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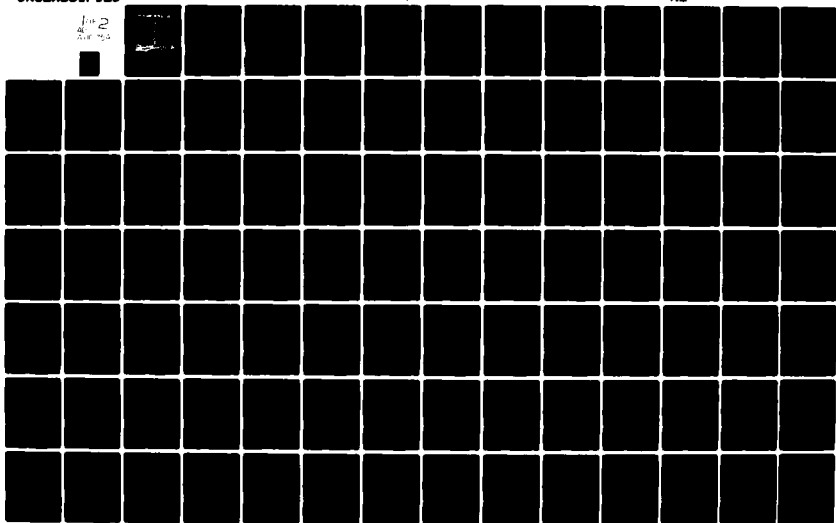
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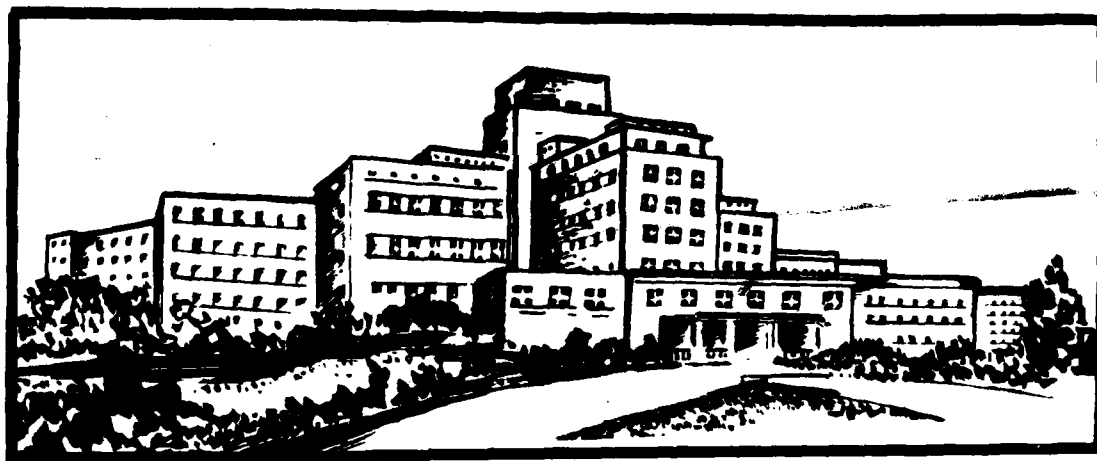
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| 19. KEY WORDS (Continue on reverse side if necessary and identify by block number)<br>Clinical investigations; experimental projects; research protocols; in-house<br>research; publications, presentations of research data; protocol status;<br>experimental design.  |   |  |
| 20. ABSTRACT (Continue on reverse side if necessary and identify by block number)<br>Subject report identifies those individuals who are conducting investigative<br>protocols at Tripler Army Medical Center. An abstract of each protocol<br>giving abbreviated technical objectives, methods, and progress is presented. |   |  |

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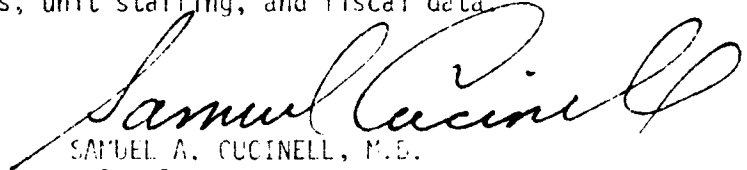
DEPARTMENT OF CLINICAL INVESTIGATION  
TRIPLER ARMY MEDICAL CENTER  
Tripler AMC, Hawaii 96859

# FOREWORD

Contained herein are progress reports on research projects fostered by the Clinical Investigation Program at Tripler Army Medical Center (TAMC) during Fiscal Year 1981.

The Clinical Investigation and Human Use Committees reviewed all proposals for their scientific merit, medical applicability, and risk to human subjects. In conducting the research described in this report, the investigators adhered to the "Guide for Laboratory Animal Facilities and Care" as promulgated by the National Academy of Sciences/National Research Council, the criteria established by the American Association for Accreditation of Laboratory Animal Care, and the principles embodied in the Declaration of Helsinki.

This Annual Progress Report contains publications, presentations, awards, proposals, preliminary findings, unit staffing, and fiscal data.



SAMUEL A. CUCINELL, M.D.

Colonel, MC

Chief, Dept of Clinical Investigation

DEPARTMENT OF CLINICAL INVESTIGATION  
TRIPLER ARMY MEDICAL CENTER

UNIT SUMMARY

A. OBJECTIVES: Previous to the provisions of 1981, the duty of the Department of Clinical Investigation (DCI) was the provision of support for medical research by the TAMC staff. Now DCI is responsible for the quality and administrative monitoring of the research as well. Emphasis on quality has required additional reviews and preparation of protocols; possibly this relates to the decrease in protocols. Unfortunately, zero of seven protocols submitted to the Human Subjects Research Review Board (HSRRB) this year have been approved in time for the work to be carried out, reflecting the increased demand for quality.

B. TECHNICAL APPROACH: All research, investigations, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-38, AR 70-25, AR 70-18, and HSC Regulation 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

C. STAFFING:

| <u>Name</u>           | <u>Rank</u> | <u>MOS</u> | <u>Title</u>               |
|-----------------------|-------------|------------|----------------------------|
| Cucinell, Samuel A.   | COL         | 61F00      | Chief                      |
| Hadick, Clayton L.    | CPT         | 64A00      | C, Veterinary Svc          |
|                       |             | 68C00      | Biochemist                 |
| Dotson, Carroll R.    | CPT         | 68A00      | C, Microbiology Svc        |
| Coussens, Wayne R.    | CPT         | 68T00      | Research Psychologist      |
| Pulu, Tavake          | SFC         | 92B40      | NCOIC                      |
| Lewis, Clifford D.    | SP5         | 01H20      | Biomed Science NCO         |
| Fallaria, Nonilon A   | SP5         | 01H20      | Biomed Science NCO         |
| Davis, Cynthia R.     | SP5         | 91T20      | Animal Sp                  |
| Smart, Thomas P.      | SP5         | 91T20      | Animal Sp                  |
| Sanders, Teresa C.    | SP4         | 91T10      | Animal Sp                  |
| Ashburn, Cynthia J.   | PFC         | 92B10      | Med Lab Sp                 |
| Claybaugh, John R.    | GS14        | 00413      | C, Physiology Svc          |
| Bryant, Gordon H.     | GS11        | 00802      | Biomedical Engineer        |
| Palmer, Carolyn A.    | GS09        | 00404      | Biological Lab Tech        |
| Sato, Aileen K.       | GS09        | 00404      | Biological Lab Tech        |
| Hashiro, Glenn M.     | GS07        | 00403      | Microbiologist             |
| Cornette, Kuuleialoha | GS07        | 00413      | Career Intern Physiologist |
| Masanaga, Lois E.     | GS06        | 01087      | Editorial Assistant        |
| Yamamoto, Cynthia T.  | GS04        | 00312      | Clerk-Steno                |
| lacial, Ernie A.      | WG02        | 03566      | Custodial Worker           |

D. FUNDING:

| Type                                      | Preceding Year | Current Year |
|---|----------------|--------------|
| Civilian personnel to include benefits    | \$151,461.22   | \$167,320.45 |
| Consumable supplies                       | 78,986.15      | 65,782.90    |
| Civilian contracts to include consultants | 3,047.30       | 1,694.20     |
| TDY                                       | 16,180.58      | 16,877.22    |
| Publications                              | 1,622.86       | 1,899.77     |
| Noninvestment equipment (Minor MEDCASE)   | 651.40         | 1,447.85     |
| Trans & Taxes                             | 409.21         | 212.99       |
| Other OMA Maint. & Rentals                | 7,586.80       | 1,509.99     |
| OMA Total                                 | 259,945.52     | 256,745.37   |
| MEDCASE                                   | 41,370.41      | 55,594.00    |
| Other                                     |                |              |
| Military                                  | 220,998.58     | 247,946.16   |
| TOTAL                                     | \$522,314.51   | \$589,864.65 |

E. PROGRESS: 97 projects are reported, of which 23 have been terminated, 17 completed, and 57 ongoing. There have been 31 publications, 15 resulting from research projects, and 23 presentations at national and regional scientific meetings, 13 resulting from research projects. The detail sheets should be examined for specific information on the individual projects.

The number of publications has climbed steadily since the start of the DCI at TAMC in 1971. As a baseline from 1968 to 1970, there were nine publications per year. From 1971 to 1980 the average was  $17.4 \pm 5.9$  per year. Even before DCI had any facilities at all in 1971, there was a sharp increase. This suggests that simply the idea of research encouraged by the command is valuable in stimulating effort (Fig. 1). Since 1979, DCI has taken responsibility for preparation of manuscripts throughout TAMC. The number of manuscripts prepared by DCI has increased during these past three years compared to the previous five years for which data is available. The number of publications prepared includes major rewrites. On the other hand, the number of manuscripts submitted for publication clearance has remained constant. This manuscript preparation service is believed to



be the single most important thing in increasing the publication rate, not any dramatic increase in research, money, or personnel.

If the measure of success is publication, then DCI does well. The following table compares the past three years. There has been an increase in the number of publications resulting from protocols. What is disturbing is that the same authors' names are repeated over again. These publications do not represent a cross-section of the hospital, but rather the efforts of a limited number of individuals. Considering the number of protocols which are not published each year, it is possible for TAMC to have 50 manuscripts per year output. Numbers of publications do not necessarily reflect quality of work or completion of the mission. But what other measure is there?

|      | No. of Publications | No. of Publications from Protocols | No. of DCI Publications |
|------|---------------------|------------------------------------|-------------------------|
| 1979 | 14                  | 2                                  | 1                       |
| 1980 | 23                  | 4                                  | 3                       |
| 1981 | 31                  | 15                                 | 6                       |

F. PROBLEMS: The main problems are delay and lack of interest, time, and money. During the past two years, 8 months have been required on the average for resolution of a protocol submitted to the HSPRL. Six months is the shortest interval, and one year to final approval has occurred. The delay involves the consultant reviewers to the HSPRL who always find imperfections in the protocols. The resolution of this problem is to prepare perfect protocols.

The number of protocols reported this year has decreased from 88 to 73 (noncancer) protocols. The total protocols submitted to the Clinical Investigation Committee were 38 in 1980 and 17 in 1981. Articles have been written on the decrease in physician research. There is no reason to suspect that military physicians should be any more research-minded than civilians. Although the reason for the decrease in the civilian sector is said to be an increased interest in primary care and increased debts from medical school, TAMC's problem is the limitation on time of the physician staff. This is compounded by the aging equipment in DCI. The x-ray equipment, sterilizers, anesthesia machines, and surgical tools are 10 years old. Since research is the new and the advanced, our equipment simply is not adequate to meet the demands of modern surgical technique and postoperative care. The veterinary section is struggling to maintain a basic animal colony, and major surgery and postoperative care are marginal. As the surgical procedures decrease, the veterinary personnel become less experienced.

A chronic problem continues to be that protocols have been completed and reached the preliminary publication stage when they are

abandoned because of PCS of the investigator. Previously, one-half of all completed protocols were left unpublished. This has been reduced to one-quarter.

During the past year we lost our full AAALAC accreditation. The HSC Inspector General's inspection team found the DCI deficient in the animal colony as well. Remarkable effort has been made to correct the deficiencies and accreditation is expected to be reinstated.

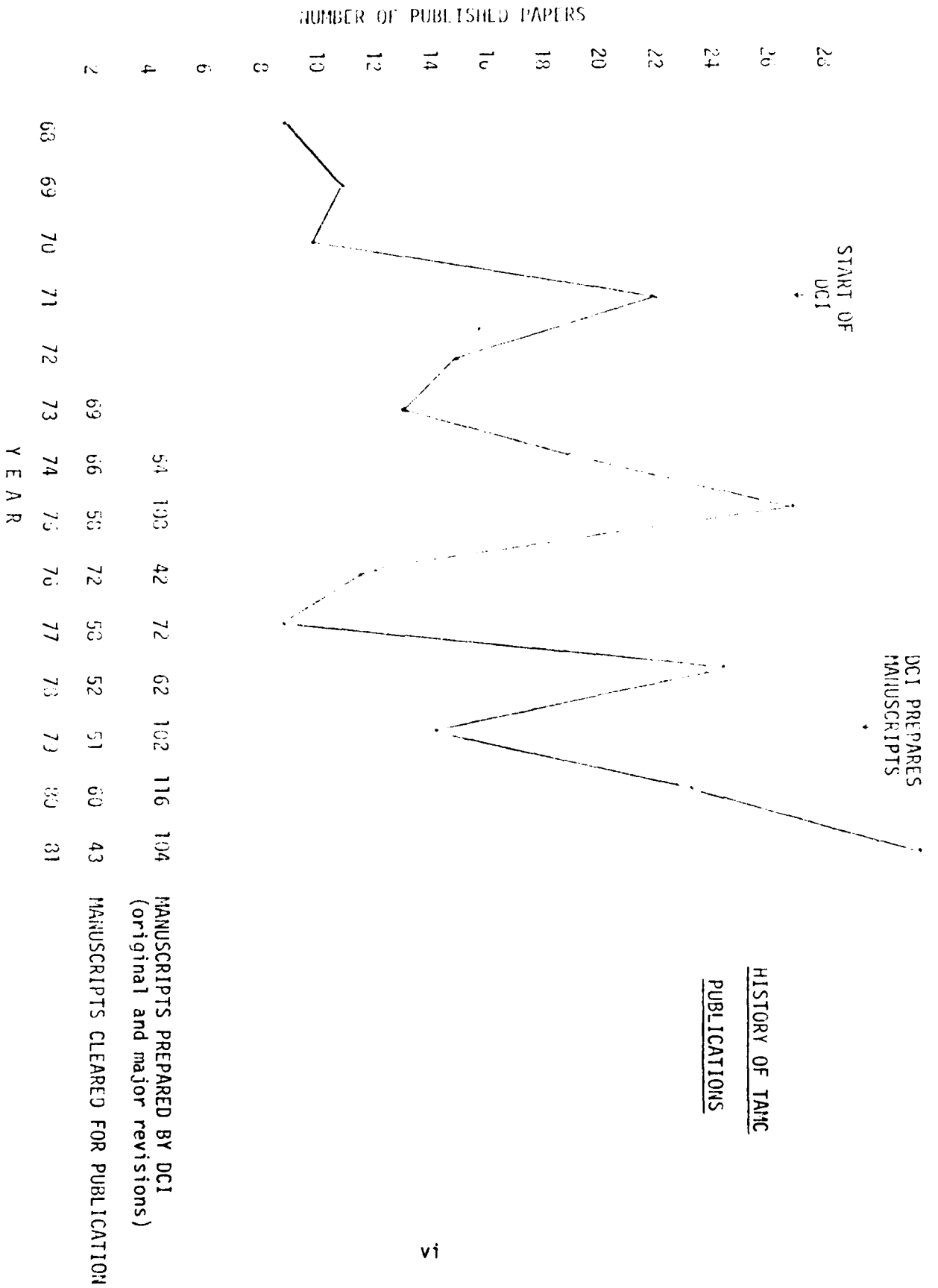
RESOLUTION OF PROBLEMS: A short-term solution of the problems of physician time and improvement of the quality of protocols is the preparation of protocols by more senior staff physicians with longer tours at TAMC, and the incorporation of the house staff into ongoing established programs. This is the classical mentor system. It may discourage novel efforts by the house staff but novel efforts by house staff have not really succeeded.

The quality of the surgical support in DCI must be improved to make experimental surgery successful. This involves improving the maintenance of our equipment and improving our MEDCASE. Although we have been awarded \$85,000 in MEDCASE funds in FY 81, not one item from these funds has arrived in Hawaii as of the submission of this report. MEDCASE support must be found to replace the X-ray system, since the radiologists cannot be expected to do advanced procedures with equipment from the 1960's.

The DCI of TAMC is ten years old. It has continued to have the support of an involved commander, MG Edward Huyke, and our former HSC program director, COL Norman Ream.

The DCI is reorienting its administrative and research programs to meet new requirements.

Figure 1



## TABLE OF CONTENTS

| Protocol<br>Number                   |   | Page |
|--------------------------------------|---|------|
|                                      | Foreword . . . . .  | i    |
|                                      | Unit Summary . . . . .  | ii   |
|                                      | Publications . . . . .  | 3    |
|                                      | Presentations . . . . .   | 4    |
| DEPARTMENT OF CLINICAL INVESTIGATION |   |      |
| 138/75                               | Bryant, G. H. Evaluation of the Cardioresophageal Sphincter Competence by Comparison of Intraluminal Esophageal Sphincter and Gastric Pressure with Thoracic, Hiatal, and Abdominal Pressure. (O) (P) | 6    |
| 34/79                                | Bryant, G. H. Fabrication of a Catheter for the Determination of Liver Blood Flow in Dog and Man. (O) (PR) (P)  | 7    |
| 5/81                                 | Bryant, G. H. Fabrication of a Nonperfused Gastric Motility Catheter. (O)   | 8    |
| 38/76                                | Claybaugh, J. R. Further Studies on the Site of Action of Circulating Angiotensin II on Plasma /DH Concentration. (O)   | 9    |
| 9/77                                 | Claybaugh, J. R. The Effect of Sodium Balance on the Vasopressin Response to Blood Volume Reduction. (O) (PR) (P)   | 10   |
| 11/77                                | Claybaugh, J. R. Enzyme Immunoassay of Arginine Vasopressin. (O)  | 11   |
| 22/79                                | Claybaugh, J. R. Comparison of Control of Vasopressin Release from Isolated Hypothalamoneurohypophyseal Explants Obtained from Normal and Hypertensive Rats. (O)                                      | 12   |
| 25/80                                | Claybaugh, J. R. Urinary Metabolites of Vasopressin: Consequences in Radioimmunoassay. (O)  | 14   |
| 15/81                                | Claybaugh, J. R. The Role of Dopamine in Angiotensin II Stimulated Antidiuretic Hormone Balance. (O) (PR) (P)   | 16   |
| 21/81                                | Coussens, W. F. . . . . stpartum Psychological Reactions to Childbirth Preparation and Experience. (T)  | 17   |

| Protocol<br>Number |  | Page |
|--------------------|--|------|
| 6/79               | Cucinell, S. A. Clinical Significance of ADH Levels in Disorders of Fluid and Electrolyte Metabolism. (T)                          | 18   |
| 26/79              | Cucinell, S. A. Determination of Liver Blood Flow and Improved Technique for Sampling Hepatic Vein Blood. (O) (PR) (P)             | 19   |
| 28/79              | Cucinell, S. A. Mechanism of Action and Antidote for Tricyclic Antidepressants. (T)  | 20   |
| 8/81               | Cucinell, S. A. Fansidar Prophylaxis in New Guinea. (C)  | 21   |
| 17/79              | Hadick, C. L. Biodetermination of Scombroid Toxin. (T)   | 22   |
| 17/81              | Hadick, C. L. Intraocular Prosthesis in a Cynomolgous Monkey ( <i>Macaca Fascicularis</i> ). (C) (F.R)                             | 23   |
| 46/78              | O'Brien, J. C. Lactic Metabolism in Isolated Liver Cells with Regard to Anoxia, Acidosis, Alkalosis, and Temperature. (C) (PR) (P) | 24   |

#### DEPARTMENT OF FAMILY PRACTICE

|       |  |    |
|-------|--|----|
| 29/79 | Aoki, J. E. Behavioral Effects of Antihypertensive Therapy in the Elderly. (O) | 25 |
|-------|--|----|

#### DEPARTMENT OF MEDICINE

|       |   |    |
|-------|---|----|
| 4/80  | Albert, H. L. Evaluation of PUVA in the Treatment of Resistant Psoriasis. (O)   | 27 |
| 1/81  | Highfill, W. T. A Prospective Trial of Propranolol in Patients with Diffuse Toxic Goiter for Subgroup Determination. (T)                        | 28 |
| 2/81  | Highfill, W. T. Coronary Arteriography in the Army. (C)   | 29 |
| 19/81 | Miller, C. F. Dexamethasone Antiemetic Study for Chemotherapy Patients. (O)   | 30 |
| 7/81  | Myers, R. L. Evaluation of Lower Gastrointestinal Bleeding: Colonoscopy Alone vs Colonoscopy as an Adjunct to Barium Enema and Proctoscopy. (T) | 31 |

| Protocol<br>Number                      |   | Page |
|---|---|------|
| 11/81                                   | Paulson, W. D. Influence of pH and Serum Protein Concentration on the Anion Gap. (C)                          | 32   |
| 25/80                                   | Rodgers, P. F. Pulmonary Function in Patients with Gastroesophageal Reflux. (T)                               | 33   |
| 2/79                                    | Shen, S. W. Glucose Modulation of Insulin Binding. (O)  | 34   |
| 3/79                                    | Shen, S. W. Free and Total Insulin Levels in Insulin-Treated Diabetics. (C) (PR)                              | 35   |
| 13/81                                   | Siddoway, R. L. Evaluation of heparin in Pericardial Effusion. (T)  | 36   |
| 19/79                                   | Thomas, H. M. Beta Blocker Heart Attack Trial. (T)  | 37   |
| 3/79                                    | Thomas, H. M. Evaluation of Amiodarone for the Therapy of Cardiac Arrhythmias. (C)                            | 38   |
| 26/80                                   | Thomas, P. M. Improved Record Keeping in MICU/CCU by Means of Table Model Computers. (C)                      | 39   |
| 4/80                                    | Underwood, C. E. Comparison of Daily Versus Alternate Prednisone Therapy in Pulmonary Sarcoidosis. (O)        | 40   |
| DEPARTMENT OF OBSTETRICS AND GYNECOLOGY |   |      |
| 32/80                                   | Burke, T. Antibiotic Prophylaxis in Vaginal Hysterectomy. (O)   | 41   |
| 18/80                                   | Matthews, M. D. Animal Surgery as an Adjunct to Gynecology Residency Program. (O)                             | 42   |
| 40/78                                   | Osterholzer, H. O. Microsurgical Anastomosis of the Rabbit Oviduct. (O)                                       | 43   |
| 12/81                                   | Osterholzer, H. O. Cold Pressor Test as a Predictor of Pregnancy-Induced Hypertension. (O)                    | 44   |
| 9/81                                    | Read, J. A. Randomized Trial of Ambulation vs Oxytocin for Various Stages of Dysplasia. (O)                   | 45   |
| 26/80                                   | Rudd, E. G. A comparison Study of Different Concentrations of Cefamandole Nafate During Cesarean Section. (T) | 46   |

| Protocol<br>Number       |  | Page |
|--------------------------|--|------|
| 10/81                    | Shaw, C. I. Retrospective Study of Conization Followed by Hysterectomy for Various Stages of Dysplasia. (C)  | 47   |
| DEPARTMENT OF PATHOLOGY  |  |      |
| 21/77                    | Angritt, P. Development of Clinical Assays. (C)  | 48   |
| DEPARTMENT OF PEDIATRICS |  |      |
| 22/80                    | Bollerup, E. J. Antidiuretic Hormone Secretion in the Asphyxiated Neonate. (C)   | 49   |
| 12/79                    | Garcia, J. Intubation and Chest Tube Placement in Small Laboratory Animals. (O)  | 51   |
| SWOG 7612                | Maybee, D. A. Comparison of Involved Field (IF) Radiotherapy and MOPP + Low Bleomycin with IF Radiotherapy and A-COPP in Stage III Hodgkin's Disease. (O)    | 52   |
| SWOG 7617                | Maybee, D. A. Combination Chemotherapy with Vincristine Sulfate and Bleomycin Infusion in Children with Metastatic Solid Tumors (Phase II). (T)              | 53   |
| SWOG 7621                | Maybee, D. A. MOPP versus OPP in the Treatment of Children with Recurrent Brain Tumors (Phase III). (T)  | 54   |
| SWOG 7623                | Maybee, D. A. Evaluation of Systemic Regimens in the Treatment of Acute Leukemia of Childhood, Phase III. (C)  | 55   |
| SWOG 7660                | Maybee, D. A. Comparison of Involved Field Radiotherapy with Adjuvant MOPP Chemotherapy in the Treatment of Stage I and II Hodgkin's Disease, Phase III. (C) | 56   |
| SWOG 7712                | Maybee, D. A. Comparison of Treatment Regimens for First CNS Relapse in Childhood Acute Lymphoblastic Leukemia (CNS Leukemia Study #6). Phase III. (O)       | 57   |
| SWOG 7721                | Maybee, D. A. Evaluation of Induction, Maintenance with and without Periodic Reinforcement, and CNS Prophylaxis in Acute Non-lymphocytic Leukemia. (C)       | 58   |
| SWOG 7810                | Maybee, D. A. Evaluation of Anguidine in Children with Acute Leukemia in Relapse Phase II. (T)   | 59   |

| Protocol<br>Number |  | Page |
|--------------------|--|------|
| SWOG 7812          | Maybee, D. A. Evaluation of Anguidine in the Treatment of Central Nervous System Tumor (Phase II). (C)                                 | 60   |
| SWOG 7818          | Maybee, D. A. Evaluation of Rubidazone in Children with Acute Leukemia in Relapse Phase II. (C)  | 61   |
| SWOG 7829          | Maybee, D. A. Comparison of Two Dose Regimens of Intrathecal Methotrexate for CNS Leukemia, Phase II. (T)                              | 62   |
| SWOG 7834          | Maybee, D. A. Second Induction and Maintenance in Acute Lymphocytic Leukemia (Phase III). (C)  | 63   |
| SWOG 7837          | Maybee, D. A. Evaluation of Systemic Therapy for Children with T Cell Acute Lymphatic Leukemia, Phase III. (C)                         | 64   |
| SWOG 7901          | Maybee, D. A. Rescue Therapy for Non-CNS Extramedullary Disease in Children with Acute Lymphoblastic Leukemia, Phase III. (C)          | 65   |
| SWOG 7905          | Maybee, D. A. A-COP Plus for Non-Hodgkin's Lymphoma in Children, Phase III. (C)  | 66   |
| SWOG 7906          | Maybee, D. A. Multidrug Adjuvant Chemotherapy in Non-metastatic Osteosarcoma Comparison of COMFADRI-I with COMFADRI-V (Phase III). (T) | 67   |
| SWOG 7919          | Maybee, D. A. Evaluation of m-AMSA in Children with Acute Leukemia and Non-Hodgkin's Lymphoma in Relapse, Phase II. (C)                | 68   |
| SWOG 7994          | Maybee, D. A. Therapy for Extraocular Retinoblastoma with Cyclophosphamide, Vincristine, Adriamycin, and Irradiation. (T)              | 69   |
| SWOG 8000          | Maybee, D. A. The National Wilms' Tumor Study III. (C)   | 70   |
| SWOG(POG) 8016     | Maybee, D. A. PCNU in Recurrent Childhood Medulloblastoma and Ependymoma, Phase II. (C)  | 71   |
| SWOG(POG) 8018     | Maybee, D. A. Evaluation of m-AMSA in Children with Solid Tumors, Phase II. (C)  | 72   |



| Protocol<br>Number |   | Page |
|--------------------|---|------|
| SWOG 8022          | Maybee, D. A. Evaluation of Vindesine Twice Weekly Plus Prednisone and a Cross-over Study of Vindesine-Prednisone vs Vincristine Prednisone in Children with Acute Lymphoblastic Leukemia, Hodgkin's Disease, and Non-Hodgkin's Lymphoma, Phase II-III. (O) | 73   |
| SWOG 8079          | Maybee, D. A. A Study of the Association of HLA Antigen Phenotype Susceptibility to Malignant Diseases and Subsequent Survival Duration. (O)  | 74   |
| SWOG 8095          | Maybee, D. A. Multimodal Therapy of Metastatic Ewing's Sarcoma with Chemotherapy, plus Irradiation and Surgery (If Feasible), Intergroup, Phase III. (O)  | 75   |

#### DEPARTMENT OF PSYCHIATRY

|       |  |    |
|-------|--|----|
| 20/81 | Chemtob, C. Interaction of Depressed Mood and Cognition as a Function of Age. (O)                                      | 76 |
| 4/81  | Schilt, S. N. The Military Child Psychiatric Population: A Study of Demographics, Referral Patterns and Diagnoses. (C) | 77 |
| 23/81 | Weiss, D. S. Adolescent Obesity: A Behavioral Treatment Program Emphasizing Exercise. (O)                              | 78 |

#### DEPARTMENT OF RADIOLOGY

|       |  |    |
|-------|--|----|
| 14/76 | Chacko, A. K. Clinical Evaluation of Cisternography Utilizing Indium-111 DTPA. (O)                     | 79 |
| 31/76 | Chacko, A. K. Clinical Evaluation of Fluorescent Scanning of the Thyroid with Americium-241. (O)       | 80 |
| 19/80 | Chacko, A. K. Study of Internal Mammary Lymph Nodes in Patients with Inner Quadrant Breast Cancer. (O) | 81 |
| 20/80 | Chacko, A. K. In Vivo Evaluation of Hepatobiliary System with Tc99m HIDA. (O)                          | 82 |
| 14/81 | Embry, R. L. Study of the Size of Thoracic Aorta with Computerized Tomography. (O)                     | 83 |
| 15/80 | Hagen, R. O. The National Study of Contrast Media Reactions. (T)                                       | 84 |

Protocol  
Number

Page

DEPARTMENT OF SURGERY

|       |  |     |
|-------|--|-----|
| 39/78 | Andersen, C. A. Value of Gallium Scans in Determining Prosthetic Aortic Graft Infections in Canines. (O) | 85  |
| 11/80 | Andersen, C. A. Audiovisual Counseling of Post-operative Patients. (C)                                   | 86  |
| 6/77  | Barcia, P. J. Regrowth of Small Intestinal Mucosal Surface Area. (O) (PR)                                | 87  |
| 25/78 | Dees, S. H. Microvascular Training Protocol. (C)   | 88  |
| 27/80 | Greenfield, G. Q. Patterns of Injury in Motorcycle Accidents. (C) (PR)                                   | 89  |
| 33/80 | Greenfield, G. Q. Evaluation of Outpatients with Low Back Pain. (C) (PR)                                 | 90  |
| 18/81 | Greenfield, G. Q. Effect of Vastus Medialis Obliquus Strength on Chondromalacia Patella. (O)             | 91  |
| 17/78 | Kearney, J. J. Human Implantation of Intraocular Lenses. (O)   | 92  |
| 29/80 | Landry, E. C. Radioisotope Scanning in Diagnosis of Bone and Joint Infections. (T)                       | 93  |
| 31/80 | Landry, E. C. Diagnosis and Treatment of Septic Arthritis. (T)   | 94  |
| 14/80 | Mygatt, G. C. Partial Cystectomy and Augmentation Cystoplasty with the Gallbladder. (T)                  | 95  |
| 3/81  | Rainey, R. K. Compartment Syndromes of the Lower Leg. (C) (P)  | 96  |
| 14/79 | Reinker, K. A. Retropatellar Pain Syndrome. (C) (PR)   | 97  |
| 21/80 | Reinker, K. A. International Study on Lateral Electrical Stimulation for Treatment of Scoliosis. (O)     | 98  |
| 30/80 | Reinker, K. A. Upper Extremity Fractures in Children. (C)  | 100 |
| 36/78 | Rutledge, K. A. T-Cell Antigenicity of Canine Tunica Albuginea. (T)                                      | 101 |

| Protocol<br>Number   |   | Page |
|--|---|------|
| 11/79  | Shetler, P. I. Indocardial Oxygen Supply-Demand Ratio: The Reliability of Clinical Approximations in Prediction of Subendocardial Ischemia. (T) | 102  |
| 22/77  | Van Sant, T. L. Teflon Injection Indications. (T)   | 103  |
| 16/81  | Van Sant, T. E. External (Combination) Rhinoplasty Approach: Access to the Problem Nasal Deformity. (O) (PR)                                    | 104  |
| 13/80  | Wan, S. P. Ureterogastric Urinary Conduits. (O)   | 105  |
| HEALTH SERVICES COMMAND  |   |      |
| 21/78  | Ohashi, D. K. Strain Differences of <u>Staphylococcus aureus</u> based on Lipid Analysis. (O)   | 106  |
| 6/81   | Ohashi, D. K. Studies on the Bacteriology of Acid-Fast Isolates Isolated from Lepromatous Leprosy Patients. (C)                                 | 107  |
|  | Author Index . . . . .  | 109  |
|  | Subject Index . . . . .   | 112  |
| Code: C - Completed; O - Ongoing; T - Terminated; P - Published;<br>PR - Presented; SP - Submitted for Publication |   |      |

## PUBLICATIONS

### DEPARTMENT OF CLINICAL INVESTIGATION

Bryant, G. H., Cucinell, S. A., and Goodwin, B. S.: Measurement of Hepatic Venous Blood Flow in Shock by Thermal Dilution. *Proc West Pharmacol Soc* 24: 23-25, 1981. (C)

Dressendorfer, R. H., Wade, C. E., and Amsterdam, E. A.: Development of Pseudoanemia in Marathon Runners During a 20-Day Road Race. *JAMA* 246(11): 1215-1217, Sep 81. (C)

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Wade, C. E. and Claybaugh, J. R.: Plasma Renin Activity, Vasopressin Concentration, and Urinary Excretory Responses to Exercise in Men. *J Appl Physiol* 49(6): 930-936, Dec 1980. (C)

Wade, C. E., Dressendorfer, R. H., O'Brien, J. C., and Claybaugh, J. R.: Renal Function, Aldosterone, and Vasopressin Excretion Following Repeated Long-Distance Running. *J Appl Physiol* 50(4): 709-712, 1981. (C)

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#### DEPARTMENT OF RADIOLOGY

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Brooks, D. P. and Claybaugh, J. P.: Reduced Mean Arterial Blood Pressure (MABP) and Plasma ADH After Aldosterone Infusion into Dehydrated Conscious Dogs. 31st Annual Fall Meeting, American Physiological Society, Toronto, Canada, Oct 1980. (C)

Bryant, G. H.: Hepatic Venous Blood Flow in Shock by Thermal Dilution Technique. 65th Annual Meeting, Federation of American Societies for Experimental Biology, Atlanta, GA, Apr 1981. (C)

Claybaugh, J. R.: Urinary Metabolites of Aldosterone: Consequences in Radioimmunoassay. 31st Annual Fall Meeting, American Physiological Society, Toronto, Canada, Oct 1980. (C)

Claybaugh, J. R.: Lack of Effect of Acetazolamide on Increase in ADH During First 24 Hrs at 13,600 Ft in Man. 65th Annual Meeting, Federation of American Societies for Experimental Biology, Atlanta, GA, Apr 1981. (C)

Cucinell, S. A.: Chemical Agent Casualties. 38th Parallel Medical Society Meeting, Yongsan Military Reservation, Seoul, Korea, Apr 1981.

Dotson, C. R.: Comparison of Antibiotic Susceptibility Patterns and Bacteriophage Types of Coagulase-Positive Staphylococci Isolated from Newborn Skin. Annual Meeting, American Microbiological Society, Dallas, TX, Feb 1981. (C)

Goodwin, B. S., Jr.: Hepatic Blood Flow Measurement and Blood Sampling Techniques in the Dog. 31st Annual Session, American Association for Laboratory Animal Science, Indianapolis, IN, Oct 1980. (C)

Hadick, C. L.: Intraocular Prosthesis in a Cynomolgous Monkey (*Macaca fascicularis*). 32nd Annual Session, American Association for Laboratory Animal Science, Salt Lake City, Utah, Sep 1981.

O'Brien, J. C., Jr.: Endotoxin Effects on Rat Hepatocytes in Monolayer Culture. 65th Annual Meeting, Federation of American Societies for Experimental Biology, Atlanta, GA, Apr 1981. (C)

### DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

Rudd, E. G.: Intrauterine Irrigation with Cefamandole Nafate Solution at Cesarean Section. Armed Forces OB-GYN Seminar, Orlando, FL, Oct 1980. (C)

#### DEPARTMENT OF PEDIATRICS

Suttle, D. L.: Sports Medicine for the Non-orthopedist. 24th Annual Postgraduate Course, University of Southern California School of Medicine, Aug 1981.

#### DEPARTMENT OF RADIOLOGY

Dean, B. L.: Hirschsprung's Disease - Pitfalls in Diagnosis. 66th Scientific Assembly and Annual Meeting, Radiological Society of North America, Nov 1980.

Leonard, T. and Johnson, J. F.: A Reappraisal of the Persistent Loop of Bowel Sign in Necrotizing Enterocolitis. Radiological Society of North America, Nov 1980. (C)

Newell, J. D.: Computerized Tomographic (CT) Appearance of the Myocardium After Reversible and Irreversible Ischemic Injury. 29th Annual Meeting of the Association of University Radiologists, Apr 1981.

#### DEPARTMENT OF SURGERY

Andersen, C. A.: Evaluation and Treatment of Common Venous Disorders. 38th Parallel Medical Society Meeting, Yongsan Military Reservation, Seoul, Korea, Apr 1981.

Greenfield, G. Q., Jr.: Low Back Pain in Outpatients. Annual Meeting, Society of Military Orthopedic Surgeons, San Antonio, TX, Nov 1980. (C)

Greenfield, G. Q., Jr.: Injuries Related to Rollerskating. Annual Meeting, Society of Military Orthopedic Surgeons, San Antonio, TX, Nov 1980. (C)

Lopez, A. G., Jr.: Case Report of Extranasal Glioma, Intracranial Extension. Annual Meeting, American Academy of Otolaryngology, Head and Neck Surgery, New Orleans, LA, Sep 1981.

Rainey, R. K.: Compartment Syndrome. Annual Seminar, American College of General Practitioners, Ohio Chapter, Dellroy, OH, Aug 1981. (C)

Reddick, E. J.: Preparation of Burn Patients for Aeromedical Evacuation. 38th Parallel Medical Society Meeting, Yongsan Military Reservation, Seoul, Korea, Apr 1981.

Reinker, K. A.: Patterns of Progression in Legg-Perthes Disease. 44th Annual Meeting, Western Orthopedic Association, Kauai, HI, Oct 1980.

Soderdahl, D. W.: Prediction of Fertility After Varicocele Correction by the Zona-Free Hamster Ova Technique. Annual Meeting, American Urological Association, Boston, MA, May 1981. (C)

Weddel, S. J.: Epidural Morphine: Serum Levels and Relief of Post-surgical Pain. ASA Meeting, St. Louis, MO, Oct 1980.



# Detail Summary Sheet

|   |   |                                   |
|---|---|-----------------------------------|
| Date: 8 Jan 82  | Prot No: 138/75                                     | Status: Ongoing                   |
| TITLE: Evaluation of the Cardioresophageal Sphincter Competence by Comparison of Intraluminal Esophageal Sphincter and Gastric Pressure with Thoracic, Hiatal, and Abdominal Pressure |   |                                   |
| Start Date: Sep 74  | Est Comp Date: Sep 83                               |                                   |
| Principal Investigator:<br>Gordon H. Bryant   | Facility:<br>Tripler Army Medical Center            |                                   |
| Dept/Sec:<br>Dept of Clinical Investigation   | Associate Investigators:<br>Tom R. De Meester, M.D. |                                   |
| Key Words:<br>Cardioresophageal sphincter   |   |                                   |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: \$3300.                  | Periodic Review Results: Continue |

**OBJECTIVES:** To obtain comparative gastric and cardioesophageal sphincter pressures during 24-hour pH testing for nocturnal reflux.

**TECHNICAL APPROACH:** For more exact analysis of causative factors of nocturnal reflux and its surgical correction, the direct measurement of gastric and cardioesophageal pressures are to be made simultaneously with pH in 24-hour studies. Reduction of errors due to perfused side-hole catheter pressure measurements in the cardioesophageal sphincter are to be made by utilizing a three-channel, semiconductor, gastro-esophageal probe presently available. This device is to be modified so as to incorporate both a Dent sleeve system in the center section and a pH probe.

**PROGRESS:** The Dent sleeve catheter has not proved to be of advantage in 24-hour pH/esophageal pressure studies. In common with all water perfused side-hold catheter systems for intraesophageal pressure measurement, hydrostatic artifacts due to patient movement introduce uncertainties in recording interpretation. An additional research study for fabrication of a nonperfused catheter system is being instituted so as to eliminate this problem. Nonavailability of a suitable catheter system for these measurements has necessitated the suspension of this project for six months.

DeMeester, TR, Wernly, JA, Bryant, GH, Little, AG, Skinner, DB: Clinical and In Vitro Analysis of Determinants of Gastroesophageal Competence: A Study of the Principles of Antireflux Surgery. Am J Surg 137:39-45, Jan 1979.

Wernly, JA, DeMeester, TR, Bryant, GH, Wang, C-I, Smith, RB and Skinner, DB: Intra-Abdominal Pressure and Manometric Data of the Distal Esophageal Sphincter. Arch Surg 115:534-539, April 1980.

# Detail Summary Sheet

Date: 5 Jan 82 Prot No: 34/79 Status: Ongoing  
 TITLE: Fabrication of a Catheter for the Determination of Liver Blood Flow in Dog and Man

|   |   |
|---|---|
| Start Date: Oct 79                          | Est Comp Date: Sep 82   |
| Principal Investigator:<br>Gordon H. Bryant | Facility:<br>Tripler Army Medical Center  |
| Dept/Sec:<br>Dept of Clinical Investigation | Associate Investigators:<br>COL Samuel A. Cucinell, MC<br>CPT Clayton L. Hadick, VC |
| Key Words:<br>Liver blood flow              |   |
| Accumulative MEDCASE Cost:                  | Est Accumulative OMA Cost: \$2500. Periodic Review Results: Continue                |

**OBJECTIVES:** Development of a thermodilution catheter which will easily and repeatedly give an accurate measure of hepatic vein blood flow in larger animals.

**TECHNICAL APPROACH:** Technique for fabrication of catheters for blood flow measurement is now a routine procedure in the Department of Clinical Investigation at TAMC. Results to date have demonstrated a degree of variability, particularly in the case of small flows, i.e., less than 250 ml/minute. Cause and cure of such deficiencies have therefore been undertaken using an in vitro model of the IVC.

**PROGRESS:** It has been found, using a more carefully designed in vitro model, that factors such as distance between thermistor and injection site, volume and velocity of injectate, and geometry of injection system all have considerable influence on accuracy of flow measurement. Reasons for these phenomena and their elucidation should lead to the desired improvement in accuracy of results in the near future.

Hepatic Blood Flow Measurement and Blood Sampling Techniques in the Dog. Presented at the 31st Annual Session of the American Association for Laboratory Animal Science, Indianapolis, IN, October 1980.

Hepatic Venous Blood Flow in Shock by Thermal Dilution Technique. Presented at the Annual Meeting of the Federation of American Societies for Experimental Biology, Atlanta, GA, April 1981.

Bryant, G. H., Cucinell, S. A., Goodwin, B. S.: Measurement of Hepatic Venous Blood Flow in Shock by Thermal Dilution. Proc West Pharmacol Soc 24:23-25, 1981.

# Detail Summary Sheet

Date: 11 Jan 82 Prot No: 5/81 Status: Ongoing  
 TITLE: Fabrication of a Nonperfused Gastric Motility Catheter

|                                |                             |
|--------------------------------|-----------------------------|
| Start Date:                    | Est Comp Date:              |
| Principal Investigator:        | Facility:                   |
| Gordon H. Bryant               | Tripler Army Medical Center |
| Dept/Sec:                      | Associate Investigators:    |
| Dept of Clinical Investigation |                             |
| Key Words:                     |                             |
| Gastric motility catheter      |                             |

|                      |                  |                          |
|----------------------|------------------|--------------------------|
| Accumulative FEDCASE | Est Accumulative | Periodic                 |
| Cost:                | OMA Cost:\$500.  | Review Results: Continue |

**OBJECTIVE:** To make possible simultaneous distal esophageal sphincter (DES) pressure monitoring with 24-hour pH studies in patients suffering from nocturnal gastric reflux.

**TECHNICAL APPROACH:** Proposal is to utilize pieze electric or thermistor techniques for pressure measurement within the DES and flaccid, water-filled balloons connected to conventional pressure transducers for gastric and esophageal pressure. Small barium titanate strips with central pivot point can be used in conjunction with field effect thermistors for required pressure measurements within the DES. Alternatively, paired spaced thermistors could be used where one unit acts as a heat source and the other a heat unit. Esophageal "squeeze" would vary the separating distance between the two thermistors in this case.

**PROGRESS:** Problems of time limitation, location and availability of suitable materials have stultified progress in this study. It has accordingly been suspended until other work of higher priority is completed.

# Detail Summary Sheet

Date: 14 Jan 82 Prot. No: 38/76 Status: Ongoing  
 TITLE: Further Studies on the Site of Action of Circulating Angiotensin II on Plasma ADH Concentration

|  |   |
|--|---|
| Start Date: Jul 76                                       | Est Comp Date: Sep 83                                 |
| Principal Investigator:<br>John R. Claybaugh, Ph.D.      | Facility:<br>Tripler Army Medical Center              |
| Dept/Sec:<br>Clinical Investigation/Physiology           | Associate Investigators:<br>CPT Clayton L. Radick, VC |
| Key Words:<br>Angiotensin<br>Antidiuretic hormone<br>Dog |   |

|                            |                                    |                                   |
|----------------------------|------------------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative CMA Cost: \$3000. | Periodic Review Results: Continue |
|----------------------------|------------------------------------|-----------------------------------|

OBJECTIVES: To determine if angiotensin II augments osmotic stimulation of ADH mediated via hepatic osmoreceptors.

TECHNICAL APPROACH: Following a report in which hepatic osmoreceptor control of vasopressin release was suggested, we conducted two pilot experiments in an attempt to verify the existence of hepatic osmoreceptor vasopressin control, and secondly, whether these osmoreceptors are also augmented by angiotensin II as are the central osmoreceptors. Chronic indwelling cannulae were surgically placed in the portal vein via the splenic vein. There were two ports allowing upstream infusion of hypertonic solutions, and downstream sampling for osmolality determinations. After the cannula was put in place the dogs were allowed to recover and subsequently used for experiments in the conscious state. Our intention was to conduct at least three experimental runs on each dog, one comparing peripheral venous hypertonic NaCl vs portal venous infusions, another comparing portal venous infusions of hypertonic NaCl with and without simultaneous infusions of angiotensin via a peripheral vein, and third peripheral intravenous infusions of hypertonic NaCl with angiotensin infused either peripherally or via the portal vein.

PROGRESS: Preliminary experiments (2) suggest the existence of hepatic osmoreceptor stimulation of vasopressin and also suggest the possibility of angiotensin II augmentation of the response, but continuation of the experiment has been delayed due to changes in veterinary officers and subsequent delays imposed by manpower shortages.

Detail Summary Sheet

Date: 7 Jan 82      Prot No: 9/77      Status: Ongoing  
 TITLE: The Effect of Sodium balance on the Vasopressin Response to  
 Blood Volume Reduction

|  |  |
|--|--|
| Start Date: Sep 76   | Est Comp Date: Sep 82  |
| Principal Investigator:<br>John P. Claybaugh, Ph.D.                      | Facility:<br>Tripler Army Medical Center   |
| Dept/Sec:<br>Clinical Investigation/Physiology                           | Associate Investigators:<br>CPT Clayton L. Hadick, VC<br>COL Peter J. Barcia, MC |
| Key words:<br>Conscious dogs<br>Blood volume reduction<br>Sodium balance |  |
| Accumulative MEDCARE<br>Cost:  | Est Accumulative<br>OMA Cost: \$1800.      Periodic<br>Review Results: Continue  |

**OBJECTIVES:** To determine whether negative sodium balance increases the vasopressin response to hemorrhage.

**TECHNICAL APPROACH:** Conscious dogs will be hemorrhaged 10% of the estimated blood volume after two weeks of low, normal, or high sodium intakes. Blood samples will be obtained prior to and five minutes after hemorrhage, and one hour after the return of hemorrhaged blood. Six dogs will be prepared with exteriorized carotid loops and with chronic indwelling left atrial cannulae. The dogs will be hemorrhaged at a rate of 0.4 ml/kg/min with blood samples taken at time 0, 10, 20, and 30 minutes, corresponding to 5, 10, and 15 percent hemorrhages. This regimen will be conducted four times on different sodium diets.

**PROGRESS:** To date we have shown that low sodium diet enhances the ADH response to equal volume hemorrhages in the same animal. This occurs despite similar initial values of plasma ADH concentration in the two states. Research by other laboratories has demonstrated a possible change in sensitivity of baroreceptor control of renin release, which may also be influencing the ADH response in a similar fashion. Inhibition of the renin-angiotensin system does not alter the ADH response to hemorrhage significantly; however, we would like to investigate this point a little further before final publication. In addition, the sensitivity of baroreceptor stimulation of ADH release in different sodium balances should be further investigated.

Claybaugh, J.R., Wade, C.E., Goodwin, B.S., and Barcia, P.J. ADH, renin, and cardiovascular responses to slow continuous hemorrhage in conscious dogs on low Na diet with inhibition of converting enzyme. Fed. Proc., 38:967, Abstract 3890, 1979.

# Detail Summary Sheet

Date: 5 Jan 80 Prot No: 11/77 Status: Ongoing  
TITLE: Enzyme Immunoassay of Arginine Vasopressin

|   |  |
|---|--|
| Start Date: Apr 77                                  | Est Comp Date: Apr 85                    |
| Principal Investigator:<br>John R. Claybaugh, Ph.D. | Facility:<br>Tripler Army Medical Center |
| Dept/Sec:<br>Clinical Investigation/Physiology      | Associate Investigators:                 |
| Key Words:<br>Enzyme immunoassay                    |  |

|                            |                                    |                                   |
|----------------------------|------------------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: \$2500. | Periodic Review Results: Continue |
|----------------------------|------------------------------------|-----------------------------------|

**OBJECTIVES:** (a) To develop the technology for and assess the clinical and research efficacy of enzyme immunoassay methods for arginine vasopressin (AV) measurements in biological fluids in comparison with standard radioimmunoassays; and (b) to partially automate enzyme immunoassay techniques to allow for greater productivity in hormone measurement by routine laboratory personnel.

**TECHNICAL APPROACH:** This study consists of two phases: (1) the validation of enzyme immunoassay for AV using hormone coupled B-galactosidase, comparing results to currently available radioimmunoassays; and (2) partial automation of the enzyme immunoassay for B-galactosidase.

**PROGRESS:** Preliminary experiments were initiated in developing the enzyme assay for B-galactosidase. Work stopped, however, due to personnel shortages. All supplies are on hand and work should resume in January 1982.

# Detail Summary Sheet

|   |  |                                   |
|---|--|-----------------------------------|
| Date: 5 Jan 82  | Prot No: 22/79                                   | Status: Ongoing                   |
| TITLE: Comparison of Control of Vasopressin Release from Isolated Hypothalamoneurohypophyseal (HNS) Explants Obtained from Normal and Hypertensive Rats |  |                                   |
| Start Date: Apr 79  | Est Comp Date: Sep 83                            |                                   |
| Principal Investigator:<br>John R. Claybaugh, Ph.D.   | Facility:<br>Tripler Army Medical Center         |                                   |
| Dept/Sec:<br>Clinical Investigation/Physiology  | Associate Investigators:<br>Kuuleialoha Cornette |                                   |
| Key Words:<br>Hypothalamoneurohypophyseal explants<br>Hypertension  |  |                                   |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: \$4,500.              | Periodic Review Results: Continue |

**OBJECTIVES:** Certain rat models of hypertension have elevated pituitary content, plasma concentration, and urinary excretion rates of vasopressin. The mechanism for this increased release of vasopressin is not clear and may be due to an alteration in the sensitivity of the hypothalamus to various known stimuli. By removing the hypothalamus with the stalk connection to the neurohypophysis still intact, we can eliminate many uncontrollable inputs to vasopressin release and test the sensitivity to acetylcholine, angiotensin, and osmotic stimuli, and possibly others, in order to test the hypothesis.

**TECHNICAL APPROACH:** Five-week-old, male, spontaneously hypertensive rats will be selected from the colony at the Department of Clinical Investigation, Tripler Army Medical Center, Okamoto-Aoki strain. Age-matched normotensive male control rats will be of the WKY strain. The rats will be surgically prepared with indwelling carotid arterial cannulae and placed individually into metabolism cages. Two days after surgery, daily collections of urine will be started for analysis of flow rate, urine concentrations of Na<sup>+</sup>, K<sup>+</sup> and antidiuretic hormone (ADH), and urine osmolality. Daily measurements of systolic and diastolic blood pressure will be made via the carotid arterial cannulae. After 5 days of measurements and urine collections, the rats will be sacrificed by guillotine and trunk blood collected for analysis of plasma osmolality, Na<sup>+</sup>, K<sup>+</sup> and vasopressin concentration, and plasma renin activity. The HNS will be dissected and prepared for incubation. Osmolality will be determined by vapor pressure method, Na<sup>+</sup> and K<sup>+</sup> by flame photometry. Vasopressin will be assayed by radioimmunoassay and plasma renin activity by the New England Nuclear radioimmunoassay kit. All methods are ongoing in our laboratory.

Comparison of Control of Vasopressin Release from Isolated Hypothalamo-neurohypophyseal (HNS) Explants Obtained from Normal and Hypertensive Rats

PROGRESS: The surgical skills necessary for successful dissection of the HNS preparation and the procedures involved in organ culture have been routinely performed during the first 1½ years. We were able to demonstrate an osmotic stimulation of vasopressin from the HNS preparation in a 1-hour exposure period. Control experiments indicated a steady vasopressin production could be achieved during the necessary 5-hour block of time on the fourth day of organ culture. Changing the osmolality of the incubation medium from 290 to 315 mOsm/kg results in a significant increase in vasopressin release. Angiotensin at  $10^{-5}$  M concentration also stimulated vasopressin release in this preparation. Having established these "standard" responses, we had confidence that the preparation was responding to normal physiological stimuli. Unfortunately, during the past year, inexplicably, we have been unsuccessful at reproducing these expected and necessary responses. Because the primary investigator on this project is a graduate student, it was felt that one year investment was all that could be afforded at this time and that a reassignment to a different thesis project was essential to her progress. Hopefully, this project will resume within one year.



# Detail Summary Sheet

Date: 14 Jan 82      Prot No: 25/80      Status: Ongoing  
 TITLE: Urinary Metabolites of Vasopressin: Consequences in Radio-immunoassay

|   |                                   |   |
|---|-----------------------------------|---|
| Start Date: Aug 80                                  |                                   | Est Comp Date: Sep 82   |
| Principal Investigator:<br>John R. Claybaugh, Ph.D. |                                   | Facility:<br>Tripler Army Medical Center                        |
| Dept/Sec:<br>Clinical Investigation/Physiology      |                                   | Associate Investigators:<br>Aileen Sato<br>Kuuleialoha Cornette |
| Key Words:<br>Vasopressin                           |                                   |   |
| Accumulative MEDCASE Cost:                          | Est Accumulative OMA Cost: \$200. | Periodic Review Results: Continue                               |

OBJECTIVES: To determine if a biologically inactive but immunologically detectable metabolite constitutes a significant amount of the vasopressin molecule excreted in the urine.

TECHNICAL APPROACH: Vasopressin has been shown to be metabolized in the renal nephron of some animals. Also, the values reported for the amount of vasopressin excreted in normal man varies greatly from one laboratory to the other. We have addressed the question as to whether the former results in the latter. Therefore, we have analyzed identical urine specimens from humans, dogs, rats, and pigs with two antisera which we have characterized as being specific to the "tail" or "ring" portion of the vasopressin molecule. If an immunological difference is determined, we will proceed in order to find out if a chemical difference is detectable. Thus, urine will be fractionated by various methods, including sephadex, electrophoresis, high pressure liquid chromatography (HPLC), ion exchange, ultrafiltration, and others. If two chemical identities can be shown that have immunological activity with one antibody but not the other, our results would clarify the need to use a specific type of vasopressin. Our hypothesis is that this is the case, and that a "ring" directed antibody detects more of the filtered vasopressin than a "tail" directed antibody and is therefore essential for the most accurate assessment of urinary vasopressin in excretion.

PROGRESS: Human, pig, rat, and dog urine contain immunologically detectable vasopressin that can be measured by both "tail" and "ring" directed antibodies, although in all species except the dog the amount measured by the "ring" directed antisera is about twofold greater than that detected by the "tail" directed antibodies. Although sephadex,

## Urinary Metabolites of Vasopressin: Consequences in Radioimmunoassay

ion exchange, ultrafiltration, and proper electrophoresis have produced fractions of vasopressin that still yield immunologically different amounts of vasopressin, we have obtained only suggestive data that there are indeed two different chemical entities (possibly more) by electrophoresis. We have conducted a recent series of experiments on HPLC in which the "ring" directed antisera detects two peaks of activity, corresponding to arginine vasopressin. The "tail" directed antisera detects only the arginine vasopressin. The peak that we propose is a metabolite of vasopressin that has not been identified as yet, although pressinoic acid and deso-Gly (NH<sub>2</sub>) arginine vasopressin have been ruled out, leaving des-Gly (NH<sub>2</sub>)<sup>1</sup>, des-Arg<sup>8</sup>, arginine vasopressin as the probable metabolite. Proof will require the purchase of this synthetic analog and subsequent comparisons on HPLC.

# Detail Summary Sheet

Date: 5 Jan 82      Prot No: 15/81      Status: Completed  
 TITLE: The Role of Dopamine in Angiotensin II Stimulated Antidiuretic  
 Hormone Release

|   |  |
|---|--|
| Start Date: Mar 81                                  | Est Comp Date:                                     |
| Principal Investigator:<br>John R. Claybaugh, Ph.D. | Facility:<br>Tripler Army Medical Center           |
| Dept/Sec:<br>Clinical Investigation/Physiology      | Associate Investigators:<br>David P. Brooks, Ph.D. |
| Key Words:<br>antidiuretic hormone                  |  |

|                               |                                       |                             |
|-------------------------------|---------------------------------------|-----------------------------|
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: \$2500. | Periodic<br>Review Results: |
|-------------------------------|---------------------------------------|-----------------------------|

**OBJECTIVES:** To determine whether dopamine is a neurotransmitter mediating angiotensin II stimulated ADH release.

**TECHNICAL APPROACH:** Angiotensin II was infused intravenously into conscious dehydrated dogs (n=6) at a rate of 10 ng/kg/min once by itself and once with a concurrent intravenous infusion of haloperidol (ng/kg/min), a dopamine antagonist. Plasma vasopressin, renin activity, and arterial blood pressure responses were compared between the two situations. Appropriate vehicle controls were also run on the same dogs.

**PROGRESS:** Angiotensin alone caused a tw -fold increase in plasma vasopressin concentration ( $P<0.05$ ), a 25 mmHg increase in mean arterial blood pressure ( $P<0.01$ ), and a 70% decrease in plasma renin activity ( $P<0.01$ ). When haloperidol was simultaneously infused with angiotensin, plasma vasopressin concentration decreased about 20% (N.S.), while the changes in mean arterial blood pressure, +25 mmHg ( $P<0.01$ ), and plasma renin activity, decrease of 65% ( $P<0.01$ ), were similar to those observed with only angiotensin infused. The results suggest that a dopaminergic mechanism may be involved in the Angiotensin II-induced vasopressin release, but not its pressor actions or the negative feedback effects on renin release.

Brooks DP, Claybaugh JR: The Role of Dopamine in the Angiotensin II-Induced Vasopressin Release in the Conscious Dehydrated Dog. J Endocrinol (submitted).

Claybaugh JR and Brooks DP: The Role of Dopamine in the Angiotensin II-Induced Vasopressin Release in the Conscious Dehydrated Dog. Fed Proc (in press).

# Detail Summary Sheet

Date: 5 Jan 82 Prot No: 21/81 Status: Terminated  
 TITLE: Postpartum Psychological Reactions to Childbirth Preparation and Experiences

|                                    |                             |
|------------------------------------|-----------------------------|
| Start Date:                        | Est Comp Date:              |
| Principal Investigator:            | Facility:                   |
| CPT Wayne R. Coussens, MSC         | Tripler Army Medical Center |
| Dept/Sec:                          | Associate Investigators:    |
| Dept of Clinical Investigation     | MAJ Clayton Shaw, MC        |
| Key Words:                         |                             |
| Postpartum psychological reactions |                             |

|                            |                                   |                                    |
|----------------------------|-----------------------------------|------------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: \$300. | Periodic Review Results: Terminate |
|----------------------------|-----------------------------------|------------------------------------|

OBJECTIVE: To assess the psychological effects of childbirth preparation on mothers who "lose control" during labor and those who have cesarean births.

TECHNICAL APPROACH: Two hundred nulliparous expectant mothers will complete questionnaires at 32 weeks, 34 weeks, confirmed labor, 24 hours postpartum, and 6 weeks postpartum. Questionnaires will assess changes in relevant psychological and demographic characteristics. Mother, physician, and nurse ratings will be used to classify mothers on level of emotional control during labor and delivery. Classifications will also be made on reported levels of preparation for childbirth (psychoprophylaxis). Post hoc comparisons will be made between classifications across repeated measures to determine changes in relevant variables in relation to level of preparation for and level of emotional control in childbirth.

PROGRESS: The project is terminated due to the inability of the Department of Nursing to support it. The protocol will be revised and resubmitted.

# Detail Summary Sheet

Date: 6 Jan 82 Prot No: 6/76 Status: Terminated  
 TITLE: Clinical Significance of Antidiuretic Hormone Levels in Disorders  
 of Fluid and Electrolyte Metabolism

|                            |                             |
|----------------------------|-----------------------------|
| Start Date: Jun 80         | Est Comp Date:              |
| Principal Investigator:    | Facility:                   |
| COL Samuel A. Cucinell, MC | Tripler Army Medical Center |
| Dept/Sec:                  | Associate Investigators:    |
| Clinical Investigation     | John R. Claybaugh, Ph.D.    |
| Key Words:                 |                             |
| Antidiuretic hormone       |                             |

|                            |                                    |                                    |
|----------------------------|------------------------------------|------------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: \$4000. | Periodic Review Results: Terminate |
|----------------------------|------------------------------------|------------------------------------|

OBJECTIVES: As a continuing part of our investigation into the influence of the antidiuretic hormone (ADH) in human metabolism, we wished to determine what influence this hormone has in a variety of clinical states.

TECHNICAL APPROACH: This study was designed to be a survey of occasional ADH levels in various clinical situations. Samples have been obtained in cirrhosis of the liver, nephrotic syndrome, renal failure, hypertension, congestive heart failure, pneumonia (particularly Legionnaires disease), and cardiac resuscitation.

PROGRESS: This study is being terminated because it has yielded the maximal amount of information possible for the nature of the study. The clinical states have shown that ADH is elevated to varying degrees in Legionnaires disease, cirrhosis of the liver, congestive heart failure, and nephrotic syndrome. ADH has proven to be low in cardiac resuscitation and gastrointestinal bleeding. The study suffers from lack of specific definition of the syndromes and incomplete design and accumulation of data. Each syndrome must be followed carefully in the clinical context for any clear-cut data to evolve. It is not surprising that ADH is elevated in pneumonia, cirrhosis, and heart failure. This data contributes little either to patient care or theory of practice. A systematic correlation of ADH with severity of these diseases may yield valuable information. The low ADH syndrome is more interesting. Patients who survive cardiac arrest, but with severe neurological deficit, seem to have depressed ADH, and one patient had diabetes insipidus. This has previously been reported, but not with ADH levels. All of these patients died eventually. The low ADH in gastrointestinal bleeding is artifact in that the samples were taken during treatment and suggest that ADH is an inconsistent hormone during this situation. Although this study is terminated because of poor design and incomplete data, it does provide suggestions for more valuable approaches.

# Detail Summary Sheet

Date: 14 Jan 82 Prot No: 2679 Status: Ongoing  
 TITLE: Determination of Liver Blood Flow and Improved Technique for  
 Sampling Hepatic Vein Blood

|   |  |
|---|--|
| Start Date: Jul 79                                    | 1st Comp Date: Sep 82                        |
| Principal Investigator:<br>COL Samuel A. Lucinell, MC | Facility:<br>Tripler Army Medical Center     |
| Dept/Sec:<br>Clinical Investigation                   | Associate Investigators:<br>Gordon B. Bryant |
| Key Words:<br>Liver blood flow                        |  |

|                               |                                       |                                      |
|-------------------------------|---------------------------------------|--------------------------------------|
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: \$2500. | Periodic<br>Review Results. Continue |
|-------------------------------|---------------------------------------|--------------------------------------|

**OBJECTIVE:** To determine liver blood flow and to develop an improved technique for sampling hepatic vein blood.

**TECHNICAL APPROACH:** Methods now available for the determination of hepatic blood flow are either invasive or based on indirect chemical clearances. None of these methods is satisfactory for the accurate noninvasive quantitation of liver blood flow necessary for our continued studies into the lactic acid metabolism by the liver. It should be possible to place a thermistor catheter in the vena cava (VC) at the level of the renal and hepatic veins. Blood flow at these points might be determined by thermodilution. Hepatic vein blood flow could be estimated by subtraction of the blood flow in the vena cava at the level of the renal veins from the vena cava blood flow at the level of the diaphragm. This should be liver blood flow. It should be possible to sample pure hepatic vein blood by inflation of a balloon-equipped, double lumen catheter at the level just above the renal veins. This should cut off blood coming from the renal veins and below from entering the vena cava in the area of the hepatic veins. Blood samples from just above the balloon should be hepatic vein blood.

**PROGRESS:** The liver blood flow system has been reported in a preliminary manner in the Proceedings of the Western Pharmacology Society, 24:23-25, 1981. Additional work is being done comparing blood flow in the portal vein to hepatic vein before final publication. Details of engineering design are to be considered. The hepatic blood sampling device has been finalized and described in Proceedings of the Society for Experimental Biology and Medicine, 168:222-227, 1981.

# Detail Summary Sheet

Date: 6 Jan 82 Prot No: 26/79 Status: Terminated  
 TITLE: Mechanism of Action and Antidote for Tricyclic Antidepressants

|   |  |
|---|--|
| Start Date: Jul 79                                    | Est Comp Date: Sep 82  |
| Principal Investigator:<br>COL Samuel A. Lucinell, MC | Facility:<br>Tripler Army Medical Center                                   |
| Dept/Sec:<br>Clinical Investigation                   | Associate Investigators:<br>LTC Harry L. Thomas, MC<br>Bert Lum, Ph.D.     |
| Key Words:<br>Tricyclic antidepressants               |  |
| Accumulative MEDCASE<br>Cost:                         | Est Accumulative<br>OMA Cost: \$200. Periodic<br>Review Results: Terminate |

OBJECTIVES: To try to define more precisely the cardiovascular toxicity of the tricyclic antidepressants and to suggest the most rational antidote for the cardiotoxicity.

TECHNICAL APPROACH: An animal model of cardiotoxicity of the TCA will be developed in the dog and rabbit. The animal will be sedated with the TCA itself. Recordings of the EKG, electrolytes, and blood gases will be made. Doses of TCA will be given to produce EKG toxicity. In some animals it will be necessary to allow the complete cardiotoxicity to evolve in order to determine the pattern of conduction abnormality leading to cardiac arrest. Once this pattern is defined, antidotes and mechanisms of altering the EKG pattern will be made. It is anticipated that a drug so rich in autonomic actions would have a cardiac effect which would operate through the autonomic nervous system. Blockade of this system at known points, i.e., ganglionic blockade, cholinergic receptor blockade, adrenergic transmitter and receptors blockade, as well as autonomic stimulants at the same levels, should alter the pharmacological pattern of TCA. If the TCA proves resistant to these manipulations, a direct quinidine-like action may exist and direct pacing may be of value.

PROGRESS: The project is terminated. The University of Hawaii group is pursuing the study alone.

# Detail Summary Sheet

Date: 5 Jan 82 Prot No: 8/81 Status: Completed  
 TITLE: Fansidar Prophylaxis in New Guinea

|   |  |
|---|--|
| Start Date: Sep 80                                    | Est Comp Date:                           |
| Principal Investigator:<br>COL Samuel A. Cucinell, MC | Facility:<br>Tripler Army Medical Center |
| Dept/Sec:<br>Dept of Clinical Investigation           | Associate Investigators:                 |
| Key Words:<br>Malaria                                 |  |

|                            |                                   |                          |
|----------------------------|-----------------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: \$300. | Periodic Review Results: |
|----------------------------|-----------------------------------|--------------------------|

**OBJECTIVE:** This is a preliminary study to design the most reasonable prophylaxis for malaria in individuals who will be exposed to both high altitude and malaria sequentially or simultaneously.

**TECHNICAL APPROACH:** A group of seven active Army personnel explored the mountainous areas of New Guinea for location of downed aircraft sites at altitudes up to 9000 feet. With regard specifically to malaria they were given Fansidar to be taken before leaving for New Guinea and at monthly intervals thereafter. The following laboratory tests were done before and after their tour in New Guinea: CBC, urinalysis, SMA-20, glucose-6 phosphate dehydrogenase determination, and sickle cell preparation. Malaria smears were done upon return.

**PROGRESS:** The 9-week mission was completed with one member removed to Hawaii because of leg trauma. One man who was allergic to sulfa drugs took CP tablets, one per week. There were no illnesses or fever. It was noted that the local inhabitants took CP tablets rather than Fansidar when they entered malaria regions of New Guinea. Although malaria was present in the area, the members of this team had no direct contact with known cases. The preliminary studies done at Tripler Army Medical Center showed all men had normal renal, hepatic, and hematologic function. All of the laboratory tests were repeated upon return to Hawaii and were found to be normal. Thick smears were done on all members and no malaria was seen. Under the conditions used, Fansidar caused no toxicity or complication in men operating at high altitude for short periods of time. No toxicity was noted.



# Detail Summary Sheet

Date: 6 Jan 82 Prot No: 17/79 Status: Terminated  
 TITLE: Biodetermination of Scombroid Toxin

|  |                             |
|--|-----------------------------|
| Start Date: 1 Jul 79                   | 1st Crp Date:               |
| Principal Investigator:                | Facility:                   |
| CPT Clayton L. Hadick, VC              | Tripler Army Medical Center |
| Dept/Sec:                              | Associate Investigators:    |
| Clinical Investigation/Veterinary (vc) |                             |
| Key Words:                             |                             |
| Scombroid toxin                        |                             |

|                       |                  |                           |
|-----------------------|------------------|---------------------------|
| Accumulative MLD/CASE | Est Accumulative | Periodic                  |
| Cost:                 | OMA Cost: \$500. | Review Results: Terminate |

OBJECTIVES: To design a bioassay to determine presence of unknown toxin in fish responsible for clinical scombroid poisoning. This will be attempted by correlating known patients, fish, specimens, and suspected outbreaks.

TECHNICAL APPROACH: A bioassay will be developed which may utilize radioactive tagged human serum used in rabbits. Intradermal injections of the fish extract gives a "wheal and flare" which can be measured by amount of radioactivity in the area. This is most tentative. Other possibilities would include oral ingestion in laboratory animals with modified guts to watch for histamine-type response. Whatever test we develop will be correlated with retrospective analysis of the 30 to 50 cases seen in Hawaii in the last two years. The fish specimens come from these suspected cases. In addition, the investigator has made arrangements to be notified as soon as possible about any new suspected cases.

PROGRESS: It has been found that it is not practical to do this study at TAMC and it is therefore terminated.

# Detail Summary Sheet

Date: 23 Dec 81 Prot No: 17/81 Status: Completed  
 TITLE: Intraocular Prosthesis in a Cynomolgous Monkey (*Macaca fascicularis*)

|                                       |                             |
|---------------------------------------|-----------------------------|
| Start Date: Mar 81                    | Est Comp Date:              |
| Principal Investigator:               | Facility:                   |
| CPT Clayton L. Hadick, VC             | Tripler Army Medical Center |
| Dept/Sec:                             | Associate Investigators:    |
| Clinical Investigation/Veterinary Svc |                             |
| Key Words:                            |                             |
| Cynomolgous monkey                    |                             |
| Intraocular prosthesis                |                             |

|                      |                   |                 |
|----------------------|-------------------|-----------------|
| Accumulative MEDCARE | Est Accumulative  | Periodic        |
| Cost:                | UNA Cost: \$1000. | Review Results: |

OBJECTIVE: To determine long-term toxicity and acceptance of an intraocular prosthesis in a primate. Also, to determine aesthetic presentability of such a device.

TECHNICAL APPROACH: To publish data on intraocular prosthesis in primates. A human prosthesis was used to determine the efficacy of this procedure in primates and the long-term toxic effects.

PROGRESS: This project was presented at the annual meeting of the American Association of Laboratory Animal Science, Salt Lake City, Utah, in September 1981. A manuscript is in preparation.

# Detail Summary Sheet

Date: 4 Jan 81 Prot No: 46/78 Status: Completed  
 TITLE: Lactic Metabolism in Isolated Liver Cells with regard to Anoxia,  
 Alkalosis, and Temperature

|   |  |
|---|--|
| Start Date: Nov 78                                  | Est. Comp. Date:                                       |
| Principal Investigator:<br>CPT John C. O'Brien, MSC | Facility:<br>Tripler Army Medical Center               |
| Dept/Sec:<br>Clinical Investigation/Biochemistry    | Associate Investigators:<br>COL Samuel A. Cucinell, MC |
| Key Words:<br>Lactic metabolism                     |  |

|                            |                                       |                             |
|----------------------------|---------------------------------------|-----------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative<br>OMA Cost: \$8000. | Periodic<br>Review Results: |
|----------------------------|---------------------------------------|-----------------------------|

OBJECTIVES: To study lactate metabolism in primary cultures of rat hepatocytes.

TECHNICAL APPROACH: Earlier in the study we characterized lactate metabolism in monolayer cultures of rat hepatocyte cells and determined that neither anoxia nor pH would account for the apparent production of lactate seen by liver during hemorrhagic shock. We wished to further study liver carbohydrate metabolism under conditions of endotoxic shock.

PROGRESS: While anoxia and acidosis inhibit lactate consumption in hepatocyte cultures, endotoxin was found to have no direct effect when added to the medium. Cells prepared from endotoxic shocked rats, however, were unable to metabolize lactate. It appears the effect of endotoxin on liver carbohydrate metabolism cannot be explained by a direct effect on the hepatocyte cell. These results are being prepared for publication.

"Effect of pH, PO<sub>2</sub> and PCO<sub>2</sub> on Lactate Consumption by Hepatocytes," presented at the 64th Annual Meeting of the Federation of American Societies for Experimental Biology, Anaheim, California, April 1980.

O'Brien, J. C. and Cucinell, S. A.: Effects of Anoxia, Acidosis, and Endotoxin on Glucose, Lactate, and Indocyanine Green Metabolism in Primary Hepatocyte Culture. Proc West Pharmacol Soc 24:123-125, 1981.

O'Brien, J. C. Jr. and Cucinell, S. A.: Lactate Consumption by Hepatocytes in Monolayer Culture. Proc Soc Exp Biol Med 166:413-417, Mar 1981.

"Endotoxin Effects of Rat Hepatocytes in Monolayer Culture," presented at the 65th Annual Meeting of the Federation of American Societies for Experimental Biology, Anaheim, CA, April 1981.

Detail Summary Sheet

Date: 12 Jan 82 Prot No: 29/79 Status: Ongoing  
 TITLE: The Behavioral Effects of Antihypertensive Therapy in the Elderly

|                          |                             |
|--------------------------|-----------------------------|
| Start Date: Aug 80       | Est Comp Date: Jun 82       |
| Principal Investigator:  | Facility:                   |
| LIC John L. Aoki, MC     | Tripler Army Medical Center |
| Dept/Sec:                | Associate Investigators:    |
| Dept of Family Practice  | Marvelu Peterson, R.N.      |
| Key Words:               | COL Samuel A. Cucinelli, MC |
| Antihypertensive therapy |                             |

|                      |                  |                          |
|----------------------|------------------|--------------------------|
| Accumulative MEDCASE | Est Accumulative | Periodic                 |
| Cost:                | OMA Cost: \$750. | Review Results: Continue |

OBJECTIVES: To determine if treatment with antihypertensive medications in elderly hypertensive subjects produces changes in measurable areas of behavioral performance. If behavioral changes occur, does the direction of change reflect improved or impaired function?

TECHNICAL APPROACH: Elderly hypertensive patients will be placed on an alternating regimen of active antihypertensive medications and placebos. Data on blood pressure response to the two different treatments and behavioral tests and outcomes will be collected at the end of each four-week period. The two groups of subjects will be matched as closely as possible and differ only in the order in which the treatment, active medications, or placebos are given. The behavioral outcomes are conceptualized as being directly influenced by the independent variable of medication status and indirectly by the intermediate variable, blood pressure. Blood pressure is directly influenced by the independent variable, medication status.

PROGRESS: The study protocol has now been completed on a total of 19 patients, utilizing two study groups over an 8-week study interval. Three patients were withdrawn from the study. One was diagnosed as having a colon carcinoma and subsequently underwent a partial colectomy. The second patient's blood pressure reached the study limit and she was placed on her active antihypertensive medication with no complications as her blood pressure stabilized. The third patient had chest pain suspicious for angina. Subsequent follow-up and evaluation proved to be normal and she resumed her vigorous exercise program. The investigators are planning two more groups of 16 patients each, which will bring the total number to over 50 patients. This will allow valid statistical analyses to be performed.

## The Behavioral Effects of Antihypertensive Therapy in the Elderly

The primary problems encountered in the study have been lack of clerical and administrative assistance. Pharmacy and clinical laboratory support have thus far been excellent.

Because one of the investigators will be leaving the Army, CPL Charles L. Henley has volunteered to assume responsibility for the medical care of the study patients. A Family Practice third-year resident has also expressed interest in the study and he has been given time to participate in this research. As more interest in research is being generated within the Department of Family Practice, it is hoped that this will be an ongoing departmental undertaking.

Detail Summary Sheet

Date: 30 Oct 81 Prot No: 4/80 Status: Ongoing  
TITLE: Evaluation of PUVA in the Treatment of Resistant Psoriasis

|   |   |
|---|---|
| Start Date: Aug 80                                  | Est Comp Date: Indefinite                       |
| Principal Investigator:<br>COL Harold L. Albert, MC | Facility:<br>Tripler Army Medical Center        |
| Dept/Sec:<br>Dept of Medicine/Dermatology           | Associate Investigators:<br>LTC Philip Chan, MC |
| Key Words:<br>Psoriasis                             | MAJ Richard Gentry, MC                          |

Accumulative MEDCASH Est Accumulative Periodic  
Cost: OMA Cost: \$500. Review Results: Continue

OBJECTIVE: To determine the potential benefits of PUVA in the treatment of psoriasis resistive to other forms of therapy.

TECHNICAL APPROACH: In August 1980 a clinical investigation of the efficacy of psoralen plus long wave ultra-violet light in the treatment of severe psoriasis was approved. The project was included under INC #12,941 with approval of COL Charles Lewis, EAMC, principal investigator. The protocol is essentially the same as that being used by several major study groups.

PROGRESS: Two patients have been enrolled in the study. Both have had essentially complete clearing of psoriasis and now are on maintenance therapy with PUVA.

# Detail Summary Sheet

Date: 23 Dec 81 Prot No: 1/81 Status: Terminated  
 TITLE: A Prospective Trial of Propranolol in Patients with Diffuse  
 Toxic Goiter for Subgroup Determination

|                             |                                    |
|-----------------------------|------------------------------------|
| Start Date:                 | Est Comp Date:                     |
| Principal Investigator:     | Facility:                          |
| CPT William T. Highfill, MC | Tripler Army Medical Center        |
| Dept/Sec:                   | Associate Investigators:           |
| Dept of Medicine/Endocrine  |                                    |
| Key Words:                  |                                    |
| Goiter, toxic               |                                    |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: \$300.  |
|                             | Periodic Review Results: Terminate |

OBJECTIVES: To determine if there is a predictable subgroup of patients with diffuse toxic goiter whose disease undergoes remission during and following treatment with propranolol.

TECHNICAL APPROACH: Patients with diffuse toxic goiter will be given propranolol, 80 mg orally 3 times a day for 6 months, after which the medication will be discontinued and the patient followed for 3 months or until clinical symptoms and/or laboratory evidence of thyrotoxicosis recur. At the end of the trial, the data of all patients who remain clinically and chemically euthyroid will be compared to that of the rest of the trial group to determine if there are any characteristics or responses to propranolol which might distinguish this subgroup.

PROGRESS: This project has been terminated as it has not been approved by OTSG.

# Detail Summary Sheet

Date: 23 Dec 81 Prot No: 2/81 Status: Completed  
 TITLE: Coronary Arteriography in the Army

|  |   |
|--|---|
| Start Date: Dec 80                                     | Est Comp Date: Dec 81                               |
| Principal Investigator:<br>CPT William T. Highfill, MC | Facility:<br>Tripler Army Medical Center            |
| Dept/Sec:<br>Dept of Medicine/Cardiology               | Associate Investigators:<br>LTC Harry H. Thomas, MC |
| Key Words:<br>Coronary arteriography                   |   |

|                            |                                   |                          |
|----------------------------|-----------------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative ONA Cost: \$300. | Periodic Review Results: |
|----------------------------|-----------------------------------|--------------------------|

OBJECTIVE: To explore the use of coronary arteriography in Army medicine, to evaluate certain technical aspects of the procedure, and to better define the nature of coronary artery disease in the active duty population.

TECHNICAL APPROACH: This is a collaborative Army study coordinated by MAJ John H. Harris, MC, of Madigan Army Medical Center, consisting of a one-year prospective chart review of the catheterization data at each center.

PROGRESS: The study has been completed with approximately 200-250 patients in the study. Data is currently being analyzed.



# Detail Summary Sheet

Date: 6 Jan 82 Prot No: 19/81 Status: Ongoing  
 TITLE: Dexamethasone Antiemetic Study for Chemotherapy Patients

|                           |                             |
|---------------------------|-----------------------------|
| Start Date:               | 1st Comp Date:              |
| Principal Investigator:   | Facility:                   |
| LTC Charles F. Miller, MC | Tripler Army Medical Center |
| Dept/Sec:                 | Associate Investigators:    |
| Dept of Medicine          |                             |
| Key Words:                |                             |

|                      |                  |                 |               |
|----------------------|------------------|-----------------|---------------|
| Accumulative MEDCASE | Est Accumulative | Periodic        | Awaiting      |
| Cost:                | OMA Cost: \$300. | Review Results: | OTSG approval |

OBJECTIVES: To determine the effectiveness of Dexamethasone in preventing or alleviating nausea and vomiting in cancer patients receiving chemotherapeutic agents.

TECHNICAL APPROACH: A double-blind study of each participating patient will be performed. Patients will be obtained from adult oncology clinic. No minors will be included in the study. Each patient will receive an envelope from the pharmacy containing three tablets of either placebo or Decadron, 4 mg. The tablets are to be taken at lunch the day before therapy, at bedtime the day before therapy, and the morning of therapy. All additional standard antiemetics will be continued since neither the patient nor the investigator has any way of knowing if the active Decadron was taken. The patients will be asked to score their nausea and other symptoms and the vomiting will be objectively followed by the clinic staff.

PROGRESS: Awaiting OTSG approval.

# Detail Summary Sheet

|  |                                   |                                    |
|--|-----------------------------------|------------------------------------|
| Date: 1 Jan 82   | Prot No: 7781                     | Status: Terminated                 |
| Title: Evaluation of Lower Gastrointestinal Bleeding: Colonoscopy Alone vs Colonoscopy as an Adjunct to Barium Enema and Proctoscopy |                                   |                                    |
| Start Date:  | Est Comp Date:                    |                                    |
| Principal Investigator:  | Facility:                         |                                    |
| LTC Robert L. Myers, MC  | Tripler Army Medical Center       |                                    |
| Dept/Sec:  | Associate Investigators:          |                                    |
| Medicine/Gastroenterology  | COL Charles C. Jones, MC          |                                    |
| Key Words:   |                                   |                                    |
| Gastrointestinal bleeding  |                                   |                                    |
| Accumulative MEDCARE Cost:   | Est Accumulative OMA Cost: \$300. | Periodic Review Results: Terminate |

**OBJECTIVE:** This study will compare colonoscopy with a multimodality evaluation of occult and overt rectal bleeding.

**TECHNICAL APPROACH:** All patients presenting to the Gastroenterology Clinic and Proctoscopy Clinic with a complaint of overt or occult rectal bleeding will be eligible for this study. Patients must meet the following criteria: (a) have a history of bright red rectal bleeding or the discovery of occult rectal bleeding in the previous six weeks; (b) be 40 years of age or older; (c) be capable of informed consent; (d) must not have had proctoscopic or barium enema in the preceding six weeks. After inclusion in the study groups, all patients will be interviewed by one of the principal investigators. Demographic and historical data will be collected. A CBC, clotting profile, and hemoccult screen will be collected on each patient. Patients will be randomized. One group will have colonoscopy alone. The other group will have proctoscopic examination, air contrast barium enema, and colonoscopy. All negative colonoscopies will be compared as to patient comfort, diagnostic rates, complications, and time of workup.

**PROGRESS:** This project is terminated due to lack of time on the part of the investigators.

# Detail Summary Sheet

Date: 5 Jan 82 Prot No: 11/81 Status: Completed  
 TITLE: The Influence of pH and Serum Protein Concentration on the Anion Gap

|                            |                             |
|----------------------------|-----------------------------|
| Start Date: Jan 81         | Est Comp Date:              |
| Principal Investigator:    | Facility:                   |
| CPT William D. Paulson, MC | Tripler Army Medical Center |
| Dept/Sec:                  | Associate Investigators:    |
| Dept of Medicine           |                             |
| Key Words:                 |                             |
| Anion gap                  |                             |

|                           |                                    |                          |
|---------------------------|------------------------------------|--------------------------|
| Accumulative MDCASI Cost: | Est Accumulative OMA Cost: \$2000. | Periodic Review Results: |
|---------------------------|------------------------------------|--------------------------|

OBJECTIVES. To determine how the acidity and alkalinity of blood and its protein concentration influence the relationship of the serum chemistries (e. g., Na, K, Cl, HCO<sub>3</sub>) to each other.

TECHNICAL APPROACH: Fourteen dogs were studied for changes in the in vivo ionization of plasma protein during respiratory acidosis and respiratory alkalosis. No effort was made to change the serum albumin concentration.

PROGRESS: The undetermined anion gap was unchanged at the extreme of acidosis and alkalosis suggesting that the ionization of plasma protein does not change ionization with pH. A manuscript is in preparation.

# Detail Summary Sheet

Date: 30 Dec 81 Prot No: 25/80 Status: Terminated  
 TITLE: Pulmonary Function in Patients with Gastroesophageal Reflux

|                             |                             |
|-----------------------------|-----------------------------|
| Start Date:                 | Est Comp Date:              |
| Principal Investigator:     | Facility:                   |
| MAJ Rosemary F. Rodgers, MC | Tripler Army Medical Center |
| Dept/Sec:                   | Associate Investigators:    |
| Dept of Medicine/Pulmonary  | COL Charles C. Jones, MC    |
| Key Words:                  | MAJ Anna E. Chacko, MC      |
| Esophageal reflux           | LTC George E. Underwood, MC |

|                                    |                                   |                                    |
|------------------------------------|-----------------------------------|------------------------------------|
| Accumulative MEDCASE Cost: \$2000. | Est Accumulative OMA Cost: \$300. | Periodic Review Results: Terminate |
|------------------------------------|-----------------------------------|------------------------------------|

**OBJECTIVE:** To determine whether there are significant abnormalities in the pulmonary function studies of nonsmoking patients diagnosed to have gastroesophageal reflux.

**TECHNICAL APPROACH:** Diagnosis of gastroesophageal reflux in nonsmoking adults will be established by (1) clinical history (with particular attention to symptoms of reflux and pulmonary disease) and physical examination, (2) barium esophagram, and (3) gastroesophageal scintiscan. Incidence of pulmonary disease in these individuals will be determined by (1) PA and lateral chest roentgenogram, (2) spirometry with and without bronchodilator (0.5 cc Isuprel in 2 cc NS), (3) gas dilution lung volume studies, (4) DLCOsb, and (5) body plethysmographic determination of FRC, RAW, lung compliance, and pulmonary elastic recoil. At conclusion of the clinical studies, results will be examined to determine the extent of cause and effect relationship between gastroesophageal reflux and pulmonary disability.

**PROGRESS:** This project is terminated due to departure of principal investigator.

# Detail Summary Sheet

Date: 15 Jan 82 Prot No: 2/79 Status: Ongoing  
 TITLE: Glucose Modulation of Insulin Binding

|                            |                             |
|----------------------------|-----------------------------|
| Start Date: Jan 79         | 1st Comp Date: Sep 82       |
| Principal Investigator:    | Facility:                   |
| MAJ Shiao W. Shen, MC      | Tripler Army Medical Center |
| Dept/Sec:                  | Associate Investigators:    |
| Dept of Medicine/Endocrine |                             |
| Key Words:                 |                             |
| Insulin Binding            |                             |

|                      |                   |                          |
|----------------------|-------------------|--------------------------|
| Accumulative MEDCARE | Est Accumulative  | Periodic                 |
| Cost: \$1500.        | UMA Cost: \$1000. | Review Results: Continuc |

OBJECTIVES: To investigate the effect of glucose concentration on insulin binding; to investigate the effect of glucose preincubation on insulin binding; and to study glucose transport under varying insulin and glucose concentrations.

TECHNICAL APPROACH: Epididymal fat pads are removed from male Sprague-Dawley rats. Isolated fat cells are prepared by shaking at 37° C for 60 minutes in Krebs-Ringer bicarbonate buffer containing collagenase (3 mg/ml) and albumin (40 mg/ml) by the method of Rodbell. Isolated fat cells are then suspended in a buffer containing 35 mM Tris, 120 mM NaCl, 1.2 mM Mg SO<sub>4</sub>, 2.5 mM KCl, 1% bovine serum albumin, pH 7.6, and varying concentrations of glucose in a Dubnoff metabolic shaker at 37° C for 45 minutes. At the end of incubation, cells are washed and ready to be used for either <sup>125</sup>I-insulin or glucose transport studies. <sup>125</sup>I-insulin binding is carried out with <sup>125</sup>I-insulin prepared at a specific activity of 100-150 µCi/µg according to the Freycht et al. modification of the method of Hunter and Greenwood. Glucose transport studies are carried out by incubating cells with 2-deoxy-II-<sup>14</sup>C-D-glucose (specific activity 2 mCi/mM) in Krebs-Ringer bicarbonate, pH 7.4, containing bovine serum albumin (10 mg/ml) at 24° C. This assay measures the total uptake of the radio-labeled 2-deoxy-glucose and is based on the principle that while 2-deoxy-glucose is transported and phosphorylated by the same process as D-glucose, it cannot be further metabolized. Calculation of glucose transport is based on the method of Olefskey.

PROGRESS: After many attempts, the cultured fibroblasts from the foreskin obtained during circumcision has proved to be an appropriate system to use. However, since the departure of MAJ O'Brien, the investigation has been temporarily suspended until another Ph.D. biochemist arrives since there is the possibility of overgrowth of virus in the culture medium.

# Detail Library Sheet

Date: 30 Dec 81 Prot No: 3/75 Status: Completed  
 TITLE: Free and Total Insulin Levels in Insulin-Treated Diabetics

|  |  |
|--|--|
| Start Date: Feb 79                               | 1st Comp Date: Sep 81                    |
| Principal Investigator:<br>PAO Shiao W. Shen, MC | Facility:<br>Tripler Army Medical Center |
| Dept/Sec:<br>Dept of Medicine/Endocrine          | Associate Investigator:                  |
| Key Words:<br>Insulin Binding                    |  |

|                             |                                    |                          |
|-----------------------------|------------------------------------|--------------------------|
| Accumulative MEDICAL COSTS: | 1st Accumulative OMA Cost: \$1000. | Periodic Review Results: |
|-----------------------------|------------------------------------|--------------------------|

**OBJECTIVES:** To measure free and total insulin level in insulin treated diabetics, to characterize the insulin-binding antibodies in the patient and to correlate the free insulin levels and the characteristics of the insulin-binding antibodies to control of diabetes.

**TECHNICAL APPROACH:** Patients were classified with regard to their diabetic control on the basis of personal knowledge, examination of the clinical notes, and 24-hr urine glucose. Heparinized blood, 10 ml, was drawn from subjects after an overnight fast and again at 4 pm for plasma glucose, insulin determinations, and characterization of insulin antibodies. Free insulin and total insulin were extracted by a modified method of Nakagawa et al. Radioimmunoassay for free insulin and total insulin were done by dextran-coated charcoal method. Deinsulinization was accomplished by combining one part plasma with 1.25 (V/V) 0.12N HCL and 0.5 parts dextran-coated suspension. The mixture was Vortex-mixed before adding 1.25 parts 0.12 N NaOH and centrifuging twice at 2500 rpm for 30 minutes at 4°C to completely remove the charcoal particles with the adsorbed insulin. The supernatant was also used for binding assay to characterize the insulin antibodies.

**PROGRESS:** It was found that (1) there is no relationship between administered insulin dosage and free insulin levels in diabetic patients, (2) insulin binding to monocytes is not correlated with bound insulin or insulin dosage, but is inversely correlated to free insulin level, and (3) the maximum binding sites of insulin antibody are inversely proportional to the ratio of free/bound insulin.

This study is to be presented at the annual meeting of Military Endocrinologists in June 1982 in conjunction with the annual meeting of the Endocrine Society and American Diabetic Association.

Detail Summary Sheet

Date: 5 Jan 62 Prot No: 13/61 Status: Terminated  
 TITLE: Evaluation of Heparin in Pericardial Effusion

|                             |                             |
|-----------------------------|-----------------------------|
| Start Date:                 | Est Comp Date:              |
| Principal Investigator:     | Facility:                   |
| Col Roger L. Siddoway, MC   | Tripler Army Medical Center |
| Dept/Sec:                   | Associate Investigators:    |
| Dept of Medicine/Cardiology | LTC Harry B. Thomas, MC     |
| Key Words:                  | COL Samuel A. Cucinell, MC  |
| Pericardial effusion        |                             |

|                      |                    |                           |
|----------------------|--------------------|---------------------------|
| Accumulative MELCASE | Est / Accumulative | Periodic                  |
| Cost:                | OWA Cost: \$300.   | Review Results: Terminate |

OBJECTIVES: To determine the indications for continued anticoagulation in pericarditis in myocardial infarction.

METHOD APPROACH: All patients with established myocardial infarction and pericardial friction rubs will be eligible for this study. After having informed consent, the patient will be entered into a randomized double blinded study. The pharmacy will send to the critical care unit appropriate intravenous solution containing heparin or not, but labeled as 'heparin study--contact pharmacy.' The physicians caring for the patient will not be blinded and will control the EKG according to current standards if the patient does not get heparin (or whose heparin is continued). An echocardiogram and a phonocardiogram will be taken daily on all patients in the study (by the investigators who will be blinded). The attending physicians will be advised daily of the fluid content of the pericardial sac. A decision to break the code and terminate the study will be made by a consultant cardiologist noninvestigator. Dressler syndrome is an indication to stop heparin. Anticoagulation with coumadin will be instituted or continued according to current practice and the heparin will be discontinued at the appropriate time in the group continued on anticoagulation. A placebo will be started in nonanticoagulated patients at the appropriate time.

PROGRESS: Because of delay in approval, this protocol has been terminated.

Detail Summary Sheet

Date: 23 Dec 81 Prot No: 19/79 Status: Terminated  
TITLE: Beta Blocker Heart Attack Trial

|                             |                             |
|-----------------------------|-----------------------------|
| Start Date:                 | Est Comp Date:              |
| Principal Investigator:     | Facility:                   |
| LTC Harry M. Thomas, MC     | Tripler Army Medical Center |
| Dept/Sec:                   | Associate Investigators:    |
| Dept of Medicine/Cardiology |                             |
| Key Words:                  |                             |
| Beta blocker                |                             |
| Propranolol                 |                             |
| Heart attack                |                             |

|                       |                  |                           |
|-----------------------|------------------|---------------------------|
| Accumulative FILECASE | 1st Accumulative | Periodic                  |
| Cost:                 | OML Cost: \$300. | Review Results: Terminate |

OBJECTIVES: To determine the efficacy of propranolol in decreasing the incidence of sudden death and/or recurrent myocardial infarction.

TECHNICAL APPROACH: Uncomplicated postinfarction patients are treated prospectively with placebo or Inderal to see if survival in these patients is prolonged by prophylactic therapy with a beta-blocker.

PROGRESS: The national study of which this was to be a part has been terminated.



# Detail Summary Sheet

Date: 23 Dec 81      Prot No: 33/79      Status: Ongoing  
 TITLE: Evaluation of Amiodirone Therapy of Cardiac Arrhythmias

|                             |                             |                          |
|-----------------------------|-----------------------------|--------------------------|
| Start Date:                 | Est Comp Date:              |                          |
| Principal Investigator:     | Facility:                   |                          |
| LTC Harry M. Thomas, MC     | Tripler Army Medical Center |                          |
| Dept/Sec:                   | Associate Investigators:    |                          |
| Dept of Medicine/Cardiology |                             |                          |
| Key Words:                  |                             |                          |
| Amiodirone                  |                             |                          |
| Arrhythmia                  |                             |                          |
| Accumulative MEDCASH        | Est / Accumulative          | Periodic                 |
| Cost:                       | CMA Cost: \$500.            | Review Results: Continue |

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

**TECHNICAL APPROACH:** Amiodirone, an investigational drug, is utilized to treat supraventricular and ventricular arrhythmias which are refractory to other drugs. All results are pooled with other Army installations utilizing Amiodirone therapy. The collecting facility for this data is Letterman Army Medical Center.

**PROGRESS:** At TAMC, two patients are currently on Amiodirone. One patient had a breakthrough of her recurrent ventricular tachycardia when she personally reduced her dosage of medication to 400 mg daily. Increase in Amiodirone to 800 mg daily has prevented recurrence of her arrhythmia. The second patient has complete control of his arrhythmia. Both patients have developed minimal side effects in the form of corneal micro deposits which do not interfere with vision. Neither patient has developed significant complications with the medication. In the overall Army series, several patients have had to discontinue the drug because of reversible peripheral neuropathy and reversible pulmonary fibrosis.

# Detail Summary Sheet

Date: 4 Jan 82 Prot No: 35/80 Status: Ongoing  
 TITLE: Improved Record Keeping in the NICU/CCU by Means of Table  
 Model Computers

|  |  |
|--|--|
| Start Date: Sep 80                                 | Est Comp Date: Sep 82                            |
| Principal Investigator:<br>LTC Harry P. Thomas, MC | Facility:<br>Tripler Army Medical Center         |
| Dept/Sec:<br>Dept of Medicine/Cardiology           | Associate Investigators:<br>MAJ Klaus Gierke, MC |
| Key Words:<br>Record Keeping                       | COL Samuel L. Cucinell, MC                       |

|                      |                   |                          |
|----------------------|-------------------|--------------------------|
| Accumulative METCASH | Est Accumulative  | Periodic                 |
| Cost:                | UMA Cost: \$4000. | Review Results: Continue |

OBJECTIVE: To increase diagnostic sensitivity by modern graphic display of clinical data.

TECHNICAL APPROACH: The Hewlett Packard 9835A computer will be programmed to display quantitative data generated by selected patients. The displays will be graphic and organized similar to data in clinical journals and textbooks. The graphic displays will include all of the quantitative clinical data generated on the patients together with time notations of the clinical progress of the patient (including drug therapy, invasive procedures, new diagnoses, etc.) After sufficient number of patients have been studied, a quasi-objective evaluation will be performed in which a physician not associated with the patient will review the patient's chart in the classic manner compared to review of the patient's chart in addition to the graphic displays. The physicians will list the diagnosis for each day of ICU hospitalization. Statistical analysis will be by diagnosis made by physicians doing alternate type of chart review by  $\chi^2$ .

PROGRESS: Additional memory and software have been obtained and initial programs are to be undertaken.

Detail Summary Sheet

Date: 7 Jan 62 Protocol: 1786 Status: Ongoing  
TITLE: Comparison of Daily versus Alternate Prednisone Therapy in  
Pulmonary Sarcoidosis

Start Date: Mar 64 Est Completion: 1966  
Principal Investigator: Facility:  
Dr. George L. Underwood Jr., II Tripler Army Medical Center  
Dept/Sec: Associate Investigators:  
Dept of Medicine/Pulmonary Disease  
Key Words:  
Pulmonary sarcoidosis

| Accumulative MEDCARE Cost: | Est Accumulative OMA Cost: \$300. | Periodic Review Results: Continue |
|----------------------------|-----------------------------------|-----------------------------------|
|----------------------------|-----------------------------------|-----------------------------------|

**OBJECTIVES:** To compare the relative efficacy of equivalent dose daily vs alternate-day Prednisone therapy in stage II sarcoidosis patients with functional impairment. Techniques of evaluation must be practical and widely applicable in clinical use.

**TECHNICAL APPROACH:** In order to compare the therapeutic effects and complications of alternate day Prednisone to daily Prednisone in patients with sarcoid, a six-month cooperative, alternate allocation, unblinded study has been adopted. Both methods of Prednisone dosing are used clinically, but with only anecdotal and personal experience type data to evaluate, it is impossible to select the best treatment for this disease.

**PROGRESS:** The multicentric study on pulmonary sarcoidosis performed under the auspices of principal investigators at WPAAC continues. To date Tripler has entered seven patients in the study. Follow-up continues on the majority of these patients, although several are being followed at other Army institutions because of PCS. The criteria for selection and actual performance of the study remain unchanged.

# Detail Summary Sheet

Date: 6 Jan 61      Protocol: 32711      Status: Ongoing  
 TITLE: Antibiotic Prophylaxis in Vaginal Hysterectomy: A Comparison of  
 Different Regimens; Single Dose, Multidose and Intraoperative  
 Irrigation with Cefamandole Nafate  
 Start Date:      1st Complete:  
 Principal Investigator:      Facility:  
 CPT Thomas W. Burke, MC      Tripler Army Medical Center  
 Dept/Sec:      Associate Investigators:  
 Dept of Obstetrics and Gynecology  
 Key Words:  
 vaginal hysterectomy

|                               |                                      |                             |                      |
|-------------------------------|--------------------------------------|-----------------------------|----------------------|
| Accumulative NEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: \$300. | Periodic<br>Review Results: | Awaiting<br>Approval |
|-------------------------------|--------------------------------------|-----------------------------|----------------------|

OBJECTIVE: To determine the efficacy of different parenteral antibiotic regimens compared with intraoperative antibiotic irrigation in decreasing the febrile morbidity and the sequelae secondary to pelvic cellulitis following vaginal hysterectomy.

TECHNICAL APPROACH: Study proposed is a prospective blinded study designed to compare antibiotic prophylaxis, single-dose parenteral, and multidose parenteral in decreasing the incidence of infectious morbidity following vaginal hysterectomy.

PROGRESS: Awaiting IRG approval.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: 18/80 Status: Ongoing  
TITLE: Animal Surgery as Adjunct to Gynecology Residency Program

Start Date: 1 June 1980 Est Comp. Date: \_\_\_\_\_  
Principal Investigator: \_\_\_\_\_ Facility: \_\_\_\_\_  
COL Marshall D. Matthews, FC Tripler Army Medical Center  
Port/Sec: \_\_\_\_\_ Associate Investigators: \_\_\_\_\_  
Dept of Obstetrics and Gynecology CPT Clayton L. Hadick, VC  
Key Words:  
Training  
Gynecological surgery

| Accumulative MEDCASE | Est Accumulative   | Periodic                 |
|----------------------|--------------------|--------------------------|
| Cost:                | OMA Cost: \$3,500. | Review Results: Continue |

OBJECTIVES: To perfect skills and increase exposure and proficiency in gastrointestinal, genitourinary and vascular procedures.

TECHNICAL APPROACH: Dogs have end-to-end anastomosis, side-to-side anastomosis, diverting colostomies, end-to-end ureteral anastomosis, and ureteral implantation as well as retroperitoneal vessel dissection and node dissection.

PROGRESS: The project continues as a training protocol. Surgery was done on 25 dogs and 29 residents were trained in the procedure.

Detail Summary Sheet

Date: 20 Jan 82 Prot No: 40/76 Status: Ongoing  
TITLE: Microsurgical Anastomosis of the Rabbit Oviduct

|                                   |                             |
|-----------------------------------|-----------------------------|
| Start Date: 1 Oct 78              | Est Comp Date:              |
| Principal Investigator:           | Facility:                   |
| LTC Heinz G. Osterholzer, MC      | Tripler Army Medical Center |
| Dept/Sec:                         | Associate Investigators:    |
| Dept of Obstetrics and Gynecology |                             |
| Key Words:                        |                             |
| Training                          |                             |
| Microsurgery                      |                             |

|                      |                  |                          |
|----------------------|------------------|--------------------------|
| Accumulative MEDCASE | Est Accumulative | Periodic                 |
| Cost:                | OMA Cost:\$2000. | Review Results: Continue |

OBJECTIVES: To perfect skills and increase proficiency in microsurgical techniques.

TECHNICAL APPROACH: Bilateral ligation of the fallopian tubes with microsurgical reconstruction is performed in rabbits. The reconstruction is either bilateral or unilateral.

PROGRESS: The project continues as a training protocol. Surgery was done on eight rabbits and ten residents were trained in the procedure.

# Detail Summary Sheet

Date: 18 Jan 82 Prot No: 12/E1 Status: Ongoing  
 TITLE: The Cold Pressor Test as a Predictor of Pregnancy-Induced Hypertension

|  |  |
|--|--|
| Start Date: June 81                                  | Est Comp Date: June 82   |
| Principal Investigator:<br>LTC Heinz Osterholzer, MC | Facility:<br>Tripler Army Medical Center   |
| Dept/Sec:<br>Obstetrics and Gynecology               | Associate Investigators:<br>Florentino V. Acalanza, M.D.<br>LTC John F. Head, MC |
| Key Words:<br>Cold pressor test<br>Hypertension      |  |

|                            |                                   |                                   |
|----------------------------|-----------------------------------|-----------------------------------|
| Accumulative PIHCASE Cost: | Est Accumulative OMA Cost: \$300. | Periodic Review Results: Continue |
|----------------------------|-----------------------------------|-----------------------------------|

OBJECTIVE: To develop a convenient means of detecting the patient destined to develop pregnancy-induced hypertension (PIH).

TECHNICAL APPROACH: All healthy, normotensive, nulliparous women attending the Obstetrics Clinic, TAMC, will be asked to participate in this study. Those women with a past history of chronic hypertension, renal disease, and cold allergy will be excluded from the investigation. During each visit, each subject will be evaluated for hyperreflexia, edema, proteinuria, and weight gain. Each subject will be tested with the cold pressor test in accordance with the protocol of Hines and Brown as described above, with the following modifications. The supine position will be avoided; the subject will rest in bed in a semi-reclining position (30°) with a slight left lateral tilt. An electronic fetal monitoring unit will be used continuously during the entire test period to externally monitor the fetal heart rate and the uterine activity. A reactive fetal heart rate pattern and absence of uterine contractions will be a prerequisite for proceeding to the cold pressor test. The subject's pulse rate will also be continuously monitored. Urinalysis for proteinuria will be done before and after the cold pressor test. Each subject will initially be tested at 28 to 30 weeks' gestation and again at 34 weeks' gestation. The subjects will then be followed again routinely in the Obstetrics Clinic and eventually in Labor and Delivery, and the presence or absence of PIH will be noted. Hyperreactors will be retested 3 months after delivery.

PROGRESS: Only one patient has been entered in the study thus far. Problems have been encountered with recruiting of volunteers due to lack of support by residents. The principal investigator plans to personally recruit volunteers in the future.

# Detail Summary Sheet

Date: 18 Jan 82 Prot No: 9/81 Status: Ongoing  
 Title: Randomized Trial of Ambulation vs Oxytocin for Labor  
 Enhancement

|                                      |                             |
|--------------------------------------|-----------------------------|
| Start Date:                          | Est Comp Date:              |
| Principal Investigator:              | Facility:                   |
| Dr John A. Read, MC                  | Tripler Army Medical Center |
| Dept/Sec:                            | Associate Investigators:    |
| Obstetrics and Gynecology/Obstetrics |                             |
| Key Words:                           |                             |
| Labor enhancement                    |                             |

|                      |                  |                          |
|----------------------|------------------|--------------------------|
| Accumulative MEDCASE | Est Accumulative | Periodic                 |
| Cost:                | OMA Cost: \$300. | Review Results: Continue |

**OBJECTIVE:** To compare the efficacy of ambulation vs oxytocin in cases of dysfunctional labor, so-called dystocia.

**TECHNICAL APPROACH:** 100 patients will be studied. All patients with demonstrated failure to progress in labor for one hour, are at least 4 cm dilated, and who are felt to require augmentation of labor are eligible for the study. Patients will be randomized into two groups, one utilizing ambulation and the other utilizing oxytocin. Examinations will be conducted at the end of one and two hours and uterine activity will be quantified. If after two hours no progress has occurred, patients on ambulation will be returned to bed and oxytocin utilized; patients on oxytocin will be given the option to ambulate. Length of labor, time from study entry to delivery, type of delivery, 1 and 5 minute Apgar scores, cord blood gases, maternal pain perception, newborn weight and neonatal problems will be noted.

**PROGRESS:** No subjects have been entered into this protocol as yet due to lack of time. Study will be started as soon as time permits.



# Detail Summary Sheet

Date: 30 Dec 81 Prot No: 26/80 Status: Terminated  
 TITLE: A Comparison Study of Different Concentrations of Cefamandole  
 nafate During Cesarean Section

|                                   |                             |
|-----------------------------------|-----------------------------|
| Start Date:                       | 1st Comp Date:              |
| Principal Investigator:           | Facility:                   |
| CPT Eugene G. Rudd, MC            | Tripler Army Medical Center |
| Dept/Sec:                         | Associate Investigators:    |
| Dept of Obstetrics and Gynecology |                             |
| Key Words:                        |                             |
| Cefamandole nafate                |                             |

|                            |                                   |                                    |
|----------------------------|-----------------------------------|------------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: \$300. | Periodic Review Results: Terminate |
|----------------------------|-----------------------------------|------------------------------------|

OBJECTIVE: To compare the efficacy of intrauterine irrigation with cefamandole nafate versus parenterally administered cefamandole nafate during cesarean section in reducing the febrile morbidity and the incidence of endomyometritis and its resulting complications following cesarean section.

TECHNICAL APPROACH: This study was designed to compare intravenous antibiotics to intrauterine irrigation with antibiotic post-cesarean section.

PROGRESS: Terminated due to departure of principal investigator.

# Detail Summary Sheet

Date: 18 Jan 82 Prot No: 10/81 Status: Completed  
 TITLE: Retrospective Study of Conization Followed by Hysterectomy  
 for Various Stages of Dysplasia

|  |  |
|--|--|
| Start Date: Jan 81                                       | Est Comp Date:   |
| Principal Investigator:<br>MAJ Clayton L. Shaw, MC, USAF | Facility:<br>Tripler Army Medical Center   |
| Dept/Sec:<br>Obstetrics and Gynecology/Gynecology        | Associate Investigators:<br>LTC Heinz O. Osterholzer, MC<br>COL Kunio Miyazawa, MC |
| Key Words:<br>Dysplasia                                  |  |
| Accumulative MEDCASE<br>Cost:                            | Est Accumulative<br>CMA Cost: \$500.   |
|  | Periodic<br>Review Results:  |

OBJECTIVE: (1) To clarify the need for reporting margin involvement in conization specimens and for follow-up histological examinations at the time of hysterectomy; and (2) to determine the incidence of persistent dysplasia in cones with negative and cones with positive margins.

TECHNICAL APPROACH: A review was made of the patients who underwent conization for dysplasia and CIS from January 1975 to July 1980, followed with a hysterectomy. This group of patients were studied by the following criteria:

| CONIZ.              | HYSTERECTOMY                        |
|---------------------|-------------------------------------|
| Age                 | Age                                 |
| Date of surgery     | Date of surgery                     |
| Depth of cone       | Type of hysterectomy                |
| Indication for cone | If BSO done                         |
| Pathology of cone   | Cuff comments                       |
| Number of slides    | Preoperative indications            |
| ICC at surgery      | Specimen gross description          |
| Margins             | Specimen pathology (residual tumor) |

Depending on the size of the specimen, a minimum of 10 slides per specimen were reviewed.

PROGRESS: Charts and slides of 77 patients have been reviewed. A paper is in preparation.

# Detail Summary Sheet

Date: 4 Jan 82 Prot No: 11/77 Status: Ingoing  
 TITLE: Development of Clinical Assays

|                         |                             |
|-------------------------|-----------------------------|
| Start Date: Sep 77      | Est Comp Date:              |
| Principal Investigator: | Facility:                   |
| MC Peter Angritt, MC    | Tripler Army Medical Center |
| Dept/Sec:               | Associate Investigators:    |
| Dept of Pathology       | CPT Willie Frazier, MSC     |
| Key Words:              | John L. Claylaugh, H.L.B.   |
| Clinical assays         | CCL Samuel J. Cucinell, MC  |
|                         | COL James L. Hastings, MC   |
| Accumulative MEDCASE    | Est Accumulative            |
| Cost:                   | OMC Cost: \$1500.           |
|                         | Periodic                    |
|                         | Review Results: Continue    |

**OBJECTIVES:** This study is designed to (a) familiarize the clinical pathology resident with the field of new and developing assay kits; (b) give him an opportunity to evaluate the various assay kits for cost, effectiveness, and technique; and (c) determine which of the kits would be of greatest service to HACC.

**TECHNICAL APPROACH:** All new laboratory tests which become available commercially will be evaluated by sending for information from the manufacturer. A number of kits will be purchased from various manufacturers. Clinical specimens will be obtained from patients with established diagnoses as well as from appropriate controls. Each kit will be compared for accuracy, sensitivity, ease of performance, cost, shelf life, etc. The investigator will estimate, based on current and future hospital requirements, which test (if any) is best.

**PROGRESS:** The Abbott Laboratories HBeAg kit will be evaluated next. As soon as evaluation is completed, a comprehensive serodiagnostic panel will be tested and compared to the current process to diagnose Hepatitis A, Hepatitis B and posttransfusional hepatitis (nonA-nonB). This panel will test for HBsAg, AntiHBc, Anti-HAV IgM, HBeAg, AntiHBe, and AntiHBs. A group of patients will be used to compare both methods of diagnosis and to establish which one is (a) faster, (b) more cost-effective (full panel vs. sequential ordering), and (c) more informative for follow-up purposes.

# Detail Summary Sheet

Date: 1P Jan 82 Prot No: 22/80 Status: Pending  
 TITLE: Antidiuretic Hormone Secretion in the Asphyxiated Neonate

|                                |                               |
|--------------------------------|-------------------------------|
| Start Date: Aug 81             | Est Comp Date: Aug 82         |
| Principal Investigator:        | Facility:                     |
| Mr Edwin Bollert, MD           | Tripler Army Hospital, Letter |
| Dept/Sec:                      | Associate Investigators:      |
| Dept of Pediatrics/Neonatology | John L. Claydon, MD           |
| Key Words:                     |                               |
| Antidiuretic Hormone           |                               |
| Asphyxiated neonate            |                               |

|  |                            |
|--|----------------------------|
| Accumulative PEUCASE (Est Accumulative | Periodic                   |
| Cost: OMA Cost \$1000.                 | Review Results: (Continue) |

**OBJECTIVE:** To evaluate and determine the physiologic response of antidiuretic hormone (ADH) secretion in cerebrospinal fluid (CSF) and plasma in the newborn infant who has experienced central nervous system (CNS) injury, hypoxemia and asphyxia, i.e., is there evidence for independent control of release of ADH into the CSF and plasma. Also, we intend to test the hypothesis that hypoxemia will increase the release of ADH into the CSF and consequently lead to increased pressure in the CSF or other evidence of cerebral edema.

**TECHNICAL APPROACH:** Subjects used for this study will be neonates admitted to the Special Care Nursery for evaluation of sepsis or possible sepsis. In addition, all newborn infants with intracranial hemorrhage, CNS injuries from birth trauma, and neonates experiencing severe asphyxia with hypoxemia, increased intracranial pressure, and cerebral edema. Asphyxia will be defined as follows: A 5 min /pgar score  $\leq 6$  and/or arterial blood pH  $< 7.25$  on admission to Special Care Nursery. On admission, each patient's APGAR scores, temperature, heart rate, blood pressure, and weight are recorded. Arterial blood gases are required for evaluation of acidosis, hypoxemia, and oxygen requirement. From each neonate, when possible, CSF opening pressure will be recorded, then 2 ml of spinal fluid will be collected and mixed with 0.1 ml of 1.0 N HCl/ml of CSF and immediately frozen for ADH assay. In addition, 0.1 ml of blood will be placed in a heparinized tube and plasma preserved with 0.1 ml of 1.0 N HCl/ml and frozen for ADH assay. Plasma and CSF will also be evaluated for Na<sup>+</sup> and K<sup>+</sup> concentration and osmolality. The data collected will be assessed to determine the correlation of CSF ADH

and plasma ADH and the correlations of each parameter to other stimulators of ADH release, i.e., plasma osmolality, pH, body temperature, and arterial blood pressure and PaO<sub>2</sub> and PaCO<sub>2</sub>. These data will be analyzed by multiple regression analysis to determine which factors most influence the independent release patterns of ADH into either the plasma or CSF. If computerized axial tomography scans are performed, an attempt will be made to correlate cerebral edema with high CSF ADH levels. It is anticipated that about 100 patients would provide sufficient information regarding the above-mentioned correlations.

PROGRESS: Project is ongoing and still active; initial data continues to be collected. Data to the present time is now being analyzed. To date, 22 neonates have been assessed for CSF ADH concentration. Of these, 20 have had sufficient blood gas analysis for preliminary statistical work-ups. None of the following results are as yet statistically significant, although expected tendencies are evident.

|  | Slope  | r    |
|--|--------|------|
| Increased p <sub>H</sub> → + CSF [ADH]   | -13.93 | 0.30 |
| Increased AFGAR @ 3 min → + CSF [ADH]    | -0.62  | 0.23 |
| Increased AFGAR @ 10 min → + CSF [ADH]   | -1.03  | 0.31 |
| Increased PCO <sub>2</sub> → + CSF [ADH] | -0.62  | 0.31 |
| Increased PCO <sub>2</sub> → + CSF [ADH] | -0.03  | 0.00 |

Additionally, 13 neonates have been assessed for six 4-hour sequential urine samples postpartum, some of whom also had CSF ADH determinations. Correlations between CSF and/or urinary ADH with PaCO<sub>2</sub>, PaO<sub>2</sub>, pH, lactate excess, body temperature, systolic blood pressure, and A/G/R scores, are presently underway. We have had difficulty getting the enthusiastic support that we need from the Department of Pediatrics in order to continue this project. We would like to emphasize the measurement of plasma [ADH] along with CSF [ADH] in future observations. It is expected that 40 to 60 more patients would be sufficient to complete this study.

Detail Summary Sheet

Date: 14 Jan 82 Prot No: 12/79 Status: Active  
Title: Intubation and Chest Tube Placement in Small Laboratory Animals

Start Date: Feb 79 End Date: 10/80  
Principal Investigator: Facility:  
C. J. Jose Garcia, MD Tripler Army Medical Center  
Dept/Sec: Associate Investigator  
Dept of Pediatrics/Neonatology  
Key Words:  
Endotracheal intubation.

Accumulative MICRASI 1st Accumulative Periodic  
Cost: OMA Cost: \$1500. Review Results: Ongoing

OBJECTIVES: To provide a teaching model for medical trainees in the proper techniques of endotracheal intubation and chest tube insertion.

TECHNICAL APPROACH: Young kittens and rabbits housed at the Tripler Army Medical Center Animal Facility will serve as animal models. The anatomy of the thorax and airway closely approximates that of the premature human infant. Standard intubation and thoracotomy equipment will be set up on a weekly basis at a time prearranged with Clinical Investigation Service and the Newborn Medicine Service. One of the above-named investigators will accompany 1-2 junior house staff officers to the facility and provide instruction in proper technique. Each house staff officer will then use the animal models to refine his own abilities.

PROGRESS: Training program continues unchanged. The above program was used in instructing all pediatric interns and some obstetrical interns during June and July 1981.

# Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOC 7612 Status: Ongoing  
 TITLE: Comparison of Involved Field (IF) Radiotherapy and MOPP + Low  
 Bleomycin with IF Radiotherapy and A-COPP in Stage III Hodgkin's  
 Disease

|                                |                               |
|--------------------------------|-------------------------------|
| Start Date: Aug 81             | Est Comp Date:                |
| Principal Investigator:        | Facility:                     |
| COL David A. Maybee, MC        | Tripler Army Medical Center   |
| Dept/Sec:                      | Associate Investigators:      |
| Pediatrics/Hematology-Oncology | COL Constance P. Hastings, MC |
| Key Words:                     |                               |
| Hodgkin's disease, stage III   |                               |

|                      |                  |                          |
|----------------------|------------------|--------------------------|
| Accumulative MEDCASE | Est Accumulative | Periodic                 |
| Cost:                | OMA Cost: \$300. | Review Results: Continue |

OBJECTIVE: To determine the effectiveness of a five chemotherapy drug  
 and radiation therapy treatment on stage III Hodgkin's disease and to  
 determine which of the five chemotherapy drug combinations gives the  
 best results with the least side effects.

TECHNICAL APPROACH: Children diagnosed as having Stage III Hodgkin's  
 disease are eligible.  
 Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into this protocol as yet.

# Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7617 Status: Terminated  
 TITLE: Combination Chemotherapy with Vinblastine Sulfate and Bleomycin  
 Infusion in Children with Metastatic Solid Tumors (Phase II)

|   |   |
|---|---|
| Start Date: Aug 81  | Est Comp Date:  |
| Principal Investigator:<br>COL David A. Maybee, MC                      | Facility:<br>Tripler Army Medical Center                  |
| Dept/Sec:<br>Pediatrics/Hematology-Oncology                             | Associate Investigators:<br>COL Constance P. Hastings, MC |
| Key Words:<br>Hodgkin's disease<br>germ cell carcinoma<br>histiocytosis |   |

|                            |                                   |                                    |
|----------------------------|-----------------------------------|------------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: \$300. | Periodic Review Results: Terminate |
|----------------------------|-----------------------------------|------------------------------------|

OBJECTIVE: To determine the effects of this combination of chemotherapy on recurrent or metastatic solid tumors.

TECHNICAL APPROACH: Patient eligibility will be limited to patients with Hodgkin's disease, germ cell carcinoma, and histiocytosis.

Treatment will be as outlined in the study protocol.

PROGRESS: 20 patients registered. This protocol is now closed to new registrants.



# Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7621 Status: Terminated  
 TITLE: MOPP versus OPP in the Treatment of Children with Recurrent  
 Brain Tumors (Phase III)

|  |   |
|--|---|
| Start Date: Aug 81                                 | Est Comp Date:  |
| Principal Investigator:<br>COL David A. Maybee, MC | Facility:<br>Tripler Army Medical Center                  |
| Dept/Sec:<br>Pediatrics/Hematology-Oncology        | Associate Investigators:<br>COL Constance P. Hastings, MC |
| Key Words:<br>Brain tumor, recurrent               |   |

|                               |                                      |                                       |
|-------------------------------|--------------------------------------|---------------------------------------|
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: \$300. | Periodic<br>Review Results: Terminate |
|-------------------------------|--------------------------------------|---------------------------------------|

OBJECTIVE: To determine the effect of the combination chemotherapy on brain tumor and to determine whether eliminating the lusterogen from the MOPP combination will be as effective as the MOPP combination but with possibly less side effects.

TECHNICAL APPROACH: Children with brain tumor not responding to standard treatment will be eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been registered. Protocol was closed to patient entry on 20 Oct 81.

# Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7623 Status: Completed  
 TITLE: Evaluation of Systemic Regimens in the Treatment of Acute  
 Leukemia of Childhood, Phase III

|  |   |
|--|---|
| Start Date: Aug 81                                 | Est Comp Date:  |
| Principal Investigator:<br>COL David A. Maybee, MC | Facility:<br>Tripler Army Medical Center                  |
| Dept/Sec:<br>Pediatrics/Hematology-Oncology        | Associate Investigators:<br>COL Constance F. Hastings, MC |
| Key Words:<br>Leukemia, acute, childhood           |   |

|                               |                                      |                             |
|-------------------------------|--------------------------------------|-----------------------------|
| Accumulative REBCASE<br>Cost: | Est Accumulative<br>OMA Cost: \$300. | Periodic<br>Review Results: |
|-------------------------------|--------------------------------------|-----------------------------|

OBJECTIVE: To determine the effect of intensive, multidrug chemotherapy on acute lymphocytic leukemia and to determine whether treating with an antibiotic called trimethoprim-sulfamethoxazole (Bactrim, Septra) tends to prevent infection during treatment for acute lymphocytic leukemia.

TECHNICAL APPROACH: Patients under 21 years of age at time of diagnosis of ALL, T-ALL, or APL, with no previous therapy except for one week or less of corticosteroids prior to admission, falling into a good or poor prognosis category and having either no markers or T-cell markers, are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: Nine patients have been registered. This protocol is now closed to new entrants due to sufficient patient accrual.

# Detail Summary Sheet

|  |   |                             |
|--|---|-----------------------------|
| Date: 15 Jan 82  | Prot No: SWOG 7660  | Status: Completed           |
| TITLE: Comparison of Involved Field Radiotherapy with Adjuvant MOPP<br>Chemotherapy in the Treatment of Stage I and II Hodgkin's<br>disease, Phase III |   |                             |
| Start Date: Aug 81   | Est Comp Date:  |                             |
| Principal Investigator:<br>COL David A. Maybee, MC   | Facility:<br>Tripler Army Medical Center                  |                             |
| Dept/Sec:<br>Pediatrics/Hematology-Oncology  | Associate Investigators:<br>COL Constance P. Hastings, MC |                             |
| Key Words:<br>Hodgkin's disease, Stage I and II  |   |                             |
| Accumulative MEDCASE<br>Cost:  | Est Accumulative<br>OMA Cost: \$300.                      | Periodic<br>Review Results: |

OBJECTIVE: To compare two forms of treatment for stage I and stage II Hodgkin's disease.

TECHNICAL APPROACH: Children 18 and under with untreated stage I and II Hodgkin's disease are eligible. Patients with massive mediastinal disease requiring local radiotherapy on an urgent basis for tumor shrinkage prior to lymphography and administration of anesthesia for staging celiotomy are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: Two patients have been registered in this protocol. The protocol is now closed to new entrants due to sufficient patient accrual.

# Detail Summary Sheet

|  |                               |                 |
|--|-------------------------------|-----------------|
| Date: 15 Jan 82  | Prot No: SWOG 7712            | Status: Ongoing |
| TITLE: Comparison of Treatment Regimens for First CNS Relapse in Childhood Acute Lymphoblastic Leukemia (CNS Leukemia Study #6), Phase III |                               |                 |
| Start Date: Aug 81   | Est Comp Date:                |                 |
| Principal Investigator:  | Facility:                     |                 |
| COL David A. Maybee, MC  | Tripler Army Medical Center   |                 |
| Dept/Sec:  | Associate Investigators:      |                 |
| Pediatrics/Hematology-Oncology   | COL Constance P. Hastings, PA |                 |
| Key Words:   |                               |                 |
| Leukemia, lymphoblastic, acute   |                               |                 |

|                            |                                   |                                   |
|----------------------------|-----------------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative UMA Cost: \$300. | Periodic Review Results: Continue |
|----------------------------|-----------------------------------|-----------------------------------|

OBJECTIVE: To determine whether, after a course of six treatments of three chemotherapy drugs given into the spinal fluid, radiation to the head and spinal column followed by no further treatment is better than radiation to the head alone followed by continuing courses of the three drugs into the spinal fluid.

TECHNICAL APPROACH: Children with acute lymphoblastic leukemia which has recurred in the central nervous system are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: 40 patients have been entered into this protocol as yet.

# Detail Summary Sheet

|  |  |                          |
|--|--|--------------------------|
| Date: 15 Jan 82  | Prot No: SK00 7721                                     | Status: Completed        |
| TITLE: Evaluation of Induction, Maintenance with and without Periodic Reinforcement, and CNS Prophylaxis in Acute Non-lymphocytic Leukemia |  |                          |
| Start Date: Aug 81   | Est Comp Date:   |                          |
| Principal Investigator: COL David A. Maybee, MC  | Facility: Tripler Army Medical Center                  |                          |
| Dept/Sec: Pediatrics/Hematology-Oncology   | Associate Investigators: COL Constance E. Hastings, MC |                          |
| Key Words: Leukemia, nonlymphocytic, acute   |  |                          |
| Accumulative ITICASE Cost:   | Est Accumulative OMA Cost: \$300.                      | Periodic Review Results: |

OBJECTIVE: to try to cause a remission, to try to prevent metastases to the central nervous system, and to try to prolong the remission as long as possible.

TECHNICAL APPROACH: Patients under 21 years of age with diagnosis of acute myelocytic leukemia or acute myelomonocytic leukemia are eligible. Patients with a diagnosis of chronic granulocytic leukemia in blastic crises, erythroleukemia, or other rare forms of myelocytic leukemia are eligible, but will not be randomized. Patients must have had no previous therapy except one week or less of corticosteroids prior to admission. Patients must be available for periodic follow-up.

Treatment will be as outlined in the study protocol.

PROGRESS: Three patients have been registered. The protocol is now closed to patient entry due to sufficient patient accrual.

# Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7810 Status: Terminated  
 TITLE: Evaluation of Anguidine in Children with Acute Leukemia in  
 Relapse, Phase II

|                                |                               |
|--------------------------------|-------------------------------|
| Start Date: Aug 81             | Est Comp Date:                |
| Principal Investigator:        | Facility:                     |
| COL David A. Maybee, MC        | Tripler Army Medical Center   |
| Dept/Sec:                      | Associate Investigators:      |
| Pediatrics/Hematology-Oncology | COL Constance P. Hastings, MC |
| Key Words:                     |                               |
| Lymphoid malignancy            |                               |

|                      |                  |                           |
|----------------------|------------------|---------------------------|
| Accumulative Phase I | Accumulative     | Periodic                  |
| Cost:                | OMA Cost: \$300. | Review Results: Terminate |

OBJECTIVE: To determine the effect of anguidine on lymphoid malignancy.

TECHNICAL APPROACH: Children having lymphoid malignancy, disseminated in relapse, previously diagnosed as acute leukemia or lymphoma, who are not eligible for protocols of higher priority and who are resistant to standard forms of therapy are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been registered. This study is now closed due to slow accrual of patients.

# Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7811 Status: Ongoing  
 TITLE: Evaluation of Anguidine in the Treatment of Central Nervous System Tumors (Phase II)

|  |   |
|--|---|
| Start Date: Aug 81                                 | Est Comp Date:  |
| Principal Investigator:<br>COL David A. Maybee, MC | Facility:<br>Tripler Army Medical Center                  |
| Dept/Sec:<br>Pediatrics/Hematology-Oncology        | Associate Investigators:<br>COL Constance P. Hastings, MC |
| Key Words:<br>Central nervous system tumors        |   |

|                            |                                   |                                   |
|----------------------------|-----------------------------------|-----------------------------------|
| Accumulative MEDCARE Cost: | Est Accumulative OMA Cost: \$300. | Periodic Review Results: Continue |
|----------------------------|-----------------------------------|-----------------------------------|

OBJECTIVE: To determine the effect of anguidine on brain or spinal cord tumor.

TECHNICAL APPROACH: Children with malignant tumor of the brain or spinal cord that has not responded to therapy or for which there is no standard therapy are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients registered as yet.

# Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7818 Status: Ongoing  
 TITLE: Evaluation of Rubidazole in Children with Acute Leukemia in  
 Relapse, Phase II

|  |   |
|--|---|
| Start Date: Aug 81                                 | Est Comp Date:  |
| Principal Investigator:<br>COL David A. Maybee, MC | Facility:<br>Tripler Army Medical Center                  |
| Dept/Sec:<br>Pediatrics/Hematology-Oncology        | Associate Investigators:<br>COL Constance I. Hastings, MC |
| Key Words:<br>Leukemia                             |   |

|                               |                                      |                                      |
|-------------------------------|--------------------------------------|--------------------------------------|
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: \$300. | Periodic<br>Review Results: Continue |
|-------------------------------|--------------------------------------|--------------------------------------|

OBJECTIVE: To determine the effect of rubidazole on leukemia.

TECHNICAL APPROACH: Children with acute leukemia not responding to standard forms of therapy are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into this protocol as yet.



Detail Summary Sheet

Date: 15 Jan 82      Prot No: SMOG /229      Status: Initiated  
 TITLE: Comparison of Two Dose Regimens of Intrathecal Methotrexate  
 for CNS Leukemia, Phase II

|                                |                               |
|--------------------------------|-------------------------------|
| Start Date: Aug 81             | Est Comp. Date:               |
| Principal Investigator:        | Facility:                     |
| COL David A. Mayber, MC        | Tripler Army Medical Center   |
| Dept/Sec:                      | Associate Investigators:      |
| Pediatrics/hematology-oncology | COL Constance E. Hastings, MC |
| Key Words:                     |                               |
| Leukemia, CNS                  |                               |

|                            |                                    |                                      |
|----------------------------|------------------------------------|--------------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative COMA Cost: \$300. | Periodic Review Results: Ten to date |
|----------------------------|------------------------------------|--------------------------------------|

OBJECTIVE: To determine whether a lower dose of methotrexate given into the spinal fluid is more effective than the larger standard dose in treating central nervous system leukemia.

SCIENTIFIC APPROACH: Children with leukemia in the central nervous system that recurs in spite of previous treatment are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients recruited. Protocol closed to new entrants as of 27 Oct 81.

# Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7734 Status: Ongoing  
 TITLE: Second Induction and Maintenance in Acute Lymphocytic Leukemia  
 (Phase III)

|                                |                              |
|--------------------------------|------------------------------|
| Start Date: Aug 81             | Est Comp Date:               |
| Principal Investigator:        | Facility:                    |
| COL David A. Haybee, MC        | Tripler Army Medical Center  |
| Dept/Sec:                      | Associate Investigators:     |
| Pediatrics/Hematology-Oncology | COL Constance E. Eastman, MC |
| Key Words:                     |                              |
| Leukemia, lymphocytic, acute   |                              |

|                     |                  |                          |
|---------------------|------------------|--------------------------|
| Accumulative MIBCSI | Est Accumulative | Periodic                 |
| Cost:               | OMA Cost: \$300. | Review Results: continue |

OBJECTIVE: To try to cause a remission, to try to prevent the spread of the leukemia to the central nervous system, and to try to prolong the remission as long as possible.

MECHANICAL APPROACH: Patients must be under 21 years of age. Patients having received prior treatment with adriamycin, daunorubicin, 6-TG, or systemic cytosine arabinoside are ineligible. Patients having had a previously treated relapse (CRS, EMB) are ineligible. For patients in their first CRS relapse, concurrent registration to SWOG 7712 is required. Patients with EMB are eligible; concurrent registration to the EMB protocol is required if patient qualifies. Patients with a combination of initial CRS and/or EMB relapse are eligible. Patients with CRS and/or EMB at initial diagnosis and previously treated are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: Two patients have been registered.

# Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWC6 7837 Status: Ongoing  
 TITLE: Evaluation of Systemic Therapy for Children with T-Cell Acute Lymphatic Leukemia, Phase II

|                                |                               |
|--------------------------------|-------------------------------|
| Start Date: Aug 81             | Est Comp Date:                |
| Principal Investigator:        | Facility:                     |
| COL David A. Maybee, Ft        | Tripler Army Medical Center   |
| Dept/Sec:                      | Associate Investigators:      |
| Pediatrics/Hematology-Oncology | COL Constance B. Hastings, Ft |
| Key Words:                     |                               |
| Leukemia, T-cell               |                               |

|                           |                                   |                                   |
|---------------------------|-----------------------------------|-----------------------------------|
| Accumulative MICASE Cost: | Est Accumulative OMA Cost: \$300. | Periodic Review Results: Continue |
|---------------------------|-----------------------------------|-----------------------------------|

OBJECTIVE: To determine the effectiveness of aggressive treatment of T-cell acute lymphatic leukemia and to determine which of two protocols is most effective with the least amount of side effects.

TECHNICAL APPROACH: Children with T-cell leukemia are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into the protocol as yet.

# Detail Summary Sheet

Date: 15 Jan 62      Prot No: 11117901      Status: Pending  
 Title: Rescue Therapy for Non-CNS Extramedullary Disease in Children  
 With Acute Lymphoblastic Leukemia, Phase III

|                                |                               |
|--------------------------------|-------------------------------|
| Start Date: Aug 61             | Est. Completed:               |
| Principal Investigator:        | Facility:                     |
| COL David A. Maybee, MC        | Tripler Army Medical Center   |
| Dept/Sec:                      | Associate Investigators:      |
| Pediatrics/Hematology-Oncology | COL Constance M. Hastings, MC |
| Key Words:                     |                               |
| Leukemia, acute lymphoblastic  |                               |

|                      |                   |                          |
|----------------------|-------------------|--------------------------|
| Accumulative MEDCARE | Est. Accumulative | Periodic                 |
| Cost:                | OMA Cost: \$300.  | Review Results: Continue |

OBJECTIVE: To determine the effectiveness of radiation therapy in controlling acute lymphoblastic leukemia outside of the bone marrow and outside of the central nervous system.

TECHNICAL APPROACH: Children with acute lymphoblastic leukemia recurring outside of the bone marrow and outside the central nervous system are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: As of 15 Jan 62, no patients have been entered into study.

Detail Summary Sheet

Date: 18 Jan 81 Project: 1401-75-1 Status: Opened  
TITLE: A-COP Plus for Non-Hodgkin's Lymphoma in Children, Phase III

|                              |                               |           |
|------------------------------|-------------------------------|-----------|
| Start Date: Aug 81           | Principal Investigator:       | Facility: |
| Col David A. Paylee, MC      | Tripler Army Medical Center   |           |
| Dept/Sec:                    | Associate Investigator:       |           |
| Pediatrics/Oncology-Clinical | Col Constance A. Hastings, MC |           |
| Key Words:                   |                               |           |
| Lymphoma, non-Hodgkin's      |                               |           |

|                      |                  |                          |
|----------------------|------------------|--------------------------|
| Accumulative MEDCARE | Est Accumulative | Periodic                 |
| Cost:                | OMA Cost: \$300. | Review Results: Continue |

OBJECTIVE: To determine the effect of the combination of chemotherapy and radiation therapy on non-Hodgkin's lymphoma and to determine which of two protocols is more effective with the least side effects.

TECHNICAL APPROACH: Children with non-Hodgkin's lymphoma are eligible. Treatment will be as outlined in the study protocol.

PROGRESS: One patient has been registered.

# Detail Summary Sheet

Date: 15 Jan 82      Protocol: SWOG 7900      Status: Completed  
 Title: Multidrug Adjuvant Chemotherapy in Nonmetastatic Osteosarcoma  
 Comparison of COMPADRI-I with COMPADRI-V (Phase III)

|  |   |                                    |
|--|---|------------------------------------|
| Start Date: Aug 81                                 | Est Comp Date:  |                                    |
| Principal Investigator:<br>COL David A. Maybee, MC | Facility:<br>Tripler Army Medical Center                  |                                    |
| Dept/Sec:<br>Pediatrics/Hematology-Oncology        | Associate Investigators:<br>COL Constance E. Hastings, MC |                                    |
| Key Words:<br>Osteosarcoma, nonmetastatic          |   |                                    |
| Accumulative MEDCASE Cost:                         | Est Accumulative OMA Cost: \$300.                         | Periodic Review Results: Terminate |

OBJECTIVE: To determine the effect of a combination of chemotherapy on osteosarcoma, to determine the effect of adding high-dose methotrexate to the combination of chemotherapy drugs in COMPADRI-I, and to determine which combination, COMPADRI-I or COMPADRI-V, is more effective in treating osteosarcoma.

TECHNICAL APPROACH: Children with osteosarcoma.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been registered. Protocol is now closed to patient entry.

# Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7919 Status: Ongoing  
 TITLE: Evaluation of m-AMSA in Children with Acute Leukemia and  
 Non-Hodgkin's Lymphoma in Relapse, Phase II

|                                |                               |
|--------------------------------|-------------------------------|
| Start Date: Aug 81             | Est Comp Date:                |
| Principal Investigator:        | Facility:                     |
| COL David A. Haylee, MC        | Tripler Army Medical Center   |
| Dept/Sec:                      | Associate Investigators:      |
| Pediatrics/Hematology-Oncology | COL Constance F. Hastings, MC |
| Key Words:                     |                               |
| Leukemia                       |                               |
| Lymphoma, non-Hodgkin's        |                               |

|                      |                  |                          |
|----------------------|------------------|--------------------------|
| Accumulative PD/CASE | Est Accumulative | Periodic                 |
| Cost:                | UNA Cost: \$300. | Review Results: Continue |

OBJECTIVE: To determine the effect of m-AMSA on acute leukemia or non-Hodgkin's lymphoma.

STUDY/ACCP/PROACH: Children with acute lymphoblastic leukemia, acute non-lymphoblastic leukemia, or non-hodgkin's lymphoma are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into this protocol as yet.

# Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 7994 Status: Terminated  
 TITLE: Therapy for Extraocular Retinoblastoma with Cyclophosphamide,  
 Vincristine, Adriamycin, and Irradiation

|                                |                               |
|--------------------------------|-------------------------------|
| Start Date: Aug 81             | Est Comp Date:                |
| Principal Investigator:        | Facility:                     |
| COL David A. Maybee, MC        | Tripler Army Medical Center   |
| Dept/Sec:                      | Associate Investigators:      |
| Pediatrics/Hematology-Oncology | COL Constance L. Hastings, MC |
| Key Words:                     |                               |
| Retinoblastoma                 |                               |

|                      |                  |                 |
|----------------------|------------------|-----------------|
| Accumulative MEDICAL | Est Accumulative | Periodic        |
| Cost:                | OMA Cost: \$300. | Review Results: |

OBJECTIVE: To determine the effectiveness of chemotherapy drugs in treating retinoblastoma and the effectiveness of combining radiation therapy and chemotherapy.

TECHNICAL APPROACH: Children with histologically proven extraocular retinoblastoma are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: This study was closed due to lack of patient accrual.



# Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWOG 8000 Status: Ingoing  
TITLE: The National Wilms' Tumor Study III

|                                  |                               |
|----------------------------------|-------------------------------|
| Start Date: Aug 81               | Est Comp Date:                |
| Principal Investigator:          | Facility:                     |
| COL David A. Naybee, MC          | Tripler Army Medical Center   |
| Dept/Sec:                        | Associate Investigators:      |
| Pediatrics/Pneumatology-Oncology | COL Constance E. Hastings, MC |
| Key Words:                       |                               |
| Wilms' tumor                     |                               |

|                     |                  |                          |
|---------------------|------------------|--------------------------|
| Accumulative MICASE | Est Accumulative | Periodic                 |
| Cost:               | OMA Cost: \$000. | Review Results: Continue |

OBJECTIVE: To determine the effect of chemotherapy on Wilms' tumor and to determine which chemotherapy schedule is best. This study is also designed to determine if radiation therapy is necessary when the tumor has been completely removed and in what dosage.

TECHNICAL APPROACH: Children diagnosed as having Wilms' tumor are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: Two patients have been registered.

Detail Summary Sheet

Date: 15 Jan 82 Prot No: SWH 1011 Status: Ongoing  
 TITLE: PCNU in Recurrent Childhood Medulloblastoma and Ependyoma.  
 Phase II

|                                |                               |
|--------------------------------|-------------------------------|
| Start Date: Aug 81             | Est Comp Date:                |
| Principal Investigator:        | Facility:                     |
| COL David A. Paybee, MC        | Tripler Army Medical Center   |
| Dept/Sec:                      | Associate Investigators:      |
| Pediatrics/Hematology-Oncology | COL Constance P. Hastings, MC |
| Key Words:                     |                               |
| Medulloblastoma                |                               |
| Ependyoma                      |                               |

|                            |                                   |                                   |
|----------------------------|-----------------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: \$300. | Periodic Review Results: Continue |
|----------------------------|-----------------------------------|-----------------------------------|

OBJECTIVE: To determine the effectiveness of the chemotherapy drug PCNU on medulloblastoma and ependyoma recurring after previous therapy.

TECHNICAL APPROACH: Children with medulloblastoma or ependyoma recurring following therapy are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: 10 patients have been entered into this protocol as yet.

# Detail Summary Sheet

Date: 15 Jan 82      Prot No: SWOG 8018      Status: Ongoing  
 Title: Evaluation of m-AMSA in children with solid tumors, Phase II

|                                |                              |
|--------------------------------|------------------------------|
| Start Date: Aug 81             | 1st Comp Date:               |
| Principal Investigator:        | Facility:                    |
| DR David A. Payton, MD         | Tripler Army Medical Center  |
| Dept/Sec:                      | Associate Investigators:     |
| Pediatrics/Hematology-Oncology | DR Constance L. Hastings, MD |
| Keywords:                      |                              |
| Solid tumor                    |                              |

|                       |                  |                          |
|-----------------------|------------------|--------------------------|
| Accumulative (TCR) ST | 1st Accumulative | Periodic                 |
| CR 1                  | CRA Cost: \$300. | Review Results: 1st time |

OBJECTIVE: To determine the effectiveness, in arm, of the investigational drug m-AMSA on solid tumor recurring after previous treatment.

TECHNICAL APPROACH: All patients with solid tumors in relapse who are 21 years of age or younger at the time of diagnosis, who are not eligible for protocols of higher priority and who are resistant to standard forms of therapy, will be eligible. Patients must have measurable tumor and a life expectancy of at least 4 weeks. Patients must have an HGB of  $\geq 10.0/\text{mm}^3$  and platelet count  $\geq 100,000/\text{mm}^3$ , unless patient has evidence of tumor invasion of the bone marrow. Normal renal (BUN  $\leq 20$  and creatinine  $\leq 1.2 \text{ mg/dl}$ ) and liver function tests pretherapy (bilirubin  $\leq 2 \text{ ng/dl}$ ) and normal serum potassium are required for all patients. Patients may have received no prior therapy with m-AMSA.

Treatment will be as outlined in the study protocol.

RESULTS: No patients have been entered into this protocol as yet.

# Detail Summary Sheet

|   |                                   |                                   |
|---|-----------------------------------|-----------------------------------|
| Date: 15 Jan 82   | Prot No: SWOC 8022                | Status: Ongoing                   |
| TITLE: Evaluation of Vindesine Twice Weekly Plus Prednisone and a Cross-over Study of Vindesine-Prednisone vs Vincristine-Prednisone in Children with Acute Lymphoblastic Leukemia, Hodgkin's Disease, and Non-Hodgkin's Lymphoma, Phase II-III |                                   |                                   |
| Start Date: Aug 81  | Est Comp Date:                    |                                   |
| Principal Investigator:   | Facility:                         |                                   |
| COL David A. Faybee, MC   | Tripler Army Medical Center       |                                   |
| Dept/Sec:   | Associate Investigators:          |                                   |
| Pediatrics/Hematology-Oncology  | COL Constance E. Hastings, MC     |                                   |
| Key Words:  |                                   |                                   |
| Leukemia, acute lymphoblastic   |                                   |                                   |
| Hodgkin's disease   |                                   |                                   |
| Lymphoma, non-Hodgkin's   |                                   |                                   |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: \$300. | Periodic Review Results: Continue |

OBJECTIVE: To compare the effectiveness of vindesine plus prednisone to the standard therapy of vincristine plus prednisone for the treatment of acute lymphoblastic leukemia, Hodgkin's disease, and non-Hodgkin's lymphoma.

TECHNICAL APPROACH: Children with acute lymphoblastic leukemia, Hodgkin's disease, and non-Hodgkin's lymphoma recurring on therapy and not shown to be resistant to vincristine and prednisone are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into this protocol as yet.

# Detail Library Sheet

Date: 15 Jan 82  
 Title: A Study of the Association of HLA Antigen Phenotype, Susceptibility to Malignant Diseases and Subsequent Survival Duration

Start Date: Aug 81  
 Principal Investigator: Dr. David A. Hader  
 Dept/Sec: Pediatrics/Hematology-Oncology  
 Key Words: leukemia, lymphocytic, acute, neuroblastoma  
 Location: 1001  
 Reviewer: Dr. Constant J. Bertrams, Jr.

|                            |                                   |                                     |
|----------------------------|-----------------------------------|-------------------------------------|
| Accumulative PECO/ST Cost: | 1st Accumulative OMA Cost: \$300. | Periodic Review Results: (continue) |
|----------------------------|-----------------------------------|-------------------------------------|

OBJECTIVE: To look at how cancer might be passed on in the genes.

TECHNICAL APPROACH: All newly diagnosed patients with ALL (black only) or neuroblastoma (white only) 15 years of age and under are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into the study as yet.

Detail Summary Sheet

Date: 15 Jan 82      Prot No: SLOG 8095      Status: Ongoing  
 TITLE: Multimodal Therapy of Metastatic Ewing's Sarcoma With Chemotherapy Plus Irradiation and Surgery (if feasible), Intergroup, Phase III

|                                |                               |
|--------------------------------|-------------------------------|
| Start Date: Aug 81             | Est Comp Date:                |
| Principal Investigator:        | Facility:                     |
| COL David A. Maybee, MC        | Tripler Army Medical Center   |
| Dept/Sec:                      | Associate Investigators:      |
| Pediatrics/Hematology-Oncology | COL Constance E. Hastings, MC |
| Key Words:                     |                               |
| Ewing's sarcoma                |                               |

|                            |                                   |                                   |
|----------------------------|-----------------------------------|-----------------------------------|
| Accumulative MEDCASI Cost: | Est Accumulative UFA Cost: \$300. | Periodic Review Results: Continue |
|----------------------------|-----------------------------------|-----------------------------------|

OBJECTIVE: To determine the effectiveness of an intensive 5-drug chemotherapy plan using Adriamycin, vincristine, cyclophosphamide, 5-fluorouracil, and actinomycin-D plus radiation therapy and surgery on metastatic Ewing's sarcoma.

TECHNICAL APPROACH: Children with metastatic Ewing's sarcoma are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: 70 patients have been entered into this protocol as yet.

Detail Summary Sheet

Project Number: 11781 Title: Interaction of Depressed Mood and Cognition as a Function of Age

Principal Investigator: [Name] [Address] [City, State, Zip]  
Sponsoring Agency: [Name] [Address] [City, State, Zip]  
Contract Number: [Number] [City, State, Zip]  
Project Period: [Start Date] to [End Date]  
Project Status: [Status]

Administrative History: [Date] [Event]  
[Date] [Event]  
[Date] [Event]

OBJECTIVES: As part of a larger program of research, it is proposed to use a retrospective chart study method to compare the decrement in cognition associated with depression in two age groups. Patients with a diagnosis of depression who are over 60 will be compared to patients with a similar diagnosis who are under 30. We specifically hypothesize a greater right hemisphere decrement in cognition as a function of depressed mood in the older group of patients.

TECHNICAL APPROACH: We plan to select all cases of patients with a diagnosis of depression in the last three years for whom intelligence testing was done, and who are either over 60 or under 30. Using the charts and psychological evaluations of these patients, we will construct an index to rate the severity of each patient's depression. Using this index, patients within each age group will be subdivided into severe and moderate depression groups. The subtest scores of each group will then be compared to the age-related norms that are published for each subtest. We will also form comparable groups made up of age-matched schizophrenic patients as comparison samples. The scores of each age group will also be compared to each other. Standard statistical techniques will be used to analyze the data.

PROCEDURE: This project currently awaits a list of names requested from Patient Administration Division.

# Final Report

Date: 3 Jan 82 Proj No: 8711 Title: The Military Child Psychiatry Outpatient Population: A Study of Demographics, Referral Patterns, and Diagnosis

|                           |                             |
|---------------------------|-----------------------------|
| Start Date: Nov 80        | 1st Corp Date               |
| Principal Investigator:   | Facility:                   |
| CPT Stephen N. Schilt, PC | Tripler Army Medical Center |
| Dept/Sec:                 | Associate Investigators:    |
| Dept of Psychiatry        |                             |
| Key Words:                |                             |

|                      |                   |             |
|----------------------|-------------------|-------------|
| Accumulative MEDCASI | 1st Accumulative  | Periodic    |
| Cost:                | OMA Cost: \$1090. | Review Res. |

**OBJECTIVES:** The purpose of this study is to assess demographic variables, referral patterns, and diagnostic categories of the clinic population.

**METHOD AND/OR DESIGN:** We reviewed all cases seen from January 1980 to June 1981. Information was obtained from standard intake forms completed by the patients' parents at the time of evaluation. Data on the following variables was compiled: age, sex, family constellation, ethnic background, educational status, previous psychiatric treatment, referral source, presenting symptoms, and final DSM III diagnosis of the child; parent's marital status, socioeconomic level, religion, and military status. The statistics compiled were compared to the statistics available on the military population of Hawaii.

**DISCUSSION:** The data of this report indicate that the incidence of child psychiatry referrals among Hawaii's military population differs little from the incidence reported by similar civilian clinics. The parenting situation was similar to the civilian community and was somewhat more stable than that reported by civilian clinics. The incidence of referral for each branch of service was quite similar, suggesting that interservice differences in military stresses do not play a role in child psychiatry referrals. The similarity between CHAMPUS and military clinic cases indicated that neither facility was servicing a sector of the military population distinct from the other. One must question whether the perpetuation and escalation of this duplication of services is the most cost-effective way of providing optimum child psychiatry services for the military. The economic and therapeutic issues are of such magnitude that this matter clearly warrants further investigation. Manuscript is in preparation.





## Initial Patient Report

Date: 15 Jan 12 ..... Project: 15778 ..... Page: 12 of 12  
11111

Clinical Indication: (If none, report "None")  
None

Referral Agency: (If none, report "None")  
None

Referring Physician: (If none, report "None")  
None

Department: (If none, report "None")  
None

Referring Hospital:

Initial-111-117

Accumulative Tl-201, 1st Accumulative Tl-201, 2nd Accumulative Tl-201  
None ..... (Tl-201 Cost: \$1.00) ..... Review by: (If none, report "None")

INDICATION: Since there is currently a moratorium on the use of I-131  
cisternography, it is our purpose to substitute Indium-111 DTPA for I-131  
in this procedure. Indium-111 DTPA (Diethylene Triamine Penta Acetic  
Acid) is presently in the third phase of investigation, and is not FDA  
approved. The agent will be used for the following: (1) Detection of herniation  
of the hydrocephalus; (2) Detection of noncommunicating hydrocephalus;  
(3) Aid in determining whether a cerebrospinal fluid shunt is in place;  
(4) Detection of rhinorrhea; and (5) Study of cerebrospinal  
fluid dynamics.

INDICATIONAL APPROACH: Radionuclide cisternography will be performed  
utilizing Indium-111 DTPA in those patients with the above-described  
clinical problems. Results obtained from these procedures will be  
compared with results obtained with earlier I-131 cisternography or with  
results obtained by other laboratories. The results will be correlated  
with the results of clinical findings, by roentgenographic studies and  
autopsy of surgical material where available to determine the accuracy  
and limitations of this procedure in each of the categories of clinical  
problems. Approximately 10-15 Indium-111 DTPA will be administered by  
intrathecal or intraventricular injection to patients referred to the  
Nuclear Medicine Laboratory for scintigraphic evaluation of cerebrospinal  
fluid pathways. The patients will meet the following criteria:  
(1) nonpregnant and over the age of 18 years unless special indications  
for study exist; (2) all will have either known or suspected alterations  
of cerebrospinal fluid flow. No subject without manifest or suspected  
disease will be studied.

RESULTS: Cisternography was performed on 1 patients during FY 11. The  
study has proved to be a useful adjunct in assessing the cerebrospinal  
fluid dynamics of all patients.

AD-A110 784

TRIPLER ARMY MEDICAL CENTER HI  
CLINICAL INVESTIGATION PROGRAM.(U)  
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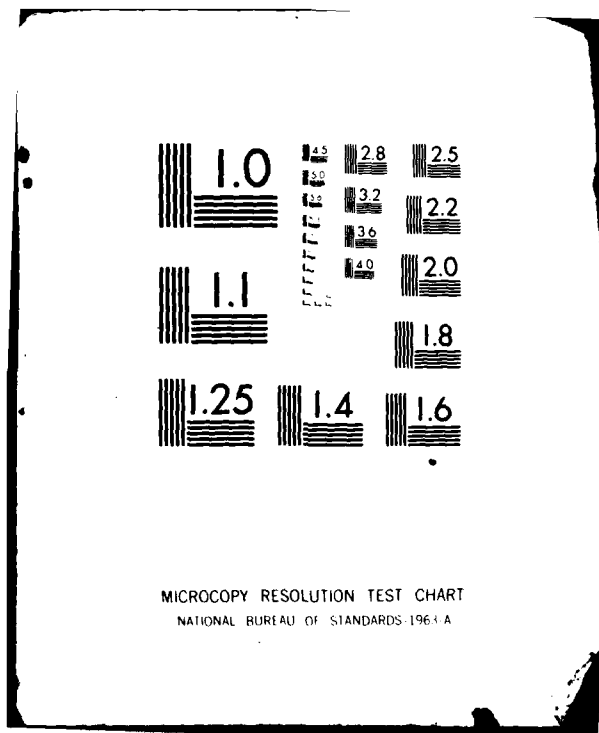
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Detail Summary Sheet

Date: 5 Jan 68 Prot No: 31/76 Status: Ongoing  
Title: Clinical Evaluation of Fluorescent Scanning of the Thyroid  
with Thallium-201

|   |                             |
|---|-----------------------------|
| Start Date: 1/Jan/76                    | Est. Comp. Date:            |
| Principal Investigator:                 | Facility:                   |
| Asst. Dir. K. Chacko, M.D.              | Tripler Army Medical Center |
| Dept/Sec:                               | Associate Investigators:    |
| Dept of Radiology, Nuclear Medicine Div |                             |
| Key Words:                              |                             |
| Fluorescent scanning                    |                             |
| Thallium                                |                             |

Cumulative Effort: 1st Cumulative Periodic  
Cost: \$9,100. 10% Cost: \$9,000. Review Results: Continue

OBJECTIVE: To determine the value of fluorescent thyroid imaging as compared with other modalities of thyroid imaging in the diagnosis and treatment of a variety of thyroid abnormalities.

DESIGN / METHOD: Dual studies are intended to involve both conventional thyroid scanning and fluorescent technique scanning in patients studied in the thyroid clinic at TAMC.

PROGRESS: No fluorescent scans were performed during FY 67, due to staff shortages. When personnel shortages are resolved, the project will again be resumed.

# Detail Summary Sheet

Date: 19 Jan 82 Prot No: 19/80 Status: pending  
 Title: Study of the Internal Mammary Lymph Nodes in Patients with  
 Inner Quadrant Breast Cancer

|                                    |                                  |
|------------------------------------|----------------------------------|
| Start Date:                        | Est Comp Date:                   |
| Principal Investigator:            | Facility:                        |
| Dr. Anna L. Chacko, MD             | Temple Army Medical Center       |
| Dept/Sec:                          | Associate Investigators:         |
| Dept of Radiology/Nuclear Medicine | Dr. Charles L. Hilner, MD        |
| Address:                           | 1400 North 12th Street, Room 211 |
| City/State:                        | Philadelphia, Pennsylvania 19104 |
| Other identifying subject column   | Dr. Howard J. Scheraga, MD       |
|                                    | Dr. Joseph A. Sparano, MD        |

|                    |                  |                       |
|--------------------|------------------|-----------------------|
| Cumulative PI/Case | Est Accumulative | Periodic PI/Case      |
| Cost: \$1200       | CFA Cost: \$200  | Review Period: 1 year |

**OBJECTIVES:** To determine if the presence or absence of lymph nodes in internal mammary nodes will make any difference in the morbidity or mortality of patients with breast cancer.

**TECHNICAL APPROACH:** Patients studied will be women who have proven or highly suspected breast carcinoma. No pregnant or lactating women, or those under 18 years of age will be administered the drug, unless the benefits to be gained by the study outweigh any risks as determined by the physician.

The antimony sulfide colloid will be obtained from the Union Carbide Corporation. Tagging will be performed locally with <sup>99m</sup>Tc.

cc 99m antimony sulfide colloid 400 uCi, will be injected into the posterior rectus sheath on the ipsilateral side. Two and one half to three hours later a camera will be utilized with a suitable collimator to image the internal mammary lymph nodes on the ipsilateral side.

**PROGRESS:** To date, approval for performing this study at WAC has not been granted by the Surgeon General's Human Subjects Research Review Board. Therefore, no progress on this study has been made.

## Retail Summary Sheet

|  |                |                 |
|--|----------------|-----------------|
| Date: 13 Jan 12  | Proj No: 20/01 | Status: Pending |
| Title: In Vivo Evaluation of Hepatobiliary System with $^{67}\text{Ga}$ DTPA |                |                 |

|                                     |                               |
|-------------------------------------|-------------------------------|
| Start Date: Jan 11                  | Est completion date: 2nd half |
| Principal Investigator:             | Facility:                     |
| Maxine Hughes, MD                   | Grinder Analytical Services   |
| Dept/EC:                            | Associate Investigator:       |
| Dept of Pathology/Medical Forensics |                               |
| EC: 10                              |                               |
| Grant/Other Agency:                 |                               |
|                                     |                               |

Procedural TFL/ASI Test: Accumulative TFL/ASI Test  
Costs: \$1000. Costs: \$1000. Review Results: Confirmed

OBJECTIVE: To demonstrate the safety and efficacy of  $^{99m}Tc$  in the detection of the in vivo evaluation of hepatobiliary system in patients suspected of having hepatobiliary disease.

INDICATIONS/APPRAISAL: The study will include patients suspected of having hepatobiliary disease which can include jaundice or any cause of right upper quadrant pain in which cholecystitis is suspected, or suspected mass lesions of the liver from other clinical or diagnostic studies. No pregnant women, lactating women, or persons under 18 years of age will be administered the drug, unless the benefits gained outweigh the risks, in the opinion of the investigator. The HIPA will be obtained in kit form from Union Carbide. Labeling will be done in the Nuclear Medicine Service by experienced personnel. The suggested dose range employed in the average (70 kg) patient is 2-15 mCi to be determined depending on the level of a recent serum bilirubin determination or clinical estimate of the degree of jaundice, if no serum bilirubin level is available.

RESULTS: Hepatobiliary scans were performed on 14 patients during FY 1981. The studies proved to be useful adjuncts in assessing hepatobiliary disease.

**T**

|  |                             |
|--|-----------------------------|
| Study No.: 169-1000                    | Investigator:               |
| Principal Investigator:                | Facility:                   |
| Reference: 1. Hrgs. 10                 | Tripler Army Medical Center |
| Report, Sec:                           | Associate Investigator:     |
| Dept of Radiology/Diagnostic Radiology | 001 50th Avenue, NE         |
| Approved:                              |                             |
| Signature of Sponsor:                  |                             |

**OBJECTIVE:** To study the size of the thoracic aorta by computerized tomography in the normal and abnormal patient.

**Computerized Tomography:** Many patients have computed tomography of the chest for various reasons, such as looking for mass lesions. In addition, for patients and patients referred to us for evaluation of the thoracic center, multiple measurements will be obtained in order to determine the chest wall. Chest radiography with the computed tomographic images will be used specifically to determine the difference between symptomatic and asymptomatic scoliosis.

FOOTNOTES: Thus far we have been obtaining and putting on negative films the computed tomographic images which will be recalled in the near future for evaluation and measurement, along with correlation with conventional radiographs.



# Detail Summary Sheet

Date: 22 Dec 81 Prot No: 15/80 Status: Terminated  
 TITLE: The National Study of Contrast Media Reactions

|                         |                             |
|-------------------------|-----------------------------|
| Start Date:             | 1st Comp Date:              |
| Principal Investigator: | Facility:                   |
| Col Raoul O. Jagen, MC  | Tripler Army Medical Center |
| Dept/Sec:               | Associate Investigators:    |
| Dept of Radiology       | Col Ronald L. Hilly, MC     |
| Keywords:               |                             |
| contrast media          |                             |

Accumulative: YES / YES Accumulative Periodic: YES  
 S331 OHS Cost: \$300. Review/Revised: 01/19/82

**OBJECTIVE:** To study the effects of premedication on the incidence of contrast media reactions.

**METHOD/ APPROACH:** This is a randomized, double-blind study involving participating medical centers across the U.S.A. As many as 100,000 patients receiving IVPs may eventually be enrolled in this study. The patients will be assigned to one of four groups: (1) 32 mg of Medrol in the evening preceding urography and 32 mg of Medrol again in the morning at least 2 hours before the IVP is given. (2) 32 mg of Medrol in the morning at least 2 hours before the IVP is given. (3) Placebo in the evening preceding urography and again in the morning at least 2 hours before the IVP is given. (4) Placebo in the morning at least 2 hours before the IVP is given. The intravenous pyelogram will be carried out with the usual technique employed in each institution. Appropriate medications to treat reactions, if they occur, will be immediately available.

**PROGRESS:** Because of the long delay in obtaining approval and the problems with communication between San Diego and Honolulu, this study was terminated prior to starting. No patients were studied.

# Detail Summary Sheet

Date: 13 Dec 81      Prot No: 39/78      Status: Pending  
 Title: The Value of Gallium Scans in Determining Prosthetic Aortic  
 Graft Infections in Canines

|                                  |                             |
|----------------------------------|-----------------------------|
| Start Date: Aug 78               | 1st Comp Date: Sept 81      |
| Principal Investigator:          | Facility:                   |
| Dr. Charles A. Andersen, MC      | Tripler Army Medical Center |
| Dept/Sec:                        | Associate Investigators:    |
| Dept of Surgery/Vascular Surgery | Dr. Anna L. Grcko, MC       |
| San Antonio                      | Dr. Clayton L. Lofgren, MC  |
| Project Graft                    | Dr. Carroll Ray Latham, MC  |
| Gallium Scans                    |                             |

|                    |                    |                        |
|--------------------|--------------------|------------------------|
| Accumulative HUCAI | 1st Accumulative   | Periodic               |
| Test:              | OMA Costs: \$2000. | Review Length: 30 min. |

Summary: To evaluate the method of diagnosing a graft infection.

Summary: Gallium scans of aortic aortic graft is placed in the aorta. The grafts are not placed in a control group or given a dose of 100 mCi of Gallium-67 to infect the graft. After several periods of time, the grafts are scanned with gallium scans to determine whether or not the gallium scans accurately predict the presence of an infection. After an appropriate time, the animals are sacrificed and the grafts are examined grossly and histologically and bacteriologically for evidence of a graft infection.

Summary: There has been no progress made in the project since the last report. It was previously determined that more control studies were needed, and this is planned for the next fiscal year.

# Detail Summary Sheet

Date: 10 Dec 77 Prot No: 11/70 Status: Completed  
 Title: Audiovisual Counseling of Preoperative Patients

Start Date: Jan 80 Est Comp Date:  
 Principal Investigator: Facility:  
 Dr Charles A. Andersen, Jr. Tripler Army Medical Center  
 Dept/Sec: Associate Investigators:  
 Dept of Surgery  
 Keywords:  
 Audiovisual counseling

|                      |                  |                 |
|----------------------|------------------|-----------------|
| Accumulative NPACASI | Est Accumulative | Periodic        |
| Cost:                | OWA Cost: 500.   | Review Results: |

OBJECTIVE: To evaluate the effectiveness of an audiovisual tape, together with a verbatim transcript of the audio portion of the tape, in preparing patients for an operation.

METHOD/DESIGN: All patients undergoing elective cholecystectomy will be counseled by the operating surgeon utilizing the format that they have previously used. In addition to the routine counseling, 10 percent of these surgeons' (randomly selected) patients will be shown a videotape on gallbladder surgery by a nurse who is not involved in their care. These patients will then be given a printed transcript of the tape. The nurse will have all cholecystectomy patients complete a questionnaire in regard to attitudes. After each patient in the study has been discharged, the nurse will review the chart and record pertinent data. All patients will be asked to complete a retrospective questionnaire.

STUDY: This study is to be conducted as a joint project with the senior investigator, with physicians from several hospitals participating. The data will be collected, compiled, and stored for 12 months. At the conclusion of the study the data analysis will be conducted in two parts. Initially, a descriptive checklist-purchase of the data will be prepared and analyzed.

RESULTS: The clinical work has been completed at Tripler Army Medical Center, Straub Clinic, Queen's Medical Center, and Kaiser Hospital. The data is currently being analyzed by physicians and statisticians, and appropriate papers will be prepared.

# Small Intestine Project

Date: 23 Dec 81      Proj No: 6/77      Status: Ongoing  
 TITLE: Regrowth of Small Intestinal Mucosal Surface Area

|                                  |                             |
|----------------------------------|-----------------------------|
| Start Date: Nov 76               | Est. to Complete: 10/82     |
| Principal Investigator:          | Facility:                   |
| COL Peter J. Garcia, MC          | Tripler Army Medical Center |
| Dept/Sec:                        | Associate Investigators:    |
| Dept of Surgery/General Surgery  | CPT Clayton L. Radick, MC   |
| Keywords:                        |                             |
| Small Intestinal Mucosal Surface |                             |
| Report                           |                             |
| Accumulative MUCASS              | Est Accumulative            |
| 1981                             | 1981 (est. 50%)             |
|                                  | Periodic                    |
|                                  | Review Results: Ongoing     |

**OBJECTIVE:** To explore methods of increasing small intestinal mucosal absorptive area following massive resections, and to determine the mechanical feasibility and functional results of certain specific techniques.

**JUSTIFICATION:** Based on previous successful studies in dogs and rats, growth of neogut on the serosal surface of the colon and small intestine will be to (1) perform similar studies in the pig, which has a gastrointestinal tract and physiologic responses similar to man, and (2) attempt growth of neogut on the peritoneal surface of the abdominal wall. This would mirror the clinical circumstance if no suitable colonic recipient site were available. Five pigs will undergo laparotomy under general anesthesia and each animal will have two grafts placed. After varying periods of time (maximum 8-12 weeks) at a second procedure, these grafts could be harvested and intestinal continuity would be restored.

**BACKGROUND:** An initial series of dogs has provided us with the following data: (1) A new small intestinal mucosa will grow across the serosa of the colon under these circumstances; and (2) the graft is mechanically functional, i.e., food is propelled in a relatively normal fashion through the graft, and these animals do not develop small intestinal obstruction. We have been unable to work on this project in FY 81. With increased staff, we hope to complete the study in FY 82.

This project won second prize in the Hawaii American College of Surgeons Annual Essay Contest, Honolulu, Hawaii, June 1977. Presented to the William Beaumont Gastrointestinal Symposium, El Paso, Texas, March 1978.

## Detail Summary Table

|                 |                |                 |
|-----------------|----------------|-----------------|
| Date: 14 Jan 82 | Proc No: 25/78 | Status: Pending |
|-----------------|----------------|-----------------|

7777:

### Microvascular Training Protocol

|                                 |                             |
|---------------------------------|-----------------------------|
| Start Date: May 76              | Est Comp Date: Indefinite   |
| Principal Investigator:         | Facility:                   |
| Dr. Strawford L. Jones, M.D.    | Tripler Army Medical Center |
| Dept/Sec:                       | Associate Investigators:    |
| Dept of Surgery/Plastic Surgery |                             |
| City/State:                     |                             |
| Indiana/Henry                   |                             |

Accumulative TSS: 1st Accumulative Period:

File # \_\_\_\_\_ Date Received \_\_\_\_\_ Review Results \_\_\_\_\_ Status \_\_\_\_\_

objectives: To develop and maintain microvascular surgical techniques among the plastic surgery service staff. TAUC are to be utilized for general surgery and other specialty residents with the knowledge of microvascular anastomosis.

Practical approach: To divide and reanastomose the correct internal artery and vein of rats. The pair of vessels per week will undergo evaluation of patency is planned. Later expansion to other models such as the rabbit ear and dog intestine and vas deferens is possible.

PROGRESS: Until the arrival of a second plastic surgeon in June of 1961 the clinic workload precluded weekly laboratory sessions. Since June the workload has lessened and the project will soon be continued on a regular basis.

## Retail Pharmacy Since 1900.

Date: 15 Jan 87 Prot No: 77700 Status: Open  
Title: Patterns of Injury in Pterocyclops

|                                   |                             |
|-----------------------------------|-----------------------------|
| Start Date: Jul 10                | ISI Template                |
| Principal Investigator:           | Facility:                   |
| Dr. Gerald Q. Greenfield, Jr., MD | Tripler Army Medical Center |
| Dept/Sec:                         | Associate Investigators:    |
| Dept of Surgery/Orthopedic 'vc    |                             |
| Key Words:                        |                             |
| Summary, History:                 |                             |

|                   |  |
|-------------------|--|
| Cumulative HFO-91 | 1st Cumulative Periodic                    |
| Cost = \$786.00   | HFA Cost = \$385.00; Prior results - none. |

**OBJECTIVE:** to define the circumstances surrounding a drug resistance problem.

Additional information regarding will be obtained from a comparison of the above with the current year. This will include the number of years of intercycle, and injury produced as well as length of cycle of fluctuation or date limitation.

**HYPHESIS:** This study comprises review of 300 patients admitted to hospital for injuries sustained in motorcycle accidents over a 12-month period. All patients were cared for by the surgical house staff of A&G and operative procedures were performed by the house staff with attending staff supervision. Most of the patients were under 30 years old and lower extremity fractures occurred most frequently. Patients were hospitalized for an average of 6 weeks. An effort is being made to relate length of motorcycle ownership and riding experience to the potential for significant injury.

An abstract has been accepted for presentation at the Resident Center  
Once, American Orthopaedic Association, Washington, D. C. April 1964.

1. *Chlorophyll a* (Chl *a*)

1. The first step is to identify the problem or question that needs to be answered. This involves understanding the context and the specific requirements of the task.

2. The second step is to gather relevant information and data. This can involve research, consultation with experts, or collecting data from various sources.

3. The third step is to analyze the information and data collected. This involves identifying patterns, trends, and relationships that can help in understanding the problem.

4. The fourth step is to develop a solution or answer. This involves applying the knowledge and skills gained from the previous steps to create a plan or strategy that addresses the problem.

5. The fifth step is to implement the solution and evaluate the results. This involves putting the plan into action and monitoring the progress to ensure that the problem is solved effectively.

Sentative, not accumulative. Periodic  
cost. SIFO. Review fee.

Further studies will define the types of patients seen in the ER and the effect of the new program. Also studied will be the causes for the increase in the ER waiting.

Medical records are therefore, will be used to collect information on the medical records of these patients will be reviewed and compared in an attempt to better understand the relationship between the two groups in an effort to better understand the relationship between the two groups.

There was a 10% collection rate for the personal information of the 1000 individuals from the questionnaires solicited. The responses were sorted to indicate the type of back pain. These were divided into four categories: sitting, standing, sports or exercising, and unknown. The group of 1000 included a small amount of persons (10%) however, listed the cause of their back pain as "other" but did not state whether or not even this was a cause. The cause of the back pain was attributed to rest or specific physical therapy or self physical therapy in the form of flexion exercises for low back pain. The majority of respondents were females.

Presented at the 12th meeting of the Society of Military, Air and  
Space Medicine, London, 13-15 Nov 1989.

Effect of Vastus Medialis and Vastus Lateralis on the Patella

|                        |                                       |
|------------------------|---------------------------------------|
| Principal Investigator | Dr. Gerald C. Freudenfeld, D.O., M.D. |
| Co-Investigator        | Dr. J. H. Triplett, M.D.              |
| Associate Investigator | Dr. J. H. Triplett, M.D.              |
| Co-Investigator        | Dr. J. H. Triplett, M.D.              |
| Co-Investigator        | Dr. J. H. Triplett, M.D.              |
| Co-Investigator        | Dr. J. H. Triplett, M.D.              |

Objective: To determine the effect of vastus medialis and vastus lateralis on the course of chondroplasty.

Methods: To determine the effect of vastus medialis and vastus lateralis on the course of chondroplasty.

Results: The study included 10 patients who had undergone chondroplasty of the knee joint. The study was designed to determine the effect of vastus medialis and vastus lateralis on the course of chondroplasty. The study was divided into two groups. The first group was placed on a program of physical therapy and the second group was placed on a program of physical therapy and electrical stimulation. The study was conducted over a six-week period. At the end of the study, a second set of roentgenographs will be obtained. Those patients whose initial study was abnormal, a second study will be performed.

Conclusions: Data collection beginning. Plan to present results to the American Academy of Orthopaedic Surgeons Meeting 1987 and to the American Academy of Orthopaedic Surgeons Meeting in 1988.



Continued on p. 1000

1977, Vol. 11, No. 1, pp. 1-10. (1977) 9 pages, 1 figure.  
11. Intracapsular Implantation of Intraocular Lenses

|                                 |                                 |
|---------------------------------|---------------------------------|
| 1977, Vol. 11, No. 1, pp. 1-10. | 1977, Vol. 11, No. 1, pp. 1-10. |
| 1977, Vol. 11, No. 1, pp. 1-10. | 1977, Vol. 11, No. 1, pp. 1-10. |
| 1977, Vol. 11, No. 1, pp. 1-10. | 1977, Vol. 11, No. 1, pp. 1-10. |
| 1977, Vol. 11, No. 1, pp. 1-10. | 1977, Vol. 11, No. 1, pp. 1-10. |

1977, Vol. 11, No. 1, pp. 1-10. (1977) 9 pages, 1 figure.  
12. Intracapsular Implantation of Intraocular Lenses

1977, Vol. 11, No. 1, pp. 1-10. (1977) 9 pages, 1 figure.  
13. Intracapsular Implantation of Intraocular Lenses

1977, Vol. 11, No. 1, pp. 1-10. (1977) 9 pages, 1 figure.  
14. Intracapsular Implantation of Intraocular Lenses

1977, Vol. 11, No. 1, pp. 1-10. (1977) 9 pages, 1 figure.  
15. Intracapsular Implantation of Intraocular Lenses

Retail Sold dry Sheet

1111: Radioisotope Scanning in the Diagnosis of Bone and Joint Infections

|                                   |                             |
|-----------------------------------|-----------------------------|
| Start Date: Sep 80                | Est. Completed:             |
| Principal Investigator:           | Facility:                   |
| Col. Edmund C. Tondry, Jr., M.D.  | Tripler Army Medical Center |
| Col/Sec:                          | Associate Investigator:     |
| Dept. of Surgery/Orthopedic Svcs. |                             |
| Location:                         |                             |
| Research Topic: Acute Inj.        |                             |
| Infections, Orthopedic            |                             |

|               |                   |
|---------------|-------------------|
| Relative MFCM | Estimative Period |
| 1970-1980     | Review until 1980 |

It is also important to evaluate the usefulness of radiometric methods in the early diagnosis of cardiac infarctions, also. In heart transplantation, the use of radiotracer scanning should be explored early and thoroughly in the future.

**STATISTICAL ANALYSIS:** Orthopedic department files from 1977 through 1982 will be reviewed and patients with the diagnoses of septic arthritis, disitis, and osteomyelitis will be evaluated. X-rays and scans were performed will be analyzed in an attempt to evaluate the ultimate diagnosis as identified by clinical, radiographic, and radioisotope examination.

1. Cause: The project is terminated due to the departure of the principal investigator.

Table 1. The results of the first three steps of the regression analysis

[illegible]

Cumulative H<sub>2</sub>O<sub>2</sub> test: Cumulative Sterilant  
 test: (H<sub>2</sub>O<sub>2</sub> test) (Sterilant results: Sterilant

**OBJECTIVE:** To evaluate present diagnostic and therapeutic procedures for specific arthritis, including the identification of specific pathogens, causative organisms, and other contributing etiologic factors based upon the extensive experience at Tripler Army Medical Center.

© 2004 Blackwell Publishing Ltd, *Journal of Internal Medicine* 255: 111–118

Figure 1. The effect of the concentration of the *Agaricus bisporus* spores on the growth of *Agaricus bisporus* and *Agaricus bisporus* spores on the growth of *Agaricus bisporus* spores.

Detail Summary Sheet

Date: 5 Jan 67 Prot No: 14/66 Status: Terminated  
Title: Partial Cystectomy Followed by Cholecystectomy and Augmentative  
Cystoplasty with the Gallbladder in Dogs

|                              |                             |
|------------------------------|-----------------------------|
| Start Date: Jun 60           | 1st Comp Date:              |
| Principal Investigator:      | Facility:                   |
| Dr George G. Pygatt, MC      | Tripler Army Medical Center |
| Dept/Sec:                    | Associate Investigators:    |
| Dept of Surgery/Urology      |                             |
| Key Words:                   |                             |
| Cystoplasty, bladder defects |                             |

Objective: (1) (A) 1st Accumulative Periodic  
(2) (A) 1st Accumulative Periodic (3) (A) 1st Accumulative Periodic  
(4) (A) 1st Accumulative Periodic (5) (A) 1st Accumulative Periodic  
Purpose: To determine the feasibility of cholecystectomy defects with  
cystoplasty of gallbladder.

Technical Approach: Gallbladders have been used to correct surgical  
defects in the domes of urinary bladders in eight dogs.

Remarks: This project is terminated due to the departure of the  
principal investigator.

## Detail Summary Page

Author: [blank] Title: [blank] Date: 5/61 [blank]  
[blank] Comparison: [blank] [blank] [blank] [blank]

Author: [blank] Title: [blank] Date: [blank]  
Principal Investigator: [blank] Facility: [blank]  
Co-Investigator: [blank] Title: [blank]  
Co-Investigator: [blank] Title: [blank]  
Co-Investigator: [blank] Title: [blank]  
Co-Investigator: [blank] Title: [blank]

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Abstract: [blank] Title: [blank] [blank] [blank] [blank]  
[blank] [blank] [blank] [blank] [blank] [blank] [blank] [blank]

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1. *Chlorophyll a* and *Chlorophyll b* were determined by the method of Lichtenthaler and Sponholz (1980).

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*Journal of Management Education* 30(6)p.789-804  
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the 1990s, the number of people in the world who are under 15 years of age is expected to increase from 1.1 billion to 1.5 billion. The number of people aged 65 and over is expected to increase from 200 million to 400 million. The number of people aged 15 and over is expected to increase from 3.5 billion to 4.5 billion. The number of people aged 15 and over is expected to increase from 3.5 billion to 4.5 billion. The number of people aged 15 and over is expected to increase from 3.5 billion to 4.5 billion.

patients will be treated by electrical stimulation of the paraspinal muscles. The number of electrodes and pulse frequency will be greater than the others will be offered additional treatment if no improvement will be obtained. Standardized x-rays will be taken before and after treatment. Two stimulation electrode pairs placed at the lateral curvature of the apex of curvature and the muscles adjacent forming a 100 microsecond pulse at a rate of 10 pulses per second or 600 milliamperes, a volts is utilized. An x-ray will be taken documenting improvement of the curve with stimulation. After initial familiarization, stimulation is used nightly during the normal hours of sleep. Follow-up will be obtained two weeks following treatment and at three- week intervals thereafter. The electrical equipment will be eliminated at each clinic visit. Patients will be treated until full compliance has been obtained using standard radiographic criteria. Reasons for non-compliance or failure of patient compliance will also be grounds for termination of treatment.

Therefore, ten patients from TAU have currently been selected for the International Study on Lateral Electrical Stimulation. Six of these patients were transferred due to military orders to San Carlos and the remaining four followed by physicians at the University of California at Irvine, who are also participating in this study. We have been able to conduct the procedure in all but one patient that has a severe postoperative paralysis that would have been expected from a lesion of the motor tracts. The one patient who has a lesion of the motor tracts has a severe chronic paraparesis and is not able to actively move his legs despite the 10 days of his participation. All of the

International Atomic Energy Agency (IAEA) for the purpose of  
for facilities.

IAEA has been working with the Government of the United States  
to ensure that the IAEA's role in the field of nuclear energy  
is not restricted to the production of nuclear energy for  
peaceful purposes only.

IAEA has been working with the Government of the United States  
to ensure that the IAEA's role in the field of nuclear energy  
is not restricted to the production of nuclear energy for  
peaceful purposes only. IAEA will continue to receive  
information from the United States and will continue to  
protect the interests of the United States.





Date: 12/20/77 Proj No: 50770 Status: Not Indexed  
 Title: T Cell Antigenicity of Canine Tunica Alluinea

|                            |                                |
|----------------------------|--------------------------------|
| Start Date: Aug 76         | Est Completion: 12/77          |
| Principal Investigator:    | Facility:                      |
| Dr. Richard L. Tuttle, Jr. | Tripler Army Medical Center    |
| Co-Investigator:           | Associate Investigator:        |
| Dr. J. L. Harty/Immunology | Dr. Edward L. Smith/Immunology |
| Dr. J. L. Harty            |                                |
| Dr. J. L. Harty            |                                |

Abstract: This project was a cumulative from a project which was terminated in 1977. The project was a study of the immunogenicity of canine tunica alluinea. The project was terminated due to lack of time on the part of the investigators.

Abstract: This project was a cumulative from a project which was terminated in 1977. The project was a study of the immunogenicity of canine tunica alluinea. The project was terminated due to lack of time on the part of the investigators.

ABSTRACT: This project is terminated due to lack of time on the part of the investigators.



# Detail Summary Sheet

Date: 14 Jan 82 Prot No: 72/77 Status: Terminated  
 Title: Teflon Injection Indications

|                                |                             |
|--------------------------------|-----------------------------|
| Start Date: Aug 78             | 1st Review Date: Indefinite |
| Principal Investigator:        | Facility:                   |
| Col. Thomas L. Van Sled, M.D.  | Lepton Army Medical Center  |
| Dept Sec:                      | Associate Level Doctor      |
| Dept of Surgery/Otolaryngology | 110 Donald Ave, York, PA    |
| Keywords:                      |                             |
| After Injection                |                             |

|                       |                  |                           |
|-----------------------|------------------|---------------------------|
| Accumulative FIDUCASE | 1st Accumulative | Periodic                  |
| 500                   | OMA Cost: \$300. | Review Results: Terminate |

**INDICATIONS:** To participate in expanded clinical trials of Ethicon Polytef Paste for Injection for the following clinical indications: the selected treatment of patients with velopharyngeal insufficiency and/or abnormally patent eustachian tubes.

**TECHNICAL APPROACH:** The protocol will follow the clinical study group proposals. Patients will originate in the ENT Clinic. Only patients who have not responded to conventional treatment modalities will be considered. The procedure with its possible risks will be explained to the patient, as well as its investigative nature. If the patient agrees to participate, the case history will be forwarded for consideration to the study group who will furnish the necessary material (Teflon). Patients will require hospitalization for approximately 1-3 days for the surgical procedure which will be done under appropriate anesthesia. Surgery time will be 30 minutes to one hour. The patient's will continue to be followed on an outpatient basis for a minimum of 90 days as required by the protocol.

**DISPOSITION:** The project is terminated as ETHICON Inc. (Ethicon) no longer provides Polytef Paste for this use.

2010 年 12 月 10 日

1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2159, 2160, 2161, 2162, 2163, 2164, 2165, 2166, 2167, 2168, 2169, 2170, 2171, 2172, 2173, 2174, 2175, 2176, 2177, 2178, 2179, 2180, 2181, 2182, 2183, 2184, 2185, 2186, 2187, 2188, 2189, 2190, 2191, 2192, 2193, 2194, 2195, 2196, 2197, 2198, 2199, 2200, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2218, 2219, 2220, 2221, 2222, 2223, 2224, 2225, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238, 2239, 2240, 2241, 2242, 2243, 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2255, 2256, 2257, 2258, 2259, 2260, 2261, 2262, 2263, 2264, 2265, 2266, 2267, 2268, 2269, 2270, 2271, 2272, 2273, 2274, 2275, 2276, 2277, 2278, 2279, 2280, 2281, 2282, 2283, 2284, 2285, 2286, 2287, 2288, 2289, 2290, 2291, 2292, 2293, 2294, 2295, 2296, 2297, 2298, 2299, 2300, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2308, 2309, 2310, 2311, 2312, 2313, 2314, 2315, 2316, 2317, 2318, 2319, 2320, 2321, 2322, 2323, 2324, 2325, 2326, 2327, 2328, 2329, 2330, 2331, 2332, 2333, 2334, 2335, 2336, 2337, 2338, 2339, 2340, 2341, 2342, 2343, 2344, 2345, 2346, 2347, 2348, 2349, 2350, 2351, 2352, 2353, 2354, 2355, 2356, 2357, 2358, 2359, 2360, 2361, 2362, 2363, 2364, 2365, 2366, 2367, 2368, 2369, 2370, 2371, 2372, 2373, 2374, 2375, 2376, 2377, 2378, 2379, 2380, 2381, 2382, 2383, 2384, 2385, 2386, 2387, 2388, 2389, 2390, 2391, 2392, 2393, 2394, 2395, 2396, 2397, 2398, 2399, 2400, 2401, 2402, 2403, 2404, 2405, 2406, 2407, 2408, 2409, 2410, 2411, 2412, 2413, 2414, 2415, 2416, 2417, 2418, 2419, 2420, 2421, 2422, 2423, 2424, 2425, 2426, 2427, 2428, 2429, 2430, 2431, 2432, 2433, 2434, 2435, 2436, 2437, 2438, 2439, 2440, 2441, 2442, 2443, 2444, 2445, 2446, 2447, 2448, 2449, 2450, 2451, 2452, 2453, 2454, 2455, 2456, 2457, 2458, 2459, 2460, 2461, 2462, 2463, 2464, 2465, 2466, 2467, 2468, 2469, 2470, 2471, 2472, 2473, 2474, 2475, 2476, 2477, 2478, 2479, 2480, 2481, 2482, 2483, 2484, 2485, 2486, 2487, 2488, 2489, 2490, 2491, 2492, 2493, 2494, 2495, 2496, 2497, 2498, 2499, 2500, 2501, 2502, 2503, 2504, 2505, 2506, 2507, 2508, 2509, 2510, 2511, 2512, 2513, 2514, 2515, 2516, 2517, 2518, 2519, 2520, 2521, 2522, 2523, 2524, 2525, 2526, 2527, 2528, 2529, 2530, 2531, 2532, 2533, 2534, 2535, 2536, 2537, 2538, 2539, 2540, 2541, 2542, 2543, 2544, 2545, 2546, 2547, 2548, 2549, 2550, 2551, 2552, 2553, 2554, 2555, 2556, 2557, 2558, 2559, 2560, 2561, 2562, 2563, 2564, 2565, 2566, 2567, 2568, 2569, 2570, 2571, 2572, 2573, 2574, 2575, 2576, 2577, 2578, 2579, 2580, 2581, 2582, 2583, 2584, 2585, 2586, 2587, 2588, 2589, 2590, 2591, 2592, 2593, 2594, 2595, 2596, 2597, 2598, 2599, 2600, 2601, 2602, 2603, 2604, 2605, 2606, 2607, 2608, 2609, 2610, 2611, 2612, 2613, 2614, 2615, 2616, 2617, 2618, 2619, 2620, 2621, 2622, 2623, 2624, 2625, 2626, 2627, 2628, 2629, 2630, 2631, 2632, 2633, 2634, 2635, 2636, 2637, 2638, 2639, 2640, 2641, 2642, 2643, 2644, 2645, 2646, 2647, 2648, 2649, 2650, 2651, 2652, 2653, 2654, 2655, 2656, 2657, 2658, 2659, 2660, 2661, 2662, 2663, 2664, 2665, 2666, 2667, 2668, 2669, 2670, 2671, 2672, 2673, 2674, 2675, 2676, 2677, 26

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 Principal Investigator:  
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 Facility:  
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 Associate Administrator  
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|   |                        |
|---|------------------------|
| Approved by the Department of Administrative Services | Reviewed               |
| Date: 09/04/2009                                      | Review Result: Pending |

direction. To present an instructional course on the procedure, an analysis of the collaborative relationship approach will be needed, a description of the instructional unit on the procedure.

**Abstract ZINKM01:** The combination rhinoplasty approach is a relatively unfamiliar surgical approach to the nasal infrastructure that allows many reconstructive procedures to be performed under direct vision. The project was undertaken to explore the indications for its use, as well as provide training or information on the performance of the procedure.

DISCUSSION: The technique has been used in selective cases for approximately 1 year by the investigators. A course of instruction on the procedure illustrated by double slide projection and 3/4" video tape has been developed and presented by invitation on several occasions. A collaborative study with the Neurosurgery Service is underway comparing this approach with the sublabial approach for transseptal transsphenoidal pituitary surgery. A teaching video tape is in development. An invitation has been received to continue presenting the instruction course in its present format at the American Academy of Otolaryngology-Head and Neck Surgery Annual Meeting, instruction course program, for the next 3 years.

Presented at the American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, Louisiana, Jan. 1961.

# Ureterogastrostomy

Author: [Name] Date: 10/10/60 Project: [Project Name]  
 Title: Ureterogastrostomy for Urinary Diversion

Principal Investigator: [Name]  
 Sponsor: [Name]  
 Title of Project: [Title]  
 Date: [Date]  
 Location: [Location]  
 Objectives: [Objectives]

Accumulative NED/ASE 1st Accumulative Periodic  
 SNA Cost: \$7200. Review Result: [Result]

**OBJECTIVE:** To investigate the feasibility of using gastric pouch as an alternative conduit for urinary diversion and as a substitute for the urinary bladder. To compare the advantages/disadvantages of gastric conduit to the present methods of urinary diversion.

**TECHNICAL APPROACH:** The technical approach of this project is to make a midline laparotomy incision. A gastric pouch is created on the greater curvature of the stomach with vascular pedicle from the left gastropiploic artery. The ureter is then diverted into the gastric pouch and the gastric pouch is brought to the skin as a cutaneous urinary stoma. Preoperative and postoperative renal function, electrolytes, and gastrin are assessed.

**RESULTS:** Nine dogs have undergone ureterogastrostomy. Of these, there were two deaths, one resulting from anastomotic leakage, and one from bilateral hydronephrosis with renal failure. Of the dogs developed unilateral ureterogastrostomy, six of these resulting from stenting. Four dogs had successful results and two additional dogs to the study.

10. *Notes on the 1987 Survey*

TABLE 1. Mean (SD) number of eggs per female for *Stomatopoda* and *Decapoda* in the 1980s and 1990s. *Stomatopoda* = 134 females of *Stomatopoda* sp. collected in 1980; *Decapoda* = 134 females of *Decapoda* sp. collected in 1980.

|                         |                               |
|-------------------------|-------------------------------|
| Start Date: Per #1      | End Date: 12/1/84             |
| Principal Investigator: | Facility:                     |
| Dr. David E. Gashi, ISC | Tripler Army Medical Center   |
| Reprinted:              | Associate Investigators:      |
| Dr. James H. Gashi      | GP: Carroll L. Peterson, M.D. |
| Comments:               |                               |
| Orthodontic X-rays      |                               |

|                            |                                    |                                  |
|----------------------------|------------------------------------|----------------------------------|
| Accumulative PEPCASE Cost: | Est Accumulative OMA Cost: \$1500. | Periodic Review Results: Conting |
|----------------------------|------------------------------------|----------------------------------|

OBJECTIVE: To examine the feasibility of determining strain differences of *Staphylococcus aureus* by analysis of gas liquid chromatography (GLC) fatty acid profiles. If strain differences can be demonstrated, phage-typologic analysis can be simplified, and rapid laboratory analysis can be made without resorting to time-consuming phage typing.

**TECHNICAL APPROACH:** Strains of *S. aureus* will be collected and identified to species by the Microbiology Section, Department of Pathology, WAC. Organisms will be prepared for gas chromatographic analysis using a modification of the method of Ohashi. Briefly, whole cell will be prepared for GLC analysis using tetramethylammonium hydroxide by a very simple procedure requiring less than two hours for the preparation of a dozen samples. The organisms will grow on several media formulations to determine which media will enhance lipid accumulation by the strains being examined. Gas chromatographic data will be subjected to pattern analysis and strain differences will be defined in terms of observed variations.

FOOTNOTES: Because of higher priority being given other work, further progress in the laboratory has not been accomplished. However, a means by which oxidation of materials can be prevented has been devised, and manipulation of cell lipid composition is planned.

# REPORT OF WORK

Date: Jan 14, 1967 Project No: 7/67 Title: Studies on the Bacteriology of Acid Fast Isolates Recovered from Leprosy Patients

|                           |                             |
|---------------------------|-----------------------------|
| Start Date: Nov 66        | Est Comp Date:              |
| Principal Investigator:   | Facility:                   |
| Dr. David E. Ghosh, MSc   | Tripler Army Medical Center |
| Dept/Sec:                 | Associate Investigators:    |
| Health Services Command   |                             |
| Fort Monmouth             |                             |
| Project:                  |                             |
| Accumulative MEDCASP Test | Accumulative Periodic       |
| Test:                     | Review Results:             |
| OMA Cost: \$500.          |                             |

OBJECTIVE: To study the colonial dissociation and selected bacteriological characteristics of bacteria claimed to be the etiologic agent of leprosy.

MATERIALS/METHODS: *M. leprae*, the etiologic agent of human leprosy, has not yet been accepted as growing on cell-free media. The above two isolates were recovered from the tissues of leprosy patients and inoculated into a new hyaluronic acid based medium by Dr. Glat F. Shostack, an internationally recognized authority on leprosy. The medium was demonstrated by him to be immunologically reactive in a serological test specific for *M. leprae*. Approximately 60 standardized determinative tests selected from international collaborative studies on the taxonomy of the mycobacteria were performed on these two isolates plus a selected number of reference strains from the Trudeau collection. These two isolates were also tested in a seroagglutination procedure which has been developed to identify type-specific antigens of the mycobacterium *Mycobacterium avium-intracellulare-scrofulaceum* complex (MAIS). Careful examination of the colony morphology on translucent agar indicated that both colonies have smooth and rough forms and that either smooth or rough forms will spontaneously give rise to both forms.

RESULTS: The two strains have been identified as *M. intracellulare* closely related to type 7 and *M. scrofulaceum* type 41.

*M. intracellulare* and *M. scrofulaceum* belong to a group of mycobacteria that are usually pigmented. If one reviews the literature for the past 50 years, one finds that many famous scientists have claimed to have isolated *M. leprae*. Because standardized, determinative tests have become available for the genus mycobacterium in the past 15 years, it is almost impossible to precisely identify other isolates claimed to be



function of the bacteriophage of *M. leprae* has been a review of the literature by Jones, 1961.

Although growth is artificial, *M. leprae* has been characterized in the literature. However, no real characterization of *M. leprae* has been achieved. The organism is a fastidious bacterium and has been characterized relative to the nature of its lipid composition and its culture, and indeed its success has been limited to a few investigators.

Being *M. leprae* from both human and animal sources, it is possible that the two strains are different. However, the two strains of bacteria are much more similar than the strains of *M. leprae* which has been used for each species of mycobacteria. In fact, *M. leprae* has only a few exceptions to the three basic types of mycobacteria. It is approximately the size of *M. leprae* and has a higher surface area than all the mycobacteria with *M. leprae*. Very interestingly, mycobacteria frequently are present in the tissues of Hansen's disease patients. *M. leprae* lacks many commonly found enzymes which other mycobacteria have.

The strains isolated used in this study have been better characterized than any previous mycobacteria claimed to be *M. leprae*. In addition, the fact that both isolates are immunologically reactive, it is likely they possess a capsule since this is the immunologically active substance in the cultivation procedure. The mycosides have been characterized by a group in Denver, Colorado and the structure of the basic mycoside structure has been determined. It has been shown immunologically that this basic structure is also present in *M. leprae* and it forms the famous electron transparent zone around the cell of *M. leprae* which probably defeats phagolysosomal activity and allows *M. leprae* its intracellular existence within macrophages.

In summary, the two skinsness isolates are probably very similar to many other mycobacteria that have been claimed by other workers to be *M. leprae*. Specifically, they share a unique structure and growth only exists on *M. leprae*. On the other hand, both skinsness isolates will grow on a mineral salts medium while *M. leprae* does not. Nevertheless, it is concluded that the skinsness organisms, as well as other mycobacteria isolated from the tissues of Hansen's disease patients, are uniquely related to *M. leprae*. To account for this relationship, it is hypothesized that some means of genetic transfer may occur in which *M. leprae* acquires genetic information from other bacterial cells. This genetic transfer could come from other acid fast mycobacteria or, more probably, the Corynebacteria present in the tissues that are obtained at the time of cultivation.

A manuscript is in preparation for presentation to the American Society of Microbiology, and a separate manuscript is in preparation for inclusion in dissertation.

# AUTHOR INDEX

Acabado, L. V., 36  
 Albert, L. L., 27  
 Andersen, L. A., 1  
 Andersen, C. A., 3, 5, 83, 16  
 Angritt, P., 48  
 Aoli, J. L., 28  
  
 Garcia, F. J., 10, 17, 105  
 Diggers, R. E., 1  
 Bight, F. H., Jr., 2, 101, 105  
 Bollerup, L., 49  
 Brooks, P. L., 4, 16  
 Brennan, R. J., 1  
 Bryant, C. H., 1, 4, 6, 7, 11, 18, 102  
 Bryant-Greenwood, G., 1  
 Burt, T. E., 41  
  
 Chace, J. J., 2, 13, 79, 100, 111, 112, 115  
 Chalmers, J. C., 76  
 Chen, F., 1  
 Chentel, C. P., 16  
 Claybaugh, J. R., 1, 3, 9, 10, 11, 12, 13, 16, 17, 48, 51  
 Cornette, L., 72, 16  
 Cousins, J. J., 17  
 Crane, J. L., 1  
 Crichton, S. J., 1, 4, 7, 11, 15, 20, 21, 19, 23, 26, 39, 41  
  
 Dean, L. L., 7, 9  
 Dees, L. L., 88  
 DeBester, T. E., 6  
 Dillon, L. L., 1  
 Dotson, C. R., 4, 85, 106  
 Dressendorfer, P. H., 1  
  
 Ebry, E. L., 23, 14  
 Enzenauer, R. E., 2  
  
 Faleski, L. J., 81  
 Frazier, W., 48  
  
 Garcia, J., 51  
 Gentry, E., 27  
 Gierke, K., 39  
 Goodwin, E. S., Jr., 1, 4  
 Greenfield, C. O. Jr., 5, 89, 90, 91

Pedick, C. F., 6, 7, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000.

Johnson, J. L., 1, 2  
Jones, C. C., 31, 32

Kar, T. J., 1  
Kearney, D. J., 92

Kendry, E. C., 21, 22, 23, 24  
Leonard, J., 1  
Long, W. L., 1  
Lopez, A. C., 21, 22  
Lui, F., 20

Mack, J. L., 1  
Mack, J. L., 2  
Mack, J. L., 3  
Mack, J. L., 4  
Mack, J. L., 5  
Mack, J. L., 6  
Mack, J. L., 7  
Mack, J. L., 8  
Mack, J. L., 9  
Mack, J. L., 10  
Mack, J. L., 11  
Mack, J. L., 12  
Mack, J. L., 13  
Mack, J. L., 14  
Mack, J. L., 15  
Mack, J. L., 16  
Mack, J. L., 17  
Mack, J. L., 18  
Mack, J. L., 19  
Mack, J. L., 20  
Mack, J. L., 21  
Mack, J. L., 22  
Mack, J. L., 23  
Mack, J. L., 24  
Mack, J. L., 25  
Mack, J. L., 26  
Mack, J. L., 27  
Mack, J. L., 28  
Mack, J. L., 29  
Mack, J. L., 30  
Mack, J. L., 31  
Mack, J. L., 32  
Mack, J. L., 33  
Mack, J. L., 34  
Mack, J. L., 35  
Mack, J. L., 36  
Mack, J. L., 37  
Mack, J. L., 38  
Mack, J. L., 39  
Mack, J. L., 40  
Mack, J. L., 41  
Mack, J. L., 42  
Mack, J. L., 43  
Mack, J. L., 44  
Mack, J. L., 45  
Mack, J. L., 46  
Mack, J. L., 47  
Mack, J. L., 48  
Mack, J. L., 49  
Mack, J. L., 50  
Mack, J. L., 51  
Mack, J. L., 52  
Mack, J. L., 53  
Mack, J. L., 54  
Mack, J. L., 55  
Mack, J. L., 56  
Mack, J. L., 57  
Mack, J. L., 58  
Mack, J. L., 59  
Mack, J. L., 60  
Mack, J. L., 61  
Mack, J. L., 62  
Mack, J. L., 63  
Mack, J. L., 64  
Mack, J. L., 65  
Mack, J. L., 66  
Mack, J. L., 67  
Mack, J. L., 68  
Mack, J. L., 69  
Mack, J. L., 70  
Mack, J. L., 71  
Mack, J. L., 72  
Mack, J. L., 73  
Mack, J. L., 74  
Mack, J. L., 75  
Mack, J. L., 76  
Mack, J. L., 77  
Mack, J. L., 78  
Mack, J. L., 79  
Mack, J. L., 80  
Mack, J. L., 81  
Mack, J. L., 82  
Mack, J. L., 83  
Mack, J. L., 84  
Mack, J. L., 85  
Mack, J. L., 86  
Mack, J. L., 87  
Mack, J. L., 88  
Mack, J. L., 89  
Mack, J. L., 90  
Mack, J. L., 91  
Mack, J. L., 92  
Mack, J. L., 93  
Mack, J. L., 94  
Mack, J. L., 95  
Mack, J. L., 96  
Mack, J. L., 97  
Mack, J. L., 98  
Mack, J. L., 99  
Mack, J. L., 100

Novell, J. L., 1, 2, 3

O'Brien, J. C., 1, 2, 3, 4, 24  
Ohashi, T. K., 100, 107  
Ordenez, H. P. M., 61  
Ortiz, V., 3  
Osterholzer, E. C., 43, 44, 47

Paulson, R. B., 32  
Peterson, J., 25  
Phillips, J. L., 1  
Puls, J. L., 2

Rainey, E. E., 3, 5, 56  
Rafiroz, L., 2  
Rend, J. L., 44, 45



anion gap, 32  
 antidiuretic hormone, 1, 16, 100, 69  
 antihypertensive therapy, 78  
 aortic graft, 85  
 arrhythmia, 30  
 arthritis, septic, 94  
 asphyxiated neonate, 49  
 audiovisual counseling, 16

beta-blocker, 27  
 blood volume reduction, 16  
 brain tumor, recurrent, 94  
 breast cancer, 61

cardiopharyngeal sphincter, 6  
 ceramides sulfate, 16  
 central nervous system tumor, 66  
 chondromalacia, 91  
 cholangiogram, 79  
 clinical essays, 46  
 cold pressor test, 44  
 compartment syndrome, 11  
 computerized tomography, 62  
 conscious dogs, 10  
 contrast media, 14  
 coronary arteriography, 19  
 cynomolgous monkeys, 23  
 cystoplasty bladder defects, 95

depressed mood, 78  
 dog, 9  
 dysplasia, 47

endotracheal intubation, 51  
 enzyme immunoassay, 11  
 ependymoma, 71  
 esophageal reflux, 33  
 Ewing's sarcoma, 75

fluorescent scanning, 80  
 fractures, upper extremity, 100

gallium scans, 85  
 gastric motility catheter, 8  
 gastrointestinal bleeding, 31  
 germ cell carcinoma, 53  
 goiter, toxic, 26  
 gynecological surgery, 42

seizure attack, 37  
suprarenal system, 64  
thrombocytosis, 13  
thyroidism, 74  
hodgekin's disease, 63, 71  
hodgekin's disease, stage I and II, 66  
hodgekin's disease, stage III, 67  
hypertension, 12, 64  
hypothalamic-neurohypophyseal system, 12

infarction, 11, 117a, 72  
infections, orthopedic, 15  
injuries, otologic, 15  
insulin tolerance, 24, 25  
interocular distance, 81  
intracranial pressure, 13

intermenstrual, 16  
intraocular pressure, 13  
isoproterenol, 197  
leukemia, 61, 66  
leukemia, acute, childhood, 66  
leukemia, CLL, 66  
leukemia, lymphocytic, acute, 67, 68, 73  
leukemia, lymphocytic, acute, 68, 74  
leukemia, myeloblastic, acute, 68  
leukemia, T-cell, 68  
liver blood flow, 7, 19  
lymphadenopathy, 59  
lymphoma, non-hodgekin's, 66, 68, 73

metastasis, 11  
medulloblastoma, 71  
microsurgery, 43

menstruation, 17  
medulloblastoma, 74

obesity, 70  
osteosarcoma, nonmetastatic, 67

pain, low back, 90  
pericardial effusion, 36  
postpartum psychological reactions, 17  
propranolol, 57  
psoriasis, 17  
primary sarcoidosis, 60

radioisotope scanning, 92  
record keeping, 39  
retinoblastoma, 69  
retroauricular bone scan, 77  
rhinoplasty, 106

scoliosis, 96  
scoroid toxin, 72  
small intestinal mucosal surface, 67  
sodium balance, 10  
solid tumor, 72  
*Staphylococcus aureus*, 101  
subendocardial ischemia, 107

1:299 antimony sulfide colloid, 11  
T-299 LIDA, 62  
teflon injection, 103  
theroid, 93  
training, 42, 43  
training, microvascular, 6  
tricyclic antidepressants, 10  
tunica albuginea, 101

urologic urinary conduit, 105

urinary erections, 41  
venous sinus, 14

vitro tubes, 70

1970-1971

University of Texas Medical Branch, Port  
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— 8