 80. The radiopharmaceutical proved adequate for the intended diagnostic purpose. No detectable side effects were observed.

PUBLICATIONS and PRESENTATIONS: none

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Proj No.: 79/600 (3) Status: Ongoing
(4) Title: Non-Invasive Realtime Ultrasonic Evaluation of Carotid Occlusive Vascular Disease

(5) Start Date: 1979	(6) Est Comp Date: indefinite
(7) Principal Investigator: Gloria Hubred Komppa, M.D.	(8) Facility: FAMC
(9) Dept/Sec: Radiology/Ultrasound	(10) Assoc Investigators: Lewis Mologne, Col John Eielson, Ltc Nasser Chaed, Col
(11) Key Words: Carotid Artery Thrombus Ulcerative plaque	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
(14) Date of Review: 6/81 Review Results: Ongoing	

*Refer to Unit Summary Sheet of this report.

(15) Study Objective:

To objectively evaluate the patency of the carotid artery; to evaluate the presence and extent of a thrombus and/or ulcerative plaque in the carotid; and to employ a full pulsed doppler to measure bidirectional flow in the carotid artery.

(16) Technical Approach:

Approximately 120 patients will be evaluated. Patients will be divided into four groups as follows (with approximately 30 patients in each group); 1) Control population; 2) Patients with asymptomatic carotid bruits; 3) Symptomatic patients with or without carotid bruits; 4) Patients who have experienced a previous stroke within the last 12 months. This entire patient population will be evaluated.

(17) Progress:

There has been no progress made on this project due to Special MEDCASE funding for real-time ultrasound not being available during the fiscal year.

Publications and Presentations; None

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/601 (3) Status: Ongoing
(4) Title: Comparison of Growth Adjusted Sonographic Age (GASA) With
The Clinical Newborn Aging Examination (Dubowitz)

(5) Start Date: 1980	(6) Est Comp Date: 1982, March
(7) Principal Investigator: Stanley F. Smazal, Jr., M.D.	(8) Facility: FAMC
(9) Dept/Sec: Radiology/Ultrasound	(10) Assoc Investigators: Kenneth Hopper, Cpt Leonard Weisman, Maj Nasser Ghaed, Col
(11) Key Words: GASA	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
(14) Date of Review: 9/81 Review Results: Ongoing	

(15) Study Objective:

This study proposes to evaluate the efficacy of the growth adjusted sonographic age described by Sabbagha by comparing the growth adjusted age to the gestational age determined at birth by the Dubowitz method.

(16) Technical Approach:

Approximately 100 normal pregnancies will be evaluated by ultra-sonographic methods prior to 26 weeks of gestation and again after 33 weeks of gestation. The GASA will be used to determine age. This gestational age will be compared to the gestational age determined by examination at birth (Dubowitz Method). Statistical correlations and reflections will be made from this data.

(17) Progress:

The ultrasound examinations have been completed. The statistical evaluation is in progress

PUBLICATIONS: none

PRESENTATIONS for FY 81 Annual Progress Report

Proto No. 80/601

SERVICE Radiology/Ultrasound

DEPARTMENT Radiology

- (1) Weisman, Smazal, Hopper: "GASA". Presented: Aspen Military Conference, Perineonatal Research, Aspen, Colorado, July, 1981.
- (2) Smazal, Weisman, Hopper: "GASA". Presented: Rocky Mountain Radiological Society Annual Conference, Denver, Colorado, August, 1981.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/602 (3) Status: Ongoing
(4) Title: I.V. administration of ¹³¹I-6-B iodoethylnorcholesterol
(NP-59) for adrenal evaluation and imaging.

(5) Start Date: 1980	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Peter W. Blue, LTC, MC	(8) Facility: FAMC
(9) Dept/Sec: Nuclear Medicine Svc	(10) Assoc Investigators: Nasser Ghaed, COL, MC
(11) Key Words: iodocholesterol adrenal	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 11/80 Review Results: Ongoing	

(15) Study Objective:

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

(16) *Technical Approach:

Each patient will be studied while taking Lugol's or SSKI to protect the thyroid. Some patients will have adrenal function suppressed with Dexamethasone. Following a 2millicurie dose of NP-59, each patient will be scanned at day 3 and possibly day 5 and day 7.

(17) *Progress:

One study with ¹³¹I-W8-59 for evaluation of patients with possible adrenal function abnormalities have been performed since 1 Oct 80. The radiopharmaceutical proved adequate for the intended diagnostic purpose. No detectable side effects were observed.

PUBLICATIONS and PRESENTATIONS; none

PRIMARY CARE AND COMMUNITY MEDICINE

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 74/651 (3) Status: Ongoing
(4) Title: Establishment of and Training in Methods for Special Studies
of Abnormal Hemoglobins

(5) Start Date: January 1974	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Nicholas C. Bethlenfalvay, MD, DAC	(8) Facility: FAMC
(9) Dept/Sec: DPCCM	(10) Assoc Investigators:
(11) Key Words: Abnormal Hemoglobins Techniques on Identification	Joseph Lima, DAC
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 12/80 Review Results: Ongoing	

(15) Study Objective:

To establish and conduct training in methods for special studies of abnormal hemoglobins.

(16) Technical Approach: To acquaint and to train existing personnel in the performance of various procedures as they pertain to biochemical study of hemoglobins and red cell enzymes involved in hemoglobin function.

(17) Progress: Since 1974 the following can now be performed. Column chromatography, electrophoresis and iso-electrofocusing of hemoglobin; column chromatography and electrophoresis and iso-electrofocusing of globin and electrophoretic demonstration of iso-enzymes of both NADH and NADPH dependent methemoglobin reductases. Quantitation of NDAH-cytochrome b₅ and NADPH MR, glutathione, glutathione reductase now can be done. G-6-PD iso-enzyme patterns now can be determined. Recently equipment for the determination of hemoglobin oxygen dissociation curve has been obtained, and is operational.

Publications and Presentations: None.

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ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/650 (3) Status: Ongoing
(4) Title: Evaluation of Thalassemia as Cause of Hypochromic Microcytic Anemia and in Interaction with Hemoglobin Variants

(5) Start Date: March 1978	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Nicholas C. Bethlenfalvay, MD, DAC	(8) Facility: FAMC
(9) Dept/Sec: DPCCM	(10) Assoc Investigators:
(11) Key Words: Thalassemia-hemoglobin variants	Joseph Lima, DAC
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 2/81 Review Results: Ongoing	

(15) Study Objective:

To establish phenotype and genotype in patients with microcytic hypochromic anemia due to imbalance in globin chain synthesis.

(16) Technical Approach: Patients with (a) hypochromic-microcytic anemia (b) patients whose hemoglobin electrophoretogram reveals a variant hemoglobin in amounts greater than 50 or less than 40% will be evaluated. Peripheral blood will be incubated with ¹⁴C leucine. Alpha/beta globin synthetic ratios will be calculated.

(17) Progress: Since the inception of the study, 40 patients were evaluated resulting in the identification of the following conditions: HbC/alpha thalassemia; HbS/beta plus thalassemia HbS/beta 0 thalassemia, HbH disease, *acquired, 2 cases! HbH disease (a de-novo genetic event) alpha-thalassemia - 1 and type II normal HbA₂ - beta plus thalassemia. Active consultation is provided, in selected cases, to the Staff Division of Hematology, University of Colorado Medical Center, Denver, under this protocol.

SERVICE _____

DEPARTMENT of Primary Care & Community Medicine

- (1) Higgs, D.R., Bunch, D., Old, J.M., Hunt, D.M., Bethlenfalvay, N.C., Sjolín, S., Koler, R., Weatherall, D.J., and Clegg, J.B.: Hemoglobin H Disease and Mental Retardation - a New Syndrome or a Remarkable Coincidence? (Abst.) Brit. J. Haemat. 49:129, 1981.
- (2) Weatherall D.J., Higgs D.R., Bunch C., Old J.M., Hunt D.M., Pressley L., Clegg, J.B., Bethlenfalvay N.C., Sjolín S., Koler R.D., Magenis E., Francis J.L. and Bebbington D.: Hemoglobin H Disease and Mental Retardation: A New Syndrome or a Remarkable Coincidence?

New Eng. J. Med. 305:607-612, 1981

PRESENTATIONS:

- (1) Higgs, D.R., Bunch, D., Old, J.M., Hunt, D.M., Bethlenfalvay, N.C., Sjolín, S., Koler, R., Weatherall, D.J., and Clegg, J.B.: Hemoglobin H Disease and Mental Retardation - a New Syndrome or a Remarkable Coincidence? Presented: 22d Annual Meeting, British Society for Haematology, Sheffield, J.K., March 1981

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.) (Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 78/651 (3) Status: Ongoing

(4) Title: Evaluation and Structural Identification of Unusual Human Hemoglobin Variants

(5) Start Date: March 1978	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Nicholas C. Bethlenfalvay, MD, DAC	(8) Facility: FAMC
(9) Dept/Sec: DPCCM	(10) Assoc Investigators: Joseph E. Lima, MS, DAC
(11) Key Words: Abnormal Hemoglobins	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 2/81	Review Results: Ongoing

(15) Study Objective:

To demonstrate that variation at critical sites in hemoglobin structure is one of the reasons for anemia, polycythemia or a hemolytic state in man.

(16) Technical Approach: Cases of chronic hemolytic anemia and cases with left or right shifted oxygen dissociation curves will be studied by means of electrophoresis, chromatography and isoelectric focusing.

(17) Progress: Since the inception of the study, four cases with unusual hemoglobins were identified. Two of these were shown to have Hb Lepore/Boston, one, having heterozygosity for the hereditary persistence of Hb F (Aganina G gamma variety); the last patient with erythrocytosis and an electrophoretically silent Hb was found to have a left shifted oxygen dissociation curve and an abnormal Hb band on isoelectric focusing. Having a beta 97 his → tyr substitution, this is a hitherto unreported high oxygen affinity variant. Paper was submitted for publication. Consultation, on selected cases, is being provided to the staff division of Hematology, University of Colorado Medical Center on an ongoing manner, under this protocol.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION
FITSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/650 (3) Status: Ongoing
(4) Title: The Ontogenesis of Hemoglobin in the American Opossum
(Didelphis Virginia).

(5) Start Date: 18 March 1980	(6) Est Comp Date: Indefinite
(7) Principal Investigator: Nicholas C. Bethlenfalvay, MD, DAC	(8) Facility: FAMC
(9) Dept/Sec: DPCCM	(10) Assoc Investigators: Dr P. O'Barr, DAC J.E. Lima, DAC T. Waldrup, DAC
(11) Key Words: Opossum Hemoglobin Red Cell Energy Metabolism Methemoglobin formation & Reduction	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 4/81 Review Results: Ongoing	

(15) Study Objective:

This is a continuation of a previous Clinical Investigation study that was completed in June 1975. The overall objective is to follow and define the kinetics of methemoglobin reduction of opossum hemoglobin, in specific, as part of the overall energy metabolism of the red cell of this species.

(16) Technical Approach: In-vivo and in-vitro reduction of nitrite induced methemoglobinemia will be followed hourly by quantitative, electrophoretic and spectroscopic means. Methemoglobin reductases will be quantitated and electrophoretically demonstrated, and compared to human reductases.

(17) Progress: Opossum Hb was found to oxidise faster than human Hb in solution, the converse was observed on intact, glucose depleted erythrocytes even at acidic pH. Although opossum red cells were shown to be permeable to glucose, they did not

(17) Progress (contd): require this substrate for methemoglobin reduction in-vitro methylene blue was found to accelerate methemoglobin reduction on intact opossum erythrocytes at a rate exceeding that seen in human erythrocytes. This reaction, in contrast, was shown to be dependent on glucose in the red cell environment. The search for an intracellular energy source, which is not removed by exhaustive washing of red cells is continuing.

Two papers have been submitted for publication this FY on the observations summarized above.

Publications and Presentations: None.

NURSING

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/700 (3) Status: Completed
(4) Title: A Comparison of Primary Anesthesia Care and Team Anesthesia
Care in Regards to Perioperative Patient Management

(5) Start Date: 1 April 1981	(6) Est Comp Date: 15 August 1981
(7) Principal Investigator: CPT Thomas E. Sprague, ANC	(8) Facility: FAMC
(9) Dept/Sec: Nursing/Anesthesia	(10) Assoc Investigators: None
(11) Key Words: Perioperative complications	
(12) Accumulative MEDCASE: * *Refer to Unit Summary Sheet of this report.	(13) Est Accumulative OMA Cost: * (14) Date of Review: 11/80 Review Results: Ongoing

(15) Study Objective:
The intent of this study is to justify the need for primary care
in the field of anesthesia.

(16) Technical Approach:
Statistical data will be collected following administration of
anesthesia to ASA I Male patients from the ages of 18-40 to
analyze perioperative complications. A Chi Square test will be
used to determine whether the incidence of complications is in-
dependent of the primary or team approach to anesthesia.

(17) Progress:
It was determined at the .5% level of significance that peri-
operative difficulties were not dependent on whether a team
or primary approach was used.

PUBLICATIONS and PRESENTATIONS: none

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/701 (3) Status: Completed
(4) Title: Incidence of Post-spinal Headaches in Males versus Females

(5) Start Date: 4 November 1980	(6) Est Comp Date: 30 September 1981
(7) Principal Investigator: CPT Wayne C. Wise, ANC	(8) Facility: FAMC
(9) Dept/Sec: Nursing/Anesthesia	(10) Assoc Investigators: CPT Harold S. Booker, ANC (Walter Reed AMC)
(11) Key Words: post-spinal headaches	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 11/80 Review Results: Ongoing	

- (15) Study Objective:
Descriptive research focusing on the incidence of post-spinal headache in an attempt to determine if there is a significant difference between males and females in regard to the occurrence of spinal headaches.
- (16) Technical Approach:
Data will be collected from both male and female patients age 20 to 50 years old. Certain patients will be excluded from the study due to their possible predisposition to headaches. A standard spinal anesthetic will be performed on each patient. On the 3rd or 4th post-op day the patient will be visited by the researcher to ascertain what, if any, complications occur.
- (17) Progress:
As of this report the data collection has been accomplished and the final evaluation of the statistics is being carried out. A preliminary evaluation of the data indicates that our hypothesis, of no difference in incidence of headaches between males and females, was not supported to our desired level of significance. It is our suggestion that this study be replicated using a much larger sample size.

PUBLICATIONS and PRESENTATIONS: none

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/702 (3) Status: Completed
(4) Title: Subarachnoid Block versus Balanced General Anesthesia,
Their Effects on Apgar Score of Infants Delivered
by Cesarean Section,

(5) Start Date: 28 Oct. 80	(6) Est Comp Date: 1 Aug 81
(7) Principal Investigator: Ronald B. Ostmann Cpt ANC	(8) Facility: FAMC
(9) Dept/Sec: Anesth School	(10) Assoc Investigators:
(11) Key Words: Spinal General Anesthesia Cesarean Section	N/A
(12) Accumulative MEDCASE:*(13) Est Accumulative OMA Cost:*	(14) Date of Review: 11/80 Review Results: Ongoing
*Refer to Unit Summary Sheet of this report.	

(15) Study Objective:
To determine which anesthetic, spinal or balanced general,
is least depressive on the infant based on apgar scores.

(16) Technical Approach:
The sample consisted of elective cesarean section patients.
The patient was given the option of choosing the type of
anesthetic desired and was assigned to group A, the sub-
arachnoid block group, or group B, the balanced general
anesthesia group. The anesthetic technique used was that
which is outlined in the plan portion of the protocol.
The apgar scores were obtained at the time of the Cesarean
Section.

(17) Progress:
The project was completed 1 August 81. This study supports
that when a spinal or a balanced general anesthesia is per-
formed properly they do not cause significant fetal depres-
sion as measured by the one and five minute apgar scores.

PUBLICATIONS and PRESENTATIONS: none

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/703 (3) Status: Completed
(4) Title: The Lawn Chair and Flat Positions and Their Relationship
to Post-operative Back Pain

(5) Start Date: 15 January 1981	(6) Est Comp Date: 15 August 1981
(7) Principal Investigator: Neil C. Kerr, Jr., CPT, ANC	(8) Facility: FAMC
(9) Dept/Sec: Nursing/Anesthesia	(10) Assoc Investigators: None
(11) Key Words: lawn chair, back pain, flat, length of surgery	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) Date of Review: 11/80 Review Results: Ongoing	

(15) Study Objective:
To determine if the position of the operating room table with respect
to length of surgery has any relationship on post-operative back pain.

(16) Technical Approach:
The patients will be divided into two groups, one group in the lawn
chair position and the other group in the table flat position. The
population will be at least forty patients. The patients will be
placed into the groups according to their hospital numbers; odd and
even numbers. The lawn chair position will be a fifteen degree flexion
of the thigh-back joint and a fifteen degree flexion of the knee-thigh
joint in the reverse direction. Each patient will not have any type
of back pain prior to surgery. The length of time the surgery takes
will be recorded. The day after surgery each patient will be asked if
they have any back pain and the response will be recorded. A Chi-
square table will be used to do the statistical analysis.

(17) Progress:
The study is completed at this time. There were no problems in com-
pleting this study, and the final sample size is 134 patients. This
study did not show any statistical difference between the two groups
of patients.

PUBLICATIONS and PRESENTATIONS: none

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/704 (3) Status: Ongoing
(4) Title: Liver Enzyme Levels in Nurse Anesthetist Students Prior to
and at Six and Twelve Month After Initial Occupational Exposure.
Does the Operating Room Present a Hazard?

(5) Start Date: 26 Nov 80	(6) Est Comp Date: 1 Dec 81
(7) Principal Investigator: Lance C. Campbell Captain, ANC	(8) Facility: FAMC
(9) Dept/Sec: Nursing	(10) Assoc Investigators: Kenneth Duggan Captain, ANC
(11) Key Words: Liver Enzyme Levels Operating Room Hazard Occupational Exposure Anesthetic Pollution	
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*
(14) Date of Review: 11/80 Review Results: Ongoing	

*Refer to Unit Summary Sheet of this report.

(15) Study Objective:

The objective of this study is to quantify the occupational risk of a modern operating room environment to nurse anesthetists. We plan to compare pre-exposure liver enzymes during student classroom-only training to enzyme levels at six months and at one year after commencing regular occupational exposure with currently used medical center operating room scavenger systems.

(16) Technical Approach:

The plan utilized a sample of 31 nurse anesthetist students. A single tube of blood was drawn July 1980 (pre-occupational OR exposure), March 1981, (after 6 months exposure) and September 1981 (after 12 months exposure). These samples were submitted for liver profile (SGPT, SGOT, LDH, GGT, Alkaline Phosphatase, Total and Direct Bilirubin)

(17) Progress:

The study has been essentially accomplished at this point, except for the statistical analysis - which will be paired data using the first blood sample as control, and formulation of the results, summary and conclusions.

PUBLICATIONS and PRESENTATIONS: none

DEPARTMENT OF CLINICAL INVESTIGATION
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 Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 80/705 (3) Status: Completed
 (4) Title: A Study of the Clinical Effects of Several Different Non-depolarizing Muscle Relaxants When Used in Combination with a Specific Depolarizing Agent in Human Subjects

(5) Start Date: 26 November 1980 (6) Est Comp Date: September 1981
 (7) Principal Investigator: Steven D. Allen, CPT, ANC (8) Facility: FAMC

(9) Dept/Sec: Nursing/Anesthesia (10) Assoc Investigators: Lesley Collar, MAJ
 (11) Key Words: train of four, depolarizing agent, non-depolarizing agent, paralysis, ASA I, II, IE, IIE

(12) Accumulative MEDCASE:*(13) Est Accumulative OMA Cost:* (14) Date of Review: 11/80
 *Refer to Unit Summary Sheet of this report. Review Results: Ongoing

(15) Study Objective:
 To determine which of several combinations of drugs currently used produces the fastest onset of total paralysis, with a minimum of potentially harmful side effects.

(16) Technical Approach:
 Subjects divided into four groups, each receiving a different combination of depolarizer/non-depolarizer. The time to total paralysis was measured and recorded.

(17) Progress:
 The project is completed. Data has been accumulated, subjected to statistical analysis, and conclusions have been drawn. The final draft of the paper is presently being prepared and should be completed by 1 October 1981.

PUBLICATIONS and PRESENTATIONS: none

DEPARTMENT OF CLINICAL INVESTIGATION
 FITZSIMONS ARMY MEDICAL CENTER
 Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81 (2) Prot No.: 81-700 (3) Status: Completed
 (4) Title: The Incidence of Bacterial and/or Viral Infections in Premature Infants Following Initiation of a Sibling Visitation Policy in a Newborn Intensive Care Unit.

(5) Start Date: 1 1981		(6) Est Comp Date: 1 June 1981
(7) Principal Investigator: MAJ Barbara Turner		(8) Facility: FAMC
(9) Dept/Sec: Nursing		(10) Assoc Investigators: COL Gerald B. Merenstein CPT Cheryl J. Ellis
(11) Key Words: Infection Premature Infant Sibling Visitation		
(12) Accumulative MEDCASE:*	(13) Est Accumulative OMA Cost:*	(14) Date of Review: 2/81 Review Results: Ongoing
*Refer to Unit Summary Sheet of this report.		

(15) Study Objective: To determine if there is a higher incidence of bacterial and/or viral infection in premature infants following institution of a policy of sibling visitation in the Newborn Intensive Care Unit than prior to initiation of the policy.

(16) Technical Approach: The research design will be a retrospective review of the charts of all premature infants admitted to the Newborn Intensive Care Unit at Fitzsimons Army Medical Center from 1 December 1976 to 30 November 1978. Premature infants will be defined as those infants having a Dubowitz Gestational Age Evaluation of less than 36 weeks. The instrument for data collection will be an original flow sheet designed for the identification of independent, dependent, and extraneous variables.

(17) Progress: Study was completed on 1 June 1981. Group I, Premature Infants admitted to the NICU between 1 December 1976 and 30 November 1977 consisted of 78 infants, those not exposed to sibling visitation. Group II, Premature Infants admitted to the NICU between 1 December 1977 to 30 November 1978, consisted of 98 infants that were exposed to sibling visitation. The two groups are comparable according to mean gestational age, birth weight, length of stay and incidence of ORAL-TRACHEAL/NASOTRACHEAL Intubation. Group II had a higher mortality perhaps due to the larger number of infants less than 26 weeks gestation. Data were analyzed by simple percentages of occurrence in

both groups. Group II, after the institution of sibling visitation showed a lower incidence of infection both for sepsis and suspected sepsis. There were no positive viral cultures in either group. It can be concluded that the institution of sibling visitation in the Newborn Intensive Care Unit at Fitzsimons Army Medical Center has not been associated with an increased incidence of bacterial and/or viral infections.

PUBLICATIONS for FY 81 Annual Progress Report

1. Turner, B.S. and Ellis, C.J.: The Incidence of Bacterial and/or Viral Infections in Premature Infants Following Initiation of a Sibling Visitation Policy in a Newborn Intensive Care Unit. (Submitted for Publication to Research Nursing, September 1981.)

PRESENTATIONS for FY 81 Annual Progress Report

1. Turner, B.S. and Ellis, C.J.: The incidence of Bacterial and/or Viral Infections in Premature Infants Following Initiation of a Sibling Visitation Policy in a Newborn Intensive Care Unit. Presented: Phyllis H. Verhonick Nursing Research Symposium, Fort Sam Houston, Texas, June 1981.

PHYSICAL MEDICINE AND REHABILITATION

DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
Aurora, Colorado 80045

ANNUAL PROGRESS REPORT

(HSCR 40-23, App. C.)

(Detail Summary Sheet)

(1) Date: 30 SEP 81			(2) Prot No.: 81/750			(3) Status: Ongoing		
(4) Title: Evaluation and Comparison of Acupuncture, Electrical Transcutaneous Nerve Stimulator and Trigger Point Stimulation (Neuroprobe) in the Treatment of Musculoskeletal Pain.								
(5) Start Date: 8 May 1981						(6) Est Comp Date: 1 March 1981		
(7) Principal Investigator: COL Angelo Scavarda						(8) Facility: FAMC		
(9) Dept/Sec: Phys Med & Rehab Svc						(10) Assoc Investigators:		
(11) Key Words: Acupuncture Trigger Point Stimulation						MAJ Ernie Lin, M.D. 1LT Joan Beebe, Physical Therapist		
(12) Accumulative MEDCASE:*			(13) Est Accumulative OMA Cost:*			(14) Date of Review: 6/81 Review Results: Ongoing		
*Refer to Unit Summary Sheet of this report.								
(15) Study Objective:								

To evaluate and compare the efficacy of acupuncture and electrical trigger point stimulation as modalities in treating musculoskeletal pain syndromes in patients seen in Physical Medicine & Rehabilitation Service at Fitzsimons Army Medical Center.

(16) Technical Approach:

Forty-one patients who were referred to Physical Medicine with musculoskeletal pain were treated with transcutaneous nerve stimulator (TENS) in the Physical Therapy Clinic. Electrode placement was according to location of pain. Twenty-three patients were treated with acupuncture using the appropriate points for their particular pain locale. No patients were treated with Neuroprobe as we did not receive the equipment until late Oct 81.

(17) Progress:

Out of twenty-three acupuncture patients, seventeen patients had a favorable response and five had no response. Of forty-one TENS patients thirty-five had a favorable response. We now have the Neuroprobe equipment and will be doing a series of patients with this modality as well as with acupuncture and TENS.

Proto No. 81/750

PUBLICATIONS for FY 81 Annual Progress Report

None.

PRESENTATIONS for FY 81 Annual Progress Report

None.

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