NIH Clinical Center

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES

July 1, 1976 through September 30, 1977

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PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

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CLINICAL CENTER

OFFICE OF THE DIRECTOR

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General

The Clinical Center provided facilities, patient care, and support services for NIH physicians who conducted clinical research for 8 of the 11 Institutes and the National Institute of Mental Health during FY 1976. With the exception of direct physician care, hospital services were provided by Clinical Center staff. Department members conducted research in their own specialties to develop and improve current technology to meet the needs of the clinical programs. Opportunities for advanced training were provided to young physicians, medical students, nursing students, and members of the paramedical professions. Exchanges of information between investigators at NIH and biomedical personnel elsewhere were encouraged.

Mission of the Clinical Center

(1) To ensure the highest possible level of medical care to each patient; (2) To provide optimal resources and facilities for clinical research; (3) To perform research on methods and systems involved in patient care and study; (4) To disseminate information to professionals and to the public relevant to clinical investigation; (5) To develop and maintain training programs in the techniques and ethics of biomedical research and clinical research; (6) To interact with scientists and physicians, nationally and internationally, on mutual problems of clinical research, such as policy, education, ethics, and priorities.

Leadership Changes

The leadership of the Clinical Center changed in July 1977. Dr. Mortimer B. Lipsett, returned to the NIH as Director of the Clinical Center and Dr. Griff T. Ross became Deputy Director. Mr. Howard E. Kettl, formerly Deputy Associate Director on Operations of the NIH, assumed the position of Chief Executive Officer.

ACRF

Excavation for the Ambulatory Care Research Facility (ACRF) commenced in May 1977. Preparatory to construction, entrances were relocated, parking areas were changed, and pedestrian and vehicular traffic patterns were altered. Stage I of the construction, involving all substructures, is on schedule and should be completed during the middle of the next fiscal year.

In conjuction with ACRF construction, a planning effort was begun to assure the programmatic and spatial integration of the old and new facilities. Under

the direction of the Clinical Center Director, a committee representing the NIH community, is addressing a number of important issues, including the disruptions and inconveniences caused by ACRF/CC construction, post ACRF/CC space assignments and associated logistics, and Clinical Center modernization.

During the fiscal year the planning of a number of Clinical Center projects was completed. Construction of a nine-bed medical intensive care unit will be completed by May of 1978. Dr. Byron McLees, formerly of the Pulmonary Branch, NHLBI, has been appointed Head of the Department of Critical Care Medicine and is recruiting staff for this unit.

In a related decision, design of an expanded hospital-wide pediatric unit was completed. The NICHD unit will serve all clinical programs and will open in 1978 fiscal year.

New clinic facilities were designed in order to accommodate expanding outpatient programs and to offset the loss of space caused by ACRF construction. The project includes the remodeling of NIMH facilities, the addition of satellite services in x-ray, clinical pathology, and nutrition, and a general expansion of examination and treatment rooms.

Several construction projects began this year. These included the renovation of the main kitchen, the construction of a recovery room within the tenth-floor operating room, the conversion of the ninth-floor solarium into a 50-person conference room, and the activation of a trash chute system. Renovation of the Clinical Center's fabric care department was completed, making it one of the most advanced, environmentally sound facilities of its kind.

New Services

An endoscopy service was established for use by all Institutes. The new unit, which is in full operation, was created through the combined efforts of the NHLBI, NIAMDD, and the Clinical Center and is directed by Dr. Ronald Crystal (NHLBI) and Dr. Denis McCarthy (NIAMDD).

The Outpatient Department initiated a centralized appointment system to increase efficiency. Physician time in the clinics has been reduced while the number of clinic visits has increased.

Dr. John Fletcher has joined the Clinical Center staff on a part-time basis as a Special Assistant to the Director for Bioethics. Dr. Fletcher will be working with physicians on ethical issues in their research pursuits as well as conducting his own research on "natural third parties in the consent process." He also will be developing orientation programs for review committee members.

Dr. James Balow has joined the Clinical Center staff as Nephrology Consultant and has assumed responsibility of consultation in renal disease and renal dialysis. Need for this service has been increasing and Clinical Center capabilities for providing comprehensive medical care have been strengthened greatly.

Medical Board

The dramatic changes occuring in the Clinical Center's physical appearance this past year were accompanied by equally important changes in hospital policy. The bylaws, regulations, and responsibilities of the CC medical board, the hospital's policy making body, were revised and updated to make daily operations more efficient and bring the Clinical Center into compliance with the regulations of the Joint Commission on Accreditation of Hospitals. Changes included (1) developing procedures to delineate clinical privileges among clinical care physicians. A clinical investigator must now be granted permission by the appropriate clinical director to perform specialized procedures enumerated on a prepared list. This delineation of privileges is intended to strengthen lines of accountability and responsibility (2) establishing a Quality Assurance Committee for maintaining quality patient care. The Committee has strengthened the internal mechanisms for problem identification and resolution by combining the functions of several earlier committees and establishing four new areas of responsibility (clinical associate representative, a medical audit committee, and a therapeutic subcommittee). Significant accomplishments of the Quality Assurance Committee include codification and revision of all medical records, the establishment of a death review mechanism; restructuring of the research review process to simplify the review and approval of new clinical research protocols (3) developing a protocol impact statement that provides early warning to departments affected by proposed studies. Such an early warning device can help the departments avoid shortages and overloads.

Safety

The issue of patient and staff safety took on new importance with the initiation of ACRF construction and CC renovation. The Emergency Evacuation Plan was revised to take into account the new exit problems. The Clinical Center Multidisciplinary Safety Committee, which develops safety policy for the CC and which is responsible for maintaining a safe hospital environment, undertook a number of safety projects.

The Committee developed a patient area environmental safety program involving periodic surveys of all patient units to assure compliance with program safety requirements. The Environmental Safety Branch of DRS will conduct the surveys. It also developed a set of safety procedures for the operation, maintenance, and inspection of non-clinical electrical equipment. A list of emergency procedures was drawn up for use in times of essential equipment failure or power outages. Smoking regulations were put into effect throughout the hospital and a manual on smoking regulations has been distributed to nurses.

The safety commission also sponsored basic electrical safety seminars for nurses, strengthened the maintenance and inspection program for patient electrical equipment (particularly monitoring equipment), helped establish a cardiopulmonary resuscitation course for CC employees, and developed and implemented a CC corridor clean-up program to maintain NIH safety codes.

Training

There are excellent resources at the CC for teaching biomedicine and the ethics of biomedical research. The commitment to teaching is, indeed, secon only to the CC's primary commitment to provide the highest quality patient care while carrying out research to better understand and treat disease.

The CC offers many educational opportunities to different segments of the biomedical profession.

Clinical Electives for Medical Students is a collaborative effort by eight Institutes and the Division of Computer Research and Technology and the CC to offer nine in-depth courses in medical subspecialties: Computers in Clinical Medicine, Endocrinology-Metabolism, Immunology, Genetics, Hematology-Oncology Infectious Diseases, Nuclear Medicine, Pyschopharmacology, and Surgical Oncology. These courses involve the student in a close association with physician-scientists as well as prolonged exposure to individual patients in appropriate research studies. The patients are assigned to students for workup, discussion, and medical care. Students thus take an active part in special rounds, clinical and research conferences, and patient care duties. In the 1978-79 academic year, 126 students will participate. In the past, almost 20% of the students who have taken part in the Clinical Electives program have returned to NIH as Clinical, Research, or Staff Associates.

The NIH-Foundation for Advanced Education in the Sciences (now accredited by the American Medical Association) offers on-campus advanced courses to physicians and scientists. The series of specialty review courses has attracted 340 NIH Associates, senior NIH physicians, and area-wide physicians.

Twenty-one Foundation courses and 10 daytime rounds and lecture series have been approved for "category 1" credit. The CC also publishes as a concomitant to its graduate and undergraduate education programs, the Combined Clinical Staff Conferences. These Conferences present intramural, interdisciplinary research findings of NIH scientists. The proceedings of these Conferences are published eight times a year in the Annals of Internal Medicine, and approximately 12,000 reprints are mailed to individual physicians and dentists throughout the nation and the world.

The CC also publishes the proceedings of six to eight CC Nursing Conferences on special problems and advances in nursing practice. Ten to twelve thousand copies of these proceedings are distributed to schools of nursing, teaching hospitals, and other hospitals throughout the country.

Postgraduate education is carried on by CC personnel in the Department of Nursing, Diagnostic Radiology, Nuclear Medicine, Clinical Pathology, and Blood Bank. Programs in these Departments attract physicians and nurses throughout the country and abroad.

Associate Program

The Office of the Associate Program carried out its usual activities as a focal point for recruitment of Clinical and Research Associates for the various Institutes and Divisions of the NIH. The basic problem in the past few years has been that there are many fewer applicants since the ending of obligated military service for young physicians. The decision of the American Board of Internal Medicine to phase out the so-called "short tract" option, whereby participation in a sub-specialty training program could also be credited as a third year of residency in general internal medicine, probably also accounts for some of the loss of interest in Associateships. Finally, there may currently be less interest among young physicians in careers in research or sub-specialization, and more in primary care. How these problems can be best be addressed in the long run is still not clear.

The interview period and matching program were advanced in time from June to late April, in order to allow potential Associates to make their commitments about 15 months in advance, at a time they are likely to be considering other options, rather than two years in advance. The option of commitments 27 months in advance remains open. Thus, vacancies not filled in a given matching year are more likely to be filled in the next one.

For the second year, the catalog which describes the Associate Program was sent by direct mail to 4th year students and to physicians in the first two years of post-graduate training throughout the country. Advertisements were also placed in major medical journals.

1180 applications were distributed on request; 242 applications were made; 162 candidates were interviewed; 90 were selected for appointment. These figures are similar to those of the previous year. It appears that the information about the Associateships is reaching its target, but that the interest it generates is barely sufficient to meet recruitment requirements. In the coming year, changing the format of the catalog and the nature of the publicity effort will be considered by the NIH Education Committee and the Associate Program.

Medical Information System

The Technicon Medical Information System (MIS) is a total hospital computer system through which all patient care related activities in the Clinical Center

are initiated. The primary functions of the MIS are to accept physicians' orders, communicate the contents of those orders to nursing personnel and all ancillary departments, and generate computer printed portions of the medical record such as x-ray reports, medications given and nursing notes. Users of MIS include physicians, nurses, and ancillary medical personnel.

Sixteen of twenty-six nursing units, the operating rooms, all ancillary departments except laboratories, are using MIS for all patient-care activities. It is anticipated that the remaining units will be fully operational next year and that there will be a direct computer-to-computer link between MIS and the Honeywell system in the laboratory.

Research Accomplishments

Over the past year Clinical Center investigators produced a number of notable research advances, some of which may soon affect national and global health care practices and policies.

A hitherto unknown form of hepatitis distinct from a type A (infectious) and type B (serum) hepatitis has been uncovered. Investigators from the Clinical Center Blood Bank, together with scientists from NIAID, are presently seeking to identify the unknown agent which most likely is a virus. The "non-A-non B" hepatitis has been identified as being responsible for 80% of post-transfusion hepatitis occurring in patients receiving noncommercial blood from donors screened for the hepatitis B surface antigen. Present studies seek to achieve eradication of this residual hepatitis.

Proceeding from the observation that a majority of black Africans and Americans of African descent are resistant to P. vivax malaria, Blood Bank and investigators established that antigens present on the surface of red blood cells (Duffy system antigens) allow invasion by the malarial parasite; this antigen is absent from red cells of most blacks. Attempts to biochemically isolate the Duffy factor are now under way and could lead to an immunologic or chemical means of blocking the invasion of some malarial parasites, thereby decreasing malaria.

Clinical Center investigators in colloboration with the Division of Research Services, have developed an inexpensive real-time scanner for obtaining cross-sectional views of the upper abdomen. The scanner, which gives a continuous fluoroscopic image, is proving valuable in identifying abdominal diseases.

A new computer-based radiotracer imaging procedure called ECG-gated scintigraphic angiocardiography has been developed by CC investigators in cooperation with NHLBI and DCRT scientists. The procedure, which offers non-invasive visualization of the working heart, yields quantitative measures of left ventricular function. This technique appears to be superior to the exercise electrocardiogram for detecting heart disease, particularly coronary artery disease.

Rehabilitation department investigators have found that application of a rigid dressing immediately following limb amputation accelerates suture line healing and benefits final shaping of the limb. Implementation of these

procedures has produced significant reductions in time between surgery and fitting of the final prosthesis.

Studies by Clinical Pathology investigators on the purification and biologic characterization of coagulation proteins have revealed marked differences in the factor VIII/von Willebrand factor protein in the hemophilia A and von Willebrand's disease (two diseases associated with a similar coagulation defect and bleeding). The carbohydrate portion of the protein has been found to play a pivotal role in the interaction with platelets during normal blood clotting and may play an important role in the development of atherosclerosis.

Investigators in this department also have established that young platelets are heavier than older ones and have developed a method to isolate younger platelets from whole blood for the first time. The method of separation devised by these scientists can be used to distinguish between diseases (thrombocytopenia) resulting from either platelet destruction or failure of platelet production.

The Diagnostic Radiology Department has been intensively evaluating the CAT body scanner. They have shown that it is the best tool for diagnosing early metastatic cancer of the lung. They are comparing its diagnostic accuracy with other techniques in difficult diseases of the liver and pancreas.

EEO

The Clinical Center published its first Affirmative Action Plan for Equal Opportunity. In observance of National Secretaries Week, a two day seminar entitled "Self Assessment and Career Development for Secretaries" was conducted by an independent consultant, Ms. Barbara Thompson, an expert in the area of Career Development and Vocational guidance.

Clinical Center employees elected the following representatives and alternates to the EEO Advisory Committee: Mr. Joseph Hambrick and Ms. Rosalie Smith as representatives from Nursing and Ms. Elsilee DesBordes and Ms. Barbara Scott as alternates; Ms. Yasmin McMahon and Ms. Ella Thompson, Medical Record Department; Ms. Monica Stankus and Ms. Peggy Spina, Clinical Pathology and Blood Bank Departments; Mr. Bernard Scott and Ms. Dorothy Wiggins, Environmental Sanitation Control Department; and Ms. Annebelle Vick and Ms. Martha Thomas, Nutrition Department.

Ms. Jean Harris, Nursing and Ms. Peggy Spina, Clinical Pathology, were selected as Clinical Center delegates to the NIH Women's Advisory Committee.

Mr. Harry Hill, Clinical Pathology, was elected chairperson of the Clinical Center EEO Advisory Committee and appointed to a 3 year term as an EEO Counselor.

EEO Special Achievement awards were presented to Ms. Betty B. Colbert, Blood Bank; Mr. Harry H. Hill, Clinical Pathology; Ms. Mary E. Swader, Environmental Sanitation Control; and Chaplain Robert I. White, Spiritual Ministry.

Office of Clinical and Management Systems

The Office of Clinical and Management Systems assists the staff of the Clinical Center by providing services of systems analysis, computer systems evaluation, and management engineering. It coordinates the planning, development, implementation, and operation of all computer and automated systems within the Clinical Center; provides a working liaison between the Clinical Center, the Division of Computer Research and Technology, and the various Institutes to assure optimal and integrated clinical management and information systems; assists Clinical Center management to apply the techniques of operational planning, facility development, resource allocation, and program evaluation and review; and, initiates and conducts research and education programs in clinical and management systems.

A large portion of the Office's activities during this period involved the continuing implementation of the computerized Medical Information System (MIS). Fifteen more nursing units were added to the system bringing the implementation up to the 70% mark of inpatient services. Over 100 protocol and pre-structured order sets were gathered, processed, and implemented in the system. Over 1,000 change requests and problem reports were resolved by this office in conjunction with the MIS installation. Physician training in the use of MIS included the critical July 1 turnover period. Physicians now directly enter 70% of the orders processed via MIS. The successful conversion of the DCRT-based Admissions/Transfer/Discharge and Biographic File system was accomplished. Over 120,000 patient records were transferred successfully from one system to the other so that MIS is now the chief repository of on-line patient information. A problem tracking scheme was established to assure Clinical Center department heads that all difficulties encountered in the use of the MIS were identified and that solutions were defined and pursued in a timely fashion.

Clinical Information Utility: The Clinical Information Utility which stores medical information at DCRT and retrieves it on request for medical researchers in the various Institutes, was enhanced by MIS-acquired information. A medications file was established enabling physicians to request results of laboratory tests, biographic data, discharge diagnosis, and medication information.

Laboratory Computer System: The Chief, OCAMS, also serves as the Chief, Laboratory Computer Service, Clinical Pathology Department, permitting this office to support the Laboratory Computer Service, especially in matters pertaining to the Honeywell Laboratory Information System. During this reporting period, the Honeywell System was successfully put through acceptance testing. Various enhancements to the system's software and operating modes were designed and put into operation by OCAMS staff. The Microbiology portion of the system was successfully implemented during this period as well.

Workload Reporting System for Clinical Center Departments (RMS - Resource Monitoring System) was totally implemented throughout the Clinical Center and began serving as the Clinical Center's input to the NIH-wide manpower management program. It also serves as a base for the Clinical Center's reporting through the zero-based budgeting activities. The RMS represents three years

of development, study, and modification to the system to make it suitable for internal Clinical Center use as well as for other organizational demands which the Clinical Center must satisfy.

The office participated in a Medical Records System Working Group, with the use of an outside consultant, to define the present and future scope and role of the Clinical Center Medical Record System. This office served as a resource and a source of guidance to the Group and the consultant.

A candidate for the Masters Degree in Health Care Administration from the George Washington University completed a paper on staff input in the development of the Medical Information System. The office continued to project computer needs for the next five years as the Clinical Center's input to the NIH-wide Automatic Data Processing (ADP) plan. Through this year's and previous years' projections, the Clinical Center has been able to make rational decisions for computerization and proceed in an orderly fashion to automate various functions. The office served as a resource to the Clinical Center Bed Utilization Committee and provided the design of a mechanism to allow physicians to maintain current knowledge of the availability of beds for their patients throughout the hospital. The office continued to be a focal point of data security and Privacy Act implementation with regard to automated systems. A group of Privacy Act inspectors were given a tour through the various Clinical Center facilities. Their report was reviewed and appropriate security measures are being implemented through this office. The office continued to be the focal point for patient care statistics based on patient admissions and discharges. Statistical reports on a routine basis and on demand were produced. The office supervised the orderly conversion of source data preparation from the DCRT-based admission system to the MIS.

Outside Activities: The office continues to be a resource for the hospital community in fields of medical information systems, laboratory computer systems, and management information systems. Papers were presented to the American Institute of Industrial Engineers Health Services Division Conference, the 7th International Technicon Congress, the HEW Senior Staff Development Seminar on the use of management information systems, a Laboratory Systems Seminar at the National Naval Medical Center,and at a Computers and Patient Care Seminar for the Maryland Hospital Education Institute. The office is also represented on the Medical Information Systems Users Group, representing Technicon clients around the country, directed toward improvements in the performance of the Technicon MIS.

Staffing: The office added a Systems Analyst to the staff, thus providing needed depth in the day-to-day management of the MIS and a vitally needed source of ideas for additional functions for the system.

During the next year the Office expects to complete the inpatient aspects of the Medical Information System and the Outpatient Clinics as well. A major goal is the complete interface of the Honeywell System with MIS so that orders can be automatically exchanged between the two systems. This involves an extensive programming effort and coordination by the vendors and will be a pronounced improvement in the MIS service.

In addition to the Lab-to-MIS interface, the major objective for the laboratory system will be the successful completion of interface of the SMAC 20-channel analyzer so that automation of these results will be total.

The addition of Radiology, Nuclear Medicine, and data from other Departments to the Clinical Information Utility service will be a major objective in the next year. Such information will enable us to approach the notion of a full service utility for medical information retrieval.

As a result of changes in several departments, the RMS has restudied these Departments and re-established workload reporting standards. The objectives for the coming year will include re-evaluations in Clinical Pathology, Diagnostic Radiology, Pharmacy, and Nuclear Medicine.

The Office will establish centralized MIS training for members of all hospital departments as well as physicians. Centralized training will assure coordination and continuity of current information transmission for all users. The Office expects to extend its management engineering techniques to Clinical Center Departments through enhancement of the MIS capability and improvement in non-computer related functions. A position for Management Analyst, GS-12 was created, and after filling this position the Office expects to play a greater role in productivity studies and further applications of the Resource Monitoring System.

The Office recognizes that with the installation of the MIS, its staff is in a unique position to provide information to other government and community agencies which deal with such matters. Such an obligation is discharged by speaking to various groups, bringing representatives to the Clinical Center for on-site observations of the systems, and publication. With implementation of peak workload to be completed during this year, time availability for such support activities for others will be increased.

Office of Planning and Policy Development

Research review has continued to be the major emphasis of the office. During Fiscal Year 1977 the review process was restructured in response to a mandate from the Medical Board. The resulting mechanism provides a single uniform review of both patient and normal volunteer research protocols. Pursuant to this action the Clinical Research Committee and the Volunteer Research Review Panel were abolished and replaced by clinical research subpanels within each Institute. Memberships for each subpanel were developed in accordance with HEW guidelines as prescribed in 45 CFR 46.

The Medical Board Services Section provides staff assistance to the subpanels upon request and continues to serve as the central clearinghouse for intramural clinical research protocols. The Section's computer file has been brought up-to-date with revisions made daily in order to maximize it as an investigator resource. In addition to serving as the tool for identifying projects due for the required periodic review, the computer file is being used to prevent hospital admission abuse. On a quarterly basis each clinical branch, clinical director, nursing unit and the Admissions Office receive a listing of the clinical research protocols that are in an active status. This

list is supplemented each month with pen and ink changes for each clinical area.

As the issue of credentials has come to the medical/legal forefront the Office has been instrumental in coordinating the delineation of privileges for physicians and dentists and for establishing a category of staff affiliates. Plans have been made for performing a complete audit of the credentials to insure that JCAH requirements have been met and to assist the Office of the Director in obtaining accreditation renewal for the hospital.

The Medical Administrative Series of the Clinical Center's Policy and Communication Bulletin has continued to expand and be recognized as the sole authoratative source of policy decisions regarding clinical care. Issuances this fiscal year have ranged from a revision in the informed consent policy to meal tickets for patients' relatives boarding on nursing units.

To assist physicians and their secretaries, the MBSS published several supplementary aides. Revised staff directories were printed listing in-house staff and consultants. In addition, procedures were described for obtaining consultative services. A guide to the MBSS was issued for the first time and has proved to be an invaluable aid to secretaries of physicians participating in patient care. The guide covers nearly all the MBSS functions and instructs secretaries on procedures needed for their interactions with that office.

Two new functions were being assumed at the end of Fiscal Year 1977. With the change in review process and centralization of the approving authority for protocols with the Director, CC, the contact point for filing "Notices of Claimed Investigational Exemption for a New Drug" (INDs) was relocated to the MBSS from the Office of the Deputy Director, CC. This move was intended to streamline the protocol approval process and eliminate a duplication of protocol files.

A formal committee management function was established in the Clinical Center with the maintenance of files and processing of reports to emanate from the Office of Planning and Policy Development.

Participation in the planning function occurred on two levels. First, there was development of Institute program assumptions to aid Clinical Center departments in preparing their budgets. On the broader scene the Office collaborated with the Office of the Director in preparing the Clinical Center's first submission to the NIH Forward Plan.

Office of Clinical Reports and Inquiries

Clinical Center information, publications, press, and public affairs activities are centered in the Office of Clinical Reports and Inquiries. The office is responsible for advising the Director and Executive Staff on ways to enhance the Clinical Center's public and professional image as a preeminant clinical research facility, and on the effective interpretation and reporting of research findings produced within the Center. These findings are of interest and concern to many audiences, including Congress, the Department, and other Government agencies, scientists, physicians, voluntary health agencies, and the general public.

The Office initiates many programs and responds to Congressional and Departmental, NIH, and internal and public requests. It keeps all Clinical Center personnel informed of hospital activities, provides all hospital departments with communications assistance, and supports the functions of the CC's hospital service departments to ensure the delivery of the highest quality of patient care.

Mrs. Shelbia Lengel was appointed chief of the OCRI in August and served until May 1977, when she became Information Officer for the NIDR. CC Administrative Officer Steve Galen took over as Acting Chief until July when Lanny Newman was selected to head the Office.

Press Activities

International, national and local news media showed an increased interest in Clinical Center programs. There were a number of magazine and newspaper articles on the D'Alessio twins who underwent open-heart surgery in the NHLBI. Press interest in the Sutherland family, being followed by NIH physicians for unusual familial incidence of cancer, remained high. Communications support was provided to crews broadcasting a segment of the NBC's Today Show from the Clinical Center. The OCRI also provided support for the development of two upcoming network television programs: The NBC program, Weekend, is preparing a 20-minute segment on the Clinical Center Normal Volunteer program; NBC also is planning a 3 1/2 hour prime time program on health care in America.

Communications support was provided for visits to the Clinical Center by First Lady Rosalynn Carter and HEW Secretary Califano.

Medical and Paramedical Communications

The proceedings of ten NIH Combined Clinical Staff conferences were edited by this Office and prepared for publication in the Annals of Internal Medicine. OCRI sent out nearly 12,000 reprints in response to requests by practicing physicians. These conferences and the proceedings are a primary means of sharing the results of NIH investigations with physicians everywhere.

The Office edited an estimated 150 professional papers prepared by Clinical Center staff for publication in medical and scientific journals, and provided editorial services during manuscript preparation.

Two editions of the booklet Current Clinical Studies and Patient Referral Procedures were prepared and mailed to practicing physicians and dentists to notify them of NIH intramural clinical programs to which they may nominate patients. An additional 36 supplementary announcements of new protocols also were sent out.

Four Nursing Clinical Conferences were presented this year by the Nursing Department. In addition to assisting in the preparation of programs, invitations and publicity, the OCRI prepared and printed conference proceedings to share nursing techniques developed at the Clinical Center with nurses throughout the country. Approximately 12,000 reprints have been sent out.

A new monthly publication, Director's Update, was begun in March to communicate clinical information to over 700 physicians in the Clinical Center. The OCRI helped plan the new publication and will coordinate its preparation and distribution.

Patient Communication

A comprehensive new information program for patients regarding hospital facilities and services was begun. The first edition of the Clinical Center Patient's Handbook was published, offering general information about hospital activities and policies. There is room in the handbook for inserts covering individualized information for patients about the specific nursing unit and medical program they will encounter.

A Patient's Bill of Rights was developed in cooperation with the Director's office and the Medical Board. This publication, along with a new document explaining the Privacy Act, will be included in the kit.

A leaflet was prepared and other information made available to patients about the patient representative program.

This past year the hospital's preadmissions functions were turned over to the OCRI. Approximately 650 patient referrals to the Clinical Center from private physicians were processed through this office. The unit also responded to approximately 90 Congressional and 150 general inquiries by letter and telephone.

Recruitment

A major campaign to support the Patient Emergency Fund was undertaken this past year to bolster dwindling reserves. The fund is essential to the present patient care program since many patients would leave the hospital if the emergency financial assistance offered through the fund were not available. During the past year a brochure about the fund was developed and an extensive promotional campaign was undertaken. Over $800 was raised at the annual benefit softball game.

Recruitment of blood donors also has become critical and a major program was begun to communicate blood needs. The OCRI conducted several media and poster/table-tent campaigns and has recently completed a new full color blood donor recruitment brochure.

As a result of this effort, blood collections rose 9 percent and the list of platelet donors in the Blood Bank files rose 17 percent.

Revised editions of the Associate Training Programs catalogue and the Clinical Electives for Medical Students brochure were issued and distributed. Last year a member of the OCRI staff attended the annual National Medical Association meeting in Los Angeles with the Associate program exhibit. Literature on the program was distributed.

The OCRI helped revise the publication Clinical Electives for Nursing Students. This brochure, which goes to senior nursing students in baccalaureate programs, is a valuable recruiting tool.

In addition, this Office revised the Handbook for Staff Physicians. OCRI also helped develop a guidebook of services provided by the Whole Body Counter Section of the Nuclear Medicine Department. A guidebook on the use of the MIS which goes to physicians, dentists and nurses who attend MIS orientation training was prepared.

Employee Communications

An extensive program of employee communications was inaugurated this past year to help promote a sense of unity essential to the smooth operation of the hospital. Closeup, the employee newsletter appeared monthly and included feature articles on such topics as the meaning of black history to Clinical Center employees and the function and activities of CC administrative officers.

The OCRI prepared a number of handbooks and brochures for various hospital departments to acquaint personnel with special procedures relating to those departments. Publications were prepared for the Departments of Nutrition, Environmental Services Control, and Respiratory Therapy.

Public Education

The first of 12 weekly lectures in a series entitled Medicine for the Layman will be presented at the Masur auditorium on September 20. The series was conceived as a way of educating the public about health and disease in an interesting fashion. It is based on the premise that an informed public is the best guarantee for continued support of the biomedical research.

Special Events

The Special Events staff planned, coordinated and directed specific programs for 57,821 visitors to the NIH in FY 1977. Included were 505 visitors from 41 foreign countries and 1,574 domestic visitors. The Section consulted, planned and provided staff assistance for 298 scientific and administrative meetings attended by 55,742 visitors in the Masur Auditorium. Activities of the Special Events Section over the past year included scheduling 461 appointments with NIH researchers, arranging 275 film showings for 1,282 visitors, conducting 238 tours for 1,192 visitors, collecting, assembling, and distributing 11,374 publications, and answering 1,484 public inquiries by letter and telephone. In addition, the Section maintained the NIH Speakers Bureau, filling 47 requests for speakers, and administered an interpreter roster, calling upon individuals to assist in interpreting for 43 foreign visitors and foreign-born patients. It also maintained an invitation list for all NIH lectures, dedications and ceremonies. As Executive Secretary for the NIH Lecture Committee, the Section Head was responsible for administrative arrangements for 4 NIH Lectures, the G. Burroughs Mider Lecture and the R. E. Dyer Lecture.

SPECIAL EVENTS SECTION

MONTH	VISITORS			MEETINGS		TOURS		NIH MOVIE SHOWINGS		APPT. WITH STAFF	REQUESTS FOR SPEAKERS	REQUESTS FOR INTERPT.	PUBS. DISTRIB-UTED	PUBLIC INQUIRIES
	For.	Dom.	Total	No.	Attend-ance	No.	Attend-ance	No.	Attend-ance					
JULY	20	25	45	22	1,749	10	15	14	24	20		7	147	100
AUG.	54	157	211	15	2,070	23	135	27	167	29		5	1,266	97
SEPT.	33	23	56	10	3,036	17	21	19	26	39	6	1	501	107
OCT.	17	94	111	20	5,622	11	88	13	58	37	3	3	222	90
NOV.	23	37	60	20	4,158	12	29	11	39	27	1	1	191	82
DEC.	7	60	67	10	2,074	15	29	14	28	18		3	170	102
JAN.	5	130	135	7	2,122	17	117	18	117	26		4	813	87
FEB.	8	45	53	19	6,334	5	19	6	21	11	4	5	242	86
MARCH	18	210	228	25	3,726	16	138	17	152	43	6	1	847	99
APRIL	40	132	172	25	5,012	17	69	20	96	29	4	1	688	88
MAY	54	132	186	20	3,883	16	106	19	142	23	5	3	1,089	96
JUNE	16	84	100	14	2,956	17	39	17	62	19	0	1	758	106
JULY	88	126	214	27	1,500	15	100	20	100	45	7	3	890	100
AUG.	56	248	304	29	5,000	35	150	35	150	35	5	3	1,050	150
SEPT.	66	71	137	35	6,500	12	137	25	100	60	6	2	2,500	94
TOTAL	505	1,574	2,079	298	55,742	238	1192	279	1,282	461	47	43	11,374	1,484

SPECIAL EVENTS SECTION ACTIVITIES

Comparison-Fiscal Years 1969-1976

YEAR	VISITORS			MEETINGS		TOURS		MOVIE SHOWINGS		APPOINTMENTS WITH STAFF	REQ. FOR SPEAKERS	PUBS. DISTRIBUTED	INQUIRIES	
	For.	Dom.	Total	No.	Attendance	No.	Attendance	No.	Attendance				PUB.	CONG.
1969	1,242	3,149	4,391	129	29,194	302	1,311	475	4,023	725	44	23,541	2,170	23
1970	1,070	2,590	3,660	197	45,944	290	1,302	495	2,744	1,019	61	33,387	1,724	13
1971	629	2,533	3,162	215	48,156	241	1,210	388	2,605	583	44	23,663	1,792	2
1972	900	2,846	3,746	231	40,785	211	1,172	330	2,760	610	23	32,521	1,875	4
1973	1,010	2,489	3,499	241	48,648	179	852	343	2,315	651	56	31,237	1,660	6
1974	529	2,232	2,761	194	47,804	175	932	228	1,340	804	37	21,983	1,620	1
1975	416	23,184	23,600	258	51,368	167	1,078	229	1,654	498	31	75,777	1,482	1
1976	510	22,837	23,347	68	19,974	157	602	189	1,799	504	9	69,750	1,433	0
1977	505	1,574	2,079	298	55,742	238	1,192	275	1,282	461	47	11,374	1,346	25

VISITORS DURING FISCAL YEAR 1977 - By Discipline

A. Domestic - Total 1,574

Laboratory Science	10	Laymen	170
Medical	97	Medical Educators	2
Paramedical	309	Employees	50
Administrators	68	Science Writers	5
Hospital Administrators	25	Clergy	39
Teachers	34	Press	1
Graduate School	137	Architects	1
College	511	Statesmen	2
High School	111	Technology	1
		Patient	1

Foreign - Total 505

Laboratory Science	92	Laymen	18
Medical	198	Medical Educator	1
Paramedical	74	Science Writer	1
Administrators	68	Clergy	1
Hospital Administrators	2	Ministry of Health	5
Teachers	1	Interpreter	2
Graduate School	3	Statesmen	4
College	35		

DISTRIBUTION OF VISITORS BY CONTINENTS

Fiscal Years 1972-1977

CONTINENT	FY- 1972	FY- 1973	FY- 1974	FY- 1975	FY- 1976	FY- 1977
AFRICA	84	7	9	7	80	34
ASIA	136	180	266	143	121	219
AUSTRALIA	1	6	12	4	2	7
EUROPE	404	554	142	129	166	212
NORTH AMERICA	2,538	2,743	2,312	1,764	42,941	1,587
SOUTH AMERICA	659	9	20	25	11	20
TOTALS	3,822	3,499	2,761	2,072	43,321	2,079

Foreign Visitors by Country of Origin - Fiscal Year 1977

Africa	32
Australia	7
Austria	1
Brazil	3
Canada	5
Chile	1
Colombia	1
Denmark	3
Dominican Republic	1
Egypt	18
England	46
Estonia	1
France	61
Germany	11
Greece	1
Hungary	1
India	9
Iran	2
Israel	1
Italy	21
Japan	90
Korea	1
Kuwait	2
Latin America	1
Madagascar	1
Manila	1
Mexico	6
Netherlands	12
Pakistan	1
Philippines	4
Poland	10
Rumania	7
Sri Lanka	1
South Africa	1
South America	15
Sweden	15
Switzerland	17
Turkey	6
USSR	36
West Germany	3
Yugoslavia	1

NIH LECTURE SERIES
Fiscal 1977

The Special Events Section is responsible for administrative arrangements for the NIH Lecture Series.

R.E. Dyer Lecture:

September 29, 1976 Attendance: 350
Hugh O. McDevitt, M.D.
Professor of Medicine
Chief, Division of Immunology
Stanford University School of Medicine
Stanford, California
Title: "Selective Expression of I Region Genes in Lymphocyte Subpopulations"

NIH Lecture:

November 17, 1976 Attendance: 400
Paul Berg, Ph.D.
Willson Professor of Biochemistry and former Chairman of the Department of Biochemistry at Stanford University School of Medicine
Title: "Dissections and Reconstruction of the SV40 Genome"

NIH Lecture:

December 8, 1976 Attendance: 550
Gerald M. Edelman, M.D., Ph.D.
Professor of Biochemistry
Rockefeller University
New York, New York
Title: "Cell Surface Modulation"

NIH Lecture:

March 2, 1977 Attendance: 830
Mary Leakey, D.Sc.
Olduvai Gorge
Nairobi, Kenya
Title: "Early Man"

G. Burroughs Mider Lecture:

May 18, 1977 Attendance: 525
Maxine F. Singer, Ph.D.
Head, Section on Nucleic Acid Enzymology
Division of Cancer Biology and Diagnosis
National Cancer Institute, NIH
Title: "Monkey Business: Sequences in the Monkey Genome and Their Interaction with Simian Virus 40 DNA"

NIH Lecture:

September 19, 1977 Attendance: 530
Max F. Perutz, Ph.D.
Medical Research Council
Laboratory of Molecular Biology
University Postgraduate Medical School
Cambridge, England
Title: "Fundamental Research in Molecular Biology: Its Relevance to Medicine"

Honors and Awards

Dr. Griff Ross received the Fred Conrad Koch Award of the Endocrine Society for achievement in endocrinology and the Ashbel Smith Distinguished Alumnus Award, University of Texas Medical Branch, Galveston, Texas.

Dr. Mortimer Lipsett was presented the Distinguished Leadership Award by the Endocrine Society for his contributions to endocrinology.

Professional Activities

Dr. Lipsett was appointed as member of the Committee on Scholarly Communication with the People's Republic of China's Steriod Chemistry and Biochemistry Delegation to visit the Peoples Republic of China, sponsored by the National Academy of Sciences. He served on the Subspeciality Committee on Endocrinology and Metabolism of the American Board of Internal Medicine; the Council for Research and Clinical Investigation Awards Committee of the American Cancer Society; and the Endocrinology and Metabolism Advisory Committee, Food and Drug Administration. Dr. Lipsett was also appointed Associate Editor of Cancer Research Editorial Board, elected to office of Secretary General, International Society of Endocrinology and served as Executive Secretary of The Endocrine Society.

In addition, the Director presented a paper on "Impaired Organ System Effects of Cancer on Nutrition: Endocrine, Musculo-skeletal, and Central Nervous Systems." Workshop Conference on Nutrition & Cancer Therapy, American Cancer Society.

As member of the faculty for The Institute for Continuing Education, he participated in symposium on "Recent Advances in Endocrinology and Metabolism, St. Thomas, V.I.

He delivered lectures on "Endocrine Treatment of Cancer," at Science Writers Seminar on Endocrinology, sponsored by NIAMDD and The Endocrine Society, Bethesda, Md.; "Estrogens and Cancer" and "Hirsutism--Modern Language and Treatment" at Atlanta Graduate Medical Assembly program, "Two Days of Internal Medicine--Endocrinology for the Internist," Atlanta, Ga.; "Functioning Ovarian Tumors," at University of Tennessee Second Annual Gynecologic Endocrinology Symposium, Memphis, Tenn.; "Estrogens and Cancer," at Akron City Hospital Eleventh Annual Cancer Symposium, Akron, Ohio; "Male Hypogonadism," "Estrogens and Cancer," at Florida Endocrine Society Annual Meeting; and "Hirsutism" at University of Miami School of Medicine Reproductive Endocrinology Lecture Series.

Dr. Ross was elected president of the Endocrine Society, Honorary Fellow, American Gynecological Society and served on the Albert Lasker Medical Research Awards Jury. He was invited to present the First Carl Gemzell Lecture on "The Ovulatory Process in Women" at the Symposium on "New Leads on Contraception" on the Five Hundredth Anniversary of the University of Uppsala, Sweden. He also spoke at the French Endocrine Society Meeting, Toulouse, Franch.

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July 1, 1977, through September 30, 1977

PUBLIC HEALTH SERVICE: NATIONAL INSTITUTES OF HEALTH

SUMMARY OF ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

BLOOD BANK DEPARTMENT:

CONTENTS

I. BLOOD BANK MISSIONS AND GOALS

The NIH Clinical Center Blood Bank has three basic missions to fulfill: service to Clinical Center patients, teaching the disciplines of blood banking and immunohematology, and conducting developmental research.

The primary mission of the Blood Bank Department is service to Clinical Center patients. The largest portion of this service consists of providing safe, effective blood and components in support of patient care research at the NIH. Approximately half of the blood transfused at NIH is obtained from NIH volunteer blood donors phlebotomized in this department; the remainder is drawn from the Washington Regional Blood Program of the American Red Cross and crossmatched in the Blood Bank Department.

This department strives to make maximal use of blood and its components with minimal wastage or loss. Thus, donors registered in our computer files are recruited when needed for specific patient requirements. In addition, the maximum number of components from each unit is prepared whenever possible (e.g., red cells for those with anemia, platelets for those with thrombocytopenia, etc.)

The service mission of the Blood Bank includes provision of consultation and blood products to all the NIH Institutes and to the community when necessary. We have cooperative agreements with the American Red Cross, the American Association of Blood Banks, and other groups involved in providing blood. We maintain a sophisticated referral laboratory for the Washington metropolitan area as well as for more distant parts of the United States; we attempt to provide answers and, frequently, compatible blood. We work closely with the Red Cross in the collection of blood, with joint blood drives, and in the husbanding of blood resources in the community. The Blood Bank provides pheresis of patients and normal donors to supply numerous blood samples and components to clinical and laboratory scientists at NIH; this latter service is limited only by the demands of patient related activities. Through our "blood assurance" program we guarantee the blood needs of NIH employees and their families.

The second mission of the Blood Bank is teaching. We provide a varied educational experience to physicians enrolled in our 1-2 year blood bank training program, one of the few American Medical Association approved programs in the country. In addition, physicians from the Clinical Center Clinical Pathology Department, the Georgetown University Pathology Department and Hematology Divisions at local medical schools participate in training experiences of varying length; medical students may also spend elective time in our department. Blood Bank technologists obtain a year of graduate training in our AABB approved Specialist in Blood Banking program which qualifies them for subspecialty certification. We are active in in-service education for our staff and for other Cinical Center staff members. Members of this Department also teach and provide consultation for local hospitals, universities, military facilities and many organizations and facilities all over the country.

Research is the third mission of the Blood Bank. This research is directed toward better and safer blood products as well as the elucidation of difficult patient-care or laboratory problems. Many of the research activities here have resulted in reduction of the risk of posttransfusion hepatitis. Our hepatitis research, as well as research contributions in red cell immunology, have resulted in practical advances recognized nationally and internationally.

The goals of this Department are to improve our efforts in the three areas of service, teaching, and research. We shall continue to provide the most up-to-date, effective hemotherapy, to provide optimal patient care support, to create a stimulating learning environment, and to foster exciting investigative effort. We can thus accomplish our missions, continue to attract competent, knowledgeable staff, and maintain our position of respect in the blood banking world. We plan to continuously expand the NIH employee participation in our donor program in order to replace donors who are lost and to provide a larger donor base for the varied transfusion requests for CC patients, community needs, and for our participation in the AABB Rare Donor File.

II. DEPARTMENT ACTIVITIES

SERVICE RESPONSIBILITIES

The Blood Bank Department's primary function remains the provision of safe and effective blood and blood products. Seventy five hundred units of whole blood and red cells were transfused during the past year. Approximately 52% of this blood was drawn in the Blood Bank . This represents a 9% increase in both transfusion and collection. Blood Bank physicians continued their clinical consulting role and evaluated close to one hundred suspected transfusion reactions, 60% of which were in fact transfusion related (Table 1); however, there were no fatalities attributed to transfusion. In addition, Blood Bank physicians assisted patient care physicians in managing numerous immunohematologic problems including the first case of known recurrence of an anti-$P1^{A1}$ platelet antibody in a patient with posttransfusion purpura.

The Blood Bank continued to prepare fresh frozen plasma, cryoprecipitated antihemophilic factor, and frozen red cells. Factor VIII commercial concentrate, a dried, standardized, licensed product, again was available by contract. Use of these components has not differed substantially from 1976 to 1977.

Therapeutic procedures have increased in the past year: more than 60 phlebotomies have been performed on patients with polycythemia and hemochromatosis. The arrival of the Blood Bank's first cell separator (Haemonetics Model 30), while purchased primarily for component preparation, has added flexibility for therapeutic procedures. Requests have been received for machine-assisted exchange transfusion, plasma exchange, and cell removal for therapeutic purposes.

The plateletpheresis Center continued to function satisfactorily at close to maximum efficiency. It routinely prepared approximately 1200 units of platelets per month (17% increase) and continued to enlarge its list of HLA

typed, potential donors. The Blood Bank is the primary backup for Clinical Center platelet needs, although Red Cross single donor platelets are now available through contract with this Blood Bank should patient requirements temporarily exceed our combined platelet producing capacity.

The Blood Bank, in general, met increasing requests for blood products from the NIH research community. We performed an average of 50 plasmapheresis procedures per month for research purposes. Approximately 300 blood samples a month were drawn in the Blood Bank for NIH laboratory studies. This service has been limited at times by space and personnel restrictions. Supplying research samples must not interfere with our provision of therapeutic blood products for patients which takes precedence.

DEPARTMENT ORGANIZATION

The Blood Bank Organizational Chart is appended. Dr. Harvey G. Klein was appointed Assistant Chief and Chief of the Blood Services Section. Ms. Mary Ann Tourault has assumed the supervisory role in the Donor Recruiting Unit in addition to her responsibilities as laboratory supervisor. Dr. Richard J. Davey of the Immunology Section assumed responsibility for the Blood Bank training and education programs.

DONOR PROGRAM

The Blood Bank continued its policy of supplying all volunteer blood and began to label the blood with the "volunteer" designation. Active recruitment of volunteers continued and the roll of active donors increased to 2300 thus permitting the Blood Bank to supply more than 50% of all blood transfused in the Clinical Center, despite an increased volume of transfusions; the remainder was supplied by the Washington Regional Red Cross.

The mobile operation at the Westwood Building, begun in 1976 and sponsored jointly with the Red Cross, was carried out three times in 1977. Each effort resulted in more than 50 units of blood and an average addition of 30 new donors to the Blood Bank computer files. With the success of this operation, we further increased donor collections by reaching out to other, less accessible, NIH buildings.

The Blood Assurance Program continued to provide blood for all NIH employees and their families regardless of whether they donated blood. During the past year, some 900 units were supplied for NIH employees. This remains one of the most liberal assurance plans in the country.

LABORATORY SERVICE

The Blood Bank offers laboratory service and clinical consultation around-the-clock, seven days a week. During the past year the laboratory staff determined the blood group and type of 3000 new patients and performed 4500 direct Coombs' tests, 6200 patient screening tests for irregular antibodies, and 22000 crossmatches. There was no instance of a transfusion reaction related to clerical or technical error during this period.

Because of the unusual disease spectrum in our patient population and the number of multitransfused individuals at the Clinical Center, as well those on investigational protocols, many difficult and unusual transfusion problems were again encountered. These problems, which often involve unusual antibodies, rare red cell antigens and poorly characterized white cell antibodies, required sophisticated laboratory procedures as well as extensive investigation beyond the usual work of a service laboratory. Anti-Chido antibodies have been found in melanoma patients who are sensitized with melanoma cells. The loss of blood group antigens in patients with Hodgkins disease has been encountered and several individuals with five or more unusual red cell antibodies have been investigated and managed.

The laboratory has expanded its already extensive inventory of frozen red cells and antisera. These reagents, together with the computerized donor file, have permitted the service laboratory to solve unusual transfusion problems and locate compatible blood. In those instances when in vitro compatibility is questioned, a modified 51Cr red cell survival study has proved valuable as a rapid, reliable, in vivo determination of compatibility.

PROFESSIONAL ACTIVITIES

Members of the Blood Bank Department's professional staff made numerous contributions to the scientific and general public on a local, national and international level during the past year. The following are examples of such staff participation.

Ms. Mary H. McGinniss continued active participation on the Committee on Scientific Programs of the American Association of Blood Banks and was an invited speaker at the Florida Association of Blood Banks in Tampa and the California Blood Bank System meeting in San Francisco. She continued to be a member of the Governor of Maryland's Commission on Hereditary Diseases and was featured with Drs. Holland and Alter in the Montgomery County Sentinel's article, Blood Banking Detective.

Ms. Mary Ann Tourault was again invited to participate in the American Association of Blood Banks Invitational Conference. She continued to participate in the Rare Serum and Cell Exchange Program. She was elected to the Board of Directors of the Metropolitan Washington Blood Bank Association and reappointed to the American Association of Blood Bank's Technical Manual Committe. Ms. Tourault was also reappointed to the faculty of Montgomery Community College where she lectured and supervised student technician training.

Dr. Harvey Klein was a hematology attending physician at the Johns Hopkins Hospital each week throughout the year and attending physician of the NHLBI Molecular Hematology Branch Inpatient Service. He continued to serve as a consultant to the Blood Division of NHLBI. He was certified in Hematology by the American Board of Internal Medicine and in Blood Banking by the American Board of Pathology.

Dr. Richard Davey continued to serve as clinical assistant professor of medicine at Georgetown University where he performed attending and teaching duties. He was certified in Hematology by the American Board of Internal Medicine and in Blood Banking by the American Board of Pathology.

Dr. Harvey Alter continued as clinical associate professor of medicine at Georgetown University and helped teach the hematology course to second year medical students there. He was guest speaker at the National Academy of Science, visiting Professor at the American College of Physicians, and advisor to the National Library of Medicine. He served on the American Red Cross Advisory Committee, the NIH Infectious Disease Committee, the NHLBI Chimpanzee Utilization Committee and the NIH Hepatitis Liaison Committee, becoming Chairman of the scientific working group of that committee. He has been appointed to the committee on Scientific Programs of the American Association of Blood Banks.

Dr. Paul Holland was reappointed clinical associate professor of medicine at George Washington University and clinical associate professor of pathology at Georgetown University. He spoke at conferences at each medical school and supervised the training of their residents and fellows who rotated through the Blood Bank Department. Dr. Holland continued to be an active consultant to NHLBI for studies on transfusion transmitted viruses, plastic toxicity in transfusion, and non-A, non-B hepatitis. He was active as a member of the NIH Viral Hepatitis Studies Coordinating Committee and a member of the Technical Manual Committee of the American Association of Blood Banks. He was guest speaker at the Hematology Institute in Warsaw and the Medical Academy in Kracow, Poland and at the Institute of Medicine and Mathematics at Ohio University.

HONORS AND AWARDS

Dr. Harvey Alter received the Distinguished Service Medal for his outstanding research contributions in hepatitis.

Ms. Mary McGinniss received the NIH Director's Award for her outstanding achievement in the field of immunohematology. Ms. McGinniss also received the Ivor Dunsford Memorial Award given by the American Association of Blood Banks for research and development of technics in immunohematology.

Ms. Wanda Chappell received the NIH Merit Award for her outstanding work in blood banking.

Ms. Betty Colbert received the Equal Employment Opportunity Award.

Ms. Mary Ann Tourault, Ms. Helen Burgess and Ms. Lucille Kilmain received individual Superior Performance Awards. The technical staff of the laboratory unit received a Group, Superior Work Performance Award.

The Blood Bank Nursing Unit, Ms. Wanda Chappell, Ms. Marie Moroney, Ms. Frances Shoup, Ms. Marilyn Vander Ven, Ms. Virginia Weber, and Ms. Elsie Yanchulis received a Superior Performance Group Award.

Ms. Shirley Gregg, Ms. Deloris Koziol, Ms. Barbara Orr, Ms. Elaine Collins and Ms. Virginis Weber received Quality Increase Awards.

Ms. Elaine Collins received a cash award for an employee suggestion.

III. MAJOR PROGRESS

PROGRESS IN RESEARCH

Developmental research is, with service and training, one of the three major areas of responsibility and progress in the NIH Blood Bank. The research efforts of the Blood Bank can be conveniently divided into research in hepatitis, research in immunohematology, and research in other related fields.

HEPATITIS

This year has seen the expansion and near completion of several hepatitis investigations, under the overall direction of Dr. Harvey Alter. This includes expansion of an existing study of post-transfusion hepatitis (PTH) and the initiation of a large collaborative effort relating to hepatitis B in dialysis units in preparation for clinical trial of a hepatitis B vaccine. A summary of projects nearing completion is as follows:

(1) In a study of the use of Hepatitis B Immune Globulin (HBIG) following accidental needlestick, there is thus far significantly greater protection when HBIG is given in divided doses one month apart as compared to the same dose given initially as a single bolus. This study was instrumental in the recent FDA recommendation for HBIG to be administered in two 5 ml. doses one month apart.

(2) In a study of the efficacy of frozen-deglycerolized red cells in the prevention of PTH, it was shown that such mechanical intervention was not successful in totally removing the hepatitis B virus (HBV). Units of human blood were "spiked" with a known infectious dose of HBV and subsequently frozen and then deglycerolized by the two major methods currently in use for the preparation of frozen red cells for human use. A total of four such units were prepared and transfused to chimpanzees. Each of the four chimpanzees developed hepatitis B; in two the disease was mild and delayed but in two it was typical of acute hepatitis following the transfusion of HBsAg positive blood which was not frozen. This is the first study to definitively test the efficacy of frozen blood in relation to hepatitis prevention and may have major impact on the usage of this product.

(3) A cooperative study was undertaken to ascertain the importance of the "e" antigen (HBeAg) in predicting hepatitis B infectivity. Using donor-recipient pairs in a VA study of accidental needlestick exposure to HBsAg, it was clearly shown that HBsAg-positive blood which is also "e" antigen-positive is markedly more infectious than HBsAg-positive blood which is "e" antigen-negative. In collaboration with the VA and NIAID, we are currently expanding the number of donor-recipient pairs to further evaluate the importance of

"e" antigen and to correlate it with DNA polymerase. We are also looking at the impact of HBeAg on the interpretation of clinical trials for HBIG. Thus far the close association of "e" antigen with infectivity has been maintained. Among those who received HBeAg-positive needlesticks (i.e. infectious material), HBIG has been shown to be clearly superior to ISG as a prophylactic measure in the prevention of Hepatitis B.

(4) Since not all HBsAg positive material is equally infectious and since some might not be infectious at all, the infectivity of HBsAg-positive saliva and semen was assessed in chimpanzees. Two chimps were given either HBsAg-positive saliva or semen intravenously and both showed evidence of type B infection. This demonstrated that these secretions contained not only HBsAg, but also infectious viral particles. The experiments did not prove that saliva and semen are infectious by their natural routes of transmission; but, combined with previously published epidemiologic studies, this conclusion seems highly likely. Hepatitis B thus may be spread by oral and venereal contact as well as by blood.

(5) A 4 year study of hepatitis prevalence in a large dialysis unit was completed but the data are not yet collated.

(6) The Blood Bank was unsuccessful in its attempts to establish a reliable test for cell mediated immunity to hepatitis B and has abandoned this project. Although there have been sporadic reports of success in this area, these have been difficult to confirm and most laboratories are also having difficulty with this assay.

(7) Our study of the causes and prevention of PTH continues,and we have now enrolled over 450 open heart surgery patients in our most recent phase. These studies indicate that approximately 8% of multiply-transfused open-heart surgery patients developed PTH and that 80% of this is due to the "non-A, non-B" hepatitis virus(es) with the remainder due to hepatitis B despite the exclusion of HBsAg-positive donors by RIA. In addition to these incidence figures, this large study has had several interesting ramifications, including: (a) the evaluation of a very promising radioimmunoassay for antibody to the hepatitis B core antigen; (b) the evaluation of a test for detecting hepatitis B carriers who may carry this virus in a complexed and previously undetectable form; (c) the evaluation of the chronic sequelae of non-A, non-B hepatitis. A major effort has been made to follow and recall patients whose SGPT remains elevated greater than 6 months following transfusion. Preliminary evidence indicates that at least 25% of acute non-A, non-B hepatitis progresses to chronic transaminitis, chronic persistent hepatitis, chronic active hepatitis, or cirrhosis. Non-A, non-B appears to have more serious chronic sequelae than type B hepatitis; and, since many cases are anicteric in their acute form, non-A, non-B hepatitis may be the precipitating event in many cases which later present as unexplained chronic active hepatitis or cryptogenic cirrhosis. (d) The evaluation of implicated donors-a major effort has been made to recall donors involved in one or more cases of non-A, non-B PTH to see if they themselves have a chronic asymptomatic hepatitis that might be detected by persistent liver enzyme elevations. Such recall has implicated two potential donors and has led us to re-evaluate, in a

prospective fashion, the value of screening donors for SGPT. (e) The accumulation of pedigreed donor and recipient sera which may harbor the non-A, non-B virus: Acute phase sera from two hepatitis patients, chronic phase plasma from two patients and plasma from an implicated donor have been inoculated into five chimpanzees to see if a transmissible agent can be detected. (f) In collaboration with Dr. Purcell of NIAID, we are continuing to search for a serologic marker for the non-A, non-B agent(s). There have been some encouraging results thus far, but it is too early for speculation regarding such a marker.

(8) Work has continued in evaluating the significance of HBsAg subtypes. We have been evaluating individuals with the unusual finding of heterotypic subtype antibody which coexists with antigen of an alternate subtype. Dr. Holland has been instrumental in organizing a pedigreed panel of subtype reagents which will be distributed internationally by NIAID.

Lastly, CCBB has entered into a large, multihospital, collaborative study under the direction of Dr. Wolf Szmuness of the New York Blood Center, which, over the next 1-1/2 to 2 years, will establish baseline hospital incidence figures of hepatitis B in renal dialysis units (we are conducting surveillance in 5 units of the Metropolitan Washington Renal Dialysis Center). At the end of this time these units will serve as the primary study areas for clinical trials of hepatitis B vaccines currently in preparation.

IMMUNOHEMATOLOGY

The immunohematology laboratory, under the direction of research biologist Mary H. McGinniss, has continued to serve as a major reference center for problems in transfusion related immunohematology. Approximately 80 cases were referred to this laboratory from both local and distant hospital laboratories, with the vast majority of these referred problems being satisfactorily resolved.

Two especially interesting cases at the Clinical Center involved the loss of normal red blood cell antigens (one not previously reported) in patients with hematologic malignancies. In one patient, the loss of group A antigen predated the ultimate diagnosis of acute myelogenous leukemia and thus may be a marker for this disease in some patients. The second patient's red cells also showed acquisition of a cell antigen with terminal sepsis; this was thought to be due to coating of red cells by bacterial polysaccharides with specificity similar to the red cell antigen. Three papers on these findings are in preparation. In addition, based on studies of a patient at Georgetown University, a case of the saline agglutinating phenomenon was identified and will be published.

A strong research interest in the realtionship of drug therapy to transfusion related problems has continued during the past year. Data continue to accumulate on the possible untoward effects of the passive transfer of penicillin-antibodies through transfusion to patients who are receiving penicillin. While this may be a rare consequence of transfusion, the documentation of this possible reaction is important since the clinical symptoms could erron-

eously be attributed to other factors, such as a reaction to white cells or plasma proteins. When this study is completed, statistical data will be available which will allow correlation of these rare patient reactions with the presence or absence of hemagglutinating penicillin antibody or IgE penicillin antibody in donor plasma. In addition to the penicillin project, antibodies to neomycin, nafcillin, and chloramphenicol have been studied and related laboratory test systems delineated. The chloramphenicol work will result in a publication.

Ms. McGinniss, along with Louis H. Miller, M.D., LPD, NIAID, continued to study the relationship between the infectivity of various malaria species and the presence or absence of certain blood group antigens. Present work consists of:

(1) biochemically isolating the Duffy factor (implicated in P. vivax) from the red cell surface

(2) studying the evolution of the Duffy antigens from old world and new world monkeys

(3) further defining the possible role of the En^{a-} blood group factor implicated in the invasion of red blood cells by P. falciparum.

Other, shorter investigative studies by the immunohematology laboratory were done at the request of blood bank and clinical pathology physicians, plus on occasion for NIAID physicians.

OTHER RESEARCH ACTIVITIES

In collaboration with the NHLBI, Dr. Harvey Klein is investigating alterations in whole blood oxygen affinity following blood transfusion. Patients with varying types of anemia are being studied to determine whether changes in oxygen affinity occur in transfused red cells which may influence or alter the course or presentation of the underlying disease.

Dr. Richard Davey is studying the characteristics of poorly defined red cell allo- and autoantibodies through the use of the rapid-sequence, 51 chromium red cell survival technique. Of particular interest in these studies has been the characterization of the in vivo behavior of the anti-H antibody found in the plasma of individuals with the rare "Bombay" red cell phenotype. Work is in progress on elucidating the mechanism of red cell destruction in patients without demonstrable alloantibodies. Dr. Davey is also delineating the health maintenance benefits associated with blood donor screening.

A major project of the entire senior staff, now in the developmental stages, is the preparation of a concise manual of blood banking and immunohematology for use by medical students and housestaff. It is anticipated that the major writing and editing efforts related to this manual will take place over the next year, with publication scheduled for late 1978.

PROGRESS IN TRAINING AND DEVELOPMENT

The training of health professionals in the fields of blood banking and immunohematology and the continuing education and development of the permanent staff are major goals of the Blood Bank Department.

The central element of the training program for physicians is the Blood Bank rotation for NIH Clinical Pathology residents. This 3 month program has recently been reorganized into well-defined teaching modules, each module addressing an important aspect of blood banking. Individual modules are under the direction of one of the Blood Bank's senior staff. Key elements of this program include teaching by objectives and the extensive use of case study material. Hematology fellows and pathology residents from Georgetown University hospital again participated in this training program during the past year.

In addition to this basic rotation, the Blood Bank offers more extensive training experiences for pathology residents during the second year of their residency. Drs. Ritchard Cable and Jerry Kolins have recently completed more extensive, second year training experiences in the Blood Bank. They actively participated in the service, teaching and research activities of the Department. Dr. Cable has subsequently accepted the Directorship of the Syracuse Regional Blood Program and Dr. Kolins has accepted a position as blood bank director in a community hospital.

In July 1977 the Blood Bank accepted its first physician in the recently AMA accredited fellowship program in Blood Banking. This fellowship is designed to prepare the trained pathologist or hematologist for a career in blood banking or related disciplines.

A further major educational committment of the Blood Bank is directed toward the technical staff and trainees. There are three students currently enrolled in the AABB accredited program for Specialists in Blood Banking (SBB). These students are progressing through a structured experience in both theoretical and practical aspects of blood banking. Many recent graduates of this program are now chief technologists at major local and regional hospitals. The SBB program is currently being revised in accordance with suggestions made by the AABB.

Major changes include:

1. Formalization of admission criteria

2. Development of a standard curriculum which insures coverage of major subject areas

3. Development of specific content objectives to be used as learning guides and as standards for evaluation

The new SBB curriculum will be instituted with the class of students entering in the summer of 1977.

In addition to the SBB program, the Blood Bank has other teaching programs on a technical level. Medical laboratory students from the Allied Health School of Montgomery College rotate through the Blood Bank, learning basic laboratory techniques of immunohematology. Visiting technologists from various parts of the U.S. have spent time in the Blood Bank during the past year, reviewing and updating their skills in laboratory immunohematology.

The Blood Bank continues to conduct regularly scheduled meetings and conferences for the continuing education of the entire staff. These conferences include a journal club, clinical-laboratory correlation conference, residents' rounds, and weekly staff meetings with invited guest lecturers. Members of the Blood Bank professional staff have attended and participated in numerous professional meetings and conferences during the past year. The senior staff is now responsible for the FAES evening course, Immunohematology and Blood Banking (Immunology 508). Taught for years by Dr. Holland and Ms. McGinniss, it had to be expanded to include both spring and fall sessions during the past year to meet increasing enrollment requests.

It is anticipated that this strong commitment to education and training will result in continued progress in this area during the forthcoming year.

IV. FUTURE OBJECTIVES

Within the limitations of space and money, the future of the Blood Bank is optimistic and exciting. There are major opportunities for expanded research, teaching, and service functions.

There are several functions at NIH which would be best integrated into a cohesive unit which most logically would have the Blood Bank as the focal point. These would include the procurement and storage of HLA matched platelets and white cells and the establishment of an HLA typing laboratory. In most institutions where granulocytes and platelets are provided, this function is logically integrated with the provision of red cells, frozen cells, and other specialized blood products. The Blood Bank looks forward to its expansion into these service functions and forsees excellent opportunities for collaborative research with NCI and other institutes. Similarly, the ability to perform HLA typing and possibly other tissue typing would provide the Blood Bank with an expanded role not only in transfusion service, but possibly also in transplantation programs. It is our feeling that, with the necessary space and a somewhat expanded staff, the Blood Bank could provide these services at considerable savings to the government as compared with the current contract mechanism. Future transfusion practice will probably also call for an expanded use of frozen blood and we are already moving rapidly into this area. Although our chimpanzee studies mitigate against the safety of frozen blood from hepatitis, this product has many other advantages which justify its use.

With the acquisition of a Haemonetics Model 30 plasmapheresis apparatus, and possible future acquisition of more complex apparatus, the Blood Bank may become increasingly involved in therapeutic plasmapheresis and plasma exchange. This would be for such conditions as macroglobulinemia, hyperlipidemia, immune complex disease and exchangeable toxins.

We will do further studies on the importance of the HBeAg, on the mechanisms of non-percutaneous hepatitis transmission, on the management of the chronic HBsAg carrier and particularly on the risk of HBsAg positive health workers. In addition we will continue our surveillance of hepatitis in dialysis units (as a prelude to our participation in hepatitis B vaccine trials) in the future.

In the area of immunohematology, we will continue to seek relationships between blood groups and disease. This will include investigations of an anti-precursor antibody found primarily in leukemic families, evaluation of red cell antigens as malaria parasite receptor sites, and searches for loss of rb antigens in malignant states and the acquisition of antigens in sepsis. Studies on malaria in collaboration with Dr. Louis Miller will be directed primarily toward establishing a receptor site for Falciparum malaria similar to the Duffy site in Vivax malaria. Possibly such sites can be altered to prevent cell penetration of this parasite.

Lastly, the Blood Bank looks to an intensified teaching program. The resident rotation for physicians from our Clinical Pathology Department and from local hospitals and our technologist program for Specialist in Blood Banking are undergoing further re-evaluation and revision. These programs will be even more comprehensive and organized in the future. In addition, several of our medical staff will participate in the teaching program of the Uniformed Services Medical University School as well as continue to participate and expand their teaching committments at other nearby medical schools.

BLOOD BANK DEPARTMENT (ORGANIZATIONAL CHART)

BLOOD SERVICES SECTION

Laboratory Unit

Birrow
Burghardt
Casper
Codell
Dorset
DuChez
Eberhard
Gregg
Gustafson
Kolasinski
Maytag
Schey
Smith
VanDegrift

Tourault (Supervisor)

Recruiting Unit

Brown
Collins
Driscoll
Kendall

Nursing Unit

Allen
Mason
Moroney
Shoup
Weber
Yanchulis

Chappell (Supervisor)

CHIEF: KLEIN

IMMUNOLOGY SECTION

Hudson
James
Koziol
McGinniss
Solomon
Whipple

Davey

CHIEF: ALTER

OFFICE OF THE CHIEF

Kilmain
Leach
Orr
Thomas

Colbert (Supervisor)

Chance

Garner

CHIEF: HOLLAND

Rev. 9/77

TABLE I

TRANSFUSION REACTION DATA

CLINICAL CENTER - JAN -DEC, 1976

Units Transfused	#	
Whole blood and Packed RBC's	6704	
Washed RBC's	371	
Frozen RBC's	436	
TOTAL		7511

Reported Reactions (confirmed)	#	%	Risk
Febrile, non-hemolytic	46	78	0.61%
Urticarial	11	19	0.15
Other *	2	3	0.03
Hemolytic	0	-	-
TOTAL	59	100	0.79%

* 1 case non-immunologic hemolysis, 1 case chills only

V. PUBLICATIONS

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SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (DO NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-02001-02-BB

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

51 Cr RBC Survival as a Measure of Transfusion Compatibility

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Richard Davey, M.D., Senior Investigator, Blood Bank Department, CC

Other: Paul V. Holland, M.D., Chief, Blood Bank Department, CC
Harvey J. Alter, M.D., Chief, Immunology Section, Blood Bank, CC
Mary Ann Tourault, Supervisory Technologist, Blood Bank, CC

COOPERATING UNITS (if any)

LAB/BRANCH

Blood Bank Department

SECTION

Immunology

INSTITUTE AND LOCATION

Clinical Center, Building 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1	1	

CHECK APPROFRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

The inability to find compatible blood for transfusion is not an uncommon occurrence. A procedure has been developed whereby a small amount of 51 Cr labeled donor red cells which are incompatible by in-vitro techniques are transfused into the potential recipient and the in-vivo survival of the transfused cells determined. Survival characteristics of these cells allow decisions to be made with greater certainty regarding the safety of standard transfusions.

In the patients studied thus far, two cases of the rare "saline auto-agglutinating phenomenon" have been shown to have no significance clinically when appropriate precautions are taken. In addition the suspected incompatibility of group O red cells with a rare "Bombay O" recipient has been documented. In other instances "incompatible" blood for important surgery has been able to be released, whereas previously it would have been difficult to predict the relative hazard of transfusing such blood.

It is anticipated that further patients will continue to be included in this study when in-vivo crossmatch incompatibility is encountered.

ZO1-CC-02001-02-BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: A Rapid Technique for Determining In-Vivo Red Cell Survival in Patients Demonstrating In-Vitro Incompatibility with all Donor Red Cells

Previous Serial Number: NIH-76-CC-36

Principal Investigator: Richard J. Davey, M.D.

Other: Paul V. Holland, M.D.
Harvey J. Alter, M.D.
Mary Ann Tourault, MT(ASCP)SBB

Cooperating Units: None

Man Years: Total: 1
Professional: 1

Project Description

Objectives:

A. To evaluate in detail a procedure for the rapid determination of the survival in-vivo of Chromium (51 Cr) labeled red blood cells (RBC's) and to determine this procedure's clinical significance in predicting transfusion safety in patients for whom compatible blood cannot be found by in-vitro techniques.

B. To utilize this rapid 51 Cr survival procedure to clarify the clinical significance of certain specific rare red cell antibodies (e.g. anti-H in Bombay O, anti-Chido).

Methods Employed:

A small sample (1.0 - 2.0 ml) of test red cell suspension is labeled with 20 u Ci of 51 Cr, washed, and infused into the patient. Serial blood samples are subsequently drawn and the survival characteristics of the infused cells determined by measuring the radioactivity of each sample.

Major Findings:

Since approval of this study the following observations have been made.

A. Two unusual cases of "saline agglutinating phenomenon" have been documented and described. Patients with this phenomenon have a serum factor which agglutinates all red cells which have been washed in saline, thus complicating laboratory crossmatching efforts and rendering the infusion of saline containing fluids potentially hazardous. Survival studies using cells washed in various media permitted a decision to be made which resulted in a safe open-heart surgical procedure being done on one patient.

B. People with the rare inherited blood group called "Bombay O" have in their serum an antibody which reacts in-vitro against all normal ABO blood groups. The clinical significance of this antibody was investigated through 51 Cr survival studies in a person with the "Bombay O" blood group. It was determined that the antibody was strongly active in-vivo and that "Bombay O" people can safely receive blood only from other "Bombay O" donors.

C. Patients who required transfusion with panagglutinating antibodies and with antibodies against high incidence or poorly described RBC antigens were studied. The clinical significance of each patient's antibodies was determined by a 51 Cr survival study, with decisions made as to the relative safety of transfusion.

Significance to Biomedical Research and the Program of the Clinical Center

The primary goal of the Clinical Center Blood Bank is to provide safe blood products to Clinical Center patients. This 51 Cr red cell survival procedure provides a valuable tool in defining the relative safety of transfusion in patients for whom compatible blood cannot be found by in-vitro techniques. If this procedure proves to have significant clinical value, it is hoped that it will become a widely used blood bank investigative technique.

Proposed Course:

Continued use of 51 Cr survival technique in appropriate patients.

Presentations:

"The Saline Agglutinating Phenomenon" - Presentation at the Annual Meeting of the American Association of Blood Banks, San Francisco, California, November 1976.

Publications in Preparation:

The Saline Agglutinating Phenomenon
Signifance of Anti-H in the Bombay (O_h) Patient

SMITHSONIAN SCIENCE INFORMATION EXCHANGE
PROJECT NUMBER (DO NOT use this space)

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NOTICE OF INTRAMURAL RESEARCH PROJECT

PROJECT NUMBER

Z01-CC-02002-02-BB

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Use of Hepatitis B Immune Globulin Following Accidental Exposure

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Harvey G. Klein, M.D., Chief, Blood Services Section, Blood Bank Department, CC

Other: Harvey J. Alter, M.D., Chief, Immunology Section, Blood Bank, CC
Paul V. Holland, M.D., Chief, Blood Bank, CC
David DeMets, Ph.D. Biometrics Researcher, National Heart and Lung Institutes

COOPERATING UNITS (if any)

NHLBI

LAB/BRANCH

Blood Bank Department

SECTION

Immunology Section

INSTITUTE AND LOCATION

Clinical Center, Bldg. 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
2	1	1

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Two recently reported, randomized double blinded trials have demonstrated the efficacy of high titer hepatitis B immune globulin (HBIG) in affording temporary passive immunity to individuals accidentally exposed to low doses of HBsAg-positive material. In both studies, a 5 ml injection of HBIG was given within one week of exposure and a second injection one month later. This dosage schedule was chosen arbitrarily.

A single dose schedule of HBIG has proved efficacious in prophylaxis of spouses exposed to hepatitis B. However, these two dosage schedules, single injection and divided injections, have never been compared in a controlled study. This study plans to enroll 300 individuals accidentaly exposed to hepatitis B positive materials for development of hepatitis. Candidates will be randomized in a double blinded fashion and treated with the same dose of HBIG in either a single or double injection. Two hundred and ninety-six individuals have been enrolled to date. Samples are collected at monthly intervals, following exposure, for six months and at 9 and 12 months.

PHS-6040
(Rev. 10-76)

Z01-CC-02002-02-BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Comparison of single dose and divided dose administration schedules of Hepatitis B immune globulin: Efficacy in preventing hepatitis B following accidental exposure (needle stick).

Previous Serial Number: 76-CC-2

Principal Investigator: Harvey G. Klein, M.D.

Other: Harvey J. Alter, M.D
Paul V. Holland, M.D.
David DeMets, Ph.D.

Cooperating Units: NHLBI

Man Years: Total: 2
Professional: 1
Other: 1

Project Description

Objectives:

To determine whether a single injection of hepatitis B immune globulin (HBIG) is as effective as a divided dose injection schedule in preventing hepatitis B caused by accidental exposure.

Methods Employed:

Exposed individuals are referred by telephone to the Clinical Center Blood Bank. The purpose of the study is explained and a telephone questionnaire is used to determine eligibility for study.

Individuals who qualify are required to send blood specimens to the Blood Bank to assure exposure to an infectious source and susceptibility of the individual. Simultaneously, the individual is supplied with an informed consent form which further explains the purpose of the study.

Individuals who enter the study are randomized in a double blinded fashion to the single injection or divided dose schedule. Each receives the same total dose of HBIG. Serial blood samples are mailed and a follow-up clinical symptom questionnaire must be completed at month six and month 12.

Major Findings:

This study was initiated eighteen months ago. Two hundred and ninety-six individuals have been entered. Initial results show statistical superiority for a two dose injection regimen. We are in the final stages of the follow-up period.

Significance to Biomedical Research and Programs of the Clinical Center

The Clinical Center Blood Bank has had a longstanding interest in the problem of hepatitis caused by blood and blood products. This study should (1) add further information about the natural history of hepatitis following HBIG administration (2) answer the question of whether a single injection is as effective as a divided dose schedule, a question of great practical importance and (3) provide valuable serum samples for studying other markers of hepatitis and hepatitis infectivity.

Proposed Course: The study should be completed within one year.

Publications: None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-02003-03 BB

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

"Role of Hemagglutinating and IgE penicillin antibody in donor blood"

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Mary H. McGinniss AB(ASCP)SBB
Biologist Clinical Center Blood Bank

Other: Harvey J. Alter, M.D., Chief, Immunology Section
Clinical Center Blood Bank
Richard J. Davey, M.D., Senior Investigator
Clinical Center Blood Bank

COOPERATING UNITS (if any)

LAB/BRANCH
Blood Bank Department

SECTION
Immunology

INSTITUTE AND LOCATION
Clinical Center, Bldg. 10A, Room 1E33, NIH, Bethesda, Md. 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
0.5	0.5	

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☑ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Several years ago it was reported by us that some patients on penicillin therapy, when transfused with donor blood containing hemagglutinating penicillin antibody, suffered an untoward reaction similar to anaphylaxis or serum sickness. We are attempting to establish a prospective, control study to determine if passively transferred antipenicillin antibody can induce allergic manifestations in patients who are receiving penicillin or penicillin derivatives as part of their therapy. Donors will be screened for a history of penicillin hypersensitivity and their blood will be tested for anti-pencillin antibodies by hemagglutination and radioimmunoassay techniques. Recipients of blood from donors with a history of penicillin hypersensitivity will be followed for untoward reactions following penicillin therapy and will also be tested for IgG and IgE anti-penicillin antibodies. Appropriate controls will be similarly followed.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02003-03 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Passive Transfer of Penicillin Hypersensitivity in Transfused Blood

Previous Serial Number: Z01-CC-02003-02 BB

Principal Investigtator: Mary H. McGinniss, AB(ASCP)SBB

Other Investigators: Harvey J. Alter, M.D.
Richard J. Davey, M.D.

Cooperating Units: Inside NIH
None

Outside NIH
None

Man Years: Total: 0.5
Professional: 0.5
Other: 0

Project Description

Objectives:

A. To study the incidence and type of untoward reaction patients on penicillin therapy may experience when transfused with blood from a donor having a history of penicillin allergy and/or hemagglutinating or IgE penicillin antibody.

B. To gather data on the number of NIH donors having these types of antibodies and to do a statistical analysis on the data.

Methods Employed:

1. All donors will be questioned regarding a history of penicillin allergy. Those with such history will be divided into those with anaphylactic reactions and those with just rash. The next consecutive donor after the donor giving a positive history of penicillin allergy will serve as a control.

2. An aliquot of serum will be obtained from both allergic and control patients and the aliquot tested for IgM, IgG (hemagglutination) and IgE (RAST) anti-penicillin antibody.

3. Recipients of blood from allergic and control patients will be followed for untoward reactions occurring within 48 hours of transfusion. Such reactions will be correlated with whether or not the recipient is being treated with penicillin or a penicillin derivative.

4. Pre and post transfusion samples will be obtained from those recipients who received blood from a donor with detectable anti penicillin antibody to determine if passive transfer can be documented.

Major Findings:

In 1971, at the American Association of Blood Banks meeting, we reported findings in three patients on penicillin suffering untoward reactions which retrospectively could only be attributed to the passive infusion of penicillin antibody in donor blood. This was the impetus for the present study.

In the original study, of 29 patients who received a unit(s) of blood known to contain hemagglutinating penicillin antibody, three (10%) had untoward reactions of the serum sickness variety which could not be attributed to any other factor.

Subsequently 9 new cases of possible urticarial or serum sickness type of reactions following blood transfusion to patients receiving penicillin have been observed. A causal relation between donor anti-penicillin antibody and recipient reaction has, however, been difficult to document because the radioimmunoassay for IgE anti-penicillin antibodies is not working optimally.

Significance to Biomedical Research and the Program of the Institute:

A. Identification of another possible cause of untoward reaction of blood transfusion.

B. If it can be shown that some penicillin reactions in patients are due to passive transfer of anti-penicillin antibody, then such patients will not need to be restricted from future penicillin therapy.

C. Similary if it can be shown that such a mechanism for penicillin reactions exists, then patients being treated with penicillin will have to receive blood from donors without a history of penicillin allergy and/or without demonstratable anti-penicillin antibodies.

Proposed Course:

Setting up a working radioimmunoassay test for detecting IgE penicillin antibody, continued testing of new NIH donors for hemagglutinating penicillin antibody and monitoring of patient's response to such transfusions.

Publications: None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (DO NOT use this space)

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NOTICE OF
INTRAMURAL RESEARCH PROJECT

PROJECT NUMBER

Z01-CC-02005-08 BB

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Prospective Study of Post-transfusion Hepatitis in Open Heart Surgery Patients

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Harvey J. Alter, M.D., Chief, Immunology Section, Clinical Center Blood Bank

Other: Paul V. Holland, M.D., Chief, Clinical Center Blood Bank
Robert H. Purcell, M.D., Head, Hepatitis Virus Section, LID, NIAID
Andrew G. Morrow, M.D., Chief, Clinic of Surgery, NHLI

COOPERATING UNITS (if any)

NIAID, NHLI

LAB/BRANCH
Blood Bank Department

SECTION
Immunology Section

INSTITUTE AND LOCATION
Clinical Center, Bldg. 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
12	4	8

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☑ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

To prospectively follow all adult patients undergoing open heart surgery for the development of post-transfusion hepatitis and by appropriate serologic tests to determine the causative agents. Primarily interested in investigating the incidence of "non-A, non-B" hepatitis and to see if there are any epidemiologic or serologic clues to its prevention. This study will also compare the clinical course of the various forms of PTH and determine the frequency with which chronic hepatitis developes.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02005-08 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Prospective Study of Posttransfusion Hepatitis (PTH) in Open Heart Surgery Patients.

Previous Serial Number: Z01-CC-02005-07 BB

Principal Investigator: Harvey J. Alter, M.D.

Other Investigators: Robert Purcell, M.D.
Paul V. Holland, M.D.
Andrew G. Morrow, M.D.

Cooperating Units: Inside NIH
NIAID, NHLI

Outside NIH
None

Man Years: Total: 12
Professional: 4
Other: 8

Project Description

Objectives:

1. To prospectively follow all adult patients undergoing open heart surgery at NIH for evidences of PTH.

2. To determine the relative occurrences of type B, type A and type non-A, non-B hepatitis.

3. To determine the effectiveness of various tests for HBsAg for screening blood donors.

4. To compare the clinical course of the various forms of PTH and to determine the frequency with which chronic hepatitis develops.

5. To develop improved screening methods for type B and type non-B hepatitis.

Methods:

1. All adult patients undergoing open heart surgery are followed for six to nine months with serial tests for SGPT, HBsAg and anti-HBs.

2. Cases of hepatitis are additionally tested for serologic response to CMV, EBV and the hepatitis A virus; if type B disease, they are tested for anti-core antibody, e antigen, DNA polymerase and are subtyped.

3. Donors are tested by the most sensitive methods for HBsAg currently available. In addition donors will be tested for SGPT to see if this relates to recipient hepatitis.

Major findings: Studies to date have demonstrated:

1. The increased risk of blood containing HBsAg.

2. A 90% reduction in hepatitis by exclusion of commercial and HBsAg positive donors.

3. The superiority of RIA over CEP as a donor screening method.

4. The fact that approximately 90% of PTH is now due to a previously unrecognized virus (or viruses) currently termed "non-A, non-B."

5. That the type A hepatitis virus is almost never implicated in PTH: neither have the CMV or EBV been implicated in our cases.

6. That non-A, non-B hepatitis is generally less acutely severe than type-B but that it tends to frequently become chronic.

Significance to Biomedical Research and the Program of the Clinical Center

These studies have been instrumental in establishing many key points concerning the frequency, etiology and prevention of PTH at the Clinical Center and across the United States.

Proposed Course: See objectives and methods.

Publications:

Holland, P.V., Alter, H.J., Purcell, R.H., Walsh, J.H., Morrow, A.G., and Schmidt, P.J.: The infectivity of blood containing the Australia antigen. In Prier, J.E. and Friedman, H. (Eds.): Australia Antigen. Baltimore, University Park Press, 1973, pp. 205-211.

Alter, H.J., Holland, P.V., Purcell, R.H., Lander, J.J., Feinstone, S.M. Morrow, A.G., and Schmidt, P.J.: Posttransfusion hepatitis after exclusion of the commercial and hepatitis B antigen positive donor. Ann. Int. Med. 77: 691-699, 1972.

Feinstone, S.M., Kapikian, A.Z., Purcell, R.H., Alter, H.J., and Holland, P.V.: Transfusion-associated hepatitis not due to viral hepatitis type A or B. N. Eng. J. Med. 292: 767-770, 1975.

Alter, H.J., Holland, P.V., and Purcell, R.H.: The emerging pattern of post-transfusion hepatitis. Am. J. Med. Sci. 270: 329-334, 1975.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-02006-03 BB

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Investigation of the Efficacy of Frozen Washed Blood for the Prevention of Post-transfusion Hepatitis

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Harvey J. Alter, M.D., Chief, Immunology Section, CCBBD

Other: Paul V. Holland, M.D., Chief, Blood Bank Department, CC
Lewellys Barker, M.D., Chief, DBBP, Bureau of Biologics, FDA
Edward Tabor, M.D., Clinical Associate, Bureau of Biologics, FDA
Robert Gerety, M.D., Head, Hepatitis Section, Bureau of Biologics, FDA
Jay Hoofnagle, M.D., Hepatology Fellow, VA Hospital, Wash., D.C.
Richard Kahn, Ph.D., Scientist, American Red Cross
Harold Merryman, M.D., Research Scientist, American Red Cross

COOPERATING UNITS (if any)

American Red Cross and Bureau of Biologics, FDA

LAB/BRANCH
Blood Bank Department

SECTION
Immunology Section

INSTITUTE AND LOCATION
Clinical Center, Building 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
2	1	1

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☑ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Human blood will be inoculated with a well characterized inoculum known to uniformly cause hepatitis in chimpanzees. The infected blood will then be frozen and washed by two different methods and then transfused to four to six chimpanzees. If the chimps do not develope hepatitis suggesting freezing is effective, they will serve as their own controls and the second time receive the same inoculum which has been washed but not frozen. If they still do not get hepatitis, they will then receive the same inoculum in direct transfusion without prior washing or freezing.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02006-03 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Study in Chimpanzees of the Efficacy of Frozen Blood for the Prevention of Post-transfusion Hepatitis

Previous Serial Number: Z01-CC-02006-02-BB

Principal Investigator: Harvey J. Alter, M.D.

Other: L. Barker, M.D., P.V. Holland, M.D., E. Tabor, M.D., R. Gerety, M.D., H. Merryman, M.D., R. Kahn, Ph.D. and J. Hoofnagle, M.D.

Cooperating Units: Inside NIH
None

Outside NIH
ARC and BOB, FDA

Man Years: Total: 2
Professional: 1
Other: 1

Project Description

Objectives:

1. To see if blood with a known infectious dose of hepatitis B virus can be rendered non-infectious by freeze-washing or washing alone.

Methods:

1. Blood will be "spiked" with a dose of HBV-proven to be uniformly infective in chimps.

2. Two units of inoculated blood will undergo the typical freeze wash cycle employed at NIH (IBM method) and two will undergo the standard freeze-wash cycle at ARC (Haemonetics method). These will then be transfused to four susceptible chimpanzees.

3. If the chimpanzees do not develop hepatitis or serologic evidence of type B infection, they will then serve as their own controls and receive a second transfusion of "spiked" blood this time being washed but not frozen.

4. If the chimpanzees do not develop hepatitis after step (3), they will receive the same inoculum this time without any prior treatment.

Major Findings:

All four inoculated chimps developed evidence of type B infection despite prior treatment of the blood by freezing and deglycerolization (F and D). In two of the chimps it appeared that this process attenuated the disease and prolonged the incubation period, but in the other two full blown hepatitis B developed. We would conclude that in the chimpanzee model freezing and deglycerolization as typically performed on human blood units was not adequate to prevent type B hepatitis infection.

Significance to Biomedical Research and the Program of the Clinical Center

This study refutes previous claims in uncontrolled human studies that freezing and deglycerolization of blood renders blood hepatitis free. It does not negate the use of frozen blood because this product has many other potential advantages, but it does potentially negate the one use of frozen blood which would justify its routine application in all transfusion settings. The study does not answer the question of the efficacy of freezing and deglycerolization for the prevention of type non-A, non-B hepatitis and, at present, human trials will be necessary for this.

Proposed Course:

Because each of the chimps became infected in the first phase of the study, there is no need for them to serve as their own controls to receive washed but unfrozen blood or to receive blood which has not been treated. The study will thus be prepared for publication and terminated.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-02007-02 BB

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Infectivity of HBsAg-positive saliva and semen

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Harvey J. Alter, M.D., Chief, Immunology Section, CCBBD

Other: Robert Purcell, M.D., Chief, Hepatitis Viruses Section, NIAID
John Gerin, M.D., Chief, Molecular Anatomy Program, Union Carbide
Paul V. Holland, M.D., Chief, Blood Bank Department, CC

COOPERATING UNITS (if any)

NIAID and AEC

LAB/BRANCH

Blood Bank Department

SECTION

Immunology Section

INSTITUTE AND LOCATION

Clinical Center, Building 10A, Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1.5	0.5	1

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

HBsAg-positive saliva and semen from persons with an epidemiologic history suggesting non-parenteral transmission of hepatitis B will be inoculated into chimpanzees. The chimps will be followed for clinical, enzymatic, and serologic evidence of type B hepatitis and the inoculum will be characterized for the predominant type of particle and for DNA polymerase and e antigen.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02007-02 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Infectivity of HBsAg-positive saliva and semen

Previous Number: Z01-CC-02007-01-BB

Principal Investigator: Harvey J. Alter, M.D.

Other: Robert Purcell, M.D.
John Gerin, M.D.
Paul V. Holland, M.D.

Cooperating Units: Inside NIH
NIAID

Outside NIH
AEC

Man Years: Total: 1.5
Professional: 0.5
Other: 1

Project Description

Objectives:

To determine if HBsAg-positive saliva and semen are infectious.

Methods:

1. HBsAg-positive saliva and semen specimens obtained from individuals with a history suggesting non-parenteral spread of type B hepatitis will be inoculated into chimpanzees. The chimps will then be followed with serial tests to establish the development of hepatitis and serologic responses to the type B hepatitis virus. If hepatitis developes, liver biopsies will be obtained.

2. The inocula will be characterized regarding the presence of Dane particles, DNA polymerase, and e antigen as well as the subtype of HBsAg.

Major Findings:

One chimp inoculated intravenously with HBsAg-positive saliva has developed type B hepatitis. This has proven that HBsAg-positive saliva is infectious. A second chimp inoculated intravenously with HBsAg-positive semen has developed probable hepatitis (died before completion of study).

Significance to Biomedical Research and the Program of the Clinical Center

There is increasing indirect evidence that hepatitis B can be transmitted by routes other than blood. In addition, HBsAg has been detected in both saliva and semen. This suggests that these secretions might be the vehicle for non-parenteral transmission. However, there is also considerable evidence that most hepatitis B antigen is non-infectious. No one has ever demonstrated that HBsAg when found in saliva and semen is associated with infectious particles. Our experiment has now documented that saliva, and probably semen, with HBsAg in it is indeed infectious and can result in hepatitis B after inoculation.

Proposed Course: Study complete

Publications:

Alter, H.J., Purcell, R.H., Gerin, J.L., London, W.T., Kaplan, P.M., McAuliffe, V.J., Wagner, J.A., and Holland, P.V.: Transmission of Hepatitis B to chimpanzees by hepatitis B surface antigen positive saliva and semen. Infection and Immunity 16: 928-933 (June 1977).

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-02008-05-BB

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Hepatitis Transmission in a Renal Dialysis Unit

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Harvey J. Alter, M.D., Chief, Immunology Section, Blood Bank Department, CC

Other: Paul V. Holland, M.D., Chief, Blood Bank Department, CC
Jacqueline C. Melpolder, Research Technologist, CCBBD
L. Segal, M.D., Staff Physician, MWRDC
J. Frank, Chief Nurse, MWRDC
W. Cirksena, M.D., Staff Physician, MWRDC
J. Knepschield, M.D., Staff Physician, MWRDC

COOPERATING UNITS (if any)

Metropolitan Washington Renal Dialysis Center

LAB/BRANCH
Blood Bank Department

SECTION
Immunology Section

INSTITUTE AND LOCATION
Clinical Center, Building 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
4	2	2

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☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☑ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

This study consists of the long-term, prospective follow-up of patients undergoing renal dialysis in a large metropolitan center. Patients will be monitored for the development of hepatitis B antigen and antibody and for the development of other forms of hepatitis. Epidemiologic patterns of spread will be analyzed and the frequency and severity of hepatitis among patients and staff will be compared.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02008-05-BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Hepatitis Transmission in a Renal Dialysis Unit

Previous Project Number: Z01-CC-02008-04-BB

Principal Investigator: Harvey J. Alter, M.D.

Other: L. Segal, M.D., J. Melpolder, B.S., W. Cirksena, M.D.
J. Knepschield, M.D., J. Frank, R.N., and P.V. Holland, M.D.

Cooperating Units: Inside NIH
None

Outside NIH
Metropolitan Washington Renal Dialysis Unit

Man Years: Total: 4
Professional: 2
Other: 2

Project Description

Objectives:

1. To determine the overall incidence of hepatitis in a large renal dialysis unit, and to determine the proportion which is B and non-B.

2. To determine the duration of HBsAg-positivity among patients and the number who develope serologic evidence of type B infection without enzymatic evidence of hepatitis.

3. To test the hypothesis that renal dialysis patients, as opposed to staff, are unable to clear HBsAg and tend to become chronic carriers.

4. To determine the relative infectivity of dialysis patients with HBsAg by measuring e antigen in their sera.

5. To try to elucidate the mode of hepatitis B virus transmission within dialysis units.

Methods Employed:

1. Renal dialysis patients and staff at the MWRDC will be tested monthly for SGPT, HBsAg and anti-HBs.

2. HBsAg positive individuals will be subtyped and tested for e antigen.

3. From these data, the incidence of hepatitis, serologic response to HBsAg, duration of HBsAg, subtype of HBsAg, duration of transaminase elevation and relative infectivity can be assessed in patients and staff.

4. To establish epidemiologic patterns from logbooks and environmental sampling for HBsAg.

Major Findings:

To date, the frequency of hepatitis B virus (HBV) transmission is extremely high. At least 25% of patients show evidence of HBV infection. A previously unreported finding is that most dialysis patients handle HBV infection very well and manifest only transient antigenemia. Those who have transient antigenemia tend to have HBsAg detectable only by RIA, whereas chronic carriers have higher titers of HBsAg. As in other dialysis units, the ayw subtype predominates. Hepatitis B infection is less frequent, but more severe, among staff members. Data from this study through 12/31/76 is currently being analyzed for publication.

Significance to Biomedical Research and the Program of the Clinical Center

This dialysis unit has been closely followed almost since its inception, and the incidence figures and patterns of spread provide useful data on hepatitis transmission in this setting. The finding that most dialysis patients actually handle HBV infection quite well has not been previously reported. This dialysis unit will provide baseline data for clinical trials of a hepatitis B vaccine and will likely be one of the units involved in these trials.

Proposed Course: See objectives.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-02009-03-BB

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Assessment of the Infectivity of HBsAg-Containing Blood Using In-Vitro Assays of DNA Polymerase and e-Antigen

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Harvey J. Alter, M.D., Chief, Immunology Section, Blood Bank Department, CC

Other: Leonard Seeff, M.D., Head Hepatitis Studies, Veterans Administratio Hospital, Wash., D.C.
Paul Kaplan, Ph.D., Research Scientist, Molecular Anatomy Branch, AEC
Vincent McAuliffe, M.D., Clinical Associate, LID, NIAID
John Gerin, Ph.D., Head, Molecular Anatomy Program, Union Carbi
Elizabeth Wright, Ph.D., Statistician, VA Hospital, Wash., D.C.
Robert Purcell, M.D., Head, Hepatitis Virus Section, LID, NIAID
Paul V. Holland, M.D., Chief, Blood Bank Department, CC

COOPERATING UNITS (if any)

VA Hospital, Washington, D.C.
NIAID, Molecular Anatomy Program, AEC

LAB/BRANCH
Blood Bank Department

SECTION

Immunology Section

INSTITUTE AND LOCATION

Clinical Center, Bldg. 10A, Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
3	2	1

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Donor-recipient pairs involved in the VA cooperative study to evaluate hepatitis B immune globulin following accidental needlestick will be tested to determine the association between DNA polymerase and e antigen in the donor and hepatitis in the recipient. Preliminary evidence indicates these will be good indicators of infectivity.

In addition, health workers with acute and chronic hepatitis will be tested for these same parameters to assess their relative infectivity.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02009-03 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Assessment of the Infectivity of HBsAg-Containing Blood Using In-Vitro Assays for DNA Polymerase and e Antigen

Previous Serial Number: Z01-CC-02009-02 BB

Principal Investigator: Harvey J. Alter, M.D.

Other: L. Seeff, M.D., P. Kaplan, Ph.D., V. McAuliffe, M.D. J. Gerin, Ph.D., E. Wright, Ph.D., R. Purcell, M.D. and P. Holland, M.D.

Cooperating Units: Inside NIH
NIAID

Outside NIH
Washington V.A. Hospital and AEC

Man Years: Total: 3
Professional: 2
Other: 1

Project Description

Objectives:

1. To test donor and recipient pairs enrolled in a VA cooperative study of hepatitis following accidental needlestick to determine if:

   (a) the measurement of DNA-polymerase and e antigen in the donor will predict the hepatitis outcome in the recipient and,

   (b) to see if the infectivity of the inoculum correlates better with recipient hepatitis than does the treatment received (i.e. type of gamma globulin).

2. To test HBsAg-positive health workers to see if DNA polymerase and e-antigen correlate with the duration of antigenemia and the degree of SGPT elevation.

Methods Employed:

1. In the VA study, donors will be tested under code to determine the presence of hepatitis B specific DNA polymerase and e antigen. When the determinations are complete, the code will be broken and an estimate made of the correlation between these in vitro parameters in the donor and hepatitis in the recipient. DNA polymerase will be measured by incorporation of 3H thymidine into DNA and e antigen by gel diffusion. Needlestick recipients have been prospectively and carefully monitored for hepatitis.

2. In the health worker study, serial samples will be obtained from those with acute disease, those with chronic hepatitis, and the asymptomatic carrier state.

Major Findings:

A very strong association was found between the presence of DNA polymerase and the presence of e antigen in HBsAg-positive sera. More significantly, each was strongly associated with the infectivity of the blood in which they were detected; DNA and e antigen positive blood resulted in hepatitis in the vast majority of recipients accidently inoculated with such blood whereas DNA and e negative blood did not result in infection ($p<.001$). (See publications).

Significance to Biomedical Research and the Program of the Clinical Center

The ability to determine the relative infectivity of an HBsAg carrier by an in-vitro method is extremely important in situations of potential non-parenteral transmission or in situations where the inoculum is small, such as accidental needlestick. It may have major implications for antigen-positive health workers.

These studies also suggest that the recently completed clinical trials of HBIG must be reevaluated to determine the infectivity of the inoculum because this may be more important than the treatment received.

Proposed Course:

This study is now being expanded so as to examine all patients and recipients in the VA trial of HBIG for the prevention of hepatitis following accidental needlestick. The impact of e antigen testing on interpretation of this clinical trial is also being evaluated. Preliminary evidence indicates that if one looks only at recipients of infectious blood (i.e. e or DNA positive) then the effect of HBIG as compared with ISG is even more striking than previously reported.

Publications:

Alter, H.J., Seeff, L.B., Kaplan, P.M., McAuliffe, V.J., Wright, E.C., Gerin, J.L., Purcell, R.H., Holland, P.V. and Zimmerman, H.J.: Type B Hepatitis: The infectivity of blood positive for e antigen and DNA polymerase after accidental needlestick exposure. New Engl. J. Med. 295: 909-913, 1976.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-02010-03 BB

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Chronic Sequelae of Non-A, Non-B Hepatitis

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Harvey J. Alter, M.D., Chief, Immunology Section, Blood Bank Department, CC

Other: Paul V. Holland, M.D., Chief, Blood Bank Department, CC
Robert Purcell, M.D., Head Hepatitis Virus Section, LID, NIAID
Paul Berk, M.D., Chief, Section on Diseases of the Liver, DDB, NIAMDD

COOPERATING UNITS (if any)

NIAID, NIAMDD

LAB/BRANCH

Blood Bank Department

SECTION

Immunology Section

INSTITUTE AND LOCATION

Clinical Center, Building 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
2	2	0

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☑ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Patients identified as having non-A, non-B hepatitis will be followed as long as possible. Liver biopsy will be obtained when the SGPT is elevated for more than 6 months and then as indicated thereafter. Biopsy material will be saved for fluorescent studies when reagents for non-A, non-B hepatitis become available.

All patients developing non-A, non-B hepatitis following open heart surgery will be followed with serial studies of SGPT to determine the incidence of chronic liver disease and to compare this incidence with those having type B hepatitis.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02010-03 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Chronic Sequelae of Non-A, Non-B Hepatitis

Previous Serial Number: 76-CC-2

Principal Investigator: Harvey J. Alter, M.D.

Other: R. Purcell, M.D.
P. Berk, M.D.
P. Holland, M.D.

Cooperating Units: Inside NIH
NIAID, NIAMDD

Outside NIH
None

Many Years: Total: 2
Professional: 2

Project Description

Objectives:

1. To establish long-term follow-up of patients identified as having non-A, non-B hepatitis in post-transfusion hepatitis (PTH) studies conducted at NIH since 1963.

2. To determine by SGPT the frequency of chronic hepatitis.

3. To determine by liver biopsy the histologic pattern of non-A, non-B hepatitis and to save biopsy specimens for future immunofluorescent studies when reagents become available for non-A, non-B hepatitis.

Methods Employed: See objectives

Major Findings:

Chronic hepatitis frequently follows acute non-A, non-B hepatitis and in the patients thus far biopsied the histologic picture is similar to chronic type B hepatitis, showing features of either chronic persistent or chronic active hepatitis.

Significance to Biomedical Research and the Program of the Clinical Center

Non-A, non-B hepatitis now accounts for 80% of PTH and is thus a major transfusion hazard. While it tends to be less acutely severe than type B hepatitis, preliminary evidence suggests that it progresses to chronic hepatitis with considerable frequency. Very little is known about this disease and it is imperative that clinical and serologic studies be undertaken. It is possible that a high percentage of chronic active hepatitis and cryptogenic cirrhosis represent the chronic sequelae of a previously unrecognied case of anicteric non-A, non-B hepatitis.

Proposed Course: See objectives.

Publications: None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-02011-03-BB

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

The Duffy Blood Group Determinant and Susceptibility to Malaria

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Louis H. Miller, M.D., Head Malaria Section, LPD, NIAID

Other: Mary McGinniss, AB(ASCP)SBB, Research Biologist, Clinical Center Blood Bank
Paul V. Holland, M.D., Chief, Clinical Center Blood Bank

COOPERATING UNITS (if any)

Laboratory Parasitic Diseases, NIAID

LAB/BRANCH

Blood Bank Department

SECTION

Immunology Section

INSTITUTE AND LOCATION

Clinical Center, Bldg. 10A, Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
2	2	

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☑ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Working with an in vitro model for invasion of red cells by malaria merozoite, this study has demonstrated that human red cells lacking the Duffy a and b antigens are resistant to invasion. This corresponds well with epidemiologic studies which show that approximately 70% of West African and American blacks are resistant to Vivax malaria. A similar proportion of these blacks are Duffy a and b negative whereas the Duffy negative genotype is extremely rare in other racial groups. The close association between the Duffy negative genotype and resistance to Vivax malaria has also been confirmed by retrospective analysis of 11 volunteers experimentally inoculated with P. Vivax. A larger study in humans is planned; this will involve correlation of Duffy phenotypes of U.S. servicemen who acquired malaria in South-East Asia and comparison with the frequencies of Duffy phenotypes in a control population.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02011-03-BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: The Duffy Blood Group Determinant and Susceptibility to Malaria

Previous Serial Number: Z01-CC-02011-02-BB

Principal Investigator: Louis H. Miller, M.D.

Other: Mary H. McGinniss, AB(ASCP)SBB
Paul V. Holland, M.D.

Cooperating Units: Lab. Parasitic Disease, NIAID

Man Years: Total: 1
Professional: 1

Project Description

Objectives:

1. To use a red cell culture technique to determine if invasion of erythrocytes by Plasmodium falciparum is dependent upon antigenic determinants on the erythrocyte membrane similar to that found for Vivax malaria.

2. To characterize the antigens involved and determine the sequence of events when malarial invasion occurs.

3. To determine the Duffy phenotypes of servicemen who acquired malaria, vivax or falciparum, in South-East Asia.

4. To determine if different antigenic receptors are responsible for different forms of human malaria.

Methods Employed:

1. P. falciparum merozoites are added to RBC in culture and the degree of RBC invasion is observed microscopically. The degree of invasion of RBC with differing phenotypes is compared.

2. When a specific antigen is identified as being involved in the attachment or invasion by malaria parasites (as in (1)), attempts are made to block or destroy that site with specific antibody or enzyme treatment.

3. Blood Samples for Duffy phenotype are being collected in U.S. servicemen who had malaria in South-East Asia.

Major Findings:

Thus far one cell among many tested was not invaded normally by P. falciparum parasites. This is a very rare cell known as En(a-). This cell lacks sialic acid and therefore M and N antigens. This cell is also Wr(b-) which is a universal antigen. One person who is En(a+) is Wr(b-). We have made plans to secure these rare cells and other cells having low levels of sialic acid to see if low invasion by P. falciparum parasites is due to lack of sialic acid, or the lack of the En^a or Wr^b antigens.

Significance to Biomedical Research and the Program of the Clinical Center

1. Elucidation of the mechanisms of red cell invasion by P. falciparum.

2. Increased knowledge of erythrocyte polymorphisms.

3. Accumulation of data which could culminate in a vaccine or other means of malaria prevention.

Publications

1. Miller, L.H., Mason, S.J., Clyde, D.F., and McGinniss, M.H.: The resistance factor to Plasmodium vivax in blacks. N. Eng. J. Med. 295: 302-304, 1976.

2. Miller, L.H., Haynes, J.D., McAuliffe, F.M., Shiroishi, T., Durocher, J.R., and McGinniss, M.H.: Evidence for differences in erythrocyte surface receptors for the malarial parasites, Plasmodium falciparum and Plasmodium knowlesi. J. Exp. Med. 146: 277-281, 1977.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-02012-01 BB

PERIOD COVERED
April 1, 1977 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Chido (Ch^a) Antibody Production Induced by Cancer Immunotherapy

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI: Mary L. Gustafson, MS, MT(ASCP)SBB, Senior Technologist, Clinical Center Blood Bank

Other: Ritchard G. Cable, M.D., Assistant Chief, Blood Services Section, Clinical Center Blood Bank

William D. Terry, M.D., Associate Director, Immunology Branch, DCBD, NCI

Richard J. Hodes, M.D., Head, Immunology Section, Immunology Branch, DCBD, NCI

Susan Gross, R.N., Immunotherapy Research Nurse, Immunology Branch, DCBD, NCI

COOPERATING UNITS (if any)

NCI

LAB/BRANCH
Blood Bank Department

SECTION
Blood Services Section

INSTITUTE AND LOCATION
Clinical Center, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
0.5	0.5	0

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☑ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

On routine testing, it was discovered that two patients with malignant melanoma had developed the red blood cell antibody, anti-Chido(Ch^a), folllowing the initiation of cancer immunotherapy in the treatment of their disease. We are currently testing the Ch^a antigen status of the remaining persons in this protoco to see if the number varies from the statistical norms of 98% Ch^a positive. W are attempting to test the Ch^a antigen status of three cell lines of neuraminada treated and untreated cultured melanoma cells used for injection in this protoco to determine if these cells can be responsible for inducing antibody production.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02012-01 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: "Chido(Ch^a) Antibody Production Induced by Cancer Immunotherapy"

Previous Serial Number: None

Principal Investigator: Mary L. Gustafson, MS, MT(ASCP)SBB

Other Investigators: Ritchard G. Cable, M.D.
William D. Terry, M.D.
Richard J. Hodes, M.D.
Susan Gross, R.N.

Cooperating Units: Inside NIH
NCI

Outside NIH
None

Man Years:

Total: 0.5
Professional: 0.5
Other: 0

Project Description

Objectives:

To determine the Ch^a antigen status of the cell lines used in the treatment of persons with malignant melanoma to determine whether these cells are responsible for inducing antibody production.

Methods Employed:

Ch^a antigen status of individuals is determined by a serum agglutination inhibition procedure. Absorption-elution techniques will be employed in the experimental testing for the Ch^a antigen on the neuraminadase treated and untreated melanoma cells from culture.

Major Findings:

To date, one other person in this protocol appears to be Ch^a negative.

Significance to Biomedical Research and the Program of the Institute:

This may demonstrate the first evidence of red blood cell antibody production following treatment of cancer immunotherapy.

Proposed Course:

See objectives and methods.

Publications: None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (DO NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-02013-01 BB

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Mechanism of Vertical Transmission of Hepatitis B Virus

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: George Grady, M.D.

Others: Harvey J. Alter, M.D. CCBBD

COOPERATING UNITS (if any)

Mass. Department of Public Health

LAB/BRANCH
Blood Bank Department

SECTION
Immunology Section

INSTITUTE AND LOCATION
Clinical Center, Bldg. 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1	0.5	0.5

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☑ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Maternal-fetal transmission is felt to be responsible for a large number of chronic carriers of HBsAg. The mechanism by which the virus is transmitted from mother to infant is however unclear with the three main possibilities being: (1) transplacental transmission prior to birth (2) swallowing of maternal blood at the time of delivery (3) post partum transmission via breast feeding or maternal handling.

We will attempt to sort these possibilities by delivering the infants of HBsAg-positive chimpanzees by Caesarian section and by having the infant reared separate from the HBsAg-positive mother.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02013-01 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

NIH-PHS
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Mechanism of Vertical Transmission of Hepatitis B Virus

Previous Serial Number: None

Principal Investigator: George Grady, M.D.

Other: Harvey J. Alter, M.D., CCBBD

Cooperating Units: Massachusetts Dept. of Public Health

Man Years: Total: 1
Professional: 0.5
Other: 0.5

Project Description

1. To see is maternal-fetal hepatitis transmission occurs despite the absence of any post-partum contact between mother and infant.

2. To see if the possibility of blood ingestion by the fetus can be avoided by bloodless Caesarian section and to see what impact this has on maternal-fetal transmission.

3. To see if prepartum transmission can be documented by the presence of HBsAg in cord blood or by the presence of hepatitis related antigens in fetal liver tissue obtained at the time of delivery.

Methods:

1. Chronic HBsAg carrier chimpanzees will be housed and bred in the laboratory for Experimental Medicine and Surgery (LEMSIP). The carriers employed will be e antigen positive to document their potential infectivity.

2. Chimps will be delivered by as atraumatic and bloodless Caesarian section as possible.

3. At birth, samples will be obtained for HBsAg and e antigen testing from maternal blood, cord blood, fetal venous blood and amniotic fluid. A liver biopsy will also be obtained from the fetus and stained by fluorescent techniques for the presence of HBcAg and HBsAg.

4. The fetus will have no contact with the HBsAg-positive mother after delivery and will be followed for the development of type B hepatitis.

Major Findings:

The first infant so studied developed type B hepatitis 7 weeks after delivery. This rules out post-partum contact as the cause of hepatitis transmission, but does not distinguish the other possibilities because the Caesarian section was not entirely bloodless. Against transplacental transmission, was the finding of HBsAg-negative cord blood and fetal venous blood. However, liver biopsy was not performed at the time of birth.

Significance of Findings:

It has been estimated that maternal-fetal transmission of hepatitis B may be the major cause for the development of the HBsAg carrier state. Throughout the world this is probably a far more significant route of transmission than blood transfusion. Any studies which elucidate the mechanism of such transmission may help in its prevention. It has already been proposed that mothers who are HBsAg-positive be delivered by Caesarian section. These studies may shed light on the rationale for such an approach.

Proposed Course:

The carrier mother whose fetus has already been followed will be inpregnated as soon as possible and the second fetus delivered by a more meticulous C-section and also biopsied at the time of delivery. In addition, the offspring of other carrier chimps will be similarly followed (there are currently 3 such carriers at LEMSIP).

SMITHSONIAN SCIENCE INFORMATION EXCHANGE
PROJECT NUMBER (Do NOT use this space)

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NOTICE OF INTRAMURAL RESEARCH PROJECT

PROJECT NUMBER

Z01-CC-02014-01 CC

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Transmission of Non-A, Non-B Hepatitis to Chimpanzees

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Harvey J. Alter, M.D.

Other: Robert Purcell, NIAID
Paul V. Holland, CCBB

COOPERATING UNITS (if any)

NIAID

LAB/BRANCH
Blood Bank Department

SECTION
Immunology Section

INSTITUTE AND LOCATION
Clinical Center, Bldg. 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
2	1	1

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☑ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

80-90% post-transfusion hepatitis now appears related to a third human hepatitis "virus" tentatively termed "non-A, non-B." There are several pieces of evidence to suggest this is a virus but to date this agent has not been observed, has not had an identifiable antigenic marker, has not been grown in culture and has not been transmitted to animals. This study will attempt to identify bloods with a high probability of containing this virus and will then attempt chimpanzee inoculation.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02014-01 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Transmission of Non-A, Non-B Hepatitis to Chimpanzees

Previous Serial Number: None

Principal Investigator: Harvey J. Alter, M.D.

Other: Robert Purcell, NIAID
Paul V. Holland, CCBB

Cooperating Units: NIAID

Man Years: Total: 2
Professional: 1
Other: 1

Project Description

1. To prove that non-A, non-B hepatitis is due to a transmissable agent.

2. To transmit this agent from human blood to chimpanzees and if successful from chimpanzee to chimpanzee.

3. To obtain plasmapheresis units from infected chimpanzees to aid in characterization of the virus and development of serologic tests.

Methods:

1. Potentially infectious sera will be obtained from patients with acute and chronic non-A, non-B hepatitis and from donors implicated in such transmission.

2. Depending on the volume of sample available either 1 ml or 75 ml will be inoculated into chimpanzees and the animals followed for six months for evidence of enzyme (SGOT/SGPT) elevations.

3. Animals with elevated SGOT/SGPT will be plasmapheresed and have liver biopsies. Biopsy material will be observed for evidence of hepatitis, but will also be frozen for subsequent immunofluorescent tests should they become available.

4. Acute phase plasma from reactive chimps will be administered to additional animals in an attempt to demonstrate serial passage.

Major Findings:

Pedigreed samples have been obtained over the past year and five chimpanzees have been inoculated. No hepatitis has occurred in the first four weeks post inoculation.

Proposed Course:

Since we are dealing in the blind as regards this proposed agent(s), additional inocula will be accumulated and as many chimps as can be obtained, inoculated. The problem of transmission is complicated in that there is no way to currently assess the susceptibility of a given chimpanzee so that a single inoculum may be infectious in one chimp and not in another.

Publications: None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (DO NOT use this space)

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NOTICE OF
INTRAMURAL RESEARCH PROJECT

PROJECT NUMBER
Z01-CC-02015-01 BB

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Longitudinal Study of e Antigen in Health Workers and Patients Who Are Chronic Carriers of HBsAg

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Harvey J. Alter, M.D.

Other: Robert Purcell, M.D.
Joel Spero, M.D.
Herbert Polesky, M.D.

COOPERATING UNITS (if any)

Lab Infectious Disease, NIAID, University of Pittsburg Blood Bank, Minneapolis War Memorial Blood Bank

LAB/BRANCH

Blood Bank Department

SECTION

Immunology Section

INSTITUTE AND LOCATION

Clinical Center, Bldg. 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1.5	0.5	1

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

e antigen has been shown to be an excellent marker to define those HBsAg-positive individuals most likely to transmit hepatitis B. Implicit in this statement is the fact that e antigen-positive health workers and patients will carry an additional stigma and may be placed under more stringent restrictions than HBsAg-positive individuals who are e antigen negative. Before any such decisions can be rendered, it must be ascertained if the presence or absence of e antigen is an invariant feature of any given HBsAg-positive individual or if it varies over the course of time.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02015-01 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Longitudinal Study of e Antigen in Health Workers and Patients Who Are Chronic Carriers of HBsAg

Previous Serial Number: None

Principal Investigator: Harvey J. Alter, M.D.

Other: Robert Purcell, M.D.
Joel Spero, M.D.
Herbert Polesky, M.D.

Cooperating Units: Lab Infectious Disease, NIAID, University of Pittsburg Blood Bank, Minneapolis War Memorial Blood Bank

Man Years: Total: 1.5
Professional: 0.5
Other: 1

Project Description

Objectives:

1. To measure e antigen in serial samples from the same HBSAg-positive individuals including a minimum of 3 samples over at least one year period. Samples will be obtained from health workers, dialysis patients, hemophiliacs and asymptomatic blood donors.

2. To ascertain if e antigen is persistent or variable over this time span and thus whether its predictive value can be reliably interpreted.

Methods:

1. e antigen will be measured by rheophoresis or counterelectrophoresis until a more sensitive test is developed.

Major Findings: None to date

Proposed Course: See objectives

Significance:

If judgements regarding the management of HBsAg-positive carriers are to be made on the basis of the presence or absence of e antigen, it is essential to know if such presence or absence is an invariant feature of a given individual or subject to change over time. If the latter pertains, then a differential handling of HBsAg carriers based on the presence or absence of e antigen is probably not warranted.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-02016-01 BB

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Evaluation of Anti-Core Antibody and Serum Transaminase as Indicators of the Infectivity of HBsAg-Negative Donors

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Harvey J. Alter, M.D.

Other: Paul V. Holland, M.D., Chief, Blood Bank Department, CC
Deloris Koziol, Medical Research Technologist, CCBBD

COOPERATING UNITS (if any)

None

LAB/BRANCH

Blood Bank Department

SECTION

Immunology Section

INSTITUTE AND LOCATION

Clinical Center, Bldg. 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1.5	0.5	1

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Despite sensitive radioimmunoassay tests for HBsAg applied to all donor blood, some type B hepatitis continues to occur following transfusion. It has previously been suggested that HBsAg negative individuals who have anti-core antibody may transmit the hepatitis B virus. The availability of a new sensitive radioimmunoassay for anti-core antibody allows this postulate to be tested in our prospectively followed, open heart surgery patients. Similarly, we can ascertain if chronic carriers of non-A, non-B hepatitis have elevated serum transaminase; and, if so, whether this could be employed to screen donors and reduce the frequency of post-transfusion hepatitis due to this agent.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02016-01 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Evaluation of Anti-Core Antibody and Serum Transaminase as Indicators of the Infectivity of HBsAg-Negative Donors

Previous Serial Number: None

Principal Investigator: Harvey J. Alter, M.D.

Other: Paul V. Holland, M.D.
Deloris Koziol, Medical Research Technologist

Cooperating Units: None

Man Years: Total: 1.5
Professional: 0.5
Other: 1

Project Description

Objectives:

1. To determine if HBsAg-negative donors who have anti-core antibody are more likely to transmit type B hepatitis then those who lack anti-core antibody.

2. To determine if donors with elevated SGPT are more likely to transmit non-A, non-B hepatitis than donors with normal SGPT and to ascertain if this would be a practical way to screen for chronic carriers of this presumed virus.

Methods:

1. We have now prospectively followed over 400 patients to determine if they developed post-transfusion hepatitis and, if so, by what etiologic agent. All donors to type B and non-A, non-B hepatitis cases will be tested for anti-core antibody as will the donors to at least 30 patients who did not develope hepatitis (approximately 500 donors in all). Data will be analyzed to see if there is any positive correlation between the presence of anti-core antibody in the donor and hepatitis in the recipient.

2. All donors to open heart surgery patients will be tested for SGPT. These tests will be performed in a sample obtained at the time of donation, but

will not be tested until approximately 3 days after transfusion. The results of transaminase tests will not be known at the time of transfusion, but recipients will be followed prospectively for the development of hepatitis. Data will be analyzed to see if there is a positive correlation between the presence of elevated donor transaminase and the development of recipient hepatitis.

3. When an elevated transaminase is found (initially tested under contract by Bionetics Lab), the same sample will be retested by the Clinical Chemistry lab at NIH. If the elevated value is confirmed, the donor will be recalled and at least 2 units of plasma obtained by plasmapheresis for subsequent study should hepatitis develop in the recipient.

Major Findings: None to date

Significance to Biomedical Research and the Program of the Clinical Center

Any test system which could reliably detect carriers of hepatitis B who are below the detectability range of RIA tests for HBsAg or which could detect chronic carriers of non-A, non-B virus would have major impact on the incidence of post-transfusion hepatitis.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do **NOT** use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE **NOTICE OF INTRAMURAL RESEARCH PROJECT**	PROJECT NUMBER Z01-CC-02017-01 BB

PERIOD COVERED
July 1, 1976 to September 30, 1977

TITLE OF PROJECT (80 characters or less)

Identification of the Non-A, Non-B Hepatitis Agent and the Development of Serologic Markers

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Harvey J. Alter, M.D., CCBBD

Others: Robert Purcell, NIAID
Stephen Feinstone, NIAID
John Gerin, Molecular Anatomy Program

COOPERATING UNITS (if any)
Laboratory Infectious Disease, NIAID
Molecular Anatomy Program, AEC

LAB/BRANCH
Blood Bank Department

SECTION
Immunology Section

INSTITUTE AND LOCATION
Clinical Center, Building 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
2	1	1

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Plasma units derived from: either donors implicated in non-A, non-B hepatitis or patients with acute or chronic non-A, non-B hepatitis will be ultracentrifuged. The pellet derived by ultracentrifugation will be reacted against a radiolabelled IgG fraction obtained from patients convalescent from non-A, non-B hepatitis in a solid phase radioimmunoassay system.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02017-01-BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Identification of the Non-A, Non-B Hepatitis Agent and the Development of Serologic Markers

Previous Serial Number: None

Principal Investigator: Harvey J. Alter, M.D.

Other: Robert Purcell, NIAID
Stephen Feinstone, NIAID
John Gerin, Molecular Anatomy Program

Cooperating Units: NIAID, Molecular Anatomy Program, AEC

Man Years: Total: 2
Professional: 1
Other: 1

Project Description

Objectives:

1. To obtain a large quantity of non-A, non-B viral antigen.

2. To establish a sensitive detection system for this presumed viral agent.

Methods:

1. Semi-purify non-A, non-B viral antigen by ultracentrifugation of plasma units, clinically presumed to carry this agent.

2. Prepare radiolabelled IgG from plasma of persons who have recovered from non-A, non-B hepatitis in the hopes that they contain specific antibody.

3. React the antigen and antibody in a solid phase radioimmunoassay system.

4. If an assay can be developed, the antigen pellet will be further purified by Cesium chloride and sucrose gradients.

Major Findings: None to date

Proposed Course: See objectives and methods

Significance to Biomedical Research and the Program of the Clinical Center

The development of a detection system for non-A, non-B viral agent(s) would be highly significant in that none are currently available and in that this agent(s) currently is responsible for over 80% of post-transfusion hepatitis and probably responsible for a great deal of chronic active hepatitis.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-02018-01 BB

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Hepatitis B Vaccine Trial Among Renal Dialysis Patients

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Wolf Szmuness, M.D., Chief, Epidemiology, New York Blood Center

Other: Cladd Stevens, M.D., NYBC
Edward Harley, NYBC
Harvey J. Alter, M.D., CCBB

COOPERATING UNITS (if any)

New York Blood Center

LAB/BRANCH
Blood Bank Department

SECTION
Immunology Section

INSTITUTE AND LOCATION
Clinical Center, Building 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
6	2	4

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☑ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

A two part study is being undertaken to evaluate a hepatitis B vaccine being produced by NIAID. In the first phase baseline seroepidemiologic data will be obtained in 10 dialysis units in NYC and the Metropolitan Washington Renal Dialysis Unit. When the hepatitis B vaccine is available (approximately Fall of 1977) a prospective, controlled, randomized double blind trial of its efficacy will be undertaken in these same dialysis units.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02018-01 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Hepatitis B Vaccine Trial Among Renal Dialysis Patients

Previous Serial Number: None

Principal Investigator: Wolf Szmuness, M.D.

Other: Cladd Stevens, M.D., NYBC
Edward Harley, NYBC
Harvey J. Alter, M.D., CCBB

Cooperating Units: New York Blood Center

Man Years: Total: 6
Professional: 2
Other: 4

Project Description

Objectives:

1. To obtain baseline incidence figures on hepatitis B and non-A, non-B among a large number of renal dialysis patients and staff.

2. To try to assess patterns of hepatitis spread in these units based on serologic and epidemiologic parameters.

3. To evaluate the effectiveness of a hepatitis B vaccine in reducing the frequency of type B hepatitis among patients and staff.

Methods:

1. Patients and staff in multiple dialysis units will be monitored monthly for elevation of SGPT and appearance of HBsAg and anti-HBs. More frequent sampling and additional tests such as those for subtyping, e antigen and anti-core antibody will be employed when a positive result is obtained.

2. When the hepatitis B vaccine is ready for clinical trials, patients and staff of these dialysis units will be randomly assigned to receive hepatitis B vaccine or placebo and the effectiveness of each assessed over a one year period in each individual. The hepatitis B vaccine will be prepared from a purified preparation of 20 nm HBsAg-containing particles which

have been formalin treated and which have already been shown to be non-infectious, but immunogenic in chimpanzees. Patients and staff will be monitored as above.

3. Other potential methods of decreasing the risk of hepatitis will also be employed including the administration of HBIG to those accidentally inoculated with HBsAg-positive material and the isolation of positive patients as recommended by the CDC.

4. All serologic and epidemologic data will be computerized.

Major Findings:

Study is just in preliminary phase and sufficient data havenot been accumulated for analysis.

Significance to Biomedical Research and the Program of the Clinical Center

Dialysis patients and staff remain a very high risk population for hepatitis B and represent one of the few US populations in which a hepatitis vaccine can be clinically evaluated. If the vaccine proves effective, it will have vast implications, not only for dialysis patients and staff, but also for patients and staff in institutions, for medical personnel in general, for inner city and sexually promiscuous populations and for many foreign populations where hepatitis B frequencies are extremely high.

Proposed Course: See methods and objectives.

Publications: None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE
PROJECT NUMBER (DO NOT USE THIS SPACE)

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NOTICE OF INTRAMURAL RESEARCH PROJECT

PROJECT NUMBER

Z01-CC-02019-01 BB

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Evaluation of the hepatitis risk of hospitalized patients undergoing invasive procedures, but not receiving blood transfusion

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principle Investigator: Harvey J. Alter, M.D.
Chief, Immunology Section, CCBB

Other: Paul V. Holland, M.D.
Chief, Blood Bank Department, CC
Robert H. Purcell, M.D.
Head, Hepatitis Virus Section, LID, NIAID

COOPERATING UNITS (if any)

NIAID, NHLBI

LAB/BRANCH

Blood Bank Clinical Center

SECTION

Immunology Section

INSTITUTE AND LOCATION

Clinical Center, Building 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
3.5	0.5	3

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☑ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

This is a new study which will serve to supplement and control project Z01-CC-02005-07-BB. Cardiac patients will be enrolled if they undergo closed mitral commissurotomy or cardiac catheterization but do not receive blood. They will then be followed prospectively for 6 months and hepatitis rates compared with patients undergoing open heart surgery. This should provide data on the relative risk of hepatitis between transfusion exposure and exposure to a hospital environment and the types of hepatitis associated with each.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02019-01 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Evaluation of the hepatitis risk of hospitalized patients undergoing invasive procedures, but not receiving blood transfusion

Previous Serial Number: None

Principal Investigator: Harvey J. Alter, M.D.

Other: Paul V. Holland, M.D.
Robert H. Purcell, M.D.

Cooperating Units: NIAID, NHLBI

Man Years: Total: 3.5
Professional: 0.5
Other: 3

Project Description

1. To determine if there is a viral hepatitis risk which accompanies hospitalization and invasive procedures such as closed mitral commissurotomy and cardiac catheterization.

2. To compare this hepatitis risk with patients with similar cardiac lesions who require transfusion as part of corrective surgical procedures for their cardiac lesion.

3. To determine the type of viral hepatitis in each group (i.e. B versus non-A, non-B) and thus to establish the absolute incidence of non-A, non-B hepatitis related to blood transfusion.

Methods:

1. All patients undergoing closed mitral commissurotomy or cardiac catheterization (with or without coronary angiogram) will be followed for six months with serial tests for SGPT, HBsAg and anti-HBs.

2. Cases who develope hepatitis will be additionally tested for serologic responses to CMV, EBV and the hepatitis A virus; if type B disease, they will be additionally tested for anti-core antibody, e antigen and will be subtyped.

Major Findings: Study just beginning.

Significance to Biomedical Research and the Program of the Clinical Center

This study will serve as a control for project no. Z01-CC-02005-07-BB and will define the baseline hepatitis incidence which accompanies hospitalization and invasive procedures not accompanied by blood transfusion.

Proposed Course: See objectives and methods

Publications: None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE
PROJECT NUMBER (Do NOT use this space)

U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NOTICE OF
INTRAMURAL RESEARCH PROJECT

PROJECT NUMBER

Z01-CC-02020-01 BB

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Alterations in Whole Blood Oxygen Affinity Following Transfusion

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Harvey G. Klein, M.D., Chief, Blood Services Section, Blood Bank Department, CC

Other: Robert M. Winslow M.D., Senior Investigator, National Heart, Lung and Blood Institute

COOPERATING UNITS (if any)

NHLBI

LAB/BRANCH
Blood Bank Department

SECTION
Blood Services Section

INSTITUTE AND LOCATION
Clinical Center, Bldg. 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
2	1	1

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

It has been widely reported that whole blood oxygen affinity varies in different disease states characterized by anemia. The fact that whole blood oxygen affinity is reduced in persons with sickle cell anemia has been known for many years. A recent report indicates that non-transfused children with homozygous B thalassemia may have a paradoxical increase in anemia. There is very little quantitative information concerning serial changes in whole blood O_2 affinity post-transfusion in those disease states which require transfusion of red cells. It is quite possible that post-transfusion changes in O_2 affinity actually result in a more severe functional anemia despite the hemoglobin elevation. If the red cell milieu is important, as the report concerning thalassemia major suggests, whole blood O_2 affinity post-transfusion may differ significantly in such different disease states as thalassemia, sickle cell anemia, aplastic anemia and myeloid metaplasia. In this study, whole blood O_2 affinity will be measured in patients who require transfusion (1) prior to transfusion (2) daily for 5 days (3) weekly thereafter for three weeks. Whole blood oxygen affinity of the transfused blood will be measured as well. A quantitative estimate of the percent of transfused cells remaining in each sample will be derived by differential agglutination (Ashby technique).

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02020-01 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Alterations in Whole Blood Oxygen Affinity Following Transfusion

Previous Serial Number: None

Principal Investigator: Harvey G. Klein, M.D.

Other: Robert M. Winslow, M.D.

Cooperating Units: NHLBI

Man Years: Total: 2
Professional: 1
Other: 1

Project Description

Objectives:

1. Determine what alterations occur in whole blood oxygen affinity and 2,3 DPG following transfusion.

2. Determine whether any changes in oxygen affinity occur in the transfused red cells which might suggest an influence of the "disease milieu."

3. Determine whether such changes vary according to the blood product transfused (fresh blood, bank blood, frozen blood).

4. Follow these alterations as the transfused red cells are eliminated from the recipient's circulation.

Methods Employed:

This study will be carried out over a one year period. Patients who require transfusion on the Molecular Hematology Service will be studied. The studies will initially be confined to patients with thalassemia, sickle cell anemia and aplastic anemia. Initially patients of blood group A, B, or AB will receive group O ("universal donor") packed red cells. A 5 cc pretransfusion specimen as well as a 5 cc aliquot from the transfused cells will be obtained for measurements of whole blood oxygen affinity and 2,3 DPG levels. Whole blood O_2 affinity will be measured by the technique of Rossi-Bernardi. A one hour post-transfusion specimen, daily specimen for 5 days and weekly specimens for three weeks will be drawn. Percent of transfused cells remaining will be

measured by differential agglutination (Ashby technique) and correlated with changes in O_2 affinity. Additionally the recipient's cells will be lysed in vitro by use of an anti-A or anti-B hemolysin. This will permit separation of transfused from recipient cells in the post-transfusion specimen. Oxygen affinity can then be determined directly on the remaining transfused cells and on the whole blood. These determinations permit calculation of O_2 affinity of the lysed recipient cells. In this way it should be possible to determine whether specific changes occur in the transfused cell population posttransfusion and what component is the major influence in changes in whole blood O_2 affinity.

A second series of studies using ABO identical transfusions of red cells and whole blood can be carried out if donor and recipient are not identical for a minor blood group. This is necessary to permit separation of donor from recipient cells following transfusion. For these studies, differences in the presence of red cell M antigen will be used to distinguish donor from recipient cells. This antigen was chosen because of its low antigenicity, rarity of clinical importance of anti-M isoantibodies, and presence of an anti-M reagent potent enough to effect the required separation.

Major Findings:

This project has been underway for less than one year. Three patients have been scheduled to date. It is too early to draw firm conclusions.

Significance to Biochemical Research and the Program of the Clinical Center

This project has practical importance in the management of blood resources and the transfusion approach for chronic anemia. Results of these studies should indicate the physiologic changes that result in different anemia states when various red cell preparations are transfused.

Proposed Course:

This study should have its initial phase completed within one year.

Publications: None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-02021-02 BB

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

"Delineation of Antibody in Sera of Leukemia Family Members"

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Mary H. McGinniss AB(ASCP)SBB Research Biologist
Clinical Center Blood Bank

Other: Harvey J. Alter, M.D., Chief, Immunology Section Clinical Center Blood Bank

COOPERATING UNITS (if any)
None

LAB/BRANCH
Blood Bank Department

SECTION
Immunology Section

INSTITUTE AND LOCATION
Clinical Center, Building 10A/Room 1E33, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1/3 of 1-1/2	same	

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☑ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Several years ago an antibody was found in the sera of family members of some leukemia patients. This antibody reacts only with red cells of a very rare phenotype. 163 leukemia patients and family members and 165 normal donors sera have been tested. This antibody is found significantly more frequently in the sera of patients with leukemia and their family members as compared with controls ($p < .01$).

This antibody may define an allele of a specific blood group system thought to be amorphic. In this respect, it will expand the genetic concept of this system.

PHS-6040
(Rev. 10-76)

Serial No. Z01-CC-02021-02 BB
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Delineation of Antibody in Sera of Leukemia Family Members

Previous Serial Number: None

Principal Investigator: Mary H. McGinniss, AB(ASCP)SBB

Other: Harvey J. Alter, M.D.

Cooperating Units: Inside NIH
None

Outside NIH
None

Man Years: Total: .5
Professional: .5
Other: 0

Project Description

Objectives:

A. To establish in a larger number of patients if the association of this "anti-precursor" antibody with leukemia and leukemic families is maintained and if so if this antibody has any predictive role in the development or course of leukemia.

B. To better understand this "new" red cell antigen-antibody system, to determine its genetics and to determine any relationship to other defined red cell antigens.

Methods Employed:

Standard antibody screening techniques of sera from leukemia patients and their family members and a comparable number of sera from other sources vs routine cells and cells from donors of the rare phenotype which define this "new" antibody.

Major findings:

A. To date the sera of 163 leukemia patients and their family members and 165 normal donor sera have been tested. A chi square of difference

in antibody frequency among these two populations was found to be significant at the 1% level.

B. The antibody defines an allele thought to be amorphic in a major blood group system.

Significance to Biomedical Research and the Program of the Clinical Center:

If this antibody response proves to be induced by an environmental factor found mainly in leukemia family groups, it has potential for aiding our understanding of the etiology of leukemia and possibly of predicting those who are "leukemia prone." It may also define a basic red cell antigenic determinant which will aid our understanding of the complex structure on the cell membrane.

Proposed Course:

A. Continuation of screening program as outlayed above and extension to other target groups i.e. doctors caring for leukemia patients and other patient populations.

B. Long term follow of persons with this antibody to see if they have a lesser or greater risk of developing leukemia than family members without such antibody.

C. Potential use of this antibody to perform immune electron microscopy of red cells and serum from patients with leukemia to see if a virus particle is detected.

Publications: None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do **NOT** use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE **NOTICE OF INTRAMURAL RESEARCH PROJECT**	PROJECT NUMBER Z01MH0083-03 AP

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Hypothesis of X-linkage in Bi-polar and Uni-polar Affective Disease

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator: Elliot Gershon, M.D. NIMH AP branch

Other: Mary H. McGinniss, CCBB Research Biologist

COOPERATING UNITS (if any)
Clinical Center Blood Bank

LAB/BRANCH
NIMH AP branch

SECTION
Affective Disorders

INSTITUTE AND LOCATION
NIMH Clinical Center Building 10, Room 3N218

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
2	1	1

CHECK APPROPRIATE BOX(ES)

☑ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

It has been reported that one form of affective disease (manic-depressive disease) may be carried on the X chromosome. Phenotypes, including Xg typing, have been done on 190 bipolar and 43 unipolar patients and their family members. Statistical data are incomplete on this project.

PHS-6040
(Rev. 10-76)

Serial No. Z01MH0083-03 AP
Blood Bank Department
Clinical Center
Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 - September 30, 1977

Project Title: Hypothesis of X-linkage in Bi-polar and Uni-polar Affective Disease

Previous Serial Number: Unknown

Principal Investigator: Elliot Gershon, M.D.

Other: Mary H. McGinniss, AB(ASCP)SBB

Project Description

Objectives:

1. To confirm or reject previously published claim that a gene involved in one form of manic depressive disease may be carried on the X sex chromosome.

2. By statistical analysis to see if any correlation exists between manic depressive disease and any of the commonly known red cell antigens.

Methods Employed:

1. Mental health evaluations and complete red cell phenotyping including Xg typing.

Major Findings: None to date

Significance and Proposed Course: See Objectives

Publications: None

July 1, 1976, through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

CLINICAL PATHOLOGY DEPARTMENT

CONTENTS

July 1, 1976, through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH
CLINICAL CENTER

CLINICAL PATHOLOGY DEPARTMENT

I. DEPARTMENT MISSIONS AND GOALS

The Clinical Pathology Department of the Clinical Center has the following four major missions and goals:

1. To provide the optimum laboratory medicine support to patient-care physicians and their patients within the Clinical Center.

2. To act as a consultant to patient-care physicians regarding the interpretation of laboratory data and patient care problems in hematology.

3. To educate and train clinical pathology residents, clinical associates and visitors in the discipline of laboratory medicine.

4. To conduct a program of research and development in the area of laboratory medicine.

II. DEPARTMENT ACTIVITIES

A. Service Productivity.

Using the newly established Resource Monitoring System for counting, the Clinical Pathology Department performed 1,285,098 tests during FY-1977 and had an average monthly workload ratio index of 88. The workload from the Outpatient Clinic continued to increase and now accounts for 31% of the total workload.

The Hematology Service has continued in a major role as the Hematology consultants to the physicians and patients in the Clinical Center. This year the number of clinical consultations and interpretation of laboratory data has increased approximately 30% over the previous year. Many of these consultations resulted in improved patient care, better coordination of laboratory tests, as well as proper interpretation of the results in complex clinical settings. The Hematology Service this year has read over 3000 bone marrows of patients in the Clinical Center, including bone marrow biopsies, clot sections, iron stains and bone marrow aspirate smears.

II. DEPARTMENT ACTIVITIES

B. Personnel.

Two visiting scientists concluded their tenure: one returned to France, the other to Belgium.

Two scientists completed their fellowship training and joined the Chemistry Service as staff chemists.

Dr. Mark Zweig was appointed Assistant Chief of the Chemistry Service, replacing Dr. Maurice Green.

The Chief of the Chemistry Service resigned to accept an appointment as Head of the Clinical Chemistry Section of the Mayo Clinic and the Chief, Clinical Pathology succeeded him, while ontinuing his responsibilities as Chief of the Department.

Dr. Laurence Corash was appointed Assistant Chief of the Hematology Service, replacing Dr. Henry Tan who resigned.

A programmer has been recruited and trained to maintain and modify the Honeywell System. This has markedly increased the Service's ability to implement changes requested by the laboratories.

III. MAJOR PROGRESS

A. Service.

A Phlebotomy and Urine Collection Team under the Office of the Chief was begun in September 1976. Most of the members of the Team have been recruited to date and manuals on phlebotomy and urine collection have been written. The Team now performs all phlebotomy services for the Outpatient Department, all routine early morning phlebotomy for patients on the 5th, 10th, 11th, 12th and 13th floors of the Clinical Center and obtains all blood cultures during the day. Plans have been made to construct a new outpatient laboratory hematology area in the outpatient section which, in concert with the Phletobomy area, will allow patients to be seen and have blood drawn more quickly and efficiently than previously.

A complete and extensive revision of, "Clinical Pathology and Blood Bank Guide" was coordinated by the Office of the Chief to enable patient-care physicians to utilize laboratory services more easily and efficiently. It contains a master table of all tests available at NIH and via contract.

Inspection of the entire laboratory was conducted to meet the requirements for accreditation by the College of American Pathologists. The deficiencies were noted in a memorandum to the service involved and a written response was required. In addition, those deficiencies that involve fire and safety were sent to Mr. Vinson R. Oviatt, Chief, Environmental Safety.

III. MAJOR PROGRESS

A. Service.

The Clinical Chemistry Service continued to review and update routine methods. New procedures and reference methods have been developed for possible inclusion on the SMAC analyzer.

Improved computer operation for the Clinical Chemistry Service has enabled a more rapid reporting of data: an electrowriter is used to report data to three nursing units; efficient collection and deliverance of specimens to the laboratory by the blood drawing team has reduced delays in reporting of results. A gradual introduction of two-batch running of certain tests within a day has also reduced delay in returning results to physicians.

The analytical procedure for T_3 was re-evaluated, and TSH measurements were introduced into routine service. A simpler and more specific nephelometric method in urinary protein was introduced. More tests were made available by the Pediatric Microchemical Laboratory to ensure comparability with the results obtained by the Main Laboratory.

The Hematology Service this year has established better quality control techniques of their analytical systems. Because of the importance of platelet counts for the Clinical Center patients receiving the variety of drugs which reduce bone marrow function, a new system for quality control and maintenance of the automated platelet counters was adopted to ensure that there are at least three quality control checks on platelet counts.

New hematologic tests were added for Clinical Center patients. After thorough testing, a radioimmunoassay for ferritin was instituted as a standard procedure in the laboratory. This assay may be useful in differentiating the anemia of chronic inflammation from that of iron deficiency anemia, and also may be of value in the diagnosis of relapse of acute leukemia, Hodgkin's disease, and various lymphomas.

A Honeywell ACS 1000 microscope was acquired from the National Cancer Institute. This microscope, a semiautomated differential counter, is used in our initial attempt at automated differential counts.

A high incidence of thrombocytopenia in Clinical Center patients receiving a new drug, Valproate, was identified. Studies are underway to identify the mechanism of the thrombocytopenia.

The coagulation laboratory of the Hematology Service is the only laboratory in this area that can offer carrier detection assays of Hemophilia A, a test which measures Factor VIII procoagulant activity, and Factor VIII antigen. Up to 95% of obligate carriers of Hemophilia A can be detected by correlation of the ratio of antigen to procoagulant activity.

To improve tests to identify patients with thrombotic tendencies, the coagulation laboratory now performs the crossed antigen-antibody immunoelectrophoresis on antithrombin III, a protein that may be of importance in modulating the delicate balance between bleeding and thrombosis. Qualitative abnormalities of this protein can now be indicated by these immunologic studies or by the functional studies of the biologic activity.

To more accurately quantitate thrombocytolytic states, the Hematology Service now offers an assay of the serotonin content of peripheral blood platelets for the estimation of mean platelet age. This test appears to be sensitive and specific for the indication of a reduced mean platelet age which suggests that thrombocytopenia may be due to destruction of platelets.

Techniques using small amounts of blood to determine the electronic size distribution of human platelets have been undertaken and are a rapid and sensitive technique to discern increased mean platelet volume. Increased platelet volume suggests increased platelet destruction resulting in an altered (younger) mean platelet population.

The assay of B_{12} binding proteins, transcobalamine I, II, III, by a newly described technique requiring microliter quantities of serum was introduced which is useful in delineating different types of acute and chronic leukemias that develop following chemotherapy and may be abnormal in a variety of myeloproliferative disorders.

Plans have been developed to remodel the routine Hematology laboratory to make more efficient use of space and provide a better work flow.

Transmission of laboratory results to physicians has been improved by the Laboratory Computer Service by printing interim reports in the early afternoon each weekday and Sundays. The Microbiology Service now enters and reports their laboratory results through the Honeywell system. A statistical analysis of laboratory values obtained on normal volunteers since 1970 has been carried out to provide NIH clinical investigators data on the long-term stability of analytical methods used by the Clinical Chemistry Service.

Renovation of the Microbiology laboratory was begun in December 1976, and is now largely completed: the admissions and processing area has been enlarged from its previously extremely cramped quarters; a new biologic hazard hood permits the safe handling of both mycobacteriologic and mycologic specimens in this area; another laminar flow hood has also been installed within the TB-mycology area itself; all the diagnostic sections of the laboratory have been separated from administrative and research areas. These rearrangements have facilitated both communications and specimen transport among the various sections of the laboratory.

A newly appointed Chief Medical Technologist will be responsible for coordinating the diagnostic functions of the various subunits of the Microbiology Service, evaluating the Service's diagnostic methodologies and consulting with patient-care physicians regarding culturing techniques and the interpretation and limitation of test procedures.

All Microbiology laboratory data are now being reported out through the new Honeywell computer system. Using cathode-ray terminals and specially developed templates, microbiologic data on patients is incorporated in the patient cumulative summary reports and stored in retrievable form, thus greatly facilitating future investigational access.

The laboratory procedure manuals underwent extensive critical revision. Procedures which had been found to be unproductive have been modified or eliminated, and new procedures have been introduced. Other procedures have been changed to maximize the clinical usefulness of the data. Specific changes include the following:

1. A new set of guidelines were developed for handling specimens for anaerobic culture, both to maximize the yield of anaerobic organisms from bone fide anaerobic infections and to minimize the anaerobic processing of specimens not optimally collected for the isolation of anaerobic organisms.

2. Fungal slants on a routine basis for blood cultures was discontinued, as a) the medium currently used for bacterial culture of blood will grow most potentially pathogenic yeasts, and b) fungi which grow in tissues in the mycelial phase can almost never be cultured from blood regardless of the medium used.

3. Reporting throat cultures was changed so that only organisms known to be pathogens would be reported.

4. A new standard for performing the anaerobic dextrose test to distinguish between Micrococci and Staphylococci was introduced.

B. Research and Development.

The Office of the Chief prepared a 14 page Pathology Questionnaire which evaluated the relationships between space, personnel and test volume. This Quesionnaire was sent to approximately 100 academic pathology departments throughout the country. A 50% response rate was obtained and the data is now being analyzed.

Pyrogenicity, mitogenicity, complement activation, and limulus amebocyte lysate gelation were correlated with 17 different endotoxins

and related compounds. A correlation existed among pyrogenicity, mitogenicity and limulus activation, but complement activation did not correlate with any of these three properties.

The effect of magnesium deficiency on the structure of erythrocyte membranes was concluded. After two weeks on a magnesium-deficient diet, plaques appeared on the erythrocyte membrane and became larger with time. This membrane abnormality could not be reversed by in vitro incubation with normal concentrations of magnesium.

The utility of the limulus test for the detection of bacterial endotoxin in joint fluid was studied. The results with 71 joint fluid specimens from 47 patients indicate that the limulus test is nonspecific and has little clinical value. Synthetic adjuvants were evaluated for pyrogenicity and limulus reactivity. These studies have defined a compound (MDP) that is markedly pyrogenic but negative in the limulus test.

The effect of induced fever on the production of serum amyloid A was studidd. The results show that one episode of induced fever with etiocholanolone results in a marked elevation of serum amyloid A for a 6 to 7 day period.

Various analytical instruments including several channels of the Technicon SMAC were evaluated by the Clinical Chemistry Service. Particularly, sodium, potassium, chloride, and bicarbonate were examined with a view to incorporating these onto the SMAC and performing all the routine assays on that instrument or plasma. Several different models of blood gas analyzers were evaluated, and the Beckman chloride/CO_2 analyzer was examined for suitability for performing STAT assays in the main laboratory. A separate STAT laboratory within the main Clinical Chemistry laboratory was set up to enable more rapid turnaround of emergency requests. This involved a major redistribution of instruments within the laboratory, as well as the introduction of some specifically to process this ever-growing workload.

The Clinical Chemistry Service used the miniature centrifugal gas analyzer for the nephelometric assays of specific proteins. The system has now been completely checked out for IgG measurements and both IgA and IgM are being studied at the present time. The concept of the analyzer would enable many different specific proteins to be measured at the same time.

A technique has been developed to measure hemoglobin at the 2.0 mg/dl level to determine the influence of different blood drawing procedures, and different collection tubes on hemolysis. This study is being conducted in conjunction with the Clinical Pathology Department Phlebotomy Team and the Oak Ridge National Laboratories. At Oak Ridge, the influence of evacuated blood tubes on aerosol formation (concerned with possible dissemination of hepatitis virus) is being evaluated in conjunction with the study of problems of hemolysis.

1. A technique for the measurement of concentration of free anti-epileptic drugs in serum was developed. Comparison of both free and total concentration of drugs with the therapeutic response in epileptic patients has been initiated.

2. A study of the suitability of a recommended national protocol for the evaluation of analytical instruments using the Perkin-Elmer KA 150 enzyme analyzer as a model has been completed.

3. High pressure liquid chromatography to determine creatinine free from interference from other Jaffe reacting compounds was used.

The calorimetric estimation of lactate dehydrogenase isoenzyme activities in serum, and a study of the simultaneous calorimetric measurement of free and total cholesterol in serum was completed. Further work was done on the calorimetric determination of chymotrypsin and trypsin in body fluids. New amylase and lipase procedures were evaluated. They resulted in the introduction of the amylase procedure into routine use. Renal function in patients with muscle wasting diseases was studied and compared with creatinine clearance (using different procedures to measure creatinine) with radioisotopically labelled iothalamate to determine glomerular filtration rate.

The extraction test for occult blood measurement is now routinely used to confirm equivocal or positive screening tests. The non-carcinogenic tetramethylbenzidine may be substituted for benzidine in screening tests.

In conjunction with workers under an NHLBI contract, the association between platelet function and atherogenesis was studied. It was determined that platelet sensitivity to in vitro stimuli is increased by a prior saturated fat diet, and that platelet survival is shortened in these animals. Fibrinogen consumption is increased in these animals. Animals with most marked atherosclerosis have lowered levels of serum thyroxine and triiodothyronine. In another study it was determined that platelet function can be prolonged by adjusting the osmolality of the anticoagulant. Viability can be assessed by measurement of lactate dehydrogenase, lactic acid or phosphorus. Superoxide dismutase and/or catalase are not prophylactic in platelet preservation in vitro. The titration calorimeter has enabled a study of the binding of bilirubin to albumin and, because of its increased sensitivity, a study of the basal heat output from washed erythrocytes.

Procedures for the radioimmunoassay of the individual isoenzymes of creatine kinase were developed. The methods are being applied to a study of reference values for children and other population groups, patients with psychosis, myocardial infarction and muscular disorders, patients affected with Duchenne muscular dystrophy and relatives of patients with this disease. Further refinement of methods are

continuing. These include development of a procedure for the MB hybrid and improvement of the existing methods to reduce the assay time to one day.

In the area of research, the Hematology Service has continued in two major fronts, (1) blood coagulation and (2) morphology. In blood coagulation, the main interests have been in the studies of Factor VIII, von Willebrand factor, fibrinogen and platelets. Studies have progressed on the characterization of the Factor VIII and von Willebrand factor abnormalities in von Willebrand's disease and studies of this Factor VIII/von Willebrand factor protein in the role of this protein in the revascularization of the ischemic brain tissue. In addition, work is continuing in the investigation of ristocetin-induced platelet agglutination and the role of the ristocetin and the von Willebrand factor.

Work has continued in the area of congenital dysfibrinogenemia with two additional families being identified this year. In addition, work on the acquired dysfibrinogen found in patients with hepatoma have revealed that the abnormal fibrinogen synthesized by these patients appears to be related to abnormally high sialic acid content. This high sialic acid content interferes with the ability of the fibrinogen to properly polymerize and increases the thrombin time Partial removal of the sialic in the patient's fibrinogen results in the normalization of coagulation studies.

Progress in platelet research has included the measurement of endogenous platelet serotonin by a sensitive double isotope radioassay in total whole blood populations and in their density-dependent subpopulations. Results reveal a strong positive correlation between platelet density and serotonin content, making it a useful age-dependent platelet marker.

Patients with Chediak-Higashi syndrome have been studied in relation to the properties of their platelets. Platelet survival is shortened, platelet serotonin content is abnormal; however, alpha granule release in response to thrombin is normal. The major Chediak-Higashi platelet defect is a reduced number of dense body storage sites.

Platelets have been isolated by the Stractan system and subjected to freeze-fraction and freeze-etch microscopy to explore membrane morphology.

Accurate sizing of whole blood platelet populations is being carried out in a prospective study for the evaluation of thrombocytopenia. The data is being correlated with ^{51}Cr platelet survival and clinical presentation. Preliminary results reveal that this technique is able to determine hyperdestructive platelet disorders.

Platelet survival, platelet aggregation and bleeding time in nine normal volunteers receiving propanalol therapy was performed. Preliminary results indicate that platelet survival is normal, and that platelets do not become hyperactive during the drug withdrawal period.

Participation in the French, American, British Group (FAB) for the classification of acute leukemias has continued. A workshop and a combined clinical staff conference on the classification of acute leukemia has been sponsored.

An intense morphologic study of 41 cases of Waldenstrom's macroglobulinemia has been completed. Three morphologic subtypes of this disease were identified.

Studies on the effect of various stains on the morphologic characteristics of blast cells have been undertaken this year and demonstrate that the type of stain used can markedly alter the characteristics of blast cells.

The use of cytochemistry in the Hematology Service has increased for the diagnosis of various types of malignant tumors and has added to the specificity and accuracy of hematologic diagnosis of Clinical Center patients.

Analysis of variance techniques have been used by the Laboratory Computer Service to evaluate the performance of the SMAC multichannel analyzer used by the Chemistry Service. The effectiveness of alternate quality control strategies has been studied by computerized analysis of control specimen results.

A quality control nomogram for arterial pH and pCO_2 determinations has derived from a computer analysis of 1976 blood gas results.

In preparation for running more assays on the SMAC, several evaluation are in progress in collaboration with the Chemistry Service: comparison of serum and plasma results for tests currently run on the SMAC, comparison of SMAC plasma electrolyte results to those obtained with the currently used AutoAnalyzer system, and evaluation of the accuracy of the SMAC urine acid, LDH, and Urea Nitrogen results.

Studies continue to evaluate a technique to determine glomerular filtration rate by nonlinear regression analysis of plasma disappearance curves of labeled compounds.

Enhancements to the Honeywell hardware and software proposed by the vendor have been evaluated. The items to be ordered will permit connecting the SMAC analyzer directly to the Honeywell system, increzse the speed and responsiveness of the system, and provide more flexibility in its operation.

During the past year, two alternate laboratory computer systems proposed by Technicon were evaluated for use at NIH. Both were found unsuitable.

Specifications for a link to connect the Honeywell system to the Technicon Medical Information system in the Clinical Center have been worked out, and a contract will be signed to begin work. When completed, the interconnection will permit direct computer-to-computer transmission of test requests and test results, which will then be available to patient care personnel through MIS terminals and printouts.

A system for identifying clinical laboratory specimens with machine readable bar code labels was evaluated. Preliminary steps have begun to implement the system in the Chemistry and Hematology laboratories.

In the Microbiology Service work is continuing on the speciation of clinically significant isolates of non-Pneumococcal alpha-hemolytic Streptococci. At present, the procedures involved remain too complex and time-consuming for incorporation into the routine diagnostic areas of the laboratory.

The Mini Tek system, the API-20 Anaerobic Strip, and the API Lactobacillus 50 Strip have been evaluated to determine if the use of these materials might facilitate the speciation of the alpha-hemolytic Streptococci.

Bacteriophage typing for epidemiological purposes of clinically significant isolates of Staphylococcus aureus from Clinical Center patients and patients in other area hospitals continued. Because of a significant incidence of Clinical Center patient infections with Staphylococcus aureus lysed by bacteriophage 94, a survey of Staph. aureus nasal carriage in selected Clinical Center staff members was undertaken; several carriers were identified and subsequently treated. Overseeing has continued of the bacteriophage typing of selected isolates of Staphylococcus epidermidis and the serotyping of selected isolates of Pseudomonas aeruginosa.

The collection of lyophilized organisms has been reorganized. The organisms have been catalogued numerically and alphabetically. The collection is used for teaching and research purposes, and to provide organisms to outside investigators that may be unobtainable elsewhere.

The detection of bacteremia using an electrical impedance detection system was studied. The prototype instrument has been improved and connected to a laboratory computer, which can be queried regarding the status of particular cultures. This system, coupled with initial lysis and filtration of blood prior to its presentation to the detector, allows more rapid and sensitive detection of bacteremia than conventional methods.

The accumulation and analysis of Staphylococcus aureus bacteriophage typing data are continuing. This file of epidemiologic data extends back for approximately 20 years, and reveals the changing incidence pattern of different Staph. aureus bacteriophage types isolated from Clinical Center patients.

A survey of Staphylococcus aureus carriage was conducted in the Pediatric Oncology Branch clinic population. Comparisons will be made of the incidence of Staph. infections in carriers and non-carriers. Should the infection rate prove higher in the carriers, attempts may be made to lower the carriage rates.

The Differential III laser light scattering instrument was evaluated for its potential usefulness for the rapid determination of antibiotic synergistic effects.

The organization of the microbiology data base which has been accumulated by the laboratory computer system is in progress. Central DCRT facilities are being used to organize and retrieve the data in such a way as to expedite data searches and minimize their cost.

Studies of a resistant Corynebacterium species which has been isolated with increasing frequency for immunosuppressed Clinical Center patients were continued. Additional isolates are being collected and studied, and a selective medium was devised for this organism in an attempt to define its normal habitat.

The Dynatech MIC-2000 96 channel dispenser was evaluated to determine the accuracy and reproducibility of the amount of fluid it dispensed. In addition, a battery of antimicrobial agents was dispensed by the instrument and stored at -20°C and -70°C; these antimicrobials were subsequently examined at intervals to determine their potency. Accuracy of repetitively dispensed volume was found to be satisfactory, and the antimicrobial agents tested were found to retain their potency for at least 2 weeks at -20°C and for 4 months at -70°C.

Blastocystis hominis, a protozoan parasite of the human gastrointestinal tract, was studied with particular emphasis on ultrastructure, physiologic characteristics, life cycle, and toxin characterization.

5-fluorocytosine sensitivity tests were performed on 34 yeasts isolated from Clinical Center patients. The Service also served as a reference center for checking the sensitivities of yeasts sent from outside hospitals, as this sensitivity test is not yet routinely available. In addition, 6 molds were tested for sensitivity to miconazole, 5-fluorocytosine, and amphotericin B. Plate sensitivity tests were performed on 5 Nocardia isolates. The data obtained from these specialized sensitivity testing procedures both provided useful information in the management of individual patients and

added to the relatively small fund of knowledge available regarding the antimicrobial sensitivity of some of these organisms.

III. MAJOR PROGRESS

C. Training.

The residency training program in the Clinical Pathology Department admitted four first year residents: they joined four, second-year residents in the program. Each rotation of the first year residency training program was evaluated by the residents using an evaluation sheet developed by the Office of of the Chief. All comments and evaluations were transmitted to the Chiefs of the Services. Changes in residency program and rotation were made where indicated by the residents' appraisal.

The senior staff and residents continued to have weekly clinical pathology rounds at which interesting patients, laboratory problems and original research were presented and discussed.

The Resident-Consultant rotation for second year residents was expanded to include a one-week course in management, a series of three lectures given by the Chief of the Clinical Pathology Department, and an opportunity for the resident to attend several policy making and management meetings with the Chief of the Clinical Pathology Department. In addition, the Resident-Consultant continued to interact with all patient-care physicians concerning any problem with the laboratory. A bi-weekly conference, organized and conducted by the residents, discussed some 64 topics in clinical pathology in a systematic manner.

Two Research Fellows completed their post-doctoral fellowship training programs.

The Clinical Chemistry Service continued to provide weekly lectures on applications of clinical chemistry. The residency training program was expanded to include much more training of a practical hands-on nature, as well as providing both a practical understanding of instrumentation and the comparative merits and applicability of different analyzers. By routinely reviewing all abnormal data, the resident physicians are able to suggest the further workup of patients.

The Hematology Service coordinated the Hematology-Oncology Clinical Electives, and the Hematology Service continued its major role in the teaching of this elective and received consistently high ratings by the medical students. Fourteen medical students took rotations on the Hematology Service from September 1976 through May 1977. The senior staff gave each student a great deal of time in the instruction of bone marrow and peripheral blood interpretation. The Hematology Service and the

Molecular Hematology Branch (NHLBI) continued to cooperate in sponsoring combined monthly hematology rounds, and the staff conducted weekly bone marrow morphology conferences for the Solid Tumor Branch of the National Cancer Institute. At least twice weekly, the Senior Staff and Residents of the Hematology Service, and interested physicians from other Clinical Center Institutes participated in Hematology rounds, where patient-care and laboratory problems are presented and discussed.

The Hematology Service had three guest workers during the year. One, the Chief Medical Resident of Georgetown University Hospital, spent six months in the Hematology Service. A Clinical Associate from the Radiation-Oncology, NCI, DCT, spent six months in the Hematology Service and a Senior Staff member of the Laboratory of Pathology, NCI, spent two months in the Hematology Service.

Seven individuals from universities, hospitals and other U. S. Government agencies received training in the Microbiology Service.

Weekly conferences were held for all Microbiology Service technologists to discuss interesting cases, Service policies and new techniques and methods. Guest lecturers included Dr. Rudolph Hugh, Professor of Microbiology at George Washington University who delivered several lectures on the identification of non-fermentative Gram-negative rods.

Seniors from the University of Maryland, majoring in microbiology, received supervision on specific research project which gave them direct experience with original research.

IV. FUTURE OBJECTIVES

The Phlebotomy Team will expand to 20 permanent full time employees. During the coming year, all phlebotomy for patient-care analyses, blood cultures, and sterile urine collection will be performed by the Team between the hours of 6:30 a.m. and 11:00 p.m., so that the Clinical Pathology Department can implement quality control for specimen collection within the Clinical Center, which will enhance the accuracy of laboratory results.

The Clinical Chemistry Service will pursue further means to increase efficiency in the laboratory while attempting to introduce new tests into routine service. Many of the potential tests involved are radioimmunoassay procedures and, where feasible, automated or partially automated assay systems will be evaluated.

The Clinical Chemistry Service will add additional tests to the SMAC analyzer and work with its manufacturer to improve the specificity of the procedures we have rejected because of their inherent nonspecificity. Additional tests on this system will free manpower to perform

other tests. Interfacing of the SMAC with the computer is now feasible and when done, will reduce technologist time and facilitate early reporting of data. This will be further improved with installation of the automatic specimen identification system that is currently under evaluation by the Laboratory Computer Service.

The Hematology Service will introduce new techniques, update and increase the number of older, established laboratory procedures that will be of paramount importance to patients in the Clinical Center. In particular, attempts will be made this year to evaluate automated differential counters. The Service will continue its research in the area of clinical hematology to improve and introduce new laboratory tests to be better able to predict bleeding, thrombosis, increased platelet destruction, and qualitative and quantitative abnormalities of coagulation factor proteins. Training and clinical consultations will continue to be an important aspect of the Hematology Service goals.

It is hoped that as the Hematology Service expands its armamentarium of tests, more space will become available for the introduction and evaluation of these new tests, and equipment to facilitate handling the increasing workload in the Hematology Service.

During the coming year the Laboratory Computer Service plans to complete the linkage between the Honeywell laboratory computer and the Clinical Center Medical Information System (MIS). This goal has the highest priority and will permit laboratory tests to be requested directly through the MIS terminals and to be reported through the MIS terminals and printers on the wards. Installation of the enhanced Honeywell system will reduce the delays experienced in using the system and reduce the amount of data which must be entered manually. The computerized system for monitoring blood cultures will be expanded as use for routine patient specimens increases. Computer techniques will be applied to the automation of antimicrobial susceptibility testing. Research will continue in the computerized interpretation of clinical laboratory measurements.

We hope that significant restructuring of technologist functions in the Microbiology Service, particularly as regards supervisory level medical technologists, will result in more effective and harmonious laboratory operation.

The procedures of sensitivity testing will most probably be altered during the coming year, as it is anticipated the Dynatech MIC-2000 96 channel dispenser will be incorporated into routine laboratory use to facilitate the determination and reporting of antibiotic sensitivity patterns.

Those sections of the laboratory manual which had not been completely revised during this fiscal year will undergo a critical revision in the next several months to eliminate any procedures now considered outmoded or ineffective and to incorporate such new techniques as are useful in diagnostic microbiology.

Among new procedures that will be evaluated during the coming fiscal year are: a selective medium for the isolation of Group A beta-hemolytic Streptococci, the use of killed, antibody-coated Staphylococci to identify certain Lancefield group of beta-hemolytic Streptococci.

Many of the research and development projects in which members of the laboratory have participated during this fiscal year will be continued (see the "Proposed Course" sections of the PHS forms #6040 describing the particular projects).

V. PRESENTATIONS

Eighteen members of the Clinical Pathology Department made 79 formal presentations at universities and various national and international meetings.

VI. FORMAL TRAINING COURSES COMPLETED BY STAFF

Fourteen Commissioned Officers participated in 21 formal training courses.

Thirty-seven Civil Service employees participated in 40 formal training courses.

VII. PUBLICATIONS

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Young, D. S.: Clinical Chemistry. In McGraw Hill Yearbook of Science and Technology. Lapedes, D. N. (Ed.), 1977. (in press).

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Young, D. S.: Reporting of laboratory data in SI units. J. Forensic Sci. (in press).

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SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00001-03 CP

PERIOD COVERED

July 1, 1976 to September 30, 1977

TITLE OF PROJECT (80 characters or less)

Analytical Methodology: Development and Interpretative Application

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

D.S. Young, CC/CPD Chief, Clinical Chemistry Service
M. Green, CC/CPD Staff Chemist
R.M. Jaffe, CC/CPD Staff Physician
M.H. Zweig CC/CPD Acting assistant chief, Clinical Chemistry Service
E.A. Roberston CC/CPD Assistant chief, Laboratory Computer Service

COOPERATING UNITS (if any)

LAB/BRANCH

Clinical Pathology Department

SECTION

Clinical Chemistry Service

INSTITUTE AND LOCATION

Clinical Center, N.I.H., Bethesda, Md.

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
6	2	4

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Analytical methods in use in clinical laboratories have been evaluated. New methods and instrumentation have been studied and effects of drugs on test values determined. Continued work with automatic interpretation of effects of drugs has shown that it is possible to assist physicians in understanding influence of drug therapy in changing laboratory test values.

Project No. Z01 CC 00001-03 CP
1. Clinical Pathology Department
2. Clinical Chemistry Service
3. Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 through September 30, 1977

Project Title: Analytical Methodology: Development and Interpretative Application

Previous Serial Number: Z01-CC-00001-02-CP

Principal Investigator: Donald S. Young

Other Investigators: Maurice Green
Mark H. Zweig
Russell M. Jaffe
E. Arthur Robertson

Man Years:

Total	6
Professional	2
Other	4

Project Description

Objectives

1. To upgrade the quality of clinical laboratory data within NIH and elsewhere.

2. To facilitate the correct interpretation of laboratory data.

Methods employed:

1. Reference methods have been developed against which other methods can be compared. These methods are well characterized with respect to accuracy, precision, sensitivity and specificity.

2. Data bases have been developed in a computer file to list effects of drugs on laboratory tests, conversion factors from traditional to SI units, and centers where unusual clinical laboratory tests are performed throughout the country.

Major findings:

Deficiencies in analytical methods have been identified and alternative methods studied in depth. By appropriate selection of method it is possible to avoid erroneous answers due to nonspecificity of the procedures. Drugs have been added to serum to their therapeutic concentration and effects observed on many different procedures on several different analyzers.

Significance:

This work has upgraded the quality of some tests in this laboratory and has the potential for doing the same thing in other laboratories when the same methods are used. By alerting physicians to drugs as a possible cause of abnormal data it has been possible to explain the cause of the unusual values and to prevent extensive and unnecessary workups of patients.

Proposed course:

Continued development and evaluation of methods will be undertaken.

Honors and awards:

Dr. Young received the 1977 Bernard F. Gerulat award for the New Jersey section, American Association for Clinical Chemistry, the 1977 AACC award for outstanding contributions to clinical chemistry and one of the 1977 NIH Director's awards.

Publications:

Forman, D.T. and Young, D.S. Drug interference in laboratory testing. An. Clin, Lab. Sci. 6, 263-271, 1976.

Forman, D.T. and Young, D.S. Drug interference in laboratory testing in Clinical Chemistry, Forman, D. R. and Mattoon, R. W. eds. American Chemical Society, Washington, D. C. pp 271-284, 1976.

Jaffe, R. M. A test for occult blood. US patent serial no. 498-109.

McClean, S. W., Young, D. S. and Yonekawa, W. Anticonvulsants in serum, determined with a fully mechanized enzyme analyzer. Clin. Chem. 23, 116-118, 1977.

Rodbard, D. and McClean, S. W. Automated computer analysis for enzyme-multiplied immunological techniques. Clin. Chem. 23, 112-115, 1977.

Young, D.S. and Panek, E. Effects of drugs on the analytical procedure of a multitest analyzer in Drug interferences and drug measurement in Clinical Chemistry. Siest, G., and Young, D. S. eds. Karger, Basel, pp 10-20, 1976.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01- CC 00002-01 CP

PERIOD COVERED
July 1, 1976 to September 30, 1977

TITLE OF PROJECT (80 characters or less)

Clinical Laboratory Applications of Microcalorimetry

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Nadja N. Rehak, Visiting Scientist, CC, CPD

Russell M. Jaffe, Staff Physician, CC, CPD

Donald S. Young, Chief, Clinical Chemistry Service

COOPERATING UNITS (if any)

LAB/BRANCH
Clinical Pathology Department

SECTION
Clinical Chemistry Service

INSTITUTE AND LOCATION
Clinical Center, NIH, Bethesda, Md.

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
3.0	1.0	2.0

SUMMARY OF WORK (200 words or less - underline keywords)

Two different calorimeters have been used to study various biological phenomena in body fluids. Measurements have been made of bilirubin binding to albumin and the heat output from washed erythrocytes has also been studied. Measurements of chymotrypsin, trypsin and pepsin activity in gastrointestinal secretions have been made. Differentiation of lactate dehydrogenase isoenzymes by calorimetry has been accomplished. Studies are continuing on the measurement of free and total cholesterol using specific enzymes.

PHS-6040
(12-75)

Project No. Z01-CC 00002-01 CP
1. Clinical Pathology Department
2. Clinical Chemistry Section
3. Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 through Sept. 30, 1977

Project Title: Clinical laboratory applications of microcalorimetry

Previous Serial Number: none

Principal Investigators: Dr. N.N. Rehak
Dr. R.M. Jaffe

Other Investigators: Dr. D.S. Young

Cooperating Units: none

Man Years:

Total:	3.0
Professional:	1.0
Other:	2.0

Objectives:

To determine the feasibility of calorimetry as a practical technique in clinical laboratory practice. To use calorimetry for assessing cellular metabolism.

Methods Employed:

Calorimetric assays were compared against conventional methods. When differences in test values were observed these were actively followed up.

Major findings:

The calorimeter can be used to measure certain enzymes rapidly with obviation some of the problems that affect spectrophotometric measurements. Determination of lactate dehydrogenase subunits can be accomplished more rapidly and efficiently by calorimetry than by electrophoresis. Likewise, the determination of free and ester cholesterol is more simple using calorimetry than conventional techniques.

Significance:

It is possible to make certain determinations more accurately and with greater specificity with the calorimeter than with other methods. This has potential implications for the improvement of health care.

Proposed course:

The titration calorimeter computer programs will be further refined to improve throughput of analyzers and provide greater flexibility. Modifications to improve sensitivity are also to be undertaken, and redesign of the stirrer should eliminate problems of hemolysis that affect measurements on intact cells.

Further applications of the calorimeter to make additional measurements of substances that require complex separations at the present time are planned. These include vanillylmandelic acid and 5-hydroxyindoleacetic acid in urine. The purity of enzymes used as reagents for clinical laboratory tests will also be studied.

Honors and awards: none

Publications:

Rehak, N.N., Janes, G. and Young, D.S. Calorimetric enzymatic measurement of uric acid in serum. Clin. Chem. 23, 195-199 (1977).

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00003-01 CP

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Staphylococcus aureus Carriage and its Relationshio to Infection in a Pediatric Population with Malignant Disease

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Dr. Stephan K. Ladisch, Clinical Associate, Pediatric Oncology Branch
Division of Cancer Treatment, NCI

Dr. Charles H. Zierdt, Microbiologist, Microbiology Service, CPD, CC

Dr. Frank G. Witebsky, Asst. Chief, Microbiology Service, CPD, CC

Dr. Philip A. Pizzo, Senior Investigator, Pediatric Oncology Branch,
Division of Cancer Treatment, NCI

COOPERATING UNITS (if any)

Pediatric Oncology Branch, Division of Cancer Treatment, NCI

LAB/BRANCH

Clinical Pathology Department

SECTION

Microbiology Service

INSTITUTE AND LOCATION

Clinical Center, National Institutes of Health, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
0.5	0.1	0.4

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Carriers of Staphylococcus aureus in the Pediatric oncology Branch clinic population are being identified using cultures of anterior nares swabs. All Staphylococcus aureus isolates are phage typed. Comparisons will be made of the incidence of Staphylococcal infections in carriers and non-carriers. Should the infection rate prove higher in carriers, attempts may be made to lower the carriage rate.

PHS-6040
(Rev. 10-76)

Project No. Z01 CC 00003-01 CP
1. Clinical Pathology Department
2. Microbiology Service
3. Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 through September 30, 1977

Project Description

Objectives:

The objectives of this study are to determine the anterior nares carriage rate of Staphylococcus aureus in the Pediatric Oncology Branch clinic population. If more infections caused by Staphylococcus aureus are found in carriers as compared with non-carriers, an attempt may be made to decrease the carriage rate, and thereby, hopefully, also the infection rate.

Methods Employed:

Routine culturing procedures are employed for the identification of Staphylococcus aureus. All isolates, both from the nose and from any sites of infection, are further characterized by bacteriophage typing to assess the likelihood that in a given patient isolates of Staph. aureus from the nose and from a site of infection are both the same.

Major Findings:

Many persistent carriers of Staphylococcus aureus have been identified. However, more data is required before any general conclusions can be drawn.

Significance to Biomedical Research and rhw Program of the Institute:

Staphylococcus aureus infections are a cause of significant morbidity in immunosuppressed patients. If a predisposing factor (such as Staph. aureus nasal carriage) can be defined and eliminated, significant patient benefit will accrue.

Proposed Course:

More data will be collected in order to have sufficient members of cases to allow for meaningful conclusions to be made.

Honors and Awards:
None

Publications:
None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-00004-02-CP

PERIOD COVERED
July 1, 1976 to Sept. 30, 1977

TITLE OF PROJECT (80 characters or less)

Radioimmunoassay of Creatine Kinase: A model for RIA of human serum isoenzymes.

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Dr. Andre C. Van Steirteghem, Visiting Scientist, CP,CC

Dr. Mark H. Zweig, Staff Physician, CP,CC

COOPERATING UNITS (if any)
Dr. Alan N. Schechter, Section of Maromolecular Biology, Laboratory of Chemical Biology, NIAMDD

LAB/BRANCH
Clinical Pathology Department

SECTION
Clinical Chemistry Section

INSTITUTE AND LOCATION
CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
2.5	1.5	1.0

SUMMARY OF WORK (200 words or less - underline keywords)

Since the catalytic activity of the most commonly measured human serum enzymes is not necessarily relevant to their clinical usefulness in diagnosis and is only a convenient tool for assay, determination of the total mass of each enzyme or isoenzyme released into the circulation by normal cellular activity or damage is more relevant and desirable. Radioimmunoassay (RIA) offers the high degree of specificity and sensitivity required to measure enzyme mass and to simultaneously distinguish isoenzyme species having the same catalytic activity but having different clinical significances. Creatine kinase (CK) was chosen as a model for this approach because of its clinical importance and relatively simple isoenzyme structure and distribution. To develop RIA's for CK, isoenzyme purifications were necessary to provide material for immunization of animals as a source of antibodies for preparing an I^{125} radiolabeled tracer and for standards. The RIA's developed for these two isoenzymes are applied to the diagnosis and study of diseases of the heart skeletal muscle, brain, thyroid and other organs and to the detection of heterozygous carriers of muscular dystrophy.

PHS-6040
(12-75)

Project No. Z01-CC-00004-02-CP
1. Clinical Pathology Dept.
2. Clinical Chemistry Section
3. Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 through Sept. 30, 1977

Project Title: Radioimmunoassay of Creatine Kinase: A model for RIA of human serum isoenzymes

Previous Serial Number: Z01-CC-00004-01-CP

Principal Investigators: Dr. Andre Van Steirteghem
Dr. Mark H. Zweig

Other Investigators: None

Cooperating Units: Dr. Alan N. Schechter, LCB, NIAMDD

Man Years:

Total:	2.5
Professional:	1.5
Other:	1.0

Project Description

Objectives:

1. To develop and optimize radioimmunoassays for the muscle (CK-MM) and brain (CK-BB) isoenzymes of human creatine kinase (CK) in serum and other fluids.

2. To apply the RIA's developed to the diagnosis and study of disease of tissues and organs containing CK.

3. To apply these assays to the detection of heterozygous carriers of muscular dystrophy.

Methods Employed

1. Previously immunized sheep, rabbits and burros were boosted by injection of the original immunogens. Blood was collected two weeks later, for the preparation of antisera.

2. Radioiodination of purified CK was performed by Hazelton Laboratories (Vienna, Virginia). The chloramine-T method was used for CK-MM and the conjugation method of Bolton and Hunter for CK-BB.

3. The standard components of an RIA system, radiotracer, specific antibody, and precipitating antibody were assembled into a specific and sensitive

assay for each of the two CK isoenzymes.

Major Findings:

1. The RIAs were optimized and found to be practical, reproducible and accurate. Sensitivity and specificity were particularly high. The specificity of both assays for their respective isoenzymes was greater than the specificity reported by other workers.

2. For the muscle isoenzyme, reference ranges for healthy adults were determined by assaying the sera of laboratory workers and blood bank donors. A close correlation was found between the enzymatic activity measured by conventional assays and the mass concentration as determined by RIA in these sera. In patient sera a similar relationship between enzymatic activity was found, but the correlation was not as close.

3. Whereas the amounts of brain isoenzyme in sera have usually been low or undetectable by assays of enzymatic activity, virtually all sera from healthy subjects and from patients had measureable amounts when determined by RIA. A reference range for healthy persons was determined.

Proposed Course:

1. The RIAs for the brain and muscle isoenzymes of CK will be applied to the measurement of isoenzyme concentration in the serum, cerebrospinal fluid and muscle biopsy extracts of patients. Some of these applications are under way. Patients of interest include those with psychosis, neuromuscular disorders (especially muscular dystrophy and polymyositis), myocardial disease, prostatic carcinoma, and patients undergoing cardiac and neurosurgical procedures.

2. A RIA for the cardiac isoenzyme, CK-MB, will be developed to obtain a highly sensitive and specific measurement of the concentration in serum.

3. To obtain definitive data on the tissue distribution of CK isoenzymes, human tissue extracts will be assayed using RIA procedures.

4. Fractionation of CK into mitochondrial and non-mitochondrial forms will be attempted with the intent to determine molecular differences and to study the clinical significance of the appearance of each type in human serum.

Honors and Awards: none

Publications:

1. Van Steirteghem, A.C., Zweig, M.H. and Schechter, A.N. Radioimmunoassay of the brain isoenzyme of human creatine kinase. Clin. Chem. 23, 1125, 1977. (abstract; paper presented July, 1977 at American Association for Clinical Chemists meeting in Chicago).

2. Zweig, M.H., Van Steirteghem, A.C. and Schechter, A.N. Radioimmunoassay of the muscle isoenzyme of human creatine kinase. Clin. Chem. 23, 1143, 1977. (abstract, paper presented July, 1977 at American Association for Clinical Chemists meeting in Chicago).

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-00005-03-CP

PERIOD COVERED
July 1, 1976 to September 30, 1977

TITLE OF PROJECT (80 characters or less)

Development of a microchemical analytical system for pediatric analyses.

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

H.H. Nishi, CC, CPD - Research Biochemist, Principal Investigator
D.S. Young, CC,CPD - Chief, Clinical Chemistry Service

COOPERATING UNITS (if any)

BEIB,NIH

LAB/BRANCH
Clinical Pathology Department

SECTION
Clinical Chemistry Service

INSTITUTE AND LOCATION
Clinical Center, NIH, Bethesda, Md.

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
3.5	1.2	2.3

SUMMARY OF WORK (200 words or less - underline keywords)

Because of the increasing usage of the miniature centrifugal fast analyzer as an analytical tool for routine clinical chemistry laboratories, it was incorporated into our microchemical analytical system. The purpose of this combination was to study the flexibility and effectiveness of the microanalytical system when used with a miniature centrifugal fast analyzer. The newly created system was evaluated for specific proteins analyses using the kinetic rate measurement of human serum IgG as a model. A new assay method for the determination of immunoglobulin G was developed for the system. Technical aspects of this study has been completed save for the rechecking of certain critical points, the write-up of the study has been started and will be ready for publication soon.

Serial No. Z01-00005-03-CP
1. Clinical Center, Clinical Pathology Department
2. Clinical Chemistry Service
3. Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 through Sept. 30, 1977

Previous Serial Number: Z01-00005-02-CP

Principal Investigator: Harold Nishi

Other Investigator: Dr. Donald Young
Mrs. Jane Kestner

Cooperating Units: Inside NIH

Mr. Charles McCarthy, BEIB
Mr. Charles Wicks, BEIB
Mr. Leonard Aberbach, BEIB

Man Years:

Total:	3.5
Professional:	1.2
Other:	2.3

Project Description

Objectives:

1. To test the flexibility of the microanalytical system using the miniature centrifugal fast analyzer as the optical detection device.

2. To develop a new rapid microchemical procedure for the determination of specific proteins of neonate and infant care work.

Methods Employed:

The combined microanalytical and the miniature centrifugal analyzer systems were used to develop a kinetic rate measurement of antigen-antibody precipitin digitally controlled rotor loader and the miniature centrifugal fast analyzer used in the nepitelometric mode. The new (combined) system provided the advantage of computer assistance in assembling antilog data and computations of it parallel analyses. The hard data for each of the 17 samples were provided by the teletype machine.

Major Findings:

The microanalytical system used with the miniature centrifugal analyzer was found effectual in the assay of immunogobulin G in small quantities of human serum. Complete analysis of 17 serum samples required only 10 seconds with a coefficient of variation of ± 1.0% during within rotor analysis. The

serum immunoglobulin results agreed well with those obtained by the reference method of end-point procedure. The coefficient of correlation of the new kinetic rate procedure to the reference method was 0.97.

Significance:

Based on the aggregate of our experience, we believe that this equipment truly provides a single, simple, reliable system for emergency, routine, and pediatric analyses. The discussed tests represent only those that were selected for the purpose of critical evaluation on the newly developed micro-analytical system. We have performed other test procedures on this apparatus.

Proposed course:

The microanalytical analyzer will be installed in our micro-chemistry laboratory for use in neonate and infant care work. We will continue to develop new microchemical procedures for clinical laboratory use.

Honors and awards:

Inventor - employee award (H.H. Nishi)
Received two awards for two U.S. Patents (H.H. Nishi)

Publications:

Nishi, H.H. and Young, D.S. Rapid analysis of immunoglobulin G, A, and M by the kinetic rate procedure, Richie, (ed.). Automated Immunoassay (in press).

PUBLICATIONS 1977

1. The Preparation and Characterization of a Thymic Independent Antigen: -Dinitrophenyl-1-Lysine-Ficoll. McMaster, P.R.B., Owens, J., and W.E. Vannier. Immunochemistry 1977. 14: 189-196.

2. Hapten Specific Delayed Hypersensitivity to -2,4-Dinitrophenyl-1-Lysine-Ficoll in Guinea Pigs Immunized with 2,4 Dinitrophenyl-Keyhole Limpet Hemocyanin. McMaster, P.R.B., Owens, J., Weichbrod, R., and R. Asofsky. J. Exp. Med. 1977. 145: 1101-1114.

3. Hapten Specific Leukocyte Migration Inhibition. Inhibition of Cells from Animals Immunized with DNP-KLH by -DNP-1-Lysine-Ficoll. McMaster, P.R.B., Owens, J. and R. Asofsky. J. Immunol. 1977. 118: 1335-1337.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00006-02 CP

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Use of Laser Light Scattering for Rapid Determination of Potential Antibiotic Synergy

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Dr. James D. MacLowry, Chief, Microbiology Service

Dr. E. Arthur Robertson, Asst. Chief, Laboratory Computer Service

COOPERATING UNITS (if any)

None

LAB/BRANCH

Clinical Pathology Department

SECTION

Microbiology Service, Laboratory Computer Service

INSTITUTE AND LOCATION

Clinical Center, National Institutes of Health, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
0.9	.1	.8

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

The Differential III laser light scattering instrument is being evaluated for its potential usefulness for rapidly determining antibiotic synergy.

PHS-6040
(Rev. 10-76)

Project Description

Objectives:

Evaluation of a prototype light scattering instrument, the Differential II for its potential use in clinical microbiology.

Methods Employed:

Antibiotic combinations are being evaluated with a novel laser light scattering instrument to detect changes in bacterial growth.

Major Findings:

The laser light scattering technique is very sensitive to the presence of and shape of particles. It has been necessary to capture the output of the instrument for computer analysis to detect significant changes.

Significance to Biomedical Research and the Program of the Institute:

If this instrument and method can be made to work in a consistent fashion, it is possible that there will be a number of applications in clinical microbiology which would be useful. Specifically the ability to rapidly assay serum bactericidal activity and antibiotic bacteriocidal activity would be very useful if they can be done in a reasonable time frame with minimal cost.

Proposed Course:

Evaluation will continue until instrument has been adequately evaluated.

Honors and Awards:

None

Publications:

None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00007-01 CP

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)
Organization and use of Laboratory Data Base in Clinical Microbiology

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Dr. James D. MacLowry, Chief, Microbiology Service

Dr. Frank G. Witebsky, Asst. Chief, Microbiology Service

Dr. Thomas Lewis, Chief, Laboratory Computer Service

COOPERATING UNITS (if any)
Mr. William Vincent, DCRT

LAB/BRANCH
Clinical Pathology Department

SECTION
Microbiology Service and Laboratory Computer Service

INSTITUTE AND LOCATION Clinical Center, National Institutes of Health, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1.1	1	1.0

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

The data base accumulated by the laboratory computer system was organized. This is accomplished by using the central DCRT facilities and organizing retrieval to expedite data searches and minimize their cost.

PHS-6040
(Rev. 10-76)

Project Description

Objectives:

To efficiently utilize the patient data which is being accumulated.

Methods Employed:

Using the DCRT IBM 370 System and data derived in this laboratory, cumulative information for specific time intervals with large numbers of patients can be analyzed.

Major Findings:

Can efficiently collate large amounts of data.

Significance to Biomedical Research and the Program of the Institutes:

These programs have already been made available to interested investigators to study their patients. Also, makes it possible to analyze patient data rapidly and cheaply.

Proposed Course:

These programs will be refined as more data is accumulated to enable more sophisticated retrieval.

Honors and Awards:

None

publications:

None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE
PROJECT NUMBER (Do NOT use this space)

U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NOTICE OF
INTRAMURAL RESEARCH PROJECT

PROJECT NUMBER

Z01 CC 00008-01 CP

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Evaluation of Some Aspects of Dynatech MIC-2000
96 Channel Dispenser

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Dr. Philip R. B. McMaster, Resident Physician, Clinical Pathology Dept, CC

Dr. Frank G. Witebsky, Asst Chief, Microbiology Service, CPD, CC

Dr. James D. MacLowry, Chief, Microbiology Service, CPD, CC

Dr. E. Arthur Robertson, Asst Chief, Laboratory Computer Service, CPD, CC

COOPERATING UNITS (if any)

None

LAB/BRANCH

Clinical Pathology Department

SECTION

Microbiology Service and Laboratory Computer Service -

INSTITUTE AND LOCATION

Clinical Center, National Institutes of Health,
Bethesda, Maryland 20014

TOTAL MAN-YEARS:	PROFESSIONAL:	OTHER:
0.5	0.4	0.1

APPROPRIATE BOX(ES)

(a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

(a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

The Dynatech MIC-2000 96 channel dispenser (manufactured by Cooke Laboratory Products, 900 Slaters Lane, Alexandria, Va. 22314), an instrument comprising part of the Dynatech MIC-2000 System for antimicrobial susceptibility testing of bacteria, was evaluated to determine the accuracy and reproducibility of the amount of fluid it dispensed. Also, a battery of antimicrobial agents was dispensed and stored at -20° C and -70° C; these antimicrobials were subsequently examined at intervals to determine their potency.

FORM 2590

Project Description

Objectives:

The Dynatech MIC 2000 96 channel dispenser was evaluated to determine accuracy and reproducibility of the volumes it dispensed into each of the 96 wells of a microtiter plate. In addition, a battery of antimicrobial agents was dispensed, frozen, and stored at -20°C and -70°C; these antimicrobials were subsequently examined at intervals to determine their potency.

Methods Employed:

Disposable capillary pipettes were used to measure the volumes dispensed; it was determined that the volumes could be assessed accurately by measuring the length of the column volume of fluid in the pipette. Antimicrobial potency was determined by removing a certain amount of antimicrobial solution from the wells of the microteter plates, placing the solution on a filter paper disc and measuring the zone of inhibition of growth of Staphylococcus aureus.

Major Findings:

Accuracy of repetitively dispensed volume was found to be satisfactory. The antimicrobial agents tested were found to retain their potency for at least 2 weeks at -20°C and 4 months at -70°C.

Significance to Biomedical Research and the Program of the Institute:

As the instrument was found to be satisfactory with respect to the parameters evaluated, it is planned to incorporate it in the near future in the Microbiology Service sensitivity section, for use in routine sensitivity testing. Determination and reporting of the antimicrobic sensitivity pattern of bacterial isolates from patients at the Clinical Center should thereby be facilitated, as certain features of the machine allow combining into one array the different arrays of antimicrobials currently employed.

Proposed course:

The project has been completed. A manuscript reporting the findings in detail is in preparation.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00009-03 CP

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Blastocystis hominis, Structure, Pathegenesis, and Classification

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Dr. Charles H. Zierdt, Microbiologist, Microbiology Service, CPD, CC

COOPERATING UNITS (if any)

None

LAB/BRANCH

Clinical Pathology Department

SECTION

Microbiology Service

INSTITUTE AND LOCATION

Clinical Center, National Institutes of Health, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
0.1	0.05	0.05

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Blastocystis hominis, a protozoan parasite of the human gastrointestinal tract and an organism implicated in the causation of human diarrhea, is being studied in terms of its morphology, physiology, and pathogenetic features such as toxin production.

PHS-6040
(Rev. 10-76)

Project Description

Objectives:

Continuing study of Blastocystis hominis, newly designated protozoan parasite of man.

Methods Employed:

Study of diarrhea caused by B. hominis, and the ultrastructure, physiology and life cycle of this organism.

Proposed Source:

Study will be continued of a toxin active in the guinea pig and rabbit ileum, as well as of an infectious diarrhea model, using the guinea pig.

Honors and Awards:

None

Publications:

None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00010-02 CP

PERIOD COVERED

July 1, 1976 through September 30, 1977

TITLE OF PROJECT (80 characters or less)

Effect of Magnesium Deficiency on Erythrocyte Structure and Function

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI:	Dr. Ronald J. Elin	Chief, Clin. Path. Dept.	CP CC
OTHER:	Dr. Henry K. Tan	Asst. Chief, Hemat. Serv.	CP CC
	Dr. Laurence Corash	Staff Physician, Hemat. Serv.	CP CC

COOPERATING UNITS (if any)

None

LAB/BRANCH

SECTION

Hematology Service

INSTITUTE AND LOCATION

CP, CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1.0	0.25	0.75

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Magnesium deficiency in experimental animals produces an anemia and a shortened erythrocyte survival. Erythrocytes from rats deficient in magnesium were examined using freeze-fracture electron microscopy. The results show an erythrocyte membrane abnormality in the form of a plaque which develops after the animals have been on a magnesium-deficient diet for two weeks. These plaques enlarge in size with progressive magnesium deficiency. The plaques are unaltered by in vitro incubation of the red cells with normal concentrations of magnesium.

PHS-6040
(Rev. 10-76)

Project No. Z01 CC 00010-02 CP
1. Clinical Pathology Dept.
2. Hematology Service
3. Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 through September 30, 1977

Project Title: Effect of Magnesium Deficiency on Erythrocyte Structure and Function

Previous Serial Number: None

Principal Investigator: Dr. Ronald J. Elin

Other Investigators: Dr. Henry K. Tan
Dr. Laurence Corash

Man Years:
Total: 1.0
Professional: 0.25
Other: 0.75

Project Description

Objectives:

Define and characterize membrane abnormalities associated with deficiency of magensium. Determine the effect of magnesium deficiency on erythropoiesis.

Methods Employed:

The erythrocyte specimen was prepared by freeze-fracture and etching. The etched surface was coated with carbon and platinum. The specimen was then studied using an electron microscope. Erythrocytes from magnesium-deficient rats were separated on the basis of age using a stractan gradient. The magnesium concentration and pyrophosphatase activity were determined for each population of erythrocytes using standard techniques.

Major Findings:

The erythrocytes from magnesium-deficient rats develop a membrane alteration. The membrane abnormality which is in the form of a plaque was observed on the erythrocytes of animals who had been on a magensium-deficient diet for a period of two weeks. These membrane plaques increased in size to a maximum diameter of between 50 to 100 nm and frequency with progressive magnesium deficiency. These plaques were present on erythrocyte ghosts prepared by osmotic lysis. The membrane plaques were unaltered by incubating the cells in normal concentrations of magnesium. Erythropoiesis in magnesium-deficient rats appears to be normal since reticulocytes and very young erythrocytes

containing normal concentration of magnesium and erythrocyte pyrophosphatase.

Significance to Biomedical Research and the Program of the Department:

This is the first membrane abnormality of erythrocytes in experimental animals that is related to an abnormality in mineral metabolism. Magnesium has been clearly established as an essential element for biochemical processes involving energy production. In this study, magnesium has been shown to be important for normal membrane structures. This is part of a series of studies by the department to define factors which influence erythrocyte survival and function. The structural and biochemical abnormalities of erythrocytes in magnesium deficiency occur after the cell has entered the vascular space. Thus, the bone marrow is able to produce a normal cell but an environment deficient in magnesium produces erythrocyte abnormalities.

Proposed Course:

This project will now be extended to study factors of erythropoiesis that enable the synthesis of a relatively normal cell in magnesium deficiency.

Honors and Awards:

None

Publications:

Elin, R. J. and Tan, H. K.: Formation of plaques on erythrocyte membranes from rats with magnesium deficiency. Blood. 49: 657, 1977.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00011-04 CP

PERIOD COVERED
July 1, 1976 through September 30, 1977

TITLE OF PROJECT (80 characters or less)

Platelet Aging

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI:	Dr. L. M. Corash	Staff Physician	Hematology Service	CP,CC
Other:	Dr. Henry K. Tan	Asst. Chief	Hematology Service	CP,CC
	Dr. Mark Perlow	Staff Fellow		N, LP

COOPERATING UNITS (if any)

LAB/BRANCH
Clinical Pathology Department

SECTION
Hematology Service

INSTITUTE AND LOCATION
CP, CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1.0	0.5	0.5

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Blood platelets have a finite life span in the peripheral circulation and under normal steady state conditions are removed by a discrete aging process. Earlier studies had suggested that there were structural, metabolic, and functional differences between young and old platelets. Existing methods to isolate platelets for study were inadequate. An efficient method to quantitatively isolate pure blood platelets has been developed in this laboratory. Experiments have shown that there is a strong relationship between platelet density and platelet structure, metabolism and function. Use of a non-human primate model has shown that these density dependent characteristics do correlate with platelet age. Thus, it is now possible to isolate age dependent platelet cohorts and to measure age dependent parameters of pure whole blood platelets. These techniques provide a means to analyze mechanisms of platelet aging to estimate platelet turnover rates, and to isolate platelets of improved quality for potential use in therapeutic transfusion.

PHS-6040
(Rev. 10-76)

PHS-NIH
Individual Project Report
July 1, 1976 through September 30, 1977

Project Title: Platelet Aging

Previous Serial Number:

Principal Investigator: Dr. Laurence M. Corash

Other Investigators: Dr. Henry K. Tan
Dr. Mark Perlow

Man Years:

Total:	1.0
Professional:	0.5
Other:	0.5

Project Description

Objectives:

1. Isolation of pure whole blood platelets which are structurally and functionally intact.

2. Correlation of platelet density with structure, metabolism and function.

3. Development of a sub-human primate model to prove that platelet density is an age dependent parameter.

4. Evaluation of platlet size, serotonin content and glycolytic rate as a means to estimate platelet turnover rate in patients with various platelet disorders.

Methods Employed:

Platelets were isolated from whole blood and separated into density dependent cohorts by use of isosmolar arabino-galactan discontinuous gradients and ultra-centrifugation. Cell volume distribution was measured with an electronic particle counter equipped with a logarithmic amplifier and a small computer. Platelet ultrastructure was viewed with transmission electron-microscopy. Platelet function was evaluated by aggregation to standard platelet stimulating agents. A sensitive double isotopic radioactive assay was adopted to measure endogenous serotonin content. The rhesus monkey model was developed to isolate density dependent platelet cohorts which were labelled and radiochromium and reinfused into donor animals to measure cohort life span.

Major Findings:

1. Pure whole blood platelets in high yield can be isolated by this technique.

2. Traditional isolation methods are biased in favor of smaller, lighter platelets.

3. Platelets can be effectively isolated from plasma proteins and then be reconstituted to a functional state with autologous plasma.

4. There is a significant correlation between platelet density and cell volume, structure and organelle content.

5. A well defined range of platelet size distribution exists and was defined for a large population of normal subjects.

6. Simultaneous platelet size determination and standard radiochromium platelet survivals were performed in patients. There is a strong correlation between decreased platelet life span and increased platelet volume.

7. The rhesus monkey model has shown that heavy platelets have a longer survival than do light platelets. Introduction of a heavy platelet cohort label into the bottom of a gradient results in progressive migration of the label up through the gradient, thus clearly demonstrating that heavy platelets become light platelets.

8. Heavy platelets contain four times the serotonin content of light platelets, thus serving as a useful age dependent marker.

Significance

Earlier techniques have not been able to efficiently isolate whole blood platelets. This method removes all plasma proteins from platelets which was not possible by earlier methods. For the first time age dependent platelet cohorts from a total whole blood platelet population can be isolated. Subsequent study of these cell cohorts will permit evaluation of aging effect on platelets in disease. This method will also provide diagnostic information to discriminate diseases with increased platelet destruction from diseases with failure of platelet production. It will also facilitate studies to determine if platelet disorders are due to a qualitative protein defect or a quantitative protein defect. This study provides a new method to explore platelet aging.

Proposed Course:

The project is now being extended to apply the method to patients with platelet disorders. The animal model will be manipulated to perform *in vivo* experiments which cannot be performed in patients.

Honors and Awards

None

Publications:

1. Corash, L., Gralnick, H. R.: High Yield Quantitative Isolation of Human Platelets from Whole Blood. BLOOD 44: 919, 1974.

2. Corash, L., Tan, H., Gralnick, H.: Heterogeneity of Human Whole Blood Platelet Subpopulations. I. Relationship Between Buoyant Density, Cell Volume, and Ultrastructure. BLOOD 49: 71-87, 1977.

3. Corash, L., Shafer, B., Weinberg, D., Steinfeld, M. B.: Platelet Sizing of Whole Blood Total Platelet Populations. Workshop on Platelets. Philadelphia, Pa., October, 1976, in press.

4. Andersen, J., Gralnick, H., Corash, L.: Partial Characterization of Platelet Associated Factor VIII. Circulation 54: II-115, 1976.

5. Corash, L., Costa, J., Tan, H., Shafer, B., Fauci, A. S., Wolff, S. M.: 5-Hydroxytryptamine Metabolism, Alpha Granule Release, and Life Span of Chediak-Higashi Syndrome Platelets. Clin. Res., 1977, in press.

6. Norton, J. A., Shulman, N. R., Corash, L., Smith, R. L., Au, F., Rosenberg, S. A.: Severe Thrombocytopenia Following Intralesional BCG Therapy. Cancer, 1977, in press.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00012-09 CP

PERIOD COVERED
July 1, 1976 through September 30, 1977

TITLE OF PROJECT (80 characters or less)

Investigation of Hemorrhagic and Thrombotic Disorders in Man

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI: Dr. Harvey R. Gralnick Chief, Hematology Service CP CC

COOPERATING UNITS (if any)

LAB/BRANCH
Clinical Pathology Dept., Clinical Center

SECTION
Hematology Service

INSTITUTE AND LOCATION
CP, CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
9.0	4.5	4.5

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☒ (b) HUMAN TISSUES ☐ (c) NEITHER

☒ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Investigation of congenital and acquired hemorrhagic and thrombotic disorders in man to elucidate the clinical entities and to investigate the molecular basis for the defects. This has involved purification of coagulation proteins, immunologic investigation of coagulation proteins and inhibitors, and defining the role of these proteins in normal hemostasis and abnormal hemostasis.

PHS-6040
(Rev. 10-76)

Project No. Z01 CC 00012-09 CP

1. Clinical Pathology Dept.
2. Hematology Service
3. Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 through September 30, 1977

Project Title: Investigation of Hemorrhagic and Thrombotic Disorders in Man

Previous Serial Number:

Principal Investigator: Dr. Harvey R. Gralnick

Man Years:

Total:	9.0
Professional:	4.5
Other:	4.5

Project Description

Objectives:

Define and characterize normal and abnormal coagulation proteins, inhibitors, and cofactors associated with clinical disorders of hemostasis.

Methods Employed:

Purification and isolation of various coagulation proteins, determination of functional defects, and molecular characterization of the defect. In addition multiple immunologic techniques are utilized for elucidation of abnormal proteins.

Major Findings:

Three families with congenital dysfibrinogenemia have been fully described and elucidated. These families have defects in the conversion of fibrinogen to fibrin which interferes with normal hemostasis in two of the three families. The abnormalities vary in each family and in some families have been related to the release of fibrinopeptides and in others to polymerization of fibrin monomers. Studies of the pathological aspects of fibrinogen have indicated the importance of fibrinogen in maintenance of normal hemostasis. In particular, defects were observed in immunologic techniques, clotting techniques, and in the ability of fibrinogen to cross-link. In one family the abnormal fibrinogen also had a markedly shortened intravascular survival.

Significance to Biomedical Research and the Program of the Department:

These studies elucidate some of the molecular defects associated with abnormal hemostasis and thrombosis and have allowed a greater understanding of the pathophysiology of blood coagulation. Not only have individual patients benefited from the elucidation of these defects in proper therapy but our greater understanding of blood coagulation in general has developed. This is part of a series of studies by this service to define the factors associated with hemorrhage and thrombosis in man.

Proposed Course:

This project will be extended to study other coagulation states and thrombotic states.

Honors and Awards:

None

Publications:

1. Gralnick, H., Abrell, E., and Bagley, J.: Heparin Treatment for Hemorrhagic Diathesis of Acute Promyelocytic Leukemia. Am. J. Med. 52: 167, 1972.

2. Gralnick, H., Givelber, H., Shainoff, J., and Finlayson, J.: Fibrinogen Bethesda: A Congenital Dysfibrinogenemia with Impaired Fibrinopeptide Release. J. Clin. Invest. 50: 1819, 1971.

3. Gralnick, H. and Abrell, E.: Studies of the Procoagulant and Fibrinolytic Activity of Promyelocytes in Acute Promyelocytic Leukemia. Br. J. Haematol. 24: 89, 1973.

4. Gralnick, H. and Finlayson, J.: Congenital Dysfibrinogenemias. Ann. Int. Med. 77: 471, 1972.

5. Gralnick, H., Marchesi, S. and Givelber, H.: Intravascular Coagulation in Acute Leukemia. Blood 40: 709, 1972.

6. Gralnick, H., Givelber, H., and Finlayson, J.: A New Congenital Abnormality of Fibrinogen: Fibrinogen Bethesda II. Thromb. Diath. Haemorrh. 29: 562, 1973.

7. Gralnick, H. and Tan, H.: Acute Promyelocytic Leukemia: A Model for Understanding the Role of the Malignant Cell in Hemostasis. Hum. Pathol. 5: 661, 1974.

8. Fratantoni, J., Pollet, R., and Gralnick, H.: Heparin-induced Thrombocytopenia: Confirmation of Diagnosis with In Vitro Methods. Blood 45: 395, 1975.

9. Gralnick, H. and Sultan, C.: Acute Promyelocytic Leukemia: Haemorrhagic Manifestation and Morphologic Criteria. Br. J. Haematol. 29: 273, 1975.

10. Greipp, P. and Gralnick, H.: Platelet to Leukocyte Adherence Phenomena Associated with Thrombocytopenia. Blood 47: 513, 1976.

11. Hoover, Jr., H. C., Ketcham, A. S., Millar, R. C., and Gralnick, H. R.: Osteosarcoma: Improved Survival with Anticoagulation and Amputation. Cancer, In press.

12. Horvath, A. and Gralnick, H. R.: The ^{125}I Fibrinogen Euglobulin Lysis Test. Am. J. Clin. Path., In press.

13. Spellman, Jr., G. G., Macoviak, J. A., and Gralnick, H. R.: Comparison of Polymerization of Ancrod and Thrombin Monomers. Blood, In press.

14. Gralnick, H. R.: Intravascular Coagulation I and II. Postgraduate Medicine, In press.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00013-10 CP

PERIOD COVERED

July 1, 1976 through September 30, 1977

TITLE OF PROJECT (80 characters or less)

Chemical and Structural Studies on the Human Factor VIII/von Willebrand Factor Protein

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI: Dr. Harvey R. Gralnick Chief, Hematology Service CP CC

COOPERATING UNITS (if any)

Dr. Barry S. Coller, Div. of Hematology, School of Medicine, State Univ. of N.Y. Stony Brook, N.Y.
Dr. Yvette Sultan, Dept. of Hematology, Hopital Saint-Louis, Paris France

LAB/BRANCH

Clinical Pathology Dept., Clinical Center

SECTION

Hematology Service

INSTITUTE AND LOCATION

CP, CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
10.0	5.0	5.0

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☒ (b) HUMAN TISSUES ☐ (c) NEITHER

☒ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

The long-range purpse of this project is to initially study the immunologic aspects of the factor VIII/von Willebrand factor protein and then to study the biochemistry and structure of this protein in man. The topics of present interest are: (1) the defect of the factor VIII/von Willebrand factor protein in hemophilia A, (2) the defect of the factor VIII/von Willebrand factor protein in von Willebrand's disease, (3) the importance of carbohydrate content in biological functions, (4) the relationship of carbohydrate content to atherosclerosis, (5) the mechanism of thrombin activation, and (6) biochemical characterization of the biologically active sites of the factor VIII/von Willebrand factor protein.

PHS-6040
(Rev. 10-76)

Project No. Z01 CC 00013-10 CP

1. Clinical Pathology Dept.
2. Hematology Service
3. Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 through September 30, 1977

Project Title: Chemical and Structural Studies on the Human Factor VIII/von Willebrand Factor Protein

Previous Serial Number:

Principal Investigator: Dr. Harvey R. Gralnick

Other Investigators: Dr. Barry S. Coller
Dr. Yvette Sultan

Man Years:

Total:	10.0
Professional:	5.0
Other:	5.0

Project Description

Objectives:

Define and characterize the normal factor VIII/von Willebrand factor protein, to elucidate the defects of the protein in hemophilia and von Willebrand's disease and then to ascertain its role in atherosclerosis.

Methods Employed:

This has been accomplished by limited alpha chymotrypsin digestion of cryoprecipitate or other concentrates of factor VIII followed by gel chromatography on Sepharose 4B.

Major Findings:

Individuals with hemophilia A have a protein identical to normal in all respects except that it lacks clot-promoting activity while in von Willebrand's disease it has been found that the protein is quite heterogeneous. In some patients there is a complete absence of the protein with all its associated biological functions (quantitative defect) while in other patients there is a qualitative defect where the protein is present in normal amounts; however, it is deficient in biological activity. A major finding has been that the carbohydrate moiety of the factor VIII/von Willebrand

factor protein is most important in its interaction with the platelets and vessel wall and may play an important role in the maintenance of normal hemostasis and propagation of atherosclerosis.

Significance to Biomedical Research and the Program of the Department:

These studies further our long-term project of investigating hemorrhagic and thrombotic clinical disorders. The finding of the importance of carbohydrate in the interaction of platelets with vessel wall or with each other may not only be of major significance in the understanding of von Willebrand's disease but may be equally important in understanding the propagation of atherosclerosis.

Proposed Course:

This project will be continued in its present phase with greater emphasis placed on the contribution of carbohydrates to platelet/platelet and platelet/vessel wall interaction. In addition, studies are underway to localize the sites on the factor VIII/von Willebrand factor protein which are involved in these interactions. Modification of these sites will be attempted in an effort to reproduce *in vitro* a von Willebrand's disease-like state.

Honors and Awards:

1976 Fight for Sight Award for "von Willebrand Factor and Effect on Platelet Aggregation of Plasma from Diabetics with Retinopathy." Association for Research in Vision and Ophthalmology, Inc.

Publications:

1. Gralnick, H., Abrell, E., and Bagley, J.: Immunologic Studies of Factor VIII (Antihemophiliac Globulin) in Hemophilia A. Nature 230: 9, 1971.

2. Marchesi, S., Shulman, N., and Gralnick, H.: Studies on the Purification and Characterization of Human Factor VIII. J. Clin. Invest. 51: 2151, 1972.

3. Gralnick, H., Coller, B., and Marchesi, S.: Immunological Studies of Factor VIII in Haemophilia and von Willebrand's Disease. Nature New Biology 244: 281, 1973.

4. Gralnick, H., Coller, B., and Marchesi, S.: Studies of the Human Factor VIII/von Willebrand Factor Protein. I. Comparison of the Protein Found in Normal, von Willebrand's Disease and Hemophilia A. Thromb. Res. 6: 93, 1975.

5. Gralnick, H., Marchesi, S., and Coller, B.: Theoretical Approach to Molecular Biology of Factor VIII: Heterogeneity of the Molecule. Ann. NY Acad. Sci. 240: 378, 1975.

6. Coller, B., Hirschman, R., and Gralnick, H.: Studies of the Factor VIII/von Willebrand Factor Antigen on the Platelet Surface. Thromb. Res. 6: 469, 1975.

7. Gralnick, H. and Coller, B.: Studies on the Factor VIII/von Willebrand Factor Protein. II. Identification and Characterization of the von Willebrand Protein. Blood 46: 417, 1975.

8. Gralnick, H., Coller, B., and Sultan, Y.: Studies of the Human Factor VIII/von Willebrand Factor Protein. III. Qualitative Defect in von Willebrand's Disease. J. Clin. Invest. 56: 814, 1975.

9. Gralnick, H., Coller, B., and Sultan, Y.: Carbohydrate Deficiency of the Factor VIII/von Willebrand Factor Protein in von Willebrand's Disease Variants. Science 192: 56, 1976.

10. Gralnick, H. and Coller, B.: Molecular Defects in Hemophilia A and von Willebrand's Disease. Lancet, April 26, 1976.

11. Coller, B., Franza, Jr., B., and Gralnick, H.: The pH Dependence of Quantitative Ristocetin Aggregation: Theoretical and Practical Implications. A New Device for Maintenance of Platelet-Rich Plasma pH. Blood 47: 841, 1976.

12. Gralnick, H. R., Sultan, Y., and Coller, B. S.: von Willebrand's Disease Combined Qualitative and Quantitative Abnormalities. N. Engl. J. Med. 296: 1024, 1977.

13. Gralnick, H. R., Coller, B. S., Shulman, N. R., Andersen, J. C., and Hilgartner, M.: Factor VIII. Ann. Int. Med. 86: 598, 1977.

14. Coller, B. S. and Gralnick, H. R.: Studies on the Mechanism of Ristocetin-Induced Platelet Agglutination: Effects of Structural Modification of Ristocetin and Vancomycin. J. Clin. Invest., In press.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00014-01 CP

PERIOD COVERED

July 1, 1976 through September 30, 1977

TITLE OF PROJECT (80 characters or less)

Platelet Serotonin Metabolism

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI: L. M. Corash, M.D. Staff Physician Hematology Ser. CP, CC

Other: J. Costa, M.D. Staff Physician LCS, NIMH

COOPERATING UNITS (if any)

LAB/BRANCH

Clinical Pathology Dept.

SECTION

Hematology Service

INSTITUTE AND LOCATION

CP, CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
0.3	0.1	0.2

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Serotonin is a vaso-active amine which is highly concentrated in the blood platelet. Release of serotonin in response to platelet activating stimuli may play a role in many pathologic states. The absence of platelet serotonin is associated with severe platelet dysfunction and a hemorrhagic diathesis. We have modified a sensitive assay to accurately measure platelet endogenous serotonin content in normal subjects and patients. Young, heavy platelets contain four times the serotonin of old, light platelets. Thus, platelet serotonin content may be a useful means to measure platelet turnover rates. Isolation of age dependent platelet cohorts permits the study of serotonin uptake, content and release in a variety of pathologic states.

PHS-6040
(Rev. 10-76)

Project No. Z01 CC 00014-01 CP

PHS-NIH
Individual Project Report
July 1, 1976 through September 30, 1977

Project Title: Platelet Serotonin Metabolism

Previous Serial Number:

Principal Investigator: Dr. Laurence M. Corash

Other Investigators: Dr. J. Costa

Man Years

Total:	0.3
Professional:	0.1
Other:	0.2

Project Description

Objectives:

1. Measurement of platelet endogenous serotonin content.

2. Quantification of serotonin storage sites and transport rates in age dependent platelet cohorts.

Methods Employed:

Platelets were isolated by use of arabino-galactan gradients. Serotonin transport was measured by rapid uptake of radioactive serotonin and formaldehyde fixation. Serotonin content was measured by a specific double isotope dilution assay.

Major Findings:

1. Serotonin storage sites, platelet dense bodies, are distributed in an age dependent fashion among platelets.

2. The rate of transport is equal in young and old platelets.

3. Young platelets contain four times the serotonin content of old platelets. This is due to a decreased number of storage cites.

Significance:

Platelet serotonin is important for normal platelet function and may play a role in pathologic states that involve the platelet release reaction. The methodologies developed in this study serve to better understand these disorders.

Awards and Honors: None

Publications:

Corash, L., Costa, J., Tan, H., Shafer, B., Fauci, A. S., Wolff, S. M.: 5-Hydroxytryptamine Metabolism, Alpha Granule Release, and Life Span of Chediak-Higashi Syndrome Platelets. Clin. Res. 25: 337A, 1977.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do **NOT** use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE **NOTICE OF INTRAMURAL RESEARCH PROJECT**	PROJECT NUMBER Z01 CC 00015-01 CP

PERIOD COVERED

July 1, 1976 through September 30, 1977

TITLE OF PROJECT (80 characters or less)

Platelet Survival and Function in Patients with Hypercholesterolemia

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI:	L. M. Corash	Staff Physician	Hematology Service	CP, CC
Other:	J. C. Andersen	Staff Fellow	Hematology Service	CP, CC
	E. Schaefer	Staff Physician		IR, NHLBI

COOPERATING UNITS (if any)

LAB/BRANCH

Clinical Pathology Department

SECTION

Hematology Service

INSTITUTE AND LOCATION

CP, CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1.0	0.5	0.5

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Abnormal platelet survival and function have been postulated to play a role in the accelerated atherosclerosis seen in familial hypercholesterolemia. In order to test this hypothesis, platelet survival measured by radiochromium and platelet aggregation were determined in a series of patients with marked hypercholesterolemia. Decreased platelet survival has been found, thus implicating the platelet as a possible contributor to the atherosclerosis associated with this disorder.

PHS-6040
(Rev. 10-76)

Project No. Z01 CC 00015-01 CP

PHS-NIH

Individual Project Report

July 1, 1976 through September 30, 1977

Project Title: Platelet Survival and Function in Patients with Hypercholesterolemia

Previous Serial Number:

Principal Investigator: Dr. Laurence M. Corash

Other Investigators: Dr. J. C. Andersen
Dr. E. Schaefer

Man Years

Total:	1.0
Professional:	0.5
Other:	0.5

Project Description

Objectives:

1. To measure platelet survival in patients with familial hypercholesterolemia.

2. To measure platelet aggregation to adenosine 5 'diphosphate, epinephrine, and collagen in these patients.

Methods Employed:

Platelet survival was performed with a standard radiochromium technique. Platelet aggregation was measured by a modification of the Born and Cross method with careful control of pH and platelet concentration.

Major Findings:

Platelet survival was significantly short in five out of seven subjects and appeared to be less in older subjects with more severe artherosclerosis. Platelets from these patients were more sensitive to epinephrine than those of normal controls.

Significance:

These findings indicate that decreased platelet survival is important in the pathogenesis of atherosclerosis and that anti-platelet agents may be useful in these patients.

Honors and Awards: None

Publications:

Corash, L., Schaefer, E., Poindexter, E., Andersen, J.: Platelet Function and Survival in Familial Hypercholesterolemia. Circulation 54: II-117, 1976.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00016-01 CP

PERIOD COVERED

July 1, 1976 through September 30, 1977

TITLE OF PROJECT (80 characters or less)

Qualitative Improvement of Blood Transfusion Using Young Cell Cohorts

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI: L. M. Corash Staff Physician Hematology Service, CP, CC

COOPERATING UNITS (if any)

S. Piomelli, Dept. of Pediatrics, New York University School of Medicine
New York, New York 10016

LAB/BRANCH

Clinical Pathology Department

SECTION

Hematology

INSTITUTE AND LOCATION

CP, CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
0.8	0.5	0.3

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

The purpose of this study is to demonstrate that Stractan separated young red blood cells can be transfused into autologous non-human primate donors and that these cells have an improved survival compared to whole blood. Preliminary studies have shown that young red cells from rabbits can be isolated and transfused by this method. These cells demonstrate a markedly improved survival compared to unfractionated whole blood. The eventual goal of this project will be to explore the use of this system for human transfusion, thus reducing the transfused iron load in patients with chronic anemias.

PHS-6040
(Rev. 10-76)

Project No. Z01 CC 00016-01 CP

PHS-NIH
Individual Project Report
July 1, 1976 through September 30, 1977

Project Title: Qualitative Improvement of Blood Transfusion Using Young Cell Cohorts

Previous Serial Number:

Principal Investigator: Dr. Laurence M. Coarash

Other Investigators: None

Man Years

Total:	0.8
Professional:	0.5
Other:	0.3

Project Description

Objectives:

1. Development of a rhesus monkey model to examine the survival of Stractan separated age dependent red cell cohorts.

2. To determine if naturally occurring arabino-galactan antibodies exist in humans and rhesus monkeys and to determine if they develop in animals after exposure to arabino-galactan treated cells.

Methods:

Age dependent red cell cohorts were obtained with arabino-galactan density gradients. Red cell life span is measured with radiochromium or radioactive cyanate.

Major Findings:

Young red cells from rabbits have an improved survival compared to old red cells when transfused in autologous donors.

Significance:

This technology may provide a means for qualitatively improved red cell transfusion, thus limiting iron overload in patients with chronic transfusion requirements.

Awards and Honors: NIH Grant HL 19946-1. "Reduction of Iron Overload in Thalassemia"

Publications:

1. Corash, L., Piomelli, S., Seaman, C., Comisa, C.: High Resolution Separation of Blood Cell Types by Density Gradient Centrifugation. Blood 42: 1006, 1973.

2. Corash, L., Piomelli, S., Chen, H., Seaman, C., Gross, E.: Separation of Erythrocytes According to Age on a Simplified Density Gradient. J. Lab. Clin. Med. 84: 147-151, 1974.

3. Corash, L., Seaman, C., Comisa, C., Reibman, J. R., Piomelli, S.,: Separation of RBC's with Improved Survival from Normal Blood. Ped. Res. 8: 399, 1974.

4. Corash, L., Seaman, C., Reibman, J., Tytun, A., Piomelli, S.: Qualitatively Improved Blood Cell Transfusion: A New Approach to Therapy of Chronic Anemias. 16th Meeting, Int. Soc. Hem., Kyoto, Japan, 1976.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00017-01 CP

PERIOD COVERED
July 1, 1976 through September 30, 1977

TITLE OF PROJECT (80 characters or less)
Distribution of Erythrocyte Plaque Lesion Relative to Erythrocyte Age in Mg# Deficient Rats

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI:	Ronald J. Elin, M.D., Ph.D.,	Chief, Clin. Path. Dept.,	CP, CC
Other:	Henry K. Tan, M.D.	Assistant Chief, Hematology,	CP, CC

COOPERATING UNITS (if any)
None

LAB/BRANCH
Clinical Pathology Dept., Clinical Center

SECTION

INSTITUTE AND LOCATION
Clinical Center, Clin. Path. Dept., NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1.0	1.0	1.0

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Study initiated to further investigate the nature of the erythrocyte membrane plaque lesions in Mg# deficient rats. Initial separation of erythrocytes by Stractan gradient shows differential appearance of plaque lesions in older more senescent erythrocytes while the youngest subpopulation of erythrocytes fails to demonstrate significant lesions.

PHS-6040
(Rev. 10-76)

Project No. Z01 CC 00017-01 CP

1. Clinical Pathology Dept.
2. Hematology Service
3. Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 through September 30, 1977

Project Title: Distribution of Erythrocyte Plaque Lesion Relative to Erythrocyte Age in Mg# Deficient Rats.

Principal Investigator: Dr. Ronald J. Elin

Other Investigators: Dr. Henry K. Tan

Man Years:

Total:	1.0
Professional:	1.0
Other:	1.0

Project Description

Objectives:

Determine time of appearance of erythrocyte membrane lesions in magnesium deficient rats.

Methods Employed:

Erythrocyte separation by the Stractan method of Piomelli and Corash groups red cells by buoyant density. This correlates with red cell age. Sub-populations of erythrocytes obtained by this method are examined by freeze etch electron microscopy and the results compared for the different age groups.

Major Findings:

Membrane lesions appear in young erythrocytes, become larger and more numerous with senescence.

Significance:

This is the first membranous lesion associated with a metal ion deficiency in mammals. Previously a report by Branton described cell membrane changes in magnesium deficient bacteria.

Course:

Continue further elucidation of defect of magnesium deficiency and its relationship to membrane structure and function.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00018-01 CP

PERIOD COVERED

July 1, 1976 through September 30, 1977

TITLE OF PROJECT (80 characters or less)

Erythrocyte Changes Associated with Magnesium Deficiency in Man

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI: Ronald J. Elin, M.D., Ph.D., Chief, Clin. Path. Dept., CP, CC

Other: Henry K. Tan, M.D. Assistant Chief, Hematology, CP, CC

COOPERATING UNITS (if any)

Frederic C. Bartter, M.D., Hypertension & Endocrine Branch HLBI

LAB/BRANCH

Clinical Pathology Dept., Clinical Center

SECTION

INSTITUTE AND LOCATION

Clinical Center, Clin. Path. Dept., NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1.0	1.0	1.0

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Study initiated to determine if erythrocyte lesions are present in those rare cases of magnesium deficiency in man with concomitant low red cell magnesium. Normal controls, cases of Bartters syndrome with isolated magnesium deficiency and cases of idiopathic magnesium deficiency. All cases are examined before and after Stractan separation. Initial results indicate that magnesium deficiency in man produces both a membranous and an intracorpuscular defect.

PHS-6040
(Rev. 10-76)

Project No. Z01 CC 00018-01 CP

1. Clinical Pathology Dept.
2. Hematology Service
3. Bethesda, Maryland

PHS-NIH
Individual Project Report
July 1, 1976 through September 30, 1977

Project Title: Erythrocyte Changes Associated with Magnesium Deficiency in Man

Previous Serial Number:

Principal Investigator: Dr. Ronald J. Elin

Other Investigators: Dr. Henry K. Tan

Man Years:

Total:	1.0
Professional:	1.0
Other:	1.0

Project Description

Objectives:

To determine if erythrocyte membrane lesions occur in those patients with prolonged magnesium deficiency and anemia. Certain patients with Bartter's syndrome fall in this category.

Methods Employed:

Determination of serum and erythrocyte levels of magnesium. Freeze fracture electron microscopy.

Major Findings:

Erythrocytes from patients with low erythrocyte magnesium and anemia show an intracorpuscular as well as membranous lesion. The intracorpuscular lesion consists of multiple sac-like structures within the matrix of the red cell. The membranous lesions consist of elevated and depressed granularity irreular outline. They are not generally reminiscent of analogous lesions in the rat RBC.

Significance:

To establish first metal ion deficient anemia in man, a rare cause of deficiency anemia.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00019-01 CP

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Resistant Corynebacterium Species - Further Characterization and Identification of Normal Habitat

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Dr. Vee J. Gill, Supervisory Microbiologist, Microbiology Service, CPD, CC

Dr. Frank G. Witebsky, Asst. Chief, Microbiology Service, CPD, CC

Dr. Philip A Pizzo, Senior Investigator, Pediatric Oncology Branch, Division of Cancer Treatment

COOPERATING UNITS (if any)

Pediatric Oncology Branch, NCI

LAB/BRANCH

Clinical Pathology Department

SECTION

Microbiology Service

INSTITUTE AND LOCATION Clinical Center, National Institutes of Health, Bethesda, Maryland 20014

TOTAL MAN-YEARS:	PROFESSIONAL:	OTHER:
1.0	0.3	0.7

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

A resistant Corynebacterium species has been isolated with increasing frequency from severely immunosuppressed patients at the Clinical Center. Additional isolates of this organisms are being collected, biochemically characterized, and studied for pattern of antimicrobial susceptibility. A selective medium has been developed to isolate the organisms easily from mixed flora; this will be used to try to identify the organism's normal habitat.

Project No. Z01 CC 00019-01 CP

Project Description

Objectives:

Further characterize, with respect to biochemical characteristics and antibiotic sensitivity pattern, a resistant Corynebacterium species.

Determine the normal habitat of this organism.

Methods Employed:

Organisms isolated from a variety of clinical specimens and found to be this antibiotic - resistant Corynebacterium species are evaluated for their biochemical characteristics and specific antimicrobial - sensitivity pattern by in vitro testing procedures. An antibiotic - containing medium has been devised for the isolation of this organism from sites with a mi ed microbial flora; survey cultures are obtained from patients in whom this organism has been found, to attempt to define its normal habitat.

Major Findings: This organism has been isolated with increasing frequency from immunosuppressed patients at the Clinical Center. There has been some variation found in antibiotic sensitivity of the isolates, but all have been sensitive to low concentrations of vancomycin. There has been some variability in sensitivity to erythromycin and tetracycline. The organism has been isolated from a variety of sites; preliminary studies suggest that the organism's normal habitat is skin sites such as axilla and groin.

Significance to Biomedical Research and the Program of the Institute:

This organism can be a significant pathogen, particularly in compromised hosts. (See publication below.) Further characterization of the species and its ecology is important for understanding the pathogenesis of, and selecting appropriate treatment for, disease caused by this organism.

Proposed Course:

The project will be continued to further define the characteristics of the organism and its normal habitat.

Publications:

Hande, K.R., Witebsky, F.G., Brown, M.D., Schulman, c.B., Anderson, Jr.,M.D., Levine, A.S., MacLowry, M.D. and Chabner, B.A. Sepsis with a New Species of Corynebacterium. Ann. of Int. Med., 85:423-426, 1976.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00020-01 CP

PERIOD COVERED

July 1, 1976 to September 30, 1977

TITLE OF PROJECT (80 characters or less)

Analysis of the Plasma Membrane of Normal Human Platelets

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI: Henry K. Tan, M.D. Assistant Chief, Hematology CP, CC

Other: Laurence Corash, M.D. Staff Physician, Hematology CP, CC

COOPERATING UNITS (if any)

None

LAB/BRANCH

Clinical Pathology Dept., Clinical Center

SECTION

Hematology Service

INSTITUTE AND LOCATION

Clinical Center, Clin. Path. Dept., NIH, Bethesda, Maryland 20014

TOTAL MANYEARS: 1.0	PROFESSIONAL: 1.0	OTHER: 1.0

CHECK APPROPRIATE BOX(ES)

(a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

(a1) MINORS ☐ (a2) INTERVIEWS

ABSTRACT OF WORK (200 words or less - underline keywords)

Analysis and demonstration of true external surface of platelets obtained from normal volunteers. Correlation of changes induced by glycerol, glutaraldehyde, BSG, normal saline and distilled water on the etched platelet surface as observed by freeze fracture microscopy.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00021-01 CP

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Mycologic Sensitivity Testing

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Ms. Anne E. Jennings, Medical Technologist, Microbiology Service, CPD, CC

Dr. John E. Bennett, Head, Clinical Mycology Section, Laboratory of Clinical Investigation, NIAID

COOPERATING UNITS (if any)

Clinical Mycology Section, LCI, NIAID

LAB/BRANCH

Clinical Pathology Department

SECTION

Microbiology Service

INSTITUTE AND LOCATION

Clinical Center, National Institutes of Health, Bethesda, Maryland 20014

TOTAL MAN-YEARS:	PROFESSIONAL:	OTHER:
0.1	0.1	

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

(a1) ☐ MINORS (a2) ☐ INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Antimicrobial sensitivity testing of yeasts is being done with 5-Fluorocytosine; antimicrobial sensitivity testing of molds is being done with Miconazole, 5-Fluorocytosine, and Amphotericin B; antimicrobial sensitivity testing of Nocardia is being done with Sulfadiazine, Trimethoprim, Minocycline, Ampicillin, Rifampin, Erythromycin.

PHS-6040

Project No. Z01 CC 00021-01 CP

Project Description

Objectives:

Determination of antimicrobial sensitivity of species of pathogenic yeasts to 5-Fluorocytosine, and of species of pathogenic molds to Miconazole, 5-Fluorocytosine, and Amphotericin B.

Methods Employed:

In vitro determination of antimicrobial sensitivity testing was performed using test tube serial dilution technique involving use of roller drum for the yeasts and molds. The susceptibility of the various Nocardia sp. was determined by the use of the agar dilution technique.

Major Findings:

Most of the molds and yeasts examined proved to be susceptible to the antimicrobials tested. The sensitivity of the Nocardia isolates varies significantly among the different antimicrobials tested.

Honors and Awards:

None

Publications:

None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00022-03 CP

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Detection of Bacteremia using an Electrical Impedance Detection System

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Dr. Charles H. Zierdt, Microbiologist

Dr. James D. MacLowry, Chief, Microbiology Service

Dr. Robert Kagan, Resident, Nuclear Medicine

Mr. William Schuette, Engineer, Biomed. Engrg & Instr. Br.

Dr. E. Arthur Robertson, Asst. Chief, Laboratory Computer Service

Mr. Robert Harshman, Computer Programmer, Laboratory Computer Service

COOPERATING UNITS (if any)

Biomedical Engineering and Instrumentation Branch, DRS, NIH

LAB/BRANCH

Clinical Pathology Department

SECTION

Microbiology Service, Nuclear Med., Lab Computer Svc, Biomed Engrg & Instr Br

INSTITUTE AND LOCATION

Clinical Center, National Institutes of Health, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1.0	0.5	0.5

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☒ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

A prototype instrument has been constructed and improved which allows the monitoring of blood cultures with an electrical impedance detector. This has been connected to a laboratory computer, which can then be queried about the status of cultures.

PHS-6040
(Rev. 10-76)

Project No. Z01 CC 00022-03 CP

Project Description

Objective:

An attempt is being made to more rapidly detect positive clinical blood cultures in an automated fashion.

Methods Employed:

A prototype impedance detector has been developed and connected to a dedicated computer in the laboratory. This represents a novel approach to detection of bacterial cultures by using a very minimum amount of human intervention. The blood has been lysed and filtered before presentation to the detector to increase bacterial yield.

Major Findings:

Blood cultures are detected more rapidly and fewer colony forming units can be detected than by conventional methods.

Significance to Biomedical Research and the Program of the Institute:

This methodology may enable a routine diagnostic laboratory to detect bacteremia more rapidly than with conventional means.

Proposed Course:

We will continue to evaluate patient specimens in parallel with our traditional method to confirm the initial observations with this method.

Honors and Awards:

None

Publications::

1. Zierdt, C.H., Kagan, R. L. and MacLowry, J.D.: Development of Lysis-Filtration Blood Culture Technique. J. Clin. Microbiol. 5:46-50, 1977.

2. Kagan, R. L., Schuette, W. H., Zierdt, C. H. and MacLowry, J.D.: Rapid Automated Diagnosis of Bacteremia by Impedance Detection. J. Clin. Microbiol. 5:51-57, 1977/

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00023-01 CP

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Cell wall deficient Streptococci Causing Disease in Man

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Dr. Charles H. Zierdt, Microbiologist, Microbiology Service, CPD, CC

COOPERATING UNITS (if any)

None

LAB/BRANCH

Clinical Pathology Department

SECTION

Microbiology Service

INSTITUTE AND LOCATION

Clinical Center, National Institutes of Health, ~~Bethesda, Maryland 20014~~

TOTAL MAN-YEARS:	PROFESSIONAL:	OTHER:
.05	.05	

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

(a1) MINORS ☐ (a2) INTERVIEWS

ABSTRACT OF WORK (200 words or less - underline keywords)

A collection of cell wall deficient, Gram variable, pleomorphic organisms has been collected from cases of endocarditis, urethritis, fever of undetermined origin, brain abscess, and other deep abscesses. Two strains of this collection have recently reverted to definitive parent forms, both of which are Strepcococcus sanguis. This data is being prepared for publication. The strains have been well documented through ultrastructure, guanine-cytosine base ratios, acrylamide gel protein patterns, fatty acid profiles via gas liquid chromatography, morphological and biochemical characteristics.

Project Description

Objectives:

In-depth study of this group of pathogenic bacteria.

Methods Employed:

Electron microscopy, guanine-cytosine base ratios, acrylamide gel patterns, and gas-liquid chromatography have been used for the characterization of these organisms.

Significance to Biomedical Research and the Program of the Institute:

These organisms have been implicated in a number of infectious disease processes in man.

Proposed Course:

On completion of the studies of the organisms collected thus far, the data collected will be prepared for publication.

Honors and Awards:

None

Publications:

None

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 00024-20 CP

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

Analysis of 20 years of Staphylococcus aureus Bacteria Phage Typing

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Dr. Charles H. Zierdt, Microbiologist

Dr. James D. MacLowry, Chief, Microbiology Servcie

Dr. E. Arthur Robertson, Asst. Chief, Laboratory Computer Service

Mr. Reginald Williams, Research Medical Technologist, Microbiology Service

COOPERATING UNITS (if any)

None

LAB/BRANCH

Clinical Pathology Department

SECTION

Microbiology Service, Laboratory Computer Service

INSTITUTE AND LOCATION

Clinical Center, National Institutes of Health, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1.0	0.5	0.5

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Analysis of the phage typing data to date reveals: 1. That the "major" epidemic strains of S. aureus increased in the early 1960's to high levels and declined in the mid-1960's, not to reappear. 2. The world-wide epidemic strain 80/81 appeared in the Clinical Center in March of 1959, immediately spreading through the hospital and via employees, to their families. It disappeared from the Clinical Center in 1965, and has not reappeared. 3. At present there are in the Clinical Center no "epidemic types." 4. Phage typing patterns are less clearcut, particularly in the mixing of reactions of phage and from lytic groups I, II, III, and Miscellaneous.

PHS-6040
(Rev. 10-76)

Project No. Z01 CC 00024-20 CP

Project Description

Objectives:

Statistical analysis of 22,000 bacteriophage typed Staphylococcus aureus strains, from Clinical Center patients, 1957 to 1977.

Methods Employed:

Reconstruct the epidemiology of Staphylococcus aureus infections in the Clinical Center over the past 20 years using the central DCRT computer facilities.

Honors and Awards:

None

Publications:

None

July 1, 1976, Through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

DIAGNOSTIC RADIOLOGY DEPARTMENT

CONTENTS

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

DIAGNOSTIC RADIOLOGY DEPARTMENT

DEPARTMENTAL MISSIONS AND GOALS

While our primary mission remains to provide the best possible radiographic service to the patients of The Clinical Center, research and educational activities are of ever more importance. During the past several years, there has bee a multifold increase in our participation in inter-departmental clinical radiographic conferences, an activity which has proven intellectually stimulating and at the same time has significantly improved the quality of patient care. Even more striking has been the increase in research productivity of the Diagnostic Radiology Department which has more than doubled the number of publications sinc those listed in last year's annual report.

Increasing departmental emphasis is being placed on the use of interventional radiographic techniques with the development, perfection, and use of such techniques having become a major departmental goal. Studies of embolization in the definitive treatment of inoperable arteriovenous malformations, and as a palliative method of handling unresponsive neoplasms are receiving ever more departmental research attention. As evidence of this investigative orientation the use of the radiographic animal research facility for the development of new radiographic diagnotic and therapeutic approaches is at close to its maximal.

DEPARTMENTAL ACTIVITIES

The service demands for conventional radiographic examinations, relatively stable for several years, increased moderately during the past year (5%) from 45,168 conventional x-ray examinations on 34,074 patients, perhaps reflecting increased bed occupancy between July 1, 1976 and June 30, 1977, to 47,284 conventional x-ray examinations on 36,953 patients. (Both observed data and that projected until September 30, 1977 is detailed in the accompanying tables.)

The CT scanning units have proven an extraordinarily valuable adjunct to our diagnostic armamentarium with a total of 2200 patients receiving 2750 head scans and 619 patients receiving 704 body scans. (Scans are reported as the total number of examinations with and without contrast medium administration so that patients receiving both studies are considered as having had two scans.) The patient load for the CT head scanner is supplied by the Clinical Center and by the metropolitan area DOD hospitals. From the latter institutions we accept selected neurosurgical patients whose pathology complements our own head scanning experience. This mutually beneficial arrangement will be continued until such time as the WRAMC and NNMC purchase their own scanners. All the patients scanned on the CT body unit are from NIH - DOD patients are accepted for scanning only if their disease or expected pathology is of particular research interest to our staff. The computerized tomographic scanners require the full

time of two radiologists and four technicians.

Unexpectedly costly is the maintainance of the CT equipment with routine service contracts costing us about $30,368. per year. All emergency service after regular working hours is provided only at additional and unconscionably exorbitant cost.

Ultrasound examinations peaked last year at 1284 which we thought was our saturation point; but between July 1, 1976 and June 30, 1977, a total of 1 such examinations were performed, of that total 280 scans were done with the new real-time scanner cooperatively developed by this department. Besides creasing the number of scans performed by 21% since last year, the ultrasonographic section has remained very active in the development and evaluation new scanning equipment and techniques (see list of publications and section Project Reports). Two full-time radiologists and two full-time technicians required to provide the Clinical Center with these services.

> It should be noted here that CT head scanning, CT body scanning, and ultrasound scanning represent new diagnostic activities, the responsibilities for which we have assumed with virtually no increase in professional or technical staff.

The impact of CT and ultrasound on the nature of and number of special studies done in the department is very difficult to analyze. CT has had a profound effect upon the numbers of conventional neurodiagnostic (pneumoencephalogram and cerebral angiogram) studies, and has replaced traditional studies in many cases. At the same time the numbers of patients admitted to NINCDS who require such studies has diminished. Thus, both of these factors are responsible for the striking decrease in the number of conventional neuroradiographic examinations.

DATES	HEAD CT	CEREBRAL ANGIOS	PNEUMOS
7-1-74 - 6-30-75	-	135	52
7-1-75 - 6-30-76	1877	94	13
7-1-76 - 6-30-77	2750	67	9

In spite of the decline in neuroradiologic procedures, the total number of special studies done in the department has increased slightly from 645 in 76 to 713 in 1977. However, numbers alone are grossly misleading. A dramatic increase in the number of very time-consuming, multi-vessel angiograms, venous samplings, and embolizations has increased the number of manhours devoted to the performance of special studies by about 50%. The difference between a usual cerebral or renal angiogram and a parathyroid localization study is comparable to the difference between an appendectomy and a coronary arterial bypass - the more complex procedures requiring significantly more time as well as the involvement of a larger staff.

Operating at close to its full capacity, the radiographic research facility has produced 745 investigative studies. As radiology has evolved in the past few years towards becoming a more active and interventional medical specialty, the opportunities for promising radiologic research have burgeoned. Many of the areas of promising investigation require lengthy preliminary laboratory and

animal work - the majority of the research listed in the Project Reports has demanded such studies. Some of the anatomic and physiologic observations made in this research facility promise development of valuable new diagnostic and therapeutic tools (see Project Reports on epidural venography, intravenous hepatography, and plastics for embolization). Two full-time technicians man the research facility and work in conjunction with a rotating group of radiologists. As a result of this ever increasing workload the space allotted to us for non-human research projects has become totally inadequate.

Teaching and educational contributions by the department continue to grow. We now preside over a total of twelve regularly scheduled clinically oriented radiologic conferences per week. A number of staff members have been invited lecturers at local and state medical society meetings; and the staff continues to give teaching sessions at DC General, National Naval Medical Center, GW University, and the Armed Forces Institute of Pathology.

No new major capital equipment was installed during the past year, though the CT body unit was updated (only six months after purchase) thereby permitting more rapid acquisition of scanning data and slightly increasing the number of patients which can be scanned in a working day. An automated chest unit and diagnostic table were purchased for use in the outpatient department; but their installation is delayed because OPD renovations failed to remain on schedule. When operational, this unit will permit immediate viewing of the films in the outpatient department by physicians seeing the patients and will have the ancillary beneficial spinoff of decreasing hospital elevator traffic to the 6th floor of The Clinical Center by about 35%. From our capital expenditures budget of this year, we have committed funds for the purchase of a new ultrasonic scanning unit to replace the hopelessly outdated unit now in use. Installation is expected within the next several months.

It is our intention to postpone the purchase of major radiographic equipment until the new Department of Radiology is open. By careful planning and judicious use of our severly limited space the department is probably adequately equipped to handle our anticipated needs until the universal replacement of major capital equipment which will take place when we move into the ACRF. There is, however, an imponderable which must be mentioned - rapid advances in the special imaging techniques of CT may make it possible that between now and 1980-81 our body scanner will have to be replaced.

MAJOR PROJECTS AND RESEARCH

Listed below are the major projects now requiring the investigative eff of the department. The appended descriptions of the projects are adequ and require no summation. (See Project Reports pg. DR-11-DR-27)

1. Effect of Total Exclusion of Arterial Inflow to the Liver
2. Epidural Venography for the Detection of Epidural Masses
3. Development of a New Plastic Material for Transcatheter Embolization
4. Development and Evaluation of a Ultrasonic Real Time Scanning Device
5. Development and Clinical Evaluation of Ultrasonic Signal
6. Demonstration of the Effect of Chemotherapy on Carcinogen Induce Hepatomas on Rhesus Monkeys
7. IV Hepatosplenography
8. Evaluation of CT Body Scanning in Oncologic Patients

PROBLEMS

The major problem areas in the DRD are chronic and ongoing - they have been discussed in the past but corrective action has been minimal or lacking.

1. Adequate space for patient waiting, radiologist's reading areas, and locker room for technical staff has been sacrificed to permit the necessary addition of CT and ultrasound facilities. Our halls are congested with patients, some acutely ill, waiting for examination. Some physicians are forced to work in converted janitorial closets and technician locker space has been moved into already overused corridors.

2. Govermental physician salaries remain absolutely non competetive with those offered in university setting (note the crescendo in NIH physicia attrition rate). By reason of the absence of income incentive every effort must be made to maintain a stimulating clinical and research environment with adequate funding of research activities.

3. Last year the inadequate research facilities avilable to the staff were decried. The available research area has been further significantly erroded by the loss of animal holding space - animal subjects must now be housed in the research area - an unconscionable situation in an institution devoted and dedicated to fostering superior research.

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NUMBER OF X-RAY EXAMINATIONS

Observed 7/1/76 - 6/30/77

	Patients	X-Ray Exams	Exams per Pt.
Inpatients	21,047	26,375	1.25
Outpatients	13.230	18,143	1.37
EHS	2676	2766	1.03
TOTAL	36,953	47,284	1.29

Observed and Projected 7/1/76 - 9/30/77

Inpatients	26,817	33,862	1.26
Outpatients	17,624	24,862	1.37
EHS	3493	3641	1.04
TOTAL	47,952	61,778	1.28

COMPARISON OF ACTIVITY

Observed 7/1/76 - 6/30/77

	1976	1977	Change
Total Number of Patients examined	34,079	36,953	+2874
Total Number of X-Ray Examinations	45,168	47,284	+(5%)
Total Number of X-Rays per Pt.	1.32	1.28	-.04
Special Procedures (excludes Ultrasound and NHI Cath Studies	645	713	+68

Observed and Projected 7/1/76 - 9/30/77

Total Number of Patients Examined	34,079	47,952	+13,873
Total Number of X-Ray Examinations	45,168	61,778	+16,610
Total Number of X-Rays per Pt.	1.32	1.28	-.04
Special Procedures (Excludes Ultrasound and NHI Cath Studies	645	806	+161

SUMMARY OF DEPARTMENTAL ACTIVITIES

	FY 76	7/1/76-6/30/77	% Change	7/1/76-9/3
# MDs	12	13	+8	13
# Technicians	26	27	+3.7	27
# Other Staff	20	23	+15	23
# X-Ray Exams	45,168	47,284	+5	61,778
# Special Exams	645	713	+10	891*
# CT Head	1,877	2,750	+45%	3,437*
# CT Body	59	704	+838	880*
# Publications	19	40	+110	54
# Ultrasound Exams	1,284	1,560	+21	1,950*
# Animal Research Exams	381	735	+93	919*
Personnnel Costs	$802,882	$862,489	+7	
Budget Total	$1,256,350	$1,481,904	+18	

*Estimated figures 25% higher than those observed in period between 7/1/76 and 6/30/77

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 04008-01-DR

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

EFFECT OF TOTAL EXCLUSION OF ARTERIAL INFLOW TO THE LIVER

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI	Dr. J. L. Doppman	Chief	DRD CC
OTHER	Mary Girton	RT	DRD CC
	Richard Diggs	Technician	DRD CC

COOPERATING UNITS (if any)

LAB/BRANCH

Diagnostic Radiology Department

SECTION

INSTITUTE AND LOCATION

CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1	1	2

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS. ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Objectives:

A. to compare hepatic artery embolization accomplished by Gelfoam, autologus clot, or other commonly used clinical techniques with complete obturation of the hepatic arterial bed using an injectible plastic.

Methods Employed

The proper hepatic artery is selectively catheterized in monkeys and either the right branch or all intrahepatic branches are embolized with 1 to 2 cc of silicone rubber. Serial blood chemical determinations are performed as well as serial x-rays to document the acute insult to the liver. As hepatic function tests return to normal, arteriography is repeated to evaluate the development of hepatic arterial collaterals. The monkeys are sacrificed and their livers studied microscopically.

PHS-6040
(Rev. 10-76)

A second group of monkeys undergo embolization of a single hepatic artery branch, usually the right and will be compared with a group of monkeys whose hepatic arteries are proximally obstructed by Gelfoam, the commonly used clinical technique.

Major Findings

Gelfoam obstruction of the hepatic arteries caused minimal hepatic dysfunction and all livers at autopsy were normal. The explanation is a rapid development of hepatic arterial collaterals within several hours of proximal hepatic artery obstruction. This prevents significant disturbances in hepatic function and accounts for the normal livers at autopsy.

In livers whose arterial beds were totally perfused with silicone, acute hepatic swelling occurred and persisted for the first two weeks, coinciding with a marked elevation of liver enzymes and alkaline phosphatase. These changes gradually subsided over six weeks and in some animals never reached normal levels. Autopsy revealed multiple infarcts throughou the livers with large bile cysts which in at least two instances became grossly infected.

Significance of Research

Treatment of liver metastases by hepatic artery ligation has produced dramatic but often short lived palliation. We are particularly interested in infarcting functional hepatic metastases of islet cell or carcinoid tumors as many of these patients are incapacitated not by tumor bulk but by tumor end products. This laboratory study was under taken to demonstrate that permanent hepatic dearterialization, as produced by injectible plastics, is not tolerated by the liver.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 04009-01-DR

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

EPIDURAL VENOGRAPHY FOR THE DETECTION OF EPIDURAL MASSES

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI	Dr. N. Reed Dunnick	Staff Radiologist	DRD CC
OTHER	Dr. J. L. Doppman	Chief	DRD CC
	Mary Girton	RT	DRD CC
	Richard Diggs	Technician	DRD CC

COOPERATING UNITS (if any)

LAB/BRANCH
Diagnostic Radiology Department

SECTION

INSTITUTE AND LOCATION
CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
.16	2	2

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☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Objectives:

A. To evaluate the sensitivity of epidural venography vs. myelography in the detection of small epidural masses.

B. To clinically test epidural venography in patients with epidural metastases to determine its sensitivity and whether this single examination will permit definition of (1) multiple epidural masses as well as (2) the cranial extent of completely obstructing masses.

PHS-6040
(Rev. 10-76)

Methods Employed

The classic method for evaluating spinal cord compression in patients with known primary malignancies is myelography. By the time symptoms develop, a complete subarachnoid block is generally demonstrated and one must frequently resort to cisternal myelography to define the cranial margin of the intraspinal mass for radiation therapy port placement. In addition, metastases to the epidural space are often multiple and myelography will only demonstrate the most caudal mass producing complete obstruction. Performing lumbar puncture to inject contrast media is not totally safe in patients with incomplete spinal blocks due to epidural tumor. Cord herniation has been initiated requiring emergency laminectom to prevent irreversible cord damage.

For these reasons, the technique of epidural venography is being evaluated as an alternate diagnostic approach.

Methods Employed

Epidural masses are simulated in monkeys by percutaneously introducing through intervetebral foramina small Fr. Fogarty balloon catheters. The balloon is inflated with silicone which polymerizes to produce a permanent epidural mass. Epidural venography and myelography with a water soluble contrast have been performed in these animals. These preliminary studies indicate that myelography is a more sensitive test detecting very small epidural masses which fail to produce any abnormality in the epidural venogram. However, most symptomatic epidural masses produce complete subarachnoid block and when the myelogram demonstrates complete block in these animals, the epidural venogram was also grossly positive. In addition, by performing retrograde azygography, it was usually possible to define the upper as well as the lower margins of the epidural mass, important information not obtainable from the myelogram which demonstrates only the caudal margin of a complete obstruction.

Significance of Research:

Metastases to the epidural space are frequently encountered in the tumor population at NIH. Combined lumbar and cisternal myelography are often necessary to define the extent of the epidural mass for radiation treatment or for laminectomy. We plan to perform epidural venography in addition to myelography in patients with epidural metastases prior to radiation therapy

Proposed Course

A cooperative study with radiation therapy is being developed.

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U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NOTICE OF
INTRAMURAL RESEARCH PROJECT

PROJECT NUMBER

Z01 CC 04010-01-DR

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

DEVELOPMENT OF A NEW PLASTIC MATERIAL FOR TRANSCATHETER EMBOLIZATION

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI	Dr. J. L. Doppman	Chief	DRD CC
OTHER	Dr. Robert Bowman	Chief	IRTD NHLBI
	Mary Girton	RT	DRD CC
	William Aven	Technician	IRTD NHLBI

COOPERATING UNITS (if any)

Outside NIH: Dr. Louis L. Wood, Research Associate, W.R.Grace & Co. Columbia, MD

LAB/BRANCH

Diagnostic Radiology Department

SECTION

INSTITUTE AND LOCATION

CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1	3	2

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☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Objectives:

A. To evaluate hydrophylic polyurethane prepolymers as possible agents to be used for embolizing tumors through percutaneous catheters.

B. To determine tissue toxicity of such plastics if they prove technically suitable as transcather embolizing agents.

Methods Employed:

A varity of techniques for reducing the viscosity and decreasing the expansion of hydrophylic polyurethane prepolymers were investigated. Dimethyl sulfoxide was originally used as a diluent but caused hemorrhagic pneumonias when excreted through the lungs in animals. In

PHS-6040
(Rev. 10-76)

addition, the expansion of these polymers due to the generation of CO_2 at the time of polymerization made it difficut to prevent proximal propagation of the embolus and spill over into major vessels. These initial technical evaluations were accomplished in a series of dogs, cats and monkeys. At our request, Dr. Louis Wood at W. R. Grace & Co. developed a new polyurethane prepolymer that generated less CO_2 during polymerization and had reduced viscosity. Transcather embolization of a number of spleens, livers and kidneys in a series of cats and monkeys proved the material to be an effective embolizing agent.

Acute toxicity studies in a series of six lambs were performed. Right kidneys were embolized with Hypol and serial chemical determinations over three months were obtained. The embolized kidneys were examined histologically at the time of autopsy. No significant abnormalities of renal or hepatic function were apparent from the serial chemical determinations. At autopsy, the embolized kidneys were grossly infarcted but in many instances disolution of arterial walls and transmural migration of the polymer had occurred suggesting significant delayed tissue toxicity.

Major Findings

Hydrophilic polyurethane foams are suitable agents for transcather embolization. They polymerize on contact with serum and although some expansion occurs due to CO_2 production, it is not excessive and can easily be controlled in vivo. Although the material has no immediate toxicity, it appears to have considerable long-term tissue toxicity. Since these are hydrophylic polymers, they may be invaded by tissue enzymes and broken down with the release of potentially carcinogenic end products. Further evaluation and long term tissue toxicity is underway.

Significance of Research

Tumor embolization for palliation and reduction of bulk are becoming more frequently requested techniques. Gelfoam and silicone are the major embolizing agents but are unsatisfactory for a number of reasons. A better plastic material for transcatheter embolization would have a number of applications in the fields of oncology and congenital angiomatous lesions.

Publications:

Doppman, J.L., Aven, W., Bowman, R.L., Wood, L.L. and Girton, M.: Hypol-A Rapidly Polymerizing Polyurethane for Transcatheter Embolization. Am J Roentgenol

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 04007-01-DR

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

DEVELOPMENT AND EVALUATION OF A ULTRASONIC REAL TIME SCANNING DEVICE

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI	Dr. Thomas H, Shawker	Staff Radiologist	DRD CC
	William H. Schuette	Electrical Engineer	BEI R
OTHER	Willard C. Whitehouse	Chief	PSD CC
	Joanne Evans	RT	DRD CC

COOPERATING UNITS (if any)

LAB/BRANCH

Diagnostic Radiology Department

SECTION

INSTITUTE AND LOCATION

CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1	3	1

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Objectives:

To develop a versatile real time scanner using the sector scanning principle for use in abdominal scanning in children and adults. A sector scanner to produce real time ultrasonic imaging of the chest and abdomen has been developed in the Biomedical Engineering and Instrumentation Branch by William H. Schuette and is being clinically evaluated. Early experience has been largely directed towards defining normal vascular anatomy. We are beginning to accumulate a series of abdominal tumors as well as a group of patients with very early pregnancies and believe that this scanner represents the most versatile machine available for real time abdominal scanning.

Publications:

Schuette, W.H., Norris, G.F. and Doppman, J.L.: Real Time Two Dimen-

sional Mechanical Ultrasonic Sector Scanner with Electronic Control of Sector Width. Proceedings SPIE 96: 345-348, 1976

Shawker, T.H., Schuette, W.H. and Whitehouse, W.C.: Real Time Sector Scanning of Common Abdominal Disease. Proceeding of the Second Internati Technology Transfer Workshop on Diagnostic Ultrasound Imaging, April 1977, Cairo, Egypt. In Press

Shawker, T.H., Schuette, W.H., Whitehouse, W.C. and Rifka, S.M.: An Ultrasonic Real Time Sector Scanner for the Assessment of Early Fetal Devlopment (Work in Progrss). Proceedings of the Second International Technology Transfer Workshop on Diagnostic Ultrasound Imaging, April, 1977, Cairo, Egypt. In Press.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 04004-02-DR

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

DEVELOPMENT AND CLINICAL EVALUATION OF ULTRASONIC SIGNAL

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI	Dr. Thomas H. Shawker	Staff Radiologist	DRD	CC
OTHER	Dr. John L. Doppman	Chief	DRD	CC

COOPERATING UNITS (if any)

Outside NIH: Dr. M. Linzer, National Bureau of Standards
Gaithersburg, MD

LAB/BRANCH

Diagnostic Radiology Department

SECTION

INSTITUTE AND LOCATION

CC,NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1	3	

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Objectives:

To develop and clinically evaluate an ultrasonic tissue characterization unit.

Methods Employed:

We have completed the construction of an ultrasonic tissue analyser which provides far more qualitative and quantitative data on ultrasonic parameters than are currently available with any other imaging device. This analyser measures such variable factors as sound velocity, maximum and minimum reflections and the complex impedance of tissue interfaces. We are currently in the process of interfacing this unit with a new clinical scanner and will soon begin to acquire clinical scans for evaluation.

PHS-6040
(Rev. 10-76).

Major Findings:

Ultrasonic scanners currently available use a scan converter to produce the gray scale images of internal organs but without any evidence of quantitative analysis of the refected sound waves. Since tissues of different structures have varying ultrasonic signatures, we hope that this new analyser will enable us to begin to identify quantified tissue components on the basis of their characteristic ultrasonic reflections. The previous year was a year of technical and equipment development. The upcoming year will be the year of clinical evaluation.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 04012-01-DR

PERIOD COVERED
July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)
DEMONSTRATION OF THE EFFECT OF CHEMOTHERAPY ON CARCINOGEN INDUCED HEPATOMAS ON RHESUS MONKEYS

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI	Dr. M. Vermess	Associate Chief	DRD	CC
	Dr. R. H. Adamson	Chief	LCHPH	NCI
OTHER	Richard Cysyk, PhD		LCHPH	NCI
	Mary Girton	RT	DRD	NCI

COOPERATING UNITS (if any)

LAB/BRANCH
Diagnostic Radiology Department

SECTION

INSTITUTE AND LOCATION
CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
.6	3	2

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☒ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Objectives:

To demonstrate the effects of different cytostatic drugs on carcinogen induced hepatomas in Rhesus monkeys by different imaging techniques. Experimental testing of a new contrast material in malignant tumors of the liver is one of the primary objectives of this study.

Methods Employed:

Two imaging methods are employed in this investigation:

A. Injection of an experimental contrast material containing emulsified oily contrast material (Ethiodol). Following the injection, computerized tomographic scans of the Rhesus liver are obtained with our EMI 5005 total body scanner.

B. Selective hepatic angiography with conventional water soluble contrast media. Selective catheterization of the hepatic artery was performed by a cut-down of the external femoral artery. Flowing the injection of the contrast material directly into the hepatic artery, serial films of the liver are obtained.

Findings:

In the three Rhesus hepatomas examined to date, the chemotherapeutic agents arrested tumor growth but did not appreciatively decrease size of the existing tumors.

Significance of Research:

The significance of this project is two-fold; it permits the in vivo and repeated evaluation of the effectiveness of chemotherapeutic agents an carcinogen induced hepatoma and gives an opportunity to evaluate a new, experimental contrast media in actual tumor situations.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 04011-01-DR

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

IV HEPATOSPLENOGRAPHY

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI	Dr. Michael Vermess	Associate Chief	DRD	CC
OTHER	Dr. R. N. Adamson	Chief	LCHPH	NCI
	Dr. J. L. Doppman	Chief	DRD	CC
	Dr. Dulal Chatterji		PHAR	CC
	George Grimes		PHAR	CC
	Mary Girton	RT	DRD	CC

COOPERATING UNITS (if any)

LAB/BRANCH

Diagnostic Radiology Department

SECTION

INSTITUTE AND LOCATION

CC,NIH, Bethesda, Maryland

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1	5	2

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Objectives:

A. The develop a contrast material which if intravenously injected would selectively opacify the liver and spleen for diagnostic imaging by computerized tomographic scanners. The contrast material has to be of sufficiently low toxicity to permit clinical use with the doses required.

Methods:

Based on previous experiments performed in France, numerous emulsions of different particle sizes have been prepared and are being tested following intravenous injection of rabbits and monkeys. The emulsion consists of emulsified iodinated poppy seed oil (Ethiodol) which is a commercially available contrast material used primarily for lymphangiography.

PHS-6040
(Rev. 10-76)

Findings:

Of the eight different emulsions tested, emulsion No. 8 with the particle size primarily between 1-2 microns appears to opacify optimally the liver and spleen following low dose intravenous injection (0.2 ml/kg). Normal intrahepatic structures such as the inferior vena cava as well as some of the biliary channels becomes clearly visible thirty minutes following the intravenous injection of the above dose. The same emulsion was used at a dose rate of 2 ml/kg (intravenous dose) for conventional radiographs of the liver and spleen. No toxic effect was recognized on the animals even after the higher dose rate.

Future objectives:

After determination of the most adequate emulsion (probably No. 8) extensive toxicity work will have to be done in order to approve this contrast material for human use. Primary objective is to test this contrast material on patients with proven cancer to demonstrate liver metastases of smaller size than previously detectable.

Publications:

Vermess, M., Adamson, R.A., Doppman, J.L. and Girton, M.: Computed Tomographic Demonstration of Hepatic Tumor with the Aid of Intravenous Iodinated Fat Emulsion: An Experimental Study. Radiol In Press

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CC 04006-01-DR

PERIOD COVERED

July 1, 1976 - September 30, 1977

TITLE OF PROJECT (80 characters or less)

EVALUATION OF CT BODY SCANNING IN ONCOLOGIC PATIENTS

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI	Dr. J. L. Doppman	Chief	DRD CC
	Dr. E.G. Schaner	Staff Radiologist	DRD CC
OTHER	Dr. N.R. Dunnick	Staff Radiologist	DRD CC
	Dr. G.L. Head	Staff Radiologist	DRD CC

COOPERATING UNITS (if any)

LAB/BRANCH

Diagnostic Radiology Department

SECTION

INSTITUTE AND LOCATION

CC,NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1	4	2

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Objectives:

To compare CT scanning in the detection and follow-up of tumors with other imaging modalities, especially conventional radiography, ultrasound and isotopic scanning.

Methods Employed:

Ultrasonic scanning is being performed in patients with a variety of tumors with particular emphasis on lymphoma, pancreatic carcinoma, adrenal carcinoma and pelvic masses. In addition, we are scanning extremities and the retroperitoneum in patients with soft tissue and osseous sarcomas. Computerized scans are performed in addition to the usual staging workup and we are attempting to compare CT scanning with these more conventional modalities.

PHS-6040
(Rev. 10-76)

Major Findings:

CT scanning appears to be the most sensitive technique for detecting pancreatic masses, surpassing ultrasound in obese patients. CT does not do as well as ultrasound when the patient is cachectic and normal retroperitoneal fatty tissue planes have been lost. Normal adrenal glands can be visualized in most patients and CT scanning is an accurate way of defining both adrenal tumors and bilateral adrenal hyperplasia. These studies are being compared with ultrasound and the results of arteriography and venous sampling. CT is also providing previously unavailable anatomic information about the extent of soft tissue sarcomas both in the retroperitoneum and in the extremities. Envolvement of muscle groups can usually be predicted as well as the relation to important neurovascular structures.

Significance of Research

Both the detection of tumors and the determination of their extent are important responsibilities of imaging systems in the workup of cancer patients. CT body scanning provides, in an non-invasive manner, anatomical information about tumors that previously was unavailable or could be obtained by more invasive studies.

Publications:

Doppman, J.L., Brennan, M.F., Koehler, J.O. and Marx, S.S.: CT Scanning for Parathyroid Localization . J Comput Assisted Tomogr 1: 30-36, 1977

Schaner, E.G., Balow, J.E. and Doppman, J.L.: Computed Tomography in the Diagnosis of Subcapsular and Perirenal Hematoma. Am J Roentgenol 129: 83-88, 1977

Schaner, E.G., Head, G.L., Doppman, J.L. and Young, R.C.: Computed Tomography in the Diagnosis, Staging and Management of Abdominal Lymphoma. J Comput Assisted Tomogr 1: 176-180, 1977

Schaner, E.G., Head, G.L., Kalman, M.A., Dunnick, N.R. and Doppman, J.L.: Whole Body Computer Tomography in the Diagnosis of Abdominal and Thoracic Malignancy - Review of 600 Cases. Cancer Treatment Reports In Press

July 1, 1976 through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

ENVIRONMENTAL SANITATION CONTROL DEPARTMENT

CONTENTS

July 1, 1976 through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

ENVIRONMENTAL SANITATION CONTROL DEPARTMENT

MISSIONS AND GOALS

The primary objectives of the Environmental Sanitation Control Department during the year were to:

1. Provide the safest possible sanitary environment consistent with the activities of the various institutes and services in the Clinical Center.

2. Provide a dependable, efficient, vertical transportation service responsive to the requirements of patients, emergencies, staff, and visitors.

3. Study the Department's manpower requirements and formalize its work and personnel procedures.

4. Orient, train, and supervise its personnel so that they are proficient in carrying out the program objectives.

5. Test various products and equipment in order to utilize the most modern housekeeping practices.

6. Cope with day-to-day environmental problems within the Clinical Center and to study the total environment as it relates to an institutional setting.

7. Develop an objective evaluation of the housekeeping program.

DEPARTMENT ACTIVITIES

Employee turnover continues to be low. Fifty-one new employees entered on duty and 43 left. Table 4 shows that 14 resigned, 7 transferred, 5 retired, 15 were terminated, and 2 deceased.

Individual employees and groups received 31 letters of appreciation or commendation from building tenants for services rendered.

The Department coordinated the selection, procurement, and installation of approximately 2,000 yards of carpeting during the year. In January the Department began enforcing new, more stringent safety standards in accordance with DHEW Safety Standards for Floor Coverings. The major provisions of the new standards include a new flooring radiant panel test standard, use of the "Pill Test" for surface flammability instead of the "Tunnel Test", smoke density and static control requirements, and standards for easy access for the

handicapped. We have been able to find 13 carpet qualities within GSA Contract Schedules that meet DHEW standards.

The Department was included in the Resource Monitoring System (RMS). The RMS Index measures the amount of time assigned to housekeeping by the Clinical Center compared to a standard hospital of similar size and patient census.

The cleaning schedules in the Patient Area Section were reviewed and updated since many work plans had not been reviewed since 1967. The review panels met regularly with the affected employees, housekeeping leaders, supervisors, the Department secretary, and the Chief, ESCD.

Since the implementation of the Clinical Center's Smoking Policy, cigarette wall urns were removed from walls and public corridors. Those wall urns located at the elevator banks remained in order to give people a place to discard cigarettes. "No Smoking" signs were posted at entrances and in locations in public corridors. "Smoking Permitted" signs were posted in waiting rooms.

New personal clothing lockers were installed in the men's lockerroom B1B19A and a new ceiling, wall, and floor materials were installed in the lounge section. Changes in the women's lockerroom B1D25 are being planned.

Service elevators 9 and 15, and passenger elevators 17 and 18, were master keyed. Key control is with the Office of the Chief, ESCD.

The Department provided assistance to NIAID in a project to collect approximately 15,000 1000 ml empty IV bottles for shipment to Bangladesh.

All ESCD employees received copies of the newly revised "Handbook for Employees, Clinical Center's Environmental Sanitation Control Department."

TABLE 1

ENVIRONMENTAL SANITATION CONTROL DEPARTMENT

April 1, 1976 through June 30, 1977

Formal Training - Classroom

GOVERNMENT	STAFF-HOURS	
Leadership Training I	344	
Leadership Training II	432	
Alternative Management Approaches to the 70's	72	
Management of Conflict and Agreement	48	
Supervisory and Managerial Effectiveness	16	
Civil Service Commission		
Personnel Management for EEO Specialists	24	
Leadership and Women	24	
Department of Agriculture		
Women as Supervisors	48	
Effective Listening	21	
Impact on Management's Right to Manage	24	
Labor Management Relations	8	
EEO Orientation	6	
Pre-Retirement Planning	112	
National Bureau of Standards		
Color in the Health Care Facility	8	
Design Constraints for the Physically Handicapped	8	
Color in Mental Health Facilities	8	
Adult Education	1,053	
Effective Writing	30	
Medical Terminology	40	
ABC Stenoscript	70	
Refresher Typing	32	
Better English Useage	40	
TOTAL		2,478

NON-GOVERNMENT		
4th National Hospital Nursing Supervisors Management Conference	16	
Managing Housekeeping Services	32	
Custodial Management Workshop	21	
National Executive Housekeepers Courses		
Work Controls	20	
Psychology	20	
Oral Communications	20	
TOTAL		129

Table I continued

*Principles of Management	36	
*Modern Management and Supervision	15	
*Accouting I	36	
*Personnel Management	36	
*Management-Employee-Employee-Motivation	60	
*Management-Employee-Employee-Management	60	
*Techniques of Reading and Writing	36	
*Social Psychology	36	
*Introduction to Sociology	36	
*Successful Supervision	30	
WITHIN DEPARTMENT		
Procedures and Orientation	2,370	
Health Employee Learning Program	844	
All Employee Training	482	
TOTAL		3,696
GRAND TOTAL		6,303

*Attended course on employee non-duty time

TABLE 2

POSITIONS FILLED BY RECRUITMENT

ENVIRONMENTAL SANITATION CONTROL DEPARTMENT

April 1, 1976 through June 30, 1977

MONTH	GENERAL SCHEDULE	OTHER WAGE BOARD	WG-03	WG-02	WG-01	TOTAL
April				5		5
May				4		4
June				2	1	3
July				4	1	5
August				3		3
September						0
October						0
November				2		2
December			2	4	1	7
January				3	1	4
February				3		3
March				1		1
April				4	1	5
May				4		4
June				2		2
SUB-TOTAL			2	43	6	51*

*Total includes 15 700-hour appointments and 6 NTE 1-year appointments.

TABLE 3

NUMBER OF SEPARATIONS, RESIGNATIONS, ETC., BY MONTH & GRADE

ENVIRONMENTAL SANITATION CONTROL DEPARTMENT

April 1, 1976 through June 30, 1977

MONTH	WAGE SUPERVISOR	WAGE LEADER	WG-03	WG-02	WG-01	TOTAL
April			1	2		3
May			1	2		3
June				1		1
July				2		2
August			2	2	1	5
September		1	1	2	1	5
October				1		1
November			1	2		3
December		1	2	1	1	5
January				2		2
February				1	1	2
March				2		2
April				2	2	4
May				2		2
June	1			2		3
SUB-TOTAL	1	2	8	26	6	43*

*Total includes 8 700-hour appointments and 5 1-year appointments.

TABLE 4

REASONS FOR PERSONNEL LEAVING

ENVIRONMENTAL SANITATION CONTROL DEPARTMENT

April 1, 1976 through June 30, 1977

RESIGNATIONS	TRANSFERS	RETIREMENTS	TERMINATIONS	DECEASED
Resigned when faced with possible disciplinary action 5	Improved career opportunities 4	Retirement disability 2	Separation during probationary period 2	2
To accept non-government position 4	Transport-ation 1	Retirement optional 3	Termination of temporary appointment 4	
Moving away 1	Higher salary 2		Expiration of temporary appointment 8	
Health 2			Abandonment of position 1	
Transportation 1				
Personal 1				
SUB-TOTALS 14	7	5	15	2

TOTAL - 43

MAJOR PROGRESS IN RESEARCH, SERVICES, TRAINING AND DEVELOPMENT

Building renovations continued to present the Department with its greatest challenge. In addition to uncounted minor projects, during the year there were several major projects affecting all areas of the building. While renovations are in progress the natural reaction is to throw in the dust towel and give up on housekeeping until conditions settle and housekeeping can be handled in a normal routine fashion.

However, renovation creates conditions which call for an actual intensification of housekeeping activities. There is a very real problem of maintenance becoming considerably more difficult, both from a psychological and a practical performance standpoint, while at the same time it becomes more important.

Adjacent areas must be protected from contamination by the soils and waste material produced in renovation. Floors can become badly damaged by scratching or abrading, by tracking in of particles of concrete, metal chips, splinters, mud, etc. Air-borne waste particles and dust can damage office equipment and mechanical systems. Comfort becomes an important factor. People react to unpleasant conditions caused by excessive dust and soil. Infection control becomes more difficult.

During renovation the basic housekeeping principle is isolation: Keeping the remodeling work and its by-products completely isolated from the portion of the building not involved. Some of the more effective steps in this direction are containment barriers around the work area, mats and runners in connecting areas to entrap as much soil and dirt as possible and restriction of sightseers walking through the area and tracking soil back into other areas.

Throughout the year the Department enjoyed substantial success in its major initiatives to improve the housekeeping service offered to Clinical Center tenants. Two significant achievements resulted: A Special Projects Team was formed and a program for cleaning "Red Seal" rooms was established.

Need for a Special Projects Team was perceived as a means for ESCD becoming a positive on-going force in the Clinical Center's clean-up effort. A team consisting of 5 to 6 wage grade employees and a leader was formed under direct operational control of Chief, ESCD. The team's functions were (1) provide special cleaning in public corridors and lobbies consisting of wall and ceiling working and floor stripping and refinishing in concert with the Clinical Center's floor-by-floor Operation Clean-up effort; (2) maintain new Clinical Center entrances; (3) provide response for clean-up after building emergencies; (4) prepare meeting set-ups in Masur Auditorium and Medical Board Room; and (5) provide cleaning service for "Red Seal" rooms.

The Department began offering limited cleaning service in 81 "Red Seal" rooms located throughout the building. These rooms are in building areas normally serviced only by the Night Service Section and, because of occupant security requirements, are not available for cleaning unless the occupants are present. Assistant Chief, ESCD, and two housekeeping aids developed and coordinated

cleaning schedules for these rooms with cooperation from the various room occupants. By the end of the year there were 104 rooms on this "Red Seal" service.

The emergency assistance program for the Department operated satisfactorily during the year. Elevator Operators and others were briefed several times on emergency procedures. The Special Projects Team received special training and equipment for emergency assistance. Water pick-up equipment was renovated and replaced during the year and operated in a very satisfactory manner. The following emergencies were encountered during the year:

Floods	:	43 calls for 100	staff-hours
Fires	:	37 calls for 18-1/2	staff-hours
Acid Spills	:	3 calls for 1-1/2	staff-hours
Others	:	43 calls for 17	staff-hours

ESCD completed change-over to use of cardboard boxes for medical pathological waste handled by our personnel. This was the first operational phase of the program of conversion to paper packaging of waste, activation of trash chutes, and elimination of GI cans for waste handling in the Clinical Center. In preparation for trash chute activation several trials have been made using the paper bag system for handling waste.

Three floor maintenance machines were evaluated. A two-speed machine was the most promising. The type machine demonstrated was very effective and capable of significantly improving productivity and quality. The specific machine was too noisy for use in this house. Other two-speed machines are being evaluated. An ultra-hi-speed floor polisher and a push sweeper were also shown. Neither meet our current requirements.

Carpet extractor equipment was evaluated. After a literature review two machines were selected for evaluation. The "Brillo" extractor had several deficiencies and was found not suitable. The "Steam-X" was the best extractor we have seen. One "Steam-X" was acquired on a lease basis for long-term evaluation.

An in-use bacteriological evaluation was made on "TBQ," a quaternary ammonium germicidal detergent. This product was found to be about equal to our presently approved germicidal detergents, "1-Stroke" and "LpH."

"Brawn," a heavy-duty cleaner, and "Spritz," a spray-and-wipe cleaner, were found to be satisfactory, but not significantly better than our present products.

FUTURE OBJECTIVES DIRECTED TOWARD MEETING GOALS

1. Implement new solid waste handling system based on reactivation of existing Clinical Center trash chutes.

2. Complete refresher training and certification in basic work procedures for all Department supervisors, leaders and employees.

3. Support and encourage upward mobility for employees so that they may work at their fullest potential.

4. Continue to study the feasability of phasing out manual passenger elevator service and converting to automatic passenger elevators.

5. Continue program of replacement of Clinical Center personal lockers.

6. Publish new cleaning procedures in "Clinical Center Cleaning Procedure Manual," and revise 25% of Programmed Work Plans.

7. Continue to test new products and equipment.

8. Coordinate selection of textiles and fabrics for draperies, furniture, and wall and floor coverings within the Clinical Center.

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

FABRIC CARE DEPARTMENT

TABLE OF CONTENTS

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

FABRIC CARE DEPARTMENT

I. MISSION AND GOALS

The primary objectives of the Fabric Care Department during Fiscal Year 1977 were to:

1. Provide quality fabric care services at the most reasonable cost consistent with the needs of patient care and research in the Clinical Center and other N.I.H. installations on the Bethesda Campus, the Poolsville Animal Farm, the Landau, Westwood, Auburn Buildings, the Baltimore Cancer Research Center, and St. Elizabeth's Hospital.

2. Coordinate and adjust work schedules to allow contractors to perform major renovation activities and install equipment while still maintaining quality fabric care services to the N.I.H. community.

3. Study the department's manpower utilization requirements for possible reduction of permanent full-time staff.

4. Complete bed pillow replacement program for patient care.

5. Select and provide training for an Assistant Chief of the department.

6. Assist Material Management staff incorporate the department's new linen store inventory into the N.I.H. Uniform Cost Accounting System.

7. Reduce the number of budgeted overtime hours by 25%.

8. Select and purchase a new flatwork ironer.

9. Remove the belt conveyor and modify the existing monorail to improve transportation and storage of soiled linens.

II. ACTIVITIES

A. Production

	F.Y. '77	F.Y.'76	Percentag
Laundry Operations:			
Pounds Washed and Finished	1,800,000	1,787,940	10.5%
Pounds Dyed	15,200	14,900	1.02%
Dry Cleaning Operations:			
Pounds Dry Cleaned and Finished	170,900	153,737	9.%
New Linen Stores:			
Items Issues	56,163	49,300	8.1%
Items Repaired	6,020	4,803	4.9%
Items Altered	39,100	46,609	-6.2%
New Items Fabricated	776	849	-11.6%
Number of Items Stocked	632	615	.037%

1. The department was able to meet the increasing demands for service with no major problems or additional staff during the major renovation and equipment installation project.

2. Reduced permanent, full-time staff by two positions. We have reduced the authorized permanent, full-time staff of the department from 49 to 37 since 1974.

3. Reduced the number of budgeted overtime hours by 33 1/3%. (F.Y.'76 - 1,500 hours - - F.Y.'77 - 1,000 hours).

B. Renovation

1. The renovations are completed except for a few minor repairs and adjustments. This project to improve the work environment for employees was started August 1976 and should be completed as of September 1, 1977. The following improvements are now completed:

   a. A new mezzanine was constructed along the east wall to provide 5,000 additional square feet of floor space and now accommodates new toilet and locker room facilities and a new spacious conference/break room.

   b. The old locker room area has been renovated into larger newly designed offices.

   c. The gates at the tunnel entrance were replaced with automat roll-up doors to keep out incinerator debris, smoke, cold winter drafts, and odors.

d. A new central air conditioning system provides a cool, comfortable work environment in all work areas.

e. The illumination has been increased with the installation of new flourescent lights into a new suspended accoustical ceiling.

f. A new lint exhaust system has been installed to alleviate housekeeping problems resulting from dust and lint fallout.

g. The old office has been renovated into a new sewing and issue room.

h. A new P.A. system complete with an F.M. radio pipes music continuously throughout the plant.

i. The interior of the facility and equipment has been painted in a lively color scheme to enhance the appearence of the work areas.

j. New furniture has been purchased for offices and conference/ break room.

k. A new flatwork ironer was selected and ordered.

l. The belt conveyor removed and existing monorail was modified to improve transportation and storage of soiled linens.

m. A modern fire protection system has been installed and tested.

n. The newly designed, all glass entrance enhances the decor of the modern N.I.H. Fabric Care Facility.

C. Personnel

1. Selected an Assistant Chief of the Department.

2. Four employees attended Basic Adult Education classes (720 man hours).

3. Four employees attended selected training classes (185 man hours).

4. The department sponsored nine (9) job related training sessions (310 man hours).

5. Employees in the Fabric Care Department were awarded Superior Performance Awards (36 employees).

6. One employee attended the Alcohol Rehabilitation Counselling sessions.

7. Three employees transferred to other positions within N.I.

D. Completed Programs

1. Bed pillow replacement program completed. All bed pillows now in use and in inventory meet the Commerce Department's Flammability Standard FF-4-72.

2. The department's new linen store inventory was successfully incorporated into the N.I.H. Uniform Cost Accounting System.

III. FUTURE OBJECTIVES

1. Provide technical and administrative training for new assistant.

2. Review manpower requirements in an effort to reduce authorized permanent full-time staff by two positions.

3. Continue to improve quality of service to the N.I.H. community at a reasonable cost.

4. Establish a two to three year plan for replacing several key employees nearing retirement.

5. Reduce budgeted overtime useage by 12%.

6. Draft Employee Handbook for Fabric Care employees.

7. Complete and publish Fabric Care Procedural Manual to be used by the N.I.H. community.

July 1, 1977, through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

MEDICAL RECORD DEPARTMENT

CONTENTS

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

MEDICAL RECORD DEPARTMENT

DEPARTMENT MISSIONS AND GOALS

The Medical Record Department maintains a medical record for every registered Clinical Center patient. The prime objective is to insure that each medical record is complete, accurate, safeguarded, and available to authorized personnel. To this end, systems are maintained which provide: (1) immediate access to and release of medical records and information to authorized users; (2) a computerized listing of each patient by diagnosis and operation: (3) an analysis by Institute of discharged inpatients; (4) a systematic arrangement of reports within the medical record; (5) transcribed medical reports and communication with referring physicians.

ACTIVITIES AND PROGRESS

Education and Training

Orientation was held for employees from a number of Clinical Center Departments and Institutes. Lecture tours were given to Public Health Service student medical administrators and other visitors.

Personnel attended workshops on a variety of work-related subjects such as record management, microfilming, confidentiality aspects of medical records, Privacy Act, medical audit as well as campus sponsored office procedural courses for clerical personnel.

Continuing education and cross-training of employees within the department was effected.

Activities and Progress

Minimum medical record requirements and general policies relating to major medical record systems were codified in July 1976 and published as a Medical Record handbook. The handbook was extensively revised and expanded for release in July 1977 for use by physicians and health professionals participating in patient care.

The arrangement of medical record contents has been revised to assist users in referencing and identifying reports as well as to reduce misfiling.

A significant policy change became effective in April 1977; that is, all medical records including incomplete records and reports are retained in the Medical Record Department for review and completion. Medical records are released for inpatient readmissions and outpatient visits only. This change required major

revisions in procedures as well as acceptance and adjustment on the part of personnel and physicians. On a trial basis, an exception has been made to release completed records for a 24-hour period. This temporary change was necessary due to the need for physicians to prepare either oral or written communication to the patient's referring physician. The effectiveness of this exception to the policy will be evaluated and results analysed prior to amending the basic policy.

Six medical audits were completed during the period from January to July 197 The Medical Record Department played a key role in abstracting and tabulatir the required data, and participating in the ongoing analysis of the results the audits.

Several changes were made to improve the total turn-around time for the tran cription of medical dictation and mailing of medical reports to the referrir physician. Examples are: additional courier service for transmitting dicta tion and medical reports inhouse, to and from offsite services; revision of systems to simplify identification of physician's dictation and improve cler processing; provision of continuing education to offsite transcription servi the printing on MIS of discharge letters addressed to the referring physicia Of significance, there was a reduction in total turn-around time from 10 to days, and at present to 3 days for 42% of the workload.

A concentrated program was conducted jointly with the Medical Record Committ to improve the identification of medical reports which are received for incl sion in the medical record. Meetings were held with Clinical Directors and Clinical Center Department Heads in order to arrive at mutual resolutions. a result, basic requirements, means for the disposition of unidentified mate and a change in the patient addressograph system were established.

The implementation of the microfilm program has been delayed because of mult factoral causes. The Request for Proposal is in its final draft stage, the request for approval of the program and purchase of required equipment have been submitted; a policy for the disposal of the original medical record and archival security microfilm remains to be negotiated with the Management Pol Branch.

The Chief, Medical Record Department is a member of a work group studying th total system relating to medical records at the Clinical Center. The study includes an analysis of the present system and identifying a system which wi accommodate the needs for the Ambulatory Care Research Facility. Proposed r approaches or recommended revisions will be formalized for discussion and ac tance before implementation.

WORK PRODUCTION STATISTICS

July 1, 1976 to June 30, 1977 - Actual
July 1, 1977 to September 30, 1977 - Projected

	Column A 7-1-76/6-30-77 (Actual)	*Column B 7-1-77/9-30-77 (Projected)	Column C TOTAL
I. Medicolegal Section			
Total number of requests	7098	1739	8837
Average requests per day	32	27	30
II. Record Processing Section			
Incomplete records as of 5-31-77	731	--	--
Incomplete records as of 9-30-77	--	622	677
III. Files Section- Record Circulation			
Complete Records	24333	5776	30109
Clinics & Admissions	58687	14290	72977
Incomplete Records	13305	5492	18797
IV. Transcribing Section			
Belts received	14987	3993	18980
Belts transcribed	15009	4105	19114

Figures for belts transcribed are greater than belts received due to belts remaining at beginning of the month.

* Projected figures 7-1-77/9-30-77 are based on actual figures 7-1-76/9-30-76.

FUTURE OBJECTIVES

Develop and implement an automated system for collecting and reporting deli-
quent medical records in order to 1) provide timely and accurate informatio
to physicians to help reduce the period that a medical record remains incom
plete and to insure compliance with minimum record requirements; and
2) eliminate outdated reports and information that result from the manual s
of collecting and reporting deficiencies.

Implement by January 1978, the four year program for microfilming about 62,
medical records; finalize the microfilm system for use at the Clinical Cent

Implement new approaches identified by the special work group for the Clini
Center medical record system.

Continue the investigation of system changes for dictation of medical repor

Continue the investigation of developing an automated system for medical re
circulation and location.

Redesign the physical layout of the department in order to accommodate spac
for microfilm equipment and staff, physician's reference room, and medicole
personnel.

ANNUAL REPORT - MEDICAL RECORD DEPARTMENT

PROBLEMS

Approximately 650 unscheduled outpatient visits a month cause problems in Medical Record Services. Although cooperation from physicians has been improving, there are still temporarily lost records and records with major incompletions.

Another major problem is an inability to recruit medical record administrators. The apparent reason is that Civil Service standards set this series at a relatively low grade level, resulting in lack of incentive for prospective applicants.

July 1, 1976 through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES

CLINICAL CENTER

DEPARTMENT OF NUCLEAR MEDICINE

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DEPARTMENT OF NUCLEAR MEDICINE

DEPARTMENT MISSIONS AND GOALS

Applied Physics Section

The Applied Physics Section performs two basic functions: 1) to supply technical and professional assistance to the Department of Nuclear Medicine and other investigators in the resolution of selected diagnostic and experimental problems requiring Nuclear Medicine technology and 2) to independently develop novel diagnostic procedures, from concept through hardware, aimed at resolving selected problems of medical diagnosis.

Diagnostic Imaging Section

This section serves the clinical research goals of the NIH through the in vivo diagnostic use of radioactive pharmaceuticals in the evaluation of diseases that are under study in both the inpatient and outpatient population. Pictures (images) are created, through the use of complex detectors of radioactivity, that demonstrate the site and progression or regression of disease. The information obtained is used by the physicians in their choice of therapy and to assess the results of therapy. Improvement of existing techniques and development of new techniques of patient study are major goals, and these tests must have minimal morbidity for the patient. The primary goals are to improve accuracy and to provide more data with which to evaluate the patient.

Radiopharmaceutical Section

The major responsibilities of the Radiopharmaceutical Section are its service functions, quality control efforts, and involvement in the dose dispensing system employed in the Diagnostic Imaging Section. Services consist of the procurement, receipt, registration, formulation, and development of all radiopharmaceuticals intended for use in Clinical Center patients. Quality control efforts consist of assaying, radiochemical and radionuclide purity checks, pH determination, particle sizing, and a host of other considerations necessary to establish the pharmaceutical quality of the products.

Whole Body Counter Section

The Whole Body Counter Section provides the NIH community with a unique facility for direct quantitative measurements of uptake and retention of biologically active materials and trace elements labeled with gamma-ray emitting radionuclides, and evaluation of the amount and identity of unknown radionuclides in the human body. It also serves as a source of information and support for investigators desiring to design special counting systems for the measurement of biological samples containing radionuclides.

DEPARTMENT ACTIVITIES

Applied Physics Section

In accord with its mission, the APS intensified its collaborative efforts with NHLBI/CB, DCRT/LAS, and DCRT/CSL during FY 77 in the pursuit of non-invasive methods for detecting and diagnosing cardiac disease.

Equipment

Imaging equipment, work space, and expendables were provided by NM/CC and DCRT. Radiopharmaceuticals were provided by the Radiopharmacy Section/NM.

Diagnostic Imaging Section

The components necessary to achieve the above mission require continued upgrading. The field of Nuclear Medicine is fast changing and requires a constant refreshment of departmental physician and technician knowledge. Electronic equipment is costly and is under continual development by private industry. Medical diagnostic capability can be improved and maintained only if a program of continued, well chosen acquisition of newly created electronic devices is followed. Equipment was improved through the acquisition of an up-to-date whole body imaging device provided in the FY 77 budget. A program of improving other imaging devices (gamma cameras) is underway and should be aided by the FY 78 budget.

DIAGNOSTIC IMAGING SECTION -- PERSONNEL

	Physicians/Technicians	Secretaries/Receptionists
FY 77	7 / 7	6

Patient visits increased 26% in FY 77 compared with a 13% increase in FY 76 due in part to additional nuclear medicine studies, but it was mainly attributable to computerized transmission tomography (CT) studies. CT studies became routinely available in this section of the Department when NINCDS provided a new CT instrument September 1976. Please see updated graph titled "Growth of Clinical Center Nuclear Medicine Service" on page 15.

Whole Body Counter Section

Three major equipment changes were made in FY 77. These were the completion of our low energy photon human counter system, installation of an automatic data collection system to go with the Packard Instrument Company model 5220 "Autogamma" well counter, and the acquisition of a triple "diskette" data storage system for the Wang 2200 data processing system. The low energy photon counting system will allow measurement of previously undetectable gamma-ray and X-ray emitting radionuclides such as I-125 and will improve the ability of the Section to measure bremsstrahlung X-rays from P-32 and other high energy beta particles emitters.

The automatic data acquisition system includes an RS-232 interface which is connected between the "Autogamma" well counter and a Texas Instruments Company "silent 700" portable data terminal. The "silent 700" is in turn connected to a Memodyne model 181 cassette tape system. The cassette tape system records the data in a form compatable with the Wang 2200 system that will allow direct data transfer between the systems.

Finally, a triple "diskette" data storage device was purchased and installed for our Wang 2200 data processing system. This unit will rapidly store and retrieve up to 786,432 bytes of information on three low cost, interchangeable diskette platters. The diskette system represents a substantial increase in the data handling capability of the Section and should allow the eventual incorporation of all Section records into disk storage with a resulting large reduction in space allocated to file storage and increased efficiency in file acquisition and updating. In addition, the expanded storage capacity will provide input file areas for large volumes of raw data for computation and storage.

MAJOR PROGRESS IN RESEARCH, SERVICES, TRAINING AND DEVELOPMENT

Applied Physics Section

Four major objectives were realized in the Applied Physics Section during FY 77: 1) implementation of a minicomputer based real-time cardiac imaging system tailored to clinical requirements, (APS-DCRT); 2) Recognition and validation of the ability of this system to visualize and quantitate cardiac function during bicycle exercise as well as at rest, (NHLBI-APS); 3) assembly and preliminary patient evaluation of a (prototype) portable hand-held scintillation probe for continuous bedside measurement of cardiac function (APS-NHLBI); and (4) design assembly and human engineering evaluation of a microprocesser version of the probe system for use in the intensive care unit (DCRT/CSL-APS).

Diagnostic Imaging Section

A computerized tomography apparatus which was installed in April 1976 in the Department of Nuclear Medicine by NINCDS is now utilized to study patients and support NIH clinical research projects. In addition, clinical studies are made on patients from the Washington V.A., Walter Reed, National Naval Medical Center, and Andrews Air Force Base hospitals. This CT device, shared cooperatively with the Department of Radiology/CC/NIH, provides diagnostic support to NIH patients as well as patients of the above noted U. S. Government hospitals.

Gated Cardiac Blood Pool Studies: This project has accelerated in the past year. The Cardiology Branch/NHLBI refers approximately 25 patients per week and has purchased a computer and placed it in this department. Clinical Center support for this project is to be matched through the acquisition of a state-of-the-art gamma camera. This latter device is critically needed to further this project and will probably be acquired in FY 78.

The Pulmonary Research Protocol continues in cooperation with DCRT and the Pulmonary Branch/NHLBI. Approximately 15 patients per week are studied.

The Thrombus Detection Study is underway with the Surgery Branch/NCI and is being evaluated for its utility in the detection of post operative thrombus formation. The objective is to avoid or lower the incidence of pulmonary embolus.

Computerized renography with functional mapping continues with DCRT.

Ultrasound with computer support is also under development with DCRT. The system is being applied to comparative radionuclide studies.

New services offered by this section of the Department of Nuclear Medicine: CT brain studies; gated cardiac blood pool studies; thrombus detection; computerized renography.

A new radiopharmacy area to prepare and administer radiopharmaceuticals to patients is under construction in the Diagnostic Imaging Section. The old radiopharmacy space will be renovated and given to the Applied Physics Section.

Radiopharmaceutical Section

In its second full year of operation, the Radiopharmacy's role in the Diagnostic Imaging Section's dose dispensing system continued to be an effective means to control and dispense radiopharmaceuticals, and it ensures good radiation safety practices.

Thanks to the combined efforts of the Radiation Safety Branch and Radiopharmacy, a method for unit dose packaging of Xenon-Xe-127 was developed by modifying the existing dispensing system; the new dispensing system lowered radiation levels during its operation.

During the initial stages of the Functional Mapping of the Kidney Dynamics Research Project, Radiopharmacy labelled Sodium-Iodohippurate I-123 for the investigator until commercially prepared material became available.

A total of 23 different radionuclides were received which constituted 66 different product formulations (Table V). Products not previously received and/or formulated were Technetium-99m Red Blood Cells, Indium-111 Diethylenetriaminepentaacetic Acid, Sodium Iodide I-123, Sodium Iodohippurate I-123, and Ytterbium-169 Diethylenetriaminepentaacetic Acid.

Consultations were given to various paramedical personnel and regulatory agencies. The Radiopharmacy Section also provided two preceptorships to the Duquesne University Controlled Internship Program in Pharmacy.

Whole Body Counter Section

During FY 77 the number of research and diagnostic studies made by the Whole Body Counter Section decreased slightly due in part to the completion of a major study of zinc metabolism initiated in FY 75 by NHLBI.

The Section completed patient measurements for three major human studies: iron metabolism in patients suffering chronic iron overload, studies of the metabolism of zinc in.patients with defects of taste and smell, and studies of copper metabolism in humans using Cu-64 and Cu-67.

The zinc studies represent the largest and most detailed investigations of zinc metabolism ever done with radionuclides: they are the first human studies to involve oral and intravenous administration of zinc radionuclides to the same subjects to investigate the effects of route of entry on metabolism. Publication of these results is expected in FY 78.

Appended tables provide a complete breakdown of the number and types of studies performed by the Section in FY 77. The Whole Body Counter Section was involved in studies leading to three publications and two presentations at national scientific meetings during FY 77.

FUTURE OBJECTIVES TOWARD MEETING GOALS

Applied Physics Section

We will continue clinical studies with the real-time cardiac imaging system, and the refinement of the real-time system through continued software development and hardware acquisition.

We will evaluate the portable microprocessor-probe system in the intensive care unit.

This section will undertake planning and design for a microprocessor version of the real-time imaging system in association with DCRT.

Requirements for fabrication of a lightweight, low volume, portable imaging device tailored specifically to cardiac studies will be investigated.

Investigation of the limitations associated with these methods will continue.

Diagnostic Imaging Section

Acquisition of the latest gamma camera systems is of great importance, since the existing systems have become limitations to the support of service and clinical research of this section of the Department of Nuclear Medicine.

Improved service through better and more rapid performance of existing studies is intended along with the development of newer studies to meet clinical research needs.

Radiopharmaceutical Section

The future objectives of the Section are to continue to collaborate with the service and research efforts of the Diagnostic Imaging Section and other Clinical Center investigators with involvement in the formulation, development, and quality control of all radiopharmaceutical products intended for patient administration.

The Radiopharmaceutical Section anticipates the use of a new radiopharmaceutical dispensing area within the Diagnostic Imaging Section in FY 78 which should lend itself to a more efficient operation of the unit dose program.

Whole Body Counter Section

The Whole Body Counter Section has emphasized medical research measurements for the past six years and will continue to do so during FY 78. Efforts to inform the NIH community of the availability of our services will include the distribution of a pamphlet and presentation of information about whole body counting and other available services through the Office of Radiation Safety: "Radiation Safety Branch Courses for Employees Using Radionuclides."

TABLE I

Comparison of Whole Body Measurements
for Fiscal Years 1976 and 1977

	Isotope	1976	1977*
Research Studies			
	Zn-65	689	191
	Cu-67	564	157
	Cr-51	50	14
	K-40	137	26
	I-131	444	960
	I-125,129	32	0
	Fe-59	0	22
	Cu-64	395	115
		2311	1485
Personnel Monitoring Studies			
	I-125,131	999	1164
	Whole Body	690	832
		1689	1996

* Fiscal Year 1977 values estimated from 7/76 through 5/77 plus scheduled increases, expressed as yearly rates.

Percentage of Whole Body Counts by Institutes

	FY 1976	FY 1977*
DRS	48.0	56.4
CC	0	0.4
NCI	1.1	0
NHLI	19.3	15.6
NINDS	0.05	0.0
NIAMDD	28.5	26.8
NIA	3.1	0.8
	100.0	100.0

* Fiscal year 1977 values estimated from 7/76 through 5/77 plus scheduled increases expressed as percentage of yearly rates.

TABLE II

Ten Year Record of Whole Body Measurements

Year	Research Measurements	% of Total	Personnel Measurements	% of Total	Total Measurements	Yearly % Change	Yearly % Change from 1968
1968	1102	67	552	33	1654	---	---
1969	639	60	427	40	1066	36*	36*
1970	234	31	511	69	745	30*	55*
1971	317	36	566	64	883	19	47*
1972	1168	71	476	29	1644	86	0.6*
1973	1863	64	1030	36	2893	76	75
1974	2138	68	1292	38	3430	19	107
1975	3615	68	1721	32	5336	56	223
1976	2311	52	2135	48	4446	18*	163
1977+	1485	44	1921	56	3406	23*	106

+ Fiscal Year 1976 values estimated from 6/76 through 5/77 plus scheduled increases expressed as percentage of yearly rates.

* Decrease

TABLE III

Other Analyses Related to Whole Body Metabolism Studies

	FY 1976	FY 1977*
Excreta Studies		
Cu-67	217	90
Cu-64	97	36
Zn-65	8	0
	322	126
Blood Studies		
Samples Taken	518	247
Red Cell Washings	614	241
	1132	488
Blood Counts		
Cu-67	604	278
Cu-64	451	192
Zn-65	878	328
	1933	798
Tissue Sample Counting		
Sr-85,Ce144 and Yb-169	2263	5386
Br-82	177	0
	2440	5420

* Fiscal Year 1976 values estimated from 7/76 through 5/77 plus scheduled increases expressed as yearly rates.

TABLE IV

Radiopharmaceutical Section Statistical Data

	FY 76	*FY 77	**% Change
Service Requests	2,224	3,090	+ 11%
Work Units	24,173	36,664	+ 21%
Unit Dose Requests	5,000	8,714	+ 39%
RPS Assays	3,857	5,441	+ 13%
Radionuclidic Purity Checks	633	651	- 18%
RPS Expenditures	$111,832.93	$160,196.13	+ 15%

* - 15-month period

** - pro-rated over 12-month period

Note: The decrease in number of radionuclidic purity checks performed is attributable to the discontinuance of use of Mercury-Hg-197 Chlormerodrin.

TABLE V

Isotopes and Products Received, Registered, and Formulated - FY 77

1.	H-3	-	Bilirubin Thymidine (Methyl H-3)
2.	C-14	-	Dopamine Imipramine
3.	P-32	-	Chromic Phosphate Suspension Sodium Phosphate
4.	Ca-47	-	Calcium Chloride
5.	Cr-51	-	Erythrocytes Erythrocytes (Heat-Treated) Human Serum Albumin Platelets Sodium Chromate
6.	Co-57	-	Cyanocobalamin Capsules
7.	Co-58	-	Cyanocobalamin Capsules
8.	Fe-59	-	Ferrous Citrate
9.	Cu-64	-	Copper Chloride Copper Chloride Plasma
10.	Cu-67	-	Copper Chloride
11.	Ga-67	-	Gallium Citrate
12.	Se-75	-	Selenomethionine
13.	Mo-99	-	Mo-99/Tc-99m Generator
14.	Tc-99m	-	Diethylenetriaminepentaacetic Acid Diphosphonate Human Serum Albumin (E.M.) Macroaggregated Human Serum Albumin Pyrophosphate Red Blood Cells Sodium Pertechnetate Stannous Human Serum Albumin Sulfur Colloid

15.	In-111	-	Diethylenetriaminepentaacetic Acid Indium Chloride
16.	I-123	-	Sodium Iodide Oral Solution Sodium-o-Iodohippurate
17.	I-125	-	C-1 Esterase Inhibitor Chylomicrons Fibrinogen High Density Lipoprotein High Density Lipoprotein A-1 High Density Lipoprotein A-2 Human Growth Hormone Human Serum Albumin Low Density Lipoprotein Microaggregated Human Serum Albumin Procine Insulin Sodium Iodide Calibration Solution Sodium Iothalamate Very Low Density Liporotein
18.	Xe-127	-	Xenon Gas
19.	I-131	-	Alpha, 1-Antitrypsin High Density Lipoprotein High Density Lipoprotein A-1 High Density Lipoprotein A-2 Low Density Lipoprotein Porcine Pro-Insulin Sodium Iodide Capsules Sodium Iodide Oral Solution Sodium Iodide Uptake Solution Sodium-o-Iodohippurate Sodium Rose Bengal Very Low Density Lipoprotein
20.	Xe-133	-	Xenon Gas Xenon in Saline
21.	Yb-169	-	Diethylenetriaminepentaacetic Acid
22.	Hg-197	-	Chlormerodrin
23.	Tl-201	-	Thallium Chloride

TABLE VI

Diagnostic Nuclear Medicine Section

Patient Visits by Fiscal Year

Date	1967	1968	1969
Total	2568	3093	1637
Yearly % Change		20%	47%*
Yearly % Change from 1967		20%	36%*

Date	1970	1971	1972
Total	2181	2308	2950
Yearly % Change	33%*	0%	28%
Yearly % Change from 1967	15%*	7%*	15%

Date	1973	1974	1975
Total	4688	7039	7098
Yearly % Change	59%	50%	0%
Yearly % Change from 1967	82%	174%	176%

Date	1976	1977
Total	8054	10056
Yearly % Change	13%	25%
Yearly % Change from 1967	214%	292%

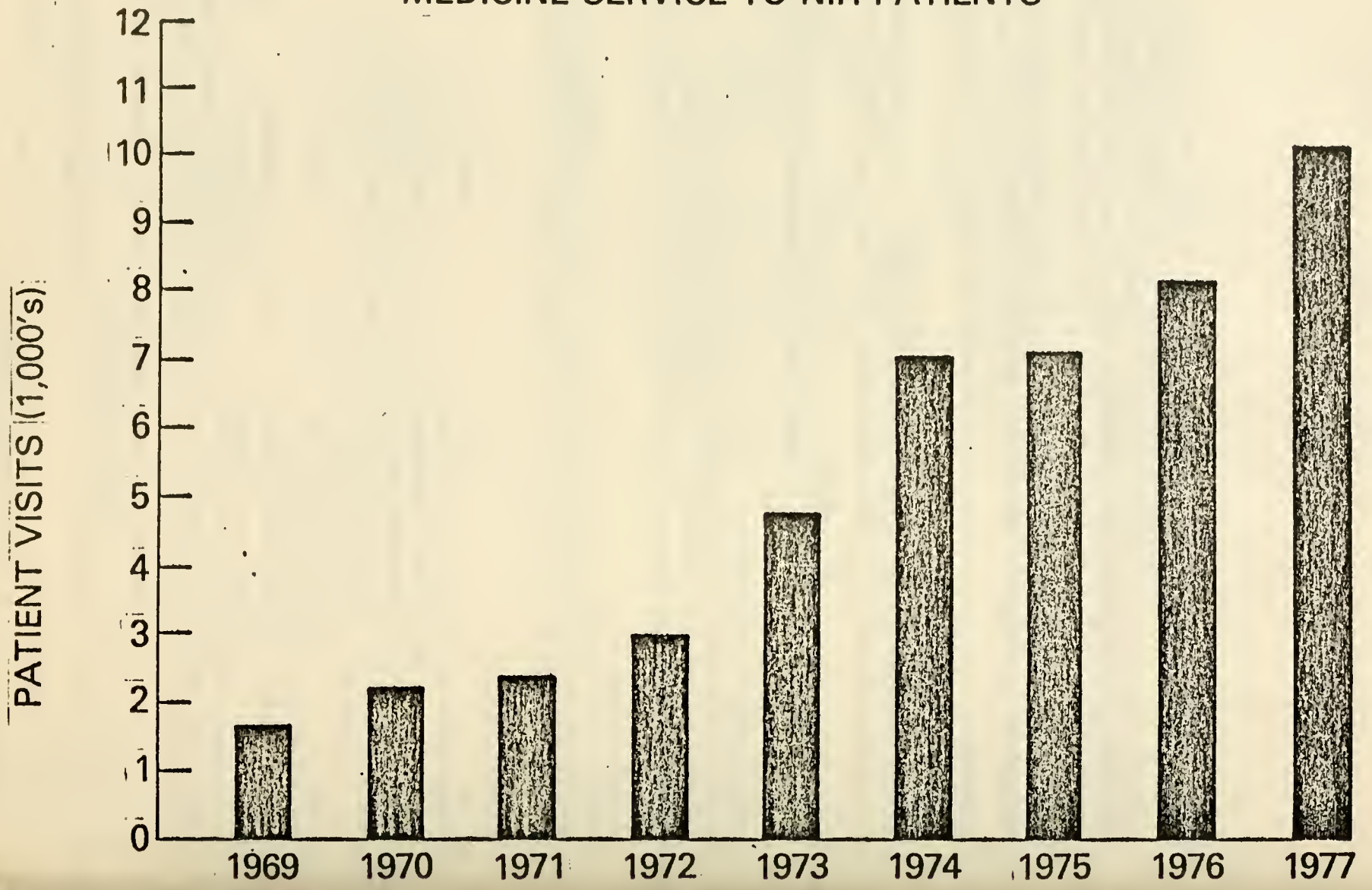
---

* Decrease

** Covers period Oct. 1, 1976 - Sept. 30, 1977 (TQ 76 not included for validity of comparison)

*** Figures for July, Aug. & Sept. are estimates

GROWTH OF CLINICAL CENTER NUCLEAR MEDICINE SERVICE TO NIH PATIENTS



PROJECT NUMBER (Do NOT use this space)	HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CL 00002-02 NM

PERIOD COVERED
July 1, 1976 to June 30, 1977

TITLE OF PROJECT (80 characters or less)

Functional Mapping of Kidney Dynamics Research Project

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI:	P. R. Bradley-Moore	Senior Staff Fellow	NM CC
OTHER:	J. J. Bailey	Head, Medical Application Section	LAS DCRT
	R. J. Farkas	Chief, Radiopharmacy Section	NM CC
	M. A. Douglas	Programmer	LAS DCRT
	B. R. Line	Research Analyst	LAS DCRT
	S. L. Bacharach	Physicist	NM CC
	A. E. Jones	Assistant Chief	NM CC
	G. S. Johnston	Chief	NM CC

COOPERATING UNITS (if any)
LAS DCRT

LAB/BRANCH
Department of Nuclear Medicine

SECTION
Diagnostic Imaging Section

INSTITUTE AND LOCATION
CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
0.75	0.60	0.15

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

This work studies diagnostic imaging of, and report generation to describe, kidney abnormalities seen by nuclear medicine methods.

It includes the application to dogs and patients of new and established radiopharmaceuticals and computer programs based on mathematical models of the kidney, with intercomparison and validation of differing methods by double-blind reporting of operated animal kidneys.

PHS-6040
(Rev. 10-76)

Project Description

Objectives:

To improve nuclear medicine diagnosis of kidney abnormality

A. By using new radiopharmaceuticals to improve the available quality and quantity of information.

B. By adapting a computer program established here to the new tracer agents and by the development of new computer programs to improve the diagnostic yield by non-invasive, non-toxic methods, that permit visualization during renal dysfunction too severe for adequate intravenous pyelography.

Methods Employed:

A. DTPA for patients. Developed at Brookhaven National Laboratories, Diethylene Triamine Pentacetic Acid (DTPA) labelled with Tc-99m is now commercially available and approved and is now being routinely used for patient care.

B. OIH-I-123 for Dogs. Ortho-Iodo-Hippuric Acid (OIH) labelled with Iodine-123 in the NIH radiopharmacy (and more recently obtained from Davis, California) has been used with DTPA and OIH-I-131 in a double-blind animal study to compare the three.

C. Data Taking. Data is being taken in a flexible format on Magnetic Tape.

D. Data Analysis. The tapes are analyzed using the established computer program (1) and a data base is being built up at the same time as new programs are being developed for trial.

Findings:

Improvement in available information is evidenced by the observed counts from one kidney of approximately 1,000,000 (DTPA); 800,000 (OIH-I-123); 3,000 (OIH-I-131).

Significance of the Research Program:

A. Much improved statistical validity of observation with expected higher resolution from the high count rate will permit seeing smaller lesions better than before.

B. Use of two radiopharmaceuticals with differing paths of excretion (DTPA-Glomerular Filtration), (OIH-Tubular Secretion) promises elucidation of differeing patho-physiological mechanisms in renal dysfunction.

Proposed Course:

Completion of data taking and data analysis.

Honors and Awards:

None.

Publications:

Agress, H., Levenson, S.M., Gelfand, M.J., Johnston, G.S., Bailey, J.J.: Functional mapping and related computer-generated images in radionuclide renography. Applied Radiology 1: 202-208, November-December, 1976.

Bradley-Moore, P.R., Line, B.R., Klickna, J., Johnston, G.S.: Proceedings of the Seventh Symposium on Sharing of Computer Programs and Technology in Nuclear Medicine, Atlanta, Georgia, January 1977.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CL 00007-02 NM

PERIOD COVERED
July 1, 1976 to June 30, 1977

TITLE OF PROJECT (80 characters or less)
ECG-Gated Scintigraphic Angiocardiography

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI:	J. S. Borer	Senior Investigator	CB NHLBI
	S. L. Bacharach	Physicist	NM CC
	M. V. Green	Chief, Applied Physics Section	NM CC
OTHER:	K. M. Kent	Senior Investigator	CB NHLBI
	J. J. Bailey	Head, MAS	LAS DCRT
	M. A. Douglas	Programmer	LAS DCRT
	H. G. Ostrow	Engineer	CSL DCRT

COOPERATING UNITS (if any)
CB NHLBI
LAS DCRT
CSL DCRT

LAB/BRANCH
Department of Nuclear Medicine, CC

SECTION
Applied Physics Section

INSTITUTE AND LOCATION
Clinical Center, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
5.0	2.5	2.5

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

High temporal resolution ECG-gated scintigraphic angiocardiography is a computer-based, radiotracer imaging procedure that allows non-invasive visualization of the chambers of the working heart, at rest, during bicycle exercise, during therapeutic intervention, etc. The procedure yields quantitative measures of left ventricular function such as ejection fraction, peak ejection rate, etc. Work is continuing to assess the accuracy of these data in man and to establish findings for the method in selected disease categories. Variations of this technique are being explored that will result in an inexpensive, portable device capable of continuous real-time measurement of left ventricular function at the bedside.

PHS-6040
(Rev. 10-76)

Project Description

Objectives:

A. To verify the ability of high temporal resolution ECG-gated scintigraphy of the heart to noninvasively visualize and measure cardiac function in man.

B. To explore variations in the concept of ECG-gated scintigraphy that will result in a bedside device capable of continuous, non-invasive monitoring of left ventricular function.

Methods Employed:

Comparative studies are continuing in which selected patients are studied with the various forms of ECG gated scintigraphy under investigation in the APS, and by conventional radiographic and echo procedures used to evaluate left ventricular function. During FY 77 these studies evolved into a large scale clinical evaluation of the technique in patients with coronary artery disease, valvular disease and other cardiac abnormalities. During this period more than 350 patients were studied in the Diagnostic Imaging Section by APS technical personnel. The increase in patient studies was the result of three factors: 1) the APS/DCRT development of a clinically useful, real-time cardiac imaging system; 2) recognition and validation of this system's ability to visualize and quantitate cardiac function during bicycle exercise (NHLBI/APS) and 3) establishment of normal values for the procedure (during rest and exercise) in 32 normal volunteers (NHLBI/APS).

Progress was also made toward a portable cardiac function monitor through assembly and testing of a prototype minicomputer-based gated scintillation probe system. Comparative camera-probe studies were performed in 50 patients to establish the operational characteristics of this device. Based on these findings, a microprocessor version of the probe system was constructed by DCRT/CSL and is now undergoing evalution in the DNM prior to its use in the intensive care unit in various NHLBI protocols.

Findings:

A. Real-time cardiac imaging during rest and bicycle exercise.

A comparison of rest-exercise results in normal subjects with those obtained in patients with coronary artery disease, but with normal left ventricular (LV) function at rest, demonstrated that the scintigraphic technique possesses a high sensitivity in detecting functionally significant coronary disease. In normal subjects LV

ejection fraction invariably increased with exercise and no wall motion abnormalities developed. In contrast, it was observed that in each patient, ejection fraction fell during exercise and at least one wall motion defect developed. These findings suggest that rest-exercise imaging can be successfully employed to detect the presence, effect, and probable location of functionally-significant coronary lesions.

In the study of symptomatic patients with aortic regurgitation it was found that LV ejection fell during exercise. In asymptomatic patients with aortic regurgitation a duality in exercise response was observed: some increased their ejection fractions (as do normals) while others diminished their ejection fractions. These findings suggest that scintigraphic rest-exercise testing might be used to time surgical intervention in these patients before a depression in myocardial function has occurred, thus improving long term post operative survival.

A comparison of pre- and post-operative exercise studies in patients undergoing coronary artery bypass grafting indicated that surgical therapy improved LV function during exercise in the majority of these patients. Pre-operative exercise studies with and without nitroglycerin produced similar results.

B. Portable probe system.

Fifty patients were studied both with the prototype probe system and with the scintillation camera. A comparison of probe-camera results indicated that timing and magnitude variations in LV volume measured by the probe were virtually identical to those determined from the camera studies. Difficulties were encountered, however, in determining an appropriate LV background correction for the probe. Fortunately, background determination is not critical when the probe is employed as a monitor, since changes in LV function are the quantity at issue. These findings imply that the probe can be used successfully to monitor LV function at the bedside.

Significance of the Research Program:

ECG-gated angiocardiography is potentially of value in the detection and management of cardiac disease. The method requires only an intravenous injection of radiotracer and is otherwise utterly non-invasive. It is rapid, safe and can be repeated under varying circumstances such as exercise, medication, etc., for periods of up to six hours without further tracer administration. This characteristic also makes the technique suitable for continuous LV function monitoring in the acutely ill patient. Efforts presently underway will result in a portable system capable of continuous LV function monitoring at the bedside.

Proposed Course:

Continuation of validation and development work.

Honors and Awards:

None.

Publications:

Bacharach, S. L., Green, M. V., Borer, J. S., Douglas, M. A., Ostrow, H. G., Johnston, G. S.: A real-time system for multi- image gated cardiac studies. J. Nucl. Med. 18: 79-84, January 1977.

Bacharach, S. L., Green, M. V., Borer, J. S., Line, B. R., Bradley-Moore, P. R., Ostrow, H. G., Johnston, G. S.: Real-time collection, analysis and display of nuclear medicine data. Proceedings of the Seventh Symposium on the Sharing of Computer Programs and Technology in Nuclear Medicine, Atlanta, Georgia, January 1977.

Bacharach, S. L., Green, M. V., Borer, J. S., Douglas, M. A., Ostrow, H. G., Johnston, G. S.: Real-time scintigraphic cineangiography. Proceedings. Computers in Cardiology. IEEE Catalog No. 76CH1160 - 1C, IEEE Computer Society, Long Beach, California, October 1976.

* Borer, J.S., Bacharach, S.L., Green, M.V., Kent, K.M., Epstein, S.E.: Rapid evaluation of left ventricular function during exercise in patients with coronary artery disease. Abstract. Circ. 54 (II-6): 4, October 1976.

Borer, J.S., Bacharach, S.L., Green, M.V., Kent, K.M., Epstein, S.E., Johnston, G.S.: Real-time radionuclide cineangiography in the noninvasive evaluation of global and regional left ventricular function at rest and during exercise in patients with coronary artery disease. N. Engl. J. Med. 296: 839-844, April 14, 1977.

* Borer, J.S., Bacharach, S.L., Green, M.V., Kent, K.M., Epstein, S.E.: Effect of nitroglycerin on global and regional left ventricular function during exercise. Abstract. Clin. Res.: 1977. (In press).

* Borer, J.S., Bacharach, S.L., Green, M.V., Kent, K.M.: Exercise response of the normal and abnormal left ventricle in man. Abstract. Amer. J. Cardiol.: 1977. (In press).

* Green, M.V.: Studies of the heart with ECG-gated scintigraphy. Invited paper. Abstract. Transactions of the Amer. Nucl. Soc., American Nuclear Society, New York, June 1977. (In press).

* Kent, K.M., Borer, J.S., Green, M.V., Bacharach, S.L., McIntosh, C.L., Conkle, D.M., Epstein, S.E.: Effects of coronary artery bypass operation on global and regional left ventricular function during exercise. Abstract. Clin. Res.: 1977. (In press).

* Mack, B.A., Farkas, S., Quigley, C., Bacharach, S.L., Green, M.V., Johnston, G.S.: Technical requirements in ECG-gated heart studies performed at rest and during exercise. Abstract. J. Nucl. Med. Tech: June 1977. (In press).

* Indicates material presented orally at corresponding meeting.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CL 00009-03

PERIOD COVERED

July 1, 1976 through September 30, 1977

TITLE OF PROJECT (80 characters or less)

The Metabolism of ^{65}Zn and ^{69m}Zn in Patients with and without Taste Abnormalities.

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator:	Gerald S. Johnston M.D.	CC:NM
Other Investigators:	Roger L. Aamodt Ph.D.	CC:NM:WBC
	Fredrick Bartter M.D.	NHLBI:IR
	Robert I. Henkin M.D.	Georgetown Universi Medical Center

COOPERATING UNITS (if any)

Georgetown University Medical Center, Washington, D.C.
NHLBI

LAB/BRANCH

Department of Nuclear Medicine

SECTION

Whole Body Counter Section

INSTITUTE AND LOCATION

Clinical Center, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1	.25	.75

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Patients with ideopathic hypogeusia show a loss of taste acuity following infection or surgery. Both of these processes are associated with increased excretion of zinc in the urine and decreased serum zinc concentration. This study is designed to investigate zinc metabolism in these patients and to compare them to patients with hypogeusia following head trauma, patients without hypogeusia, but with other unrelated diseases and patients with terminal diseases. Measurements after administration of ^{65}Zn of ^{69m}Zn will include whole body counting, partial body gamma-ray measurements, and measurements of gamma-ray activity in blood, urine and stool.

PHS-6040
(Rev. 10-76)

Project Description

Objectives:

A. To study the metabolism of zinc in patients with taste and smell dysfunction in order to identify those who exhibit abnormal absorption, distribution, retention or kinetics.

B. To determine the effects of zinc ion therapy on the metabolic parameters discussed above.

Methods Employed:

Following oral administration of 10 uCi of Zn-65, the NIH Whole Body Counter and probe systems will be used to measure Zn-65 in the total body and selected tissues for a period of 300 days. Patients will be given a placebo during this period. For a subsequent 300 day period patients will receive 100 mg/day of Zn++ orally and measurements will be continued for another 300 days. Blood and excreta samples will also be collected and Zn-65 activity determined by gamma-ray spectroscopy. During both phases of the study, measurements of taste and smell acuity (threshold and forced scaling for each sensory modality) will be made.

Findings:

A. The absorption patterns of 63 unselected, untreated patients have been characterized and found to have a much wider than expected range (20-90%). Little data had been previously available for zinc absorption by humans.

B. Retention of Zn-65 was generally found to agree with previously reported values following intravenous administration with the exception of one patient with congenital hypogeusia who exhibited a markedly shortened half-time (143 days).

C. Administration of ZnSO4 (100 mg/day) to patients who had previously been given Zn-65 resulted, in most cases, in a marked change in their retention of the radionuclide. This finding is important both in terms of the physiology of zinc in man, but also for its implications to the treatment of humans with high body burdens of zinc radionuclides.

Significance of the Research Program:

Studies of zinc metabolism in patients with taste and smell dysfunction are a small part of an interdisciplinary program which attempt clinical, metabolic, and pathophysical abnormalities in these patients. Beyond this, zinc is an essential trace metal, the importance of which is just being recognized. These studies will contribute to knowledge about zinc metabolism and may provide insights into ways of increasing absorption in people with absorption difficulties and removing radioactive Zn-65 following accidental uptake in order to reduce the radiation dose.

Proposed Course:

Patient studies with Zn-65 have now been completed. The continuation of these studies will involve data analysis and preparation of data for publication. Dr. Mones Berman (C, LTB) is assisting with analysis of data from Zn-69m studies, and is expected to also contribute to data analysis of Zn-65 studies.

Honors and Awards:

None.

Publications:

None.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01 CL 00011-03 NM

PERIOD COVERED
July 1, 1976 through September 30, 1977

TITLE OF PROJECT (80 characters or less)
Studies of Copper Metabolism in Man using ^{67}Cu and ^{64}Cu.

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Principal Investigator:	E. Anthony Jones M.D.	NIAMDD:DI
Other Investigators:	P. D. Berk, M.D.	NIAMDD:DI
	John Vierling M.D.	NIAMDD:DI
	Roger L. Aamodt Ph.D.	CC:NM

COOPERATING UNITS (if any)
NIAMDD

LAB/BRANCH
Department of Nuclear Medicine

SECTION
Whole Body Counter Section

INSTITUTE AND LOCATION
Clinical Center, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1	0.2	0.8

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Copper, although present in the body in small amounts, is essential for life. In certain diseases, copper metabolism is abnormal, however, the mechanisms of copper homeostasis are poorly understood. An important potential cause of abnormal copper metabolism is defective absorption. It is possible that increased copper absorption may contribute to the increased hepatic copper which occurs in Wilson's disease and chronic cholestasis. Alternatively, copper absorption may be impaired in diseases of the small intestine, such as adult celiac disease. Studies of copper absorption and metabolism are being conducted using the NIH whole body counter systems using simultaneous oral administration of ^{64}Cu and intravenous administration of ^{67}Cu. In-vivo gamma-ray measurements of the liver and thigh areas, total body retention, and activity in blood and excreta will provide information about absorption and retention of copper in normal subjects and in patients with disorders of copper metabolism. It is hoped that such studies will provide insights into the normal metabolism of copper on the mechanisms of abnormal copper metabolism which result in disease.

Project Description

Objectives:

A. To evaluate quantitatively the metabolism of copper in health and specific diseases associated with abnormalities of copper metabolism.

B. The ultimate goals include a comprehensive understanding of normal copper metabolism, and an evaluation of the significance of specific abnormalities of copper metabolism in patients with hepatolenticular degeneration and their relatives and patients with primary biliary cirrhosis and other disease states.

Methods Employed:

A. Studies using Cu-67 alone. After the intravenous injection of Cu-67 serial measurements are made of whole body radioactivity (using a scintillation probe), and radioactivity in whole blood, red cells, plasma, ceruloplasmin, urine and feces. With the exception of hepatic radioactivity, these measurements are made for a period of 13 days. Plasma ceruloplasmin-bound Cu-67 determination involves the removal of non-ceruloplasmin-bound Cu-67 from plasma samples by passage of these samples down small columns of activated charcoal. Plasma non-ceruloplasmin-bound Cu-67 are determined by subtracting radioactivity in ceruloplasmin from that in whole plasma. The curves of total body, hepatic, whole blood, red cell, plasma ceruloplasmin radioactivity are defined and the total excretion of radioactivity in urine and feces calculated.

B. Studies using Cu-67 and Cu-64. Studies are also being conducted in which Cu-67 is being administered by intravenous injection and Cu-64 is being administered simultaneously by mouth. The subsequent protocol is the same as for studies using Cu-67 alone except that both Cu-67 and Cu-64 radioactivity are measured in all experimental specimens. In measuring Cu-67 and Cu-64 simultaneously an appropriate correction is made for the radioactivity due to Cu-64 which cannot be excluded when measuring Cu-67. The plasma disappearance curve of non-ceruloplasmin-bound Cu-67 is used to correct the plasma non-ceruloplasmin-bound Cu-64 curve for losses employing deconvolution and integration procedures on a digital computer. This enables the total Cu-64 which passes from the gut lumen to the plasma to be calculated. This quantity less the amount of the administered Cu-64 which does not appear in feces gives an estimate of the biliary secretion of Cu-64 and hence of the enterohepatic circulation of this metal.

Findings:

A. The ranges of whole body Cu-67 retention for normals and homozygotes and heterozygotes for hepatolenticular degeneration have been defined.

B. There was appreciable incorporation of Cu-67 into ceruloplasmin in normals and a similar degree of incorporation in heterozygotes for hepatolenticular degeneration. In contrast, incorporation of Cu-67 into ceruloplasmin in homozygotes for hepatolenticular degneration was minimal.

C. After administering Cu-67 intravenously and Cu-64 orally to normal volunteers, plasma curves of non-ceruloplasmin-bound Cu-67 and Cu-64 have been defined and the feasibility of studying the enterohepatic circulation of copper using these two isotopes has been established.

Significance of the Research Program:

In certain disease states marked variation in the content of copper in plasma and various organs is known to occur. However, the mechanisms by which copper homeostasis is maintained in health and disturbed in disease are poorly understood. Increasing attention has been focused on copper metabolism in hepatolenticular degradation since the refutation of the concept that low ceruloplasmin concentration is primary biliary cirrhosis and raises the possibility that abnormal copper metabolism may contribute to the pathogenesis of this disease, the etiology of which is at present unknown.

A potentially important cause of deranged copper metabolism is a defect in the intestinal absorption of the metal. For example, it is possible that increased copper absorption may contribute to the increased hepatic copper which occurs in hepatolenticular degeneration and chronic cholestasis. Alternatively, copper absorption may be impaired in diseases of the small intestine mucosa. Lack of reliable methods, variability in hepatic copper uptake, and the presence of an enterohepatic circulation for copper have hitherto prevented acquisition of reliable data on absorption. Using the double radionuclide technique outlined, it is possible to quantitate the intestinal absorption and biliary secretion of copper in human subjects and hence to determine whether there is a derangement of intestinal absorption or biliary secretion of copper in specific diseases states.

Proposed Course:

Patient studies with Cu-64 and Cu-67 ar now essentially complete. Continuation of these studies will involve preparation and analysis of data and kinetics analysis.

Honors and Awards:

None.

Publications:

None.

PROJECT NUMBER (Do NOT use this space)

HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NOTICE OF
INTRAMURAL RESEARCH PROJECT

PROJECT NUMBER

Z01 CL 00019-02 NM

PERIOD COVERED
July 1, 1976 to June 30, 1977

TITLE OF PROJECT (80 characters or less)

Ventilation-Perfusion Relationships in Idiopathic Pulmonary Fibrosis

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

PI:	B. R. Line	Research Analyst	LAS DCRT
OTHER:	A. E. Jones	Assistant Chief, Dept. Nuc. Med.	NM CC
	J. J. Bailey	Head, Medical Application Section	LAS DCRT
	R. G. Crystal	Head, Pulmonary Branch, NHLBI	PB NHLBI
	J. D. Fulmer	Chief, Clinical Service, Pulmonary Branch, NHLBI	PB NHLBI

COOPERATING UNITS (if any)
PB NHLBI
LAS DCRT

LAB/BRANCH
Department of Nuclear Medicine

SECTION
Diagnostic Imaging Section

INSTITUTE AND LOCATION
CC, NIH, Bethesda, Maryland 20014

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
5	3.5	1.5

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Computer based scintigraphic data has been collected and characterized in more than 450 patients with a wide spectrum of functional pulmonary disorders. Algorithms to investigate this data base are under active evaluation. Progress has been made toward the goal of rapid and reliable estimation of pulmonary ventilation-perfusion characteristics. Effort is being directed toward modeling the interaction of several tracer characterized compartments (ventilation, perfusion, inflammation, tissue density).

PHS-6040
(Rev. 10-76)

Project Description

Objectives:

A. To develop and implement computer based scintigraphic data manipulation techniques to investigate time dependent regional respiratory parameters (regional alveolar gas exchange, ventilation-perfusion maps, washin and washout gas flow characteristics).

B. To apply regional descriptors to the analysis of patient clinical status. Modeling techniques are to be employed to describe the functional state of the patient and detect changes in the components of respiratory function (ventilation, perfusion, V/Q, disease activity, degree of fibrosis).

C. To evalute and develop methods of determining regional ventilation to perfusion ratio values. To derive from these regional estimtes of PCO2, PO2, CaCO2, CaO2 to evaluate regional gas exchange characteristics.

Methods Employed:

Scintigraphic studies are performed using the 99m-Tc MAA radionuclide to determine perfusion distribution. Xe-127 gas is administered for the characterization of ventilation. Ga-67 citrate and Co-57 (flood source) are used for disease activity and lung tissue density measurements. All data is collected on a minicomputer and volume information is fed into the data stream to determine respiratory cycle phase characteristics.

Findings:

Gallium 67 citrate correlates with the degree of pulmonary fibrosis and the number of PMN cells determined by analysis of bronchoalveolar lavage. Appears promising as a noninvasive technique to determine cellular infiltration and disease activity (inflammation).

Significance of the Research Program:

There are no other methods for assessing regional pulmonary function. Quantitation of gas exchange and evaluation of the competence of alveolar gas and blood distribution in various pathophysiologic states is now possible regionally. This scintigraphic technique is essentially non-invasive, repeatable and can be performed in all but the most critically ill patients. The technique can be extended to study the effects of exercise and therapy on pulmonary gas exchange.

Proposed Course:

Further efforts in data reduction, model definition and analysis. Work to date has been primarily in methods development. Future work will be centered on the analysis of the interrelationships of the data compartments sampled.

Honors and Awards:

None.

Publications:

Crystal, R.G., Fulmer, J.D., Roberts, W.C., Moss, M.L., Line, B.R., Reynolds, H.Y.: Idiopathic pulmonary fibrosis: clinical, histologic, radiographic, physiologic, scintigraphic, cytologic, and biochemical aspects. Ann. Int. Med. 85: 769-788, 1976.

Dunham, R.G., Line, B.R., Johnston, G.S.: A comprehensive software system for producing functional maps. Proceedings of the Seventh Symposium on the Sharing of Computer Programs and Technology in Nuclear Medicine, Atlanta, Georgia, January 1977.

Kushner, T.R., Line, B.R., Bacharach, S.L., Johnston, G.S.: A spirometric method for gating Xenon ventilation studies. Proceedings of the Seventh Symposium of Sharing of Computer Programs and Technology in Nuclear Medicine, Atlanta, Georgia, January 1977.

Line, B.R., Dayhoff, R.E., Bailey, J.J.: An algorithm for the production of regional gas partial pressures and blood contents from scintigraphic and physiologic data using an alveolar gas exchange model. Proceedings of the Seventh Symposium on the Sharing of Computer Programs and Technology in Nuclear Medicine, Atlanta, Georgia, January 1977.

Line, B.R., Fulmer, J.D., McLees, B.D., Jones, A.E., Crystal, R.G.: The application of scintigraphic image data to a model of alveolar function for the quantitation of regional O2-CO2 gas exchange in human disease. Abstract. Am. Rev. Resp. Dis. 115: 348, April 1977.

Line, B.R.: A command processing system for the analysis of scintigraphic data. Proceedings of the Fifth International Conference on Information Processing in Medical Imaging, June 1977.

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Line, B.R., Fulmer J.D., McLees, B.D., Crystal, R.G., Jones, A.E., Bailey, J.J.: Regional 02-C02 partial pressures and pulmonary venous contents from ventilation-perfusion scans. Abstract. J. Nuc. Med. 18: June 1977.

July 1, 1976 through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

NURSING DEPARTMENT

CONTENTS

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

NURSING DEPARTMENT

I. Department Missions and Goals

The Nursing Department at the Clinical Center exists to provide nursing services to patients and support to their families in a biomedical research environment. In addition to clearly identifiable and time-honored nursing practices, the Nursing Department assumes the responsibility for many expanding nursing activities recognized as physician services through the Joint Physician-Nurse Committee of the NIH Medical Board, i.e., the professional nurse's interdependent role is one of coordination and collaboration in patient care.

In order to achieve the departmental missions, the following goals have been identified and are being pursued:

1. To maintain an environment that supports high morale and a committed, caring performance by all members of the Nursing Department.

2. To improve nursing services to patients and to eliminate those non-nursing activities that are inconsistent with the highest quality of nursing care.

3. To provide, develop, and support the necessary nursing leadership to facilitate care.

4. To evaluate and enhance the effectiveness of the nursing program and individual nursing practice.

5. To identify and investigate areas of nursing research to improve nursing practice.

6. To foster a climate where creative approaches and the spirit of inquiry prevail.

7. To offer opportunities for students and other guests to share ideas and grow in the unique environment of the Clinical Center.

8. To influence health care and nursing practices beyond the confines of the Clinical Center through active participation in professional and community affairs.

II. Major Department Activities

A. To achieve its goals and missions, the Nursing Department has:

1. Implemented the unit manager concept in the Outpatient Department.

2. Recommended the establishment of a Phlebotomy and Urine Collection Team under the direction of the Clinical Pathology Department.

3. Supported the unit dose system.

4. Been actively involved in the computerized Medical Information System (MIS).

5. Made full use of an Administrative Assistant in the Office of the Chief Nurse.

6. Provided the first collaborative program between the Child Health and Human Development Nursing Service and the Neo-natal Nursing Service of the Navy Medical Center.

7. Developed a Patient Classification System to plan nursing care and use available staff more effectively.

8. Reorganized the Nursing Department's committee structure into four broad standing committees: Administrative Policy Committee, Nursing Practice Committee, Education Committee, and Nursing Research Review and Development Committee.

9. Established the Administrative Council as a cohesive corporate body, with comparable leadership groups in each of the nursing services.

10. Recognized that a larger nursing "float" pool of generalists would not facilitate improved nursing care to patients in the environment of the Clinical Center.

11. Selected nine clinical nurse experts and one clinical nurse educator to identify staff learning needs and advise and/or offer educational programs.

12. Continued to experiment with various models of leadership for nursing services.

B. To improve nursing services and professional leadership Nursing Department staff members participated in:

1. The Ad Hoc Committee on Rating Criteria to develop a conceptual model for recognition of the full professional nursing role.

2. The Nurse Career Development Committee, PHS.

3. The Quality Care Assurance Committee and the Joint Physician-Nurse Committee of the NIH Medical Board.

4. The Clinical Center Committee for the Ambulatory Care Research Facility and the Critical Care Medicine Unit.

5. The Easton Update, 1977.

6. The Civil Service Commission's Factor Evaluation System received substantial professional review and recommendations from the Administrative Council of the Nursing Department.

C. As a part of its continuing commitment to influence health care and nursing practices beyond the Clinical Center, dynamic involvement of Nursing Department staff members was achieved through a broad range of professional contacts.

1. Annually, a nursing service chief is appointed to the nursing program planning committee of the Annual Meeting of the Association of Military Surgeons of the United States (AMSUS). This year, two representatives were appointed because for the first time in AMSUS history, a nurse, Dr. Faye Abdellah, Chief Nurse Officer, Public Health Service, will serve as General Program Chairman.

2. The Chief of the Nursing Department has been appointed to the following national committees:

   a. American Hospital Association Committee on Physicians.

   b. National Health Council Board of Directors.

   c. American Nurses' Association Study Committee on Credentialing in Nursing.

3. The Chief of the Nursing Department serves as Consultant to the Surgeon General, U.S. Army for Nursing Service Administration.

4. Staff members serve as program consultants to the V.A. Nursing Service, V.A. Hospital, Washington, and participated in the First Research Conference on Nursing Information Systems sponsored by the College of Nursing, University of Illinois.

5. Staff members delivered papers at the 83rd Annual Meeting of the Association of Military Surgeons of the United States (AMSUS), and the Second National Cancer Conference of the American Cancer Society.

6. Many nurses are active on committees of their nursing associations and other professional organizations.

III. Major Progress in Service, Training and Development and Research

A. Nursing Service

1. Major Progress has been achieved in several ways to improve nursing care in the Clinical Center.

2. Primary nursing continues to be implemented and refined as the modality for delivering nursing care at the Clinical Center.

3. Three clinical conferences were presented. Monographs are being developed for each of them:

   a. Cancer Nursing Service - "Laminar Air Flow - Nursing Care of the Pediatric Oncology Patient." This was later repeated for the nursing community with guests attending beyond our three state area.

   b. Mental Health Nursing Service - "The Consultative Process in Mental Health Nursing."

   c. Child Health and Human Development Nursing Service - "Cystinosis: Family Centered Nursing Care."

4. The Nursing Department co-sponsored with the Association of Pediatric Oncology Nurses a program for professional nurses, "Accepting the Challenge of Pediatric Oncology," November 1976.

5. The centralized Nursing Audit Committee has stimulated the development of 31 outcome criteria sets in patient care areas. Retrospective audit data retrieval was completed on the 11 most frequently admitted patient populations. Data retrieval on the remaining 20 criteria sets continues. The Audit Committee, to share the insights gained from the audit, sponsored a seminar open to our staff and community on, "Nursing Audit: Yesterday, Today and Tomorrow." It was attended by 245 staff and visitors in May 1977.

6. The Outpatient Nursing Service developed a 28 page "Nurse Guide to Cancer Chemotherapy" for use in patient teaching.

7. The Allergy and Infectious Diseases Nursing Service's Committee on Discharge Planning which includes a pharmacist, prepared a patient teaching booklet for use on discharge, entitled "Personal Health Record."

B. Training and Development

1. A department-wide self-paced nephrology nursing course was developed and implemented. Thirty-five professional nurses completed level 1 which was planned to enhance general competencies in providing nursing care to patients with renal problems; additional staff will be offered this opportunity. Participants and extramural consultants have been laudatory. Articles are in preparation for publication.

2. Formal agreements for educational opportunities were effected with the Schools of Nursing at the University of Maryland and the Catholic University of America for master and doctoral level nursing programs. A contract was signed with Marymount College to provide clinical practice experience for students in the baccalaureate program.

3. Forty-two clinical elective students, 18 Co-Step students, and 38 Cancer work-study students, all senior students in baccalaureate programs, were offered clinical practice opportunities.

4. Twenty-six Stride (Marymount College) nursing students are counted against the Nursing Department ceiling while enrolled in their program of study and are unavailable for nursing service. Ten are first year students, twelve are second year students, while five are in the upper level baccalaureate program. Seventeen of these students are from the Clinical Center; nine are from other institutes. Since its inception, 35 NIH employees have been graduated from the two year associate degree program; 31 remain in the Nursing Department.

5. The "brown bag" luncheon feature of the monthly inservice calendar has been extended to "breakfast" and "supper club" conferences to assure broader participation of personnel on all tours of duty. In addition, summer re-runs of significant conferences of the past year have been offered.

6. Many initiatives are extant in the Nursing Department to improve orientation and staff development programs. Among them are:

   a. The complete revision of the general orientation program for professional nurses. The Nursing Department can now bring in new employees twice a month rather than once a month as previously and, in addition to its other subjects, now includes "Legal Aspects of Nursing."

   b. Two nine hour courses were developed and presented by Nursing Department staff members: "The Primary Nurse Role and the Nursing Process" and "Nursing Management for Patient Care." The latter course was primarily for RN's on the Cancer Nursing Service. In addition, a two part course was developed by a clinical nurse expert on "The Nursing Care of the Patient on a Respirator." This course was developed for the nursing staff of the Allergy and Infectious Diseases Nursing Service.

7. A Foreign Nurse Exchange Program sponsored jointly by the Clinical Center, Nursing Department and the National Cancer Institute was initiated. Mr. Peter Barkes from the Royal Marsden Hospital, London, became the first exchange nurse to gain new knowledge and skills in cancer nursing practices in a research setting.

8. A Nursing Department has been created within The Foundation for Advanced Education in the Sciences, Inc. (FAES), the Graduate School at NIH. Eleven courses will be offered.

9. The Chief, Nursing Department, offered three leadership seminars of four two-hour sessions for the Administrative Council and the Evening and Night Supervisors to enhance leadership skills and problem solving in nursing service administration.

C. Research

1. The third research symposium was held in March 1977, "Nursing Research: Issues and Answers" with six nurse scientists participating in the formal program and remaining to assist staff membersin research pursuits.

2. Two staff members completed research projects this year and one nursing service completed an evaluative study:

   a. Miss Dorothy Belling, Clinical Nurse Expert, Heart and Lung Nursing Service, "Arterial Blood Gas Alterations Using Various Suctioning Techniques."

   b. Mrs. Ruth Carlsen, Clinical Nurse Educator, Mental Health Nursing Service, "Nursing Needs Fulfillment."

   c. Allergy and Infectious Diseases Nursing Service, "Evaluation of the Tempa-dot Thermometer."

3. Research projects in progress:

   a. Miss Susan Simmons, Clinical Nurse Expert, Mental Health Nursing Service and candidate for the master's degree at Catholic University, "The Relationship of Rotating Tours to Nurses' Cognitive Capacity."

   b. Mrs. Freddie Grice and Outpatient Nursing Service, "Does Body Position During the Administration of Chemotherapy Make a Difference in the Amount of Duration of Nausea and Vomiting"

   c. Cancer Nursing Service, "An Investigation of Prophylactic Oral Hygiene to Reduce Bacterial and Fungal Mouth Flora in an Effort to Diminish Oral Mucositis Subsequent to Chemotherapy."

D. Significant Awards and Honors

1. Mrs. Josefina Sistoza, Evening-Night Supervisor, was one of 17 PHS Nurses who served in Lebanon in December 1976. She was the recipient of a Special Achievement Award for outstanding services rendered.

2. Mrs. Mary Louise Taylor, Clinical Nurse Educator, Heart and Lung Nursing Service, was the recipient of the recently established NIH Merit Award, the second highest honor award presented by NIH for Civil Service employees. She was cited "for developing and implementing the Nursing Department's instructional program for nephrology nursing."

3. Miss Beth Price, Clinical Nurse Expert, Neurology Nursing Service, received generalist certification in medical-surgical nursing practice from the American Nurses' Association.

4. Mr. Thomas Ralston, Heart and Lung Machine Technician, Surgical Nursing Service, has been certified by the American Board of Cardiovascular Perfusion.

5. Mrs. Barbara Inman, who recently received an associate degree in applied sciences through the Stride Nursing Program at Marymount College, was named to "Who's Who Among Students in American Junior Colleges."

6. Miss Ferguson will receive the honorary degree of Doctor of Science in August 1977 at the Marymount College Commencement exercises of the first B.S.N. students. This is in recognition of her belief in and support of the program as well as serving as a role model.

IV. Future Objectives Directed Toward Meeting Goals

The Nursing Department will continue to strive for excellence in nursing care and support to biomedical research as we assume the full professional role through practice, education and research. We recognize that a dynamic leadership and peer consultation facilitate goal achievement.

No major new programs are envisioned for the coming year, rather a strengthening of those in place with continual evaluation and refinement, an integral part of each endeavor. Special attention will continue to be focused on organization for care, the continued learning of staff and the improvement of communications.

Publications

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RECRUITMENT FACTS

JULY 1, 1976 - JUNE 30, 1977

MONTH	NUMBER OF RN'S INTERVIEWED	ENTERED ON DUTY	*NUMBER OF SUPPORTIVE NURSING PERSONNEL INTERVIEWED	ENTERED ON DUTY	SENIOR STUDENT NURSES ENTERED ON DUTY
JULY '76	41	15	16	4	3 Co-Steps 12 Summer N.A.'s
AUGUST	28	16	12	5	
SEPTEMBER	36	7	11	1	8 Clinical Electives
OCTOBER	36	10	19	1	
NOVEMBER	47	7	13	4	
DECEMBER	32	2	18	6	
JANUARY '77	49	10	12	1	8 Clinical Electives
FEBRUARY	49	12	14	3	
MARCH	42	6	7	2	8 Clinical Electives 5 Co-Steps
APRIL	50	12	8	2	
MAY	61	**14	13	1	8 Co-Steps
JUNE	51	22	23	3	9 Summer N.A.'s 7 Clinical Electives 18 Cancer Work Study
TOTALS	522	133	166	33	

* Supportive Nursing Personnel includes licensed practical nurses, nursing assistants, heart-lung machine technicians and clerk-typists

** Includes ten graduates of the Stride Nursing Program

STAFFING DATA - NURSING DEPARTMENT

	July 1, 1976	June 30, 1977
Total number of positions	611*	627
Total number of positions filled	597*	618
Total number of vacancies	14	9
Administrative		
Total number of positions	22	22
Total number of positions filled	22	20
Total number of vacancies	0	2
Clinical Instructors		
Total number of positions	7	8
Total number of positions filled	5	6
Total number of vacancies	2	2
Nurse Clinicians		
Total number of positions	25	32
Total number of positions filled	23	28
Total number of vacancies	2	4
Staff Nurse		
Total number of positions	324	343
Total number of positions filled	340	352
Total number of vacancies	+16	+9
Practical Nurse		
Total number of positions	44	29
Total number of positions filled	35	29
Total number of vacancies	9	0
Technical Positions		
Total number of positions	8	12
Total number of positions filled	6	11
Total number of vacancies	2	1
Nursing Assistants		
Total number of positions	89	88
Total number of positions filled	81	84
Total number of vacancies	8	4
Clerical		
Total number of positions	51	51
Total number of positions filled	46	48
Total number of vacancies	5	3

*26 students in Stride Nursing Program at Marymount not included

Nursing Department Staff in School

Position	Full Time	Part Time	Stride Program Full Time	Upward Mobility Program
RN	2 *	68	5 **	1
LPN	—	2	5 ***	1
NA	—	5	17 ***	7
Unit Clerk	—	13	3 ***	4
Secretary	—	3	1 ***	—
Heart & Lung Technician	—	1	—	—
Total	2	92	31	13

* 2 RNs fully funded by Nursing Department
** B.S. Extended Program
*** A.A. Program

July 1, 1976, through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

NUTRITION DEPARTMENT

CONTENTS

July 1, 1976, through June 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

NUTRITION DEPARTMENT

I. DEPARTMENT MISSIONS AND GOALS

The Nutrition Department of the Clinical Center assumes the responsibility for the total food service of the patients. The goal of the Nutrition Department is to achieve patient satisfaction while at the same time providing controls and services to meet a wide variety of needs of the research protocols with a nutrition component. To fully implement patient care, diet counseling services are provided for outpatient studies and for patients upon discharge from the hospital.

For a number of years these missions have been accomplished with the use of facilities and staff through decentralized tray service. In 1972-73 an administrative decision was made to change to centralized tray service, and up until May 1977, all efforts were focused on planning, remodeling, and implementing centralized tray service. To achieve this, the following changes were implemented this year:

1. The menus were revised to add items and reduce write-ins. (This required the revision of worksheets for ordering from the main kitchen, revision of recipe files, and revision of work routines to assume additional work load.)
2. Patient nourishment procedures were revised to standardize and reduce the individual preparation from each floor kitchen.
3. A number of individually-packaged food items were purchased

and introduced.

4. A new organizational structure for the total Department was designed,and work routines for 101 nonprofessional staff were written. An additional assistant kitchen manager was recruited to implement the new program.

In December 1976 the remodeling construction in the main kitchen began and during the fiscal year one-third of these remodeling plans were completed. This required complete relocation of staff and cooking and baki equipment and limited refrigeration and freezer space.

In May 1977 the decision was made to eliminate our plans for central ized tray service and to continue with decentralized tray service. This re quired a restructuring of food service worker positions in the Patient Diet ic Service by utilizing 35 hour positions on the late shift. This was init ted September 11, 1977.

The Department's goals include active participation in the Clinical Center Safety Program, the Clinical Center Equal Employment Opportunity Program, and the NIH Labor Management Relations Program.

II. DEPARTMENT ACTIVITIES

During the period July 1, 1976, through September 30, 1977, the Nutri tion Department served 436,837 meals. Twenty-seven percent of these meals were a part of a research protocol having a nutrition component. These prot cols involve the control of nutrients, calories, fluids, and/or metabolic studies. To provide these services, 13 individual service units and a main kitchen and storeroom were staffed for 15 months, and the 8th floor metabolic kitchen was operated for 13 months. These kitchens were staffed with:

101 food service workers
13 cooks and bakers

7 metabolic cooks
42 nonprofessional supervisors (dietetic assistants and kitchen managers)
9 clerical staff
22 registered dietitians

194 Total

During the 15 months of this fiscal year, 35 food service workers were on temporary appointments not to exceed one year. As of September 11, 1977, these positions were converted to part-time career conditional appointements (35 hour).

Two major decisions affecting personnel were made during this year. On August 1, 1976, the Civil Service Commission ruled in favor of the dietetic assistants' appeal and granted them grade classifications of GS-05 and GS-06. In October 1976, in a case brought to arbitration by AFGE, Lodge 2419, the decision was made that under the present negotiated agreement, a union officer would be permitted time to investigate a grievance before it was documented in written form.

The total expenditures for the Department for the 15 month period were:

Personnel	-	$3,457,650
Food	-	767,595
Equipment and Supplies	-	151,770

III. MAJOR PROGRESS IN RESEARCH, SERVICES, TRAINING, AND DEVELOPMENT

During this period on a daily basis, 16-25 patients were on Category IV diets, 73-91 patients were classified as Category III, and 88-111 patients were classified as Category II.*

* Category IV — Requires extensive professional time and care in planning diets which are an integral part of the research sutdy.

Category III — Requires professional staff to plan the diet order for the individual patient and to provide the physician with information to interpret his project.

Category II — Requires professional staff to write the diet, or food service supervisor to adapt the food service to the patient.

In addition, the Nutrition Department provided these additional se essential to the control of a number of protocols:

1. An average of 53 patients were on fluid intakes each day.
2. An average of 33 patients per day were on diets that required the accurate measurement of all food eaten.
3. An average of 81 patients were on diets each day that required the checking back of each meal tray and replacement of the appropriate nutrient being controlled by dietary intake.

The Laminar Flow Unit has serviced an average of 3-4 patients durir this period. Because of the extended length of stay, in July 1976, the cooked food diet was expanded to include additional specialty items. This change in procedure brought about an increase in petty cash purchasing, wh involved additional services from Financial Management staff and NIH Messe

Plans for a dietitian's office to provide diet counseling were made with the ACRF architects. Plans were also made with the ACRF architects t provide office space and teaching lab space for two dietitians and clerical staff.

To assist NICHHD with implementing their premature baby program, we provided their food service from the metabolic kitchen unit and located and purchased a number of special products such as a special demineralized infa formula for treatment of ideopathic hypercalcemia.

The period October 1976 through February 1977 was devoted to evaluat usage and adequacy of matrices originally designed with the Technicon repre sentative. A number of changes were requested. It is anticipated that thes changes will be made by October 1, 1977. Prior to December 1976, all dietit ians were trained to use the Technicon equipment. Five meetings were held with the Technicon staff to evaluate and identify requests for change in the matrices and in July 1977, a member of the professional staff joined the weekly advisory group.

Considerable emphasis has been placed on training for all groups in the Department. Two meetings per month were held for the professional staff with speakers invited for one of these meetings. In addition, plans were made to provide training experiences for appropriate staff members as a means of improving our service and to become aware of recent advances in the area of nutrition.

This year we have sponsored staff in the following training programs:

6 staff in Adult Education

3 staff in Upward Mobility College

1 assistant kitchen manager completed a two-year program and received an Associate of Arts Degree in Food Management

1 secretary completed a stenoscript class.

11 staff participated in the Clinical Center Leadership Training Program (including Motivational Dynamics)

7 Information Sessions were held for the entire Nutrition Department staff which included a recent health film and a report from the Nutrition Department Representative to the Clinical Center EEO Advisory Committee.

The Department provided consultation to 90 dietitians and college students throughout this year. Each has spent an average of three hours in the Department.

The dietitians and kitchen manager staff participated in six national meetings during this period.

A senior member of the staff has served as a member of the Advisory Committee to the Clinical Center's Patient Representative.

IV. FUTURE OBJECTIVES DIRECTED TOWARD MEETING GOALS

During this next year we expect to accomplish the following:

1. Finish the remodeling of the main kitchen and reestablish a quality controlled decentralized food service for the patients of

the Clinical Center.

2. Implement a program to develop diet instruction materials and procedures to be used in the Diet Instruction Service in the new ACRF Building.
3. Reveiw the Nutrition Department matrices and make changes to mee the needs of the new Institute that will be planned by Technicon during this next year.
4. Renegotiate the current agreement with AFGE Lodge 2419.
5. Reestablish an extensive inservice training program for nonprofes sional staff.

V. PROBLEMS

Many problems have been experienced this year with personnel. We ter to have 1-2 employees on jury duty throughout the year and 1-2 employees on leave due to long-term illnesses. The use of temporary appointments of food service workers has contributed to a high turnover rate.

Remodeling has required a number of adjustments for the Main Kitchen staff. With careful planning this has been achieved with minimum inconvenie to the patients.

The demand for outpatient diet instruction as a part of the new protocols has presented a need for a full-time dietitian to be assigned to these programs and office space assigned.

Many of the companies that service the Nutrition Department have initiated new service procedures as a result of the energy crisis, which has presented problems to us. For example, Ross Laboratories will accept an order only once a week, which prevents our being able to be responsive to the need for a new product not routinely stocked.

To assure the accuracy of studies we have to assume the responsibility of monitoring labels and products. In August 1976 upon analysis of the Salt Free Bread, we found the levels of sodium too high. Upon investigation we found a subcontractor was involved and that he had not adhered to the established formula.

The United Parcel Service strike influenced the increase in food costs. It forced us to use air freight on a number of occasions resulting in added expense and the need to increase our inventory on some food items.

July 1, 1976, through June 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

OFFICE OF OCCUPATIONAL MEDICINE

CONTENTS

July 1, 1976, through June 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

OFFICE OF OCCUPATIONAL MEDICINE

Department Missions and Goals

The Office of Occupational Medicine, through programs executed by the Occupational Medical Service, has several primary goals to provide a medical program to assure that employees are able to perform their duties without hazard to themselves or others: optimum job assignments in relation to medical fitness; emergency and preventive medical services to assist employees to meet their work related health needs; medical monitoring for adverse effects related to environmental health hazards including biohazards, toxic chemical hazards, and radiation hazards; and clinical consultation for occupational disease and exposure to toxic agents both for employees and Clinical Center patients at the request of Institute clinicians.

The Chief, Office of Occupational Medicine, in his additional role as NIH Occupational Health Officer, serves as the Project Officer for the Occupational Medical Service contract. He serves as the NIH Director's delegated official to monitor relationships between the contractor and NIH management and staff. He promulgates guidelines and practices to insure NIH compliance with the regulations of the Office of Workers' Compensation Programs, Occupational Safety and Health Act, and directives of the Civil Service Commission. Through personal observation, regular conferences, review of required reports submitted by the contractor, and various program effectiveness surveys, compliance with contract specifications is also insured.

The Occupational Medical Service is also responsible for maintaining essential services and facilities to provide emergency treatment for on-the-job illness or injury of employees, providing health education and preventive medical programs to make employees aware of the importance of maintaining good health, advising management and employees in resolving work related health problems, assisting management in evaluating handicapped individuals in terms of specific job assignments, developing and executing a comprehensive mental health program including alcoholism and drug abuse, and planning and carrying out medical surveillance and monitoring programs designed to minimize environmental health hazards. Close working relationships are maintained with the Division of Personnel Management, the Environmental Health and Safety Program, DRS, and NIH Institute Clinical Directors.

On July 1, 1977, the Employee Health Service title was changed to Occupational Medical Service. This change more accurately reflects the basic mission of the program as a provider of both therapeutic and preventive occupationally related medical services. The Occupational Medical Service includes all elements of the Federal Employee Occupational Health Program as specified by Executive and HEW Directives.

Department Activities

In the third year of the Occupational Medical Service contract, the departm continued and strengthened those programs initiated during the first two ye of operation. Dr. Barbara Wasserman, Assistant Medical Director, is Board Certified in Internal Medicine and has had six years of Occupational Medici experience. Dr. Wasserman assumed her duties with the OMS staff in May 197 following a year as Director of Clinical Services at University Health Cen University of Maryland. She has strenghtened the OMS clinical care program and is currently planning preventive health programs in the area of hyperte sion, rubella screening, and medical monitoring of personnel engaged in re- combinant DNA research activities.

Beginning in February 1977, the Medical Director, with the Chief, Office of Occupational Medicine, began meetings with Clinical Center Administration ar NIH Space Management and Architectural Engineering consultants to plan for relocation of the OMS due to construction of the Clinical Center Ambulatory Care Research Facility. Additional space adjacent to the Building 31 Healt Unit was allocated and it is anticipated that within the next 12 months OMS in Bldg. 10 will move to that area. An extensive review of equipment re- quirements was conducted, and suitable medical records storage and retrieval system was obtained from surplus for the relocation. Line drawings were pre pared and submitted to Facilities Engineering to allow allocation of proper functional space within the new area.

The Department participated actively in the preparation of three significant NIH Manual Issuances. Each reflected the policies and orientation of the OM in providing complete, responsive Occupational and Preventive Medical Progra for NIH employees. The Manual Issuances published during this reporting per were the following: (1) No. 2300-792-1 NIH Occupational Medical Services Pro released 9/27/76; (2) No. 2300-792-2 Employee Alcoholism and Drug Abuse, re- leased 2/7/77; and (3) No. 2300-339-1 Fitness for Duty Examinations, release 5/25/77.

Working closely with the Chief, Negotiated Contracts Section, ODA, an updat Request for Proposal (RFP) was prepared by the Occupational Health Officer ir accordance with HEW Instructions for soliciting proposals for renegotiation of the OMS contract. In preparing the technical requirements, careful consid ation was given to include the most advanced "state of the art" developments in the field of Occupational Medicine to insure that NIH, as the nation's maj health research facility, will continue to provide its staff the benefits of comprehensive, consistently outstanding, occupational and preventive medical program. Under the chairmanship of the Occupational Health Officer, a Tech- nical Factors Evaluation Committee, composed of outstanding specialists in th field of Occupational Medicine, carefully reviewed submitted proposals, follo ing criteria clearly stated in the RFP, and concluded that the present con- tractor's proposal was the most acceptable. The Committee felt confident tha National Health Services, the present contractor, has the capability and resources to execute an outstanding Occupational Medical Program for the National Institutes of Health.

Major Progress in Research, Services, Training, and Development

The average monthly frequency of employee visits to the OMS is essentially the same when compared to the previous year's report. A significant gain was made in the area of alcoholism and drug abuse now titled Public Health Employee Assistance Program. Six percent of the workload fell into this category. There was a three fold increase in alcohol and drug abuse related treatment visits. This reflected a major training effort as well as increased activity on the part of the psychiatirc staff and counselor. The other categories remained essentially the same with a slight decrease in personal visits and an increase in visits related to specific preventive medical programs. (see attached table)

During this reporting period, all workload data for the OMS was entered into the OMS Workload System. This computer system is a basic package utilizing an IBM 2741 Remote Terminal, DCRT Honeywell Computer, and the Wilbur System. To save running costs, edit programs were run during evening hours for a 20% reduction. This system provides the following: workload on a monthly basis and annual reporting required by the Civil Service Commission, epidemiological data including rates by location, occupational category, and Institute; periodic scheduling 1-365 days; and monitoring of Office of Workman's Compensation Programs actions. During the year additional programs were written and specific queries made to the data bank. OMS was the only user authorized to meet Privacy Act requirements that were reviewed by DCRT and the Clinical Center Privacy Act Coordinator.

During this reporting period, the Occupational Medical Service became one of the first Clinical Center Departments to use the Medical Information System (MIS). OMS cadre worked with the MIS contractor to develop an operations manual and trained physicians, nurses, and health technicians in the use of the System. During the entire reporting period, OMS has used the MIS for requests to Radiology, Blood Bank, and Central Sterile Supply. The System has proved efficient, and its utilization has been professionally stimulating to the OMS staff. However, MIS as used by OMS is not designed for records retention, so employee entries as patients are deleted after five days from the last change of record or report.

OMS participated in the realignment and redesignation of responsibilities among Clinical Cneter committees. Changes came about as a result of concern for the safety and health of patients and employees. OMS continued to provide preventive medical services for Clinical Center employees. In July 1976, Clinical Center Safety Planning Committee, which had previously been concerned mainly with disaster planning and fire safety, changed its name to the Multi-disciplinary Safety Committee and assumed an expanded role in safety and health for Clinical Center employees. The Medical Director, OMS, participated actively in this Committee in evaluating programs for the continued health of all Clinical Center employees. In February 1977, the Clinical Center Infections Committee was restructured and OMS was asked to participate as an Ad Hoc member, working closely with the hospital epidemiologist to provide input and participation in Committee deliberations.

The Medical Director, Psychiatric Consultant, and Mental Health Counselor participated in the education of NIH administrative and supervisory staff to

implement the NIH Alcoholism and Drug Abuse Program. OMS expanded this prog to meet the guidelines of the Public Health Employee Assistance Program deal not only with alcoholism and drug abuse, but the entire spectrum of mental h problems. Training courses and orientation seminars were held for all BID Personnel Officers, DPM Branch Chiefs, EEO Coordinators and Union Representa tives. Following this orientation, ten groups of first-line supervisors re- ceived training. These training programs consisted of two hours of formal didactic orientation, followed by discussion. The success of this orientatic and utilization of the program was reflected in increasing numbers of referra and visits to the mental health counselor and psychiatric consultant.

In August and September 1976, Occupational Medical Service nurses participate in a testing program for Swine Flu vaccination conducted by the National Inst- tute of Allergy and Infectious Disease. This program tested vaccines on different age groups of employees, monitoring the effectiveness of vaccine ar the dosage to be used in the program. In October 1976, OMS conducted health education programs through the NIH news media, which outlined availablitiy of vaccine for the NIH population. During the early part of the program, bivale vaccine was obtained from the Montgomery County Health Department to immunize laboratory workers who conducted research using the A Victoria Strain in ex- perimental subjects. (The month of November saw the culmination of several weeks of planning) OMS used a team approach to schedule immunizations in the health units as a convenience to the NIH population. An OMS physician super- vised the immunization team and reviewed requirements for bivalent vaccine. The program was accepted well by NIH employees and a total of 5,669 received the influenza vaccine. The percentage of acceptance in the NIH population fa exceeded that in the surrounding communities. It was felt that this reflecte the scientific interest of the NIH population and the convenience of the pro- gram. No central nervous system problems were diagnosed in vaccinated NIH employees.

Future Objectives Directed Toward Meeting Goals

Occupational Medical Service intends to continue to support surveillance examinations of employees exposed to hazardous work environments both in the patient care area and research. OMS will also continue working closely with the NIH Biohazards Committee and the Environmental Health and Safety Program, DRS, for early identification of hazards. The OMS medical staff will remain cognizant of infectious agents, oncogneic viral agents, and chemical carcino- gens in research. In particular, since OMS anticipates the rapid development of protocols for medical surveillance in recombinant DNA research, the staff will develop surveillance standards which will be as specific to the exposure as scientifically possible. Coordination with NIH scientists in intramural and extramural programs will be maintained to assure knowledge of the latest research and clinical developments in the area of carcinogensis and infectiou diseases. The emphasis will be on aspects of prevention with consideration of environmental controls as well as biologic monitoring.

Occupational Medical Service will expand its role in the treatment and counse ing of employees with non-occupational illness. Specifically, problems re- lated to monitoring illness and liaison with personal physicians and communit medical care services will be explored to establish a program of hypertensive

screening and hypertensive control in the work setting. The control of hypertension in the work setting is of current interest to the National Heart, Lung and Blood Institute, as well as the American Academy of Occupational Medicine and the American Occupational Medical Association. Many on-going programs have been formulated in private industry and interest is developing in the Federal sector. The OMS program will be coordinated closely with NHLBI and their Interagency Technical Committee on Hypertension. Guidelines for the care of hypertensives among Federal employees will be reviewed and applied in the development of this important preventive medical program.

Occupational Medical Service will expand the current Alcoholism and Drug Abuse Program to meet objectives of the recently established Public Health Employee Assistance Program. Two trained mental health counselors with experience in alcoholism and drug abuse have been assigned to the Program, as well as other areas of mental health, and this will allow expansion in the areas of education, treatment programs, and hours of medical support. One important future aim is to reach a higher percentage of upper grade employees. Occupational Medical Service recognizes this will require coordination particularly with Employee Relations and Recognitions Branch, DPM, and other units of PMB.

SELECTED WORKLOAD STATISTICS JULY 1976 - JULY 1977

	Total Visits	Average Monthly Frequency	Percent of Workload
Occupational Injury	3,137	262	9
Occupational Disease	966	81	3
Preventive Medical Visits	19,939	1,662	56
Personal Visits	9,347	778	26
PHEAP (Public Health Employee Assistance Program)	2,278*	189	6
Total Visits	35,667	2,972	100%

*Includes 1,630 visits for alcohol and drug abuse

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PROGRAM OBJECTIVES

The overall objective of the Outpatient Department is to give administrative support and to assist the professional members of the Clinical Center staff to provide excellence in patient care.

The following are the individual objectives for each section, which individually and collectively meet the overall objectives of the Department.

Admissions - The objective of this section is to admit both the inpatient and the outpatient in the most expeditious manner possible, ensuring that all information received and transcribed is accurate.

The Clinics - This section provides a setting in which physicians are able to conduct examinations and/or treatments of ambulatory patients on a timely basis, with assistance from other members of the Clinical Center staff.

The Travel Office - This section provides and arranges transportation for patients of the Clinical Center, taking into consideration the patients personal needs, comfort, and care, when and if medical problems are present.

Special Ambulatory Care Program - The objective of this program is to offer participating Institutes and physicians a method of treating ambulatory patients, not living within a comuting distance, on an Outpatient basis.

Local Transportation - The objective of this section is to provide transportation for patients, when the patient is essential to a study, and cannot provide his own.

Messenger and Escort Service - This section's objective is to transport patients and specimens expeditiously, always mindful of the necessary safety measures to be taken during the transportation.

DEPARTMENTAL ACTIVITIES

These activities are designed to meet the overall objectives of the Department as well as those of the individual Sections to provide the support necessary for the highest quality patient care.

1. To maintain the maximum productivity of the employees within the Department.

2. To fully implement the centralized appointment system for all the Institutes and to make refinements to meet the needs of each clinic.

3. To refine the supply system.

4. To increase the number of patients preadmitted to the Clinical Center so that the patients spend less time in the Admissions Office.

5. To reorganize the Admission Office by extending the coverage to twenty four (24) hours a day, seven (7) days a week.

6. To establish a training program in public relations, telephone procedure interviewing techniques, etc. for all clerical employees within the Department.

7. To assist the architect in the redesign of the Outpatient Department to increase treatment space and relocate some of the ancillary services to the main clinic area.

8. To expand the hours of coverage of the Messenger and Escort Service.

9. To purchase a computerized reservation system for the Patient Travel Office.

10. To inform the Institute physicians of the rules and regulations of the Special Ambulatory Care Program, the Travel Section, and the Admissions Section.

11. To effectively reduce the money spent on travel, and the Special Ambulatory Care Program, without curtailing patient care.

PROGRESS ACHIEVED

1. Some of the training programs to improve the output of work of the various employees of the Department are: Inservice training sessions (especially for the Outpatient Unit Clerks), participative management, and individual counselling sessions. This process is an indefinite one, as it is difficult to place limitations on it, if it is to be successful.

2. The centralized appointment system has been implemented for all the clinics currently using the main clinic. Currently we are refining individual clinics from block appointments to individual times for the patients.

3. A full-time supply technician has been hired, who will be helped by several students in the Stay-in-School Program. At present the examination room maintenance part of the system has begun. This was the last administrative function that nursing service was performing.

4. The number of preadmissions made by the Admissions Office is approximately 85 percent. This is an increase of 39 percent from last year. This means a patient may not have to spend more than five minutes in the Admissions Office before either going to the Clinics or to an inpatient nursing unit.

5. The reorganization of the Admission Office began in May, 1977. As a result of the reorganization, Admissions staff have a variety of functions; admissions, information duties, handling various clerical tasks which were performed by the Administrative Officer of the Day heretofore. Also, a policy and procedure manual has been developed and is being used by the clerks.

6. This course will begin in September, 1977. Since most of our work is the initial contact point between the public and NIH, we thought the course would be quite beneficial.

7. Since the Ambulatory Care Research Facility will not be completed until 1981, the present space allocated to the clinics is not large enough for the expected influx of patients through the next several years. Because of this, an architect was hired to design an expansion of the Outpatient Department. Included within this design is the concept of centralization of as many of the ancillary services as possible, or to provide satellite coverage within the clinic proper.

8. The Messenger and Escort Service provided its service on an 8:00 a.m. to 4:30 p.m. tour of duty Monday through Friday. The service is now available seven days a week from 8:00 a.m. - 11:00 p.m.

9. A contract was let with United Airlines to lease their Apollo System, a computerized reservation system. This system will effectively reduce the hiring of additional staff and the amount of time needed to process the paperwork in the office. The Apollo System will be installed September 9, 1977.

10. The physicians of the various Institutes who are authorized to use the Special Ambulatory Care Program were oriented by the supervisors of the SACP, Travel, and Admissions Sections. This is an ongoing program for all new Clinical Center associates.

11. One of the measures taken to reduce the monies spent was to decrease the number of guardians (escorts) of patients transported to the Clinical Center and placed in the SAC Program. In addition, another was to more strictly enforce Travel and SACP regulations.

OTHER ACTIVITIES

1. The Department has been involved with the architects in the design and development of the Ambulatory Care Research Facility.

2. The Department has been involved with the personnel from Technicon concerning the Hospital Information System and its interface with the Admissions Section, the Clinics, and other Clinical Center Departments.

PLANS

1. To continue to refine the centralized appointment system used by the various clinics.

2. To reorganize the clinic schedule so that the patient flow is more evenly distributed.

3. To further refine the supply system in the Outpatient Department.

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PATIENT SERVICES DEPARTMENT

GENERAL

In June 1976 physiological monitoring responsibilities transferred from the Nursing Department to an independent Section within the Patient Services Department. The Department is now composed of the Anesthesia Support Section, the Normal Volunteer Program, the Patient Activity Section, the Physiological Monitoring Section, the Respiratory Therapy Section, and the Television Engineering Section.

Within the Patient Services Department's responsibilities is management of the anesthesia contract with Georgetown University. Dr. George W. Shaffer, Chief, Patient Services Department, is project officer for this contract and Mr. Thomas Johnson, Administrative Officer, is the alternate project officer.

The administrative aspects of the clinical service provided by a nephrologist consultant, Dr. James Balow, NIAID, are also the responsibility of the Patient Services Department. The technician assigned to work with Dr. Balow is an employee of the Department.

Anesthesia Support Section

The four nurse anesthesists who were members of the Patient Services Department have transferred from NIH or resigned from Civil Service. Their responsibilities have been assumed by members of the Georgetown University contract staff as required in the contract.

The slots vacated by the nurse anesthesists have been transferred to the Patient Activity Section and the Respiratory Therapy Section.

Mr. Charles Brooks has been appointed as supervisor for the anesthesia technicians who are members of the Patient Services Department.

Normal Volunteer Program

Normal Volunteers are healthy individuals who have been admitted to the Clinical Center in order to serve as a volunteer subject for approved

research projects. The Normal Volunteer Program is responsible for recruiting volunteers through contracts with sponsoring agencies. This Section audits utilization practices of volunteers after their assignment and is responsible for the career experience aspects of the program.

During the past year, there has been an overall increase in the number of normal volunteers in all categories - inpatient, outpatient and off-si An estimate of the number of volunteers used by each Institute is indicated on Chart A.

The volunteers are from nine to seventy-six years of age with 26.30 years being the average. The average age of the college age volunteers - who represent 61.50% of all volunteers - is 22.53 years.

This year there have been more male than female volunteers. The reason for this reversal from last year is that medical research investigators have been requesting more males and more males have been applying to become volunteers.

Volunteers often spend their free time working in career development programs in laboratories, offices, and other available facilities in the Clinical Center. These experiences give volunteers a glimpse of what they might expect in a particular career.

All volunteers, with rare exception, take career assignments. During the past winter, the program was seriously jeopardized when an administrative personnel decision in one of the Institutes questioned the legality of normal volunteers working in their laboratories. Their position was/is that there is no provision in the personnel code that covers the situation and NIH would be liable if a volunteer were injured. A "temporary go-ahea provision has been endorsed pending a regulation which would permit volunt to continue learning in the labs.

Six contracts have been terminated because they produced very few volunteer Those closed are the Phoenix Indian High School of Phoenix (this closure was recommended by the NIAMDD administrative office in Phoenix), Washingto International College, Johnstown City and County Clinic, Inc., Beloit College, Sterling College and the Gila River Indian Community. The loss of these resources will have no detrimental effect on the program. A new contract with Gustavus-Adolphus College, St. Peter, Minnesota was completed the first part of this year, and their first students entered the program this summer.

Negotiations with medical and administrative personnel of Dartmouth University, Hanover, New Hampshire are in progress and should be completed in time to admit the first students from there in September 1977. Also, a new contract with "Phoenix Service Unit, Indian Health Advisory Board, In of Phoenix, Arizona, recently became operational. These new resources alon with existing ones are adequate enough to allow us to meet our volunteer needs. If the existing resources should not be adequate, there are three other colleges who wish to negotiate a contract.

The Division of Management Survey and Review completed their survey of the Normal Volunteer Program. The findings were not significant although they helped us revise a particular form for the Outpatient Department - Off-site Section of this program.

TV Channel 4 (NBC) is tentatively planning to do a late Saturday night presentation of the Normal Volunteer Program.

Patient Activity Section

The Patient Activity Section offers Clinical Center patients a diversified, patient-centered program of therapeutic recreation activities (social, music, arts and crafts, adapted sports, and dramatics), active and passive, on and off the reservation. The activities are offered to all patients in the Clinical Center, at outdoor areas on the Reservation, and in selected local sites. All programs were organized, executed, and evaluated under the guidance of a professional staff of Therapeutic Recreation Specialists and Assistants. Patient interest in the program continued to grow, and their realization of the value of recreation as a vital part of their rehabilitation and "daily living" pattern helped them to better tolerate their research protocols and to make better use of their leisure. Approximate 76% of the patient population this year became involved in our program.

With the addition of two full-time positions, the Patient Activity Section is able to provide full-time coverage of three Mental Health Units and in pediatric oncology. Full-time coverage is also provided on the Neurology Units and the West Wing Outpatient Clinic. Part-time coverage is provided on other Mental Health Units and in the Cancer Units.

A special program has been initiated on a part-time basis at the United Inn for the SACP patients and their families. Featured activities utilized motel facilities or featured trips into the community.

In addition to topical social and recreational programs, the Section has a special program entitled "A Happening." The focus of this program is geared to special interest groups. Activities include lectures, concerts, tours, and "special" trips. Attendance was small again this year, but the activity seems worthwhile enough to continue.

The children's program staff was instrumental in the design of a playroom and therapeutic recreation program on the new Pediatric Unit. The Patient Activity Section is working closely with the nursing staff on this unit in striving for the optimal approach to various child patients. The therapeutic recreation staff provides unit programs when appropriate and provides individual (one-to-one) contact with the children when necessary either because type of treatment or other special circumstances.

In addition to repeating the Jacques Cousteau film series, "Undersea World," a Classic Film Festival was initiated this year. This film series featured three - four week "theme" programs which included: 1) Classic Horror Film Festival; 2) Alfred Hitchcock Classic Films; and 3) Classic Comedy Series.

Community support via free tickets to theatres and concerts, gifts, and their response to recreational needs, especially at holiday time, was overwhelming.

The Patient Activity Section has an active student fieldwork/internship program. This year seven recreation majors came to the Clinical Center for their fieldwork/internship studies. Five of the students were from the University of Maryland, two from Florida State University, Tallahasse, Florida and one was a graduate student from Springfield College, Springfil Massachusetts. These students were given a complete exposure to the tota therapeutic recreation program, as well as other related Clinical Center disciplines including: OT, PT, Social Work, Spiritual Ministry, etc. The stay lasted from three to six months, depending upon the particular schoo curriculum requirement.

One of the University of Maryland fieldwork students, as part of her assignment within the Section, implemented a Patient Activity Section Int Survey. The results were as follows:

1) 56% (or 206) of the patient census (370) were surveyed.
2) 96% were aware of the recreation program.
3) 73% actually participate in the program.
4) Arts & Crafts is the most popular (26%) activity.
5) 38.5% became aware of activities via the Patient Activity Section Week Bulletin.
6) 91.7% are aware of the Patient Library, and 47.1% visit the Patient Li
7) 54.9% use the bookcart visits as their library contact.

Statistics: There were 5,407 adult patient activities, with an average o 14 activities per day. The average daily patient participation was 188 a the average participation per programmed activity was 14. There were 7,754 children's activities, with an average of 20 activities per day. Th average daily patient participation was 76, and the average participation per programmed activity was 4. The increase in the average number of activities and the average daily participation has risen considerably ove the past year because of the increase in "bedside" programming.

Patti Lutz, Therapeutic Recreation Specialist, was listed under "acknowle ments" in a paper written by Dr. Eric Caine on Huntington's Dementia for the Wexler Adult Intelligence Scale, which she administered on her own ti to patients on a mental health unit.

Members of the Patient Activity Section are involved in non-Clinical Cent professional activities such as:
The Executive Board of the Therapeutic Branch of the Maryland Recreation a Parks Association; meetings preparing for the White House Conference on the Handicapped held in May 1977.

The Chief, Patient Activity Section is involved in the following activitie Chairman, Therapeutic Branch, Maryland Recreation and Parks Association, Steering Committee and Education Session; Chairman, National Recreation and Parks Association Mid-Atlantic Forum on Innovative Programming;

Member, Program Committee and Educational Session; Chairman, Maryland State Conference on Recreation; Steering Committee, Mid-Eastern Symposium on Therapeutic Recreation.

Patient's Library

The Patient's Library added 502 new books to the collection this year to bring the total to 6,954. The 9,651 patients who visited the library increased the circulation to 16,146, an increase of more than 3,000 over last year. Magazine circulation also increased from 799 to 805 per month.

The Bedtime Story Hour continues on Wednesday evenings with the assistance of a Red Cross Volunteer and Normal Volunteers. Six Red Cross Volunteers also assisted the library staff in various library services including taking bookcarts to nursing units.

Mrs. Swim, Library Supervisor, was an integral part of the Mental Health inter-disciplinary team in a study of hyperactive children. Mrs. Swim worked with 30 different child patients, two per week, for approximately 2-3 hours per week. She was required to evaluate their reading ability, chart the general reactions of the patient during library activity periods, and to relay specific patient behavior in relation to the type or quality of drug intake.

Physiological Monitoring Section

The Physiological Monitoring Section transferred to the Patient Services Department from the Central Nursing Service in June 1976. The Section is responsible for supplying and applying physiological and metabolic monitoring equipment for Clinical Center patients. Services are provided from 7 a.m. to 12:30 a.m. Monday through Friday and on an on-call basis at all other times.

This Section has provided care for an increasing number of patients. With the upcoming addition of a medical intensive care unit and the expansion of the surgical intensive care unit, a critical need for more skilled technicians is anticipated. Immediate recruitment of at least two individuals with a sound background in patient care and monitoring instrumentation should provide the high quality of patient care necessary.

The statistics in Chart B indicate a marked increase in the services provided by this Section.

Respiratory Therapy Section

The Respiratory Therapy Section provides respiratory care treatments for Clinical Center patients.

During the past year, this Section has extended its coverage to provide an

in-house technician at all times except between the hours of 12 midnight through 8 a.m. Saturdays, Sundays, and holidays. A technician is availab at these other hours on a rotating on-call basis.

The Section now performs blood-gases for the Anesthesiology Service. The established hours for this service, from 8 a.m. to 4:30 p.m., fluctuate t conform to research studies.

All members of this Section are receiving training from the Rehabilitatic Department in techniques of performing chest physical therapy. Training should be completed by July 18 at which time the Respiratory Therapy Sect will assume complete responsibility for this service.

A contract agreement has been signed between Columbia Union College and t Respiratory Therapy Section. The purpose of the affiliation, which began in May, is to provide clinical experience for students enrolled in degree programs in respiratory therapy at the college. The training offered the students is in areas specifically requested by the college. There is a specific curriculum for each of the college levels.

As a result of the newly assumed duties of this Section, i.e., additional coverage, the academic affiliation, and chest physical therapy, the staff has been increased by one full-time, permanent position and four part-tim permanent positions.

Television Engineering Section

The Television Engineering Section has worked with the NIH Library to establish a location for viewing videotapes, to place selected Television Engineering videotapes in circulation for viewing by Clinical Center staf and to plan for a cooperative effort with NLM to access their videotape library to make it directly available to Clinical Center staff.

The Section collaborated with Diagnostic Radiology and the Biomedical and Instrumentation Branch, DRS to develop the circuitry which would provide te necessary synchrony for every television frame to record one complete ultra scan. Playback from videotape and transfer to the videodisc permits discr portions to be selected for stop or slow motion analysis.

As a representative of an ad hoc committee on the Patient TV System, this Section will be responsible for providing technical expertise and input fc the planning of the closed circuit channels.

An additional X-ray room in Diagnostic Radiology has been equipped with the Image Intensifier Video System and intercom system which connect with the Television Engineering Control Room for instant recording and direct communication with Television Engineering personnel. This is the fourth room in Diagnostic Radiology to be equipped with these capabilities.

Engineering support has been given the Diagnostic Radiology Department in the evaluation of the television images produced by the EMI head and bo scanners.

Existing television cables were relocated to connect the Diagnostic Methodology Section, NIDR, to Television Engineering. This collaboration was mutually advantageous in that the full capabilities of Television Engineering were immediately available to Diagnostic Methodology and Television Engineering had access to the unique digital transforms available through computer processing in Diagnostic Methodology.

Television and audio cables between Television Engineering and the Nuclear Medicine Department were reactivated to provide the capability of videotaping and video analysis. Computer generated ventricular scans are converted to the television format for storage, labeling, and replay to the heart cath conferences. These data are also available for direct replay into the surgical area if a visual refresh is necessary during open heart surgery.

The analytical facilities of this Section have been used in the analysis of the opacified ventricle in 35 dog studies conducted by NHLBI.

In collaboration with the Clinical Hemotalogy Branch, NHLBI, drawings and tracings representing clumped erythroid colony boundaries are analyzed in Television Engineering by the recently acquired commercial video analyzer. Preliminary investigations are being made to the direct determination of area from the microscopic image by placing a television camera on the microscope. This would eliminate the need for tracing and would permit area data to be acquired directly from the video image.

The use of a low light level television camera to locate and define the intercellular spaces of flat epithelia has been undertaken in cooperation with the Kidney and Electrolyte Branch, NHLBI. The use of television in conjunction with a photomultiplier tube has facilitated the repositioning and verification of exact area of interest surrounding the intercellular space. Photographs can be taken from the television image or videotapes can be made for repeated analysis of this image to determine differential reaction within the field.

During the past year, the Television Engineering Section continued its participation in the following collaborations:
- With the Cardiology Branch, NHLBI, producing ventricular determinations and net forward ejection fractions for information on the condition of heart patients.

- With the Surgery Branch, NHLBI, providing visual coverage of the surgical field with surgeon's audio and neurosurgical operating procedures while simultaneously analyzing heart catheterization material.

- With Clinical Neurosciences Branch, NINCDS, study of cortical metabolism in cats monitoring levels of NADH oxidation using a television fluorometer system to detect reflected and fluorescent light emitted from the exposed cortex.

- With Collaborative and Field Research, NINCDS, obtain information on epileptic patients through telemetered recordings.

- With Laboratory Parasitic Diseases, NIAID, generated a more efficient video system used to determine the mean projected area profile distribu in vertebrate cells.

Anesthesiology Service

Anesthesia services are provided via a contract with Georgetown Universi The contract which was awarded last year has been renewed for the perio July 1, 1977 through June 30, 1978.

The Anesthesiology Service provides anesthesia and related support servi to all patients of the Clinical Center requiring such support. These services include: administration of anesthesia to patients undergoing surgical and diagnostic procedures where anesthesia coverage is needed, provision of consultative services in anesthesia related problems, the u of pain relieving techniques to selected patients with chronic pain synd and provision of support and guidance to the Respiratory Therapy Section Patient Services Department.

The Anesthesiology Service personnel on duty included staff anesthesiolo nurse anesthetists, anesthesia residents, and medical secretaries, class as follows, based on the yearly average:

Staff Anesthesiologists	10
Nurse Anesthetists	3
Secretaries	2

Anesthesiological Services provided from April 1, 1976 through March 30, 9 Anesthesia and/or supportive treatment was given in 1495 instances, inclu 1,295 surgical operations and 200 diagnostic procedures.

Miscellaneous services (consultations, nerve blocks, and resuscitations) numbered 44.

The following statistics display the nature of the anesthesia procedures undertaken and reflect the complexity and protracted duration of many of operations.

A total of 1,295 surgical procedures were performed. These procedures classified as to type of surgery were as follows:

Thoracic	411
Neurological	58
General	313
Urological	14
Perineal	83
Face, head and neck	126
Eye, ear, nose and throat	52
Dental	4
Orthopedic	37
Miscellaneous	197

The table below classifies patients as to sponsoring Institutes:

Institute	Procedures	Percent
NCI	794	53
NHLBI	387	26
NINCDS	104	7
NEI	38	3
NICHD	21	1
NIAMDD	94	6
NIAID	44	3
NIMH	13	.9

The surgical staffs of the Institutes listed below were responsible for the number of procedures done under anesthesia as indicated:

Institute	Procedures	Percent
NCI	921	62
NHLBI	383	26
NINCDS	110	8
NEI	44	2
NIDR	4	.3
NIAMDD	17	1
Special	16	1

Changes and Improvements

An extensive in-depth investigation of the effects of hyperthermia on cancer treatment in selected patients was undertaken in collaboration with physicians from NCI with the serendipitous objective of quantitating physiologic changes in patients requiring anesthesia for these hyperthermia treatments.

Recruitment of anesthesiology staff has markedly increased to provide more efficient and intensive anesthesia and respiratory support to the Clinical Center patients and investigative functions. An improvement in anesthesia and respiratory care will follow with the availability of new recovery room facilities which are about to be instituted. With the establishment of a new recovery room facility and appropriate staffing, the immediate postoperative difficulties encountered by surgical patients may be expeditiously solved.

Future Objectives

Basic work is underway to reach the goal of even more complete respiratory therapy coverage when the new Ambulatory Care Facility and its expanded recovery, intensive care, and respiratory areas are available. The Anesthesiology Department has been closely associated with the plans for this facility which will provide expanded opportunities for improvements in anesthesia and respiratory care.

Opportunities to combine the Department's clinical functions with appropr
investigative activities related to anesthesia and physiology, such as
the hyperthermia program, will be eagerly accepted by the enlarged, capab
and versatile staff presently at hand.

CHART A

ESTIMATE OF THE NUMBER OF VOLUNTEERS BY INSTITUTE
FOR PERIOD JULY 1, 1976 - SEPTEMBER 30, 1977

Institute	Inpatient Volunteers	Total Days	Outpatient Total Visits	Total Hours	Off-site Total Days	Total Hours
NIAMDD	50	3,288				
NIAMDD-Phoenix	246	4,023				
NCI	10	759	2,740	2,745		
NICHD	65	4,278	78	84	442	778
NEI	9	637	135	347		
NHLBI	175	6,268	145	528	138	138
NIAID	77	4,940			7	15
NIMH	90	4,159	687	2,241	1,094	2,119
NIDR			30	60		
NINCDS			837	2,285		
TOTAL	722	28,352	4,652	8,290	1,681	3,050

CHART B

PHYSIOLOGICAL MONITORING SECTION

DATE	HEART RATE	TEMPERATURE	ARTERIAL PRESSURE	VENOUS PRESSURE	PULMONARY ARTERY PRESSURE & PULMONARY CAPILLARY WEDGE PRESSURE	ECG VIA RADIO TELEMETRY	RESPIRATION RATE	SPECIAL PROCEDURE ON PATIENTS
7/76	8,370	298	2,147	2,724	40	3,345		
8/76	8,019	725	2,948	2,752	108	3,687		
9/76	6,423	459	1,260	1,752		3,612	48	93
10/76	9,052	589	2,750	2,471	186	3,684	613	60
11/76	9,541	1,246	2,348	2,448	126	4,265	656	32
12/76	6,753	645	2,529	2,358	15	2,345	468	32
1/77	5,621	286	1,167	568	171	3,172	678	138
2/77	10,963	561	3,093	3,201	636	5,001	408	72
3/77	9,122	581	3,159	3,346	371	3,679	241	
4/77	6,185	335	1,319	996	69	3,582	144	48
5/77	7,872	352	1,731	1,617	120	5,192	474	67
6/77	18,159	934	5,480	4,297	1,006	10,193	1,169	70

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PHARMACY DEPARTMENT

PHARMACY SERVICE

I. Mission and Goals

Pharmacy Service is responsible for the interpretation and transcription of medication orders, and for the monitoring and dispensing of all medications ordered for patients in the Clinical Center. Specifically, this is accomplished by dispensing unit dose medication to individual patients with each dose individually packaged and labeled; filling drug orders for patients going on pass, being discharged, or outpatients; extemporaneously preparing all intravenous additive solutions ordered for inpatients and outpatients; filling drug requisitions for nursing units and clinics not on unit dose system; bulk compounding and packaging products not available commercially; maintaining all investigational drug dispensing records; providing drug information and clinical services for physicians and nurses.

II. Service Activities (based on 12 months - 7-1-76 to 6-30-77)

a. Unit doses of medications dispensed to inpatients increased by 52% and total number of unit doses packaged increased by 41%.
b. Total number of intravenous admixtures prepared increased by 22%.
c. Total number of outpatient prescriptions filled increased by 6.5%.
d. Requests filled by the Officer-of-the-Day increased by 29%.
e. Pharmacy service hours were extended in the Unit Dose and Intravenous Additive Units. The Unit Dose Dispensing Unit extended hours from 8:30 a.m. to 5 p.m., 5 days/week, to 7 a.m. to 11:30 p.m., 7 days/week. The Intravenous Additive Unit extended hours from 7 a.m. to 5 p.m., 5 days/week, to 7 a.m. to 9 p.m., Monday through Friday, and Saturdays, Sundays, and holidays, 7 a.m. to 6 p.m.
f. Additional space of 150 sq. ft. was provided for the Pharmacy Service for the expansion of the unit dose program.
g. The Unit Dose Dispensing Unit, Intravenous Additive Unit, and Inpatient Dispensing Unit was physically rearranged and new modular shelving units were purchased for each Unit. This was done to provide a more efficient work flow and traffic pattern with the limited floor space in the pharmacy.

III. Major Progress

The unit dose drug distribution system was expanded to include 7 additional nursing units (NHLBI Nursing Service and NIAMDD Nursing Service). This

resulted in an increase in coverage from 175 beds in FY 1976 to 335 beds i FY 1977. Pharmacy Service continued its policy of assigning specific pharmacists clinical responsibilities for these 7 additional units in addi tion to the drug distribution functions. Pertinent information concerning each new unit (protocols, staffing patterns, and drug information) was com piled by these pharmacists. By familiarizing themselves with the drug therapy and protocols used on their assigned units they were better prepar to interpret and review all new drug orders for appropriateness, dosage, a possible interactions. The pharmacists made daily visits to their assigne nursing units to communicate directly with physicians and nurses; they became the prime providers of drug information on their assigned units. Although requested to do so by physicians and nurses, lack of time and inadequate staffing prevented the pharmacist from providing more formalized clinical services such as conducting drug histories on new patients and providing drug counseling to patients being discharged.

The Chief, Pharmacy Service, served on an Executive Committee designed to facilitate MIS computer implementation throughout the hospital. Through h close interaction with the system, alterations and modifications were made in various pharmacy matrices and ordering paths to best accommodate new nursing units entering the MIS system.

Staff pharmacists also provided invaluable assistance in the MIS computer implementation on their assigned units by acting as a liaison between nursing unit and the Pharmacy Service. In some cases they provided direct instruction to physicians on the medication ordering portion of the MIS system and, in all cases, the pharmacist interpreted, reviewed, and verifie all medication orders input by physicians and "agents for" the physician. They suggested improvements and refinements in the MIS system that were relative to their functions as pharmacists.

A large increase (22%) in the number of intravenous admixtures prepared by the Intravenous Additive Unit necessitated the distribution of the workload in the evenings and a change in the expiration times, and delivery of the intravenous admixtures to the unit. In addition, the Intravenous Additive Unit pharmacist went daily to 4 NCI nursing units to monitor the intravenou admixture usage. This procedure has enabled the pharmacists to better predict the need for continuation and preparation of the intravenous bottle and has helped decrease waste and intravenous admixture returns.

The Intravenous Additive Unit provided the data for every patient on total parenteral nutrition. The data was then entered into a computer and analyzed by the NCI Surgery Branch.

All nursing units, as well as ancillary patient care areas, were routinely inspected to insure proper drug control and storage.

The Pharmacy Service assisted the Infections Control Committee in their review of antibiotic usage in the Clinical Center by surveying intravenous gentamicin usage throughout the hospital. This was done by a staff pharmacist monitoring, on a daily basis, all gentamicin admixtures prepared by the Intravenous Additive Unit.

The Pharmacy Department's one-year residency program in hospital pharmacy was approved for accreditation by the American Society of Hospital Pharmacists. The program has been operational for 3 years.

This residency training program included practical experience in hospital pharmacy dispensing, and clinical experience and training through rotation to different nursing units conducted by a clinical pharmacist, and familiarization with Clinical Center ancillary departments such as Diagnostic Radiology, Blood Bank, etc. Completion of residency required an administrative project to develop a surveillance program for microbial contamination of intravenous admixtures prepared by the Pharmacy Department. A procedure was developed and data collected to determine the feasibility and cost effectiveness of continuing this surveillance project on a routine basis.

A Pharmacy and Therapeutics Committee was established to serve as an advisory group to the medical staff and to serve as an organizational line of communication between the medical staff and the Pharmacy Department on all matters related to the use of drugs. Recommendations of this Committee are presented to the Quality Assurance Committee and then to the Medical Board for adoption.

Members of the Pharmacy Department continued to meet on several occasions with architects and consultants regarding space allocations, renovations, and planned Pharmacy Department activities in the Ambulatory Care Research Facility.

A revised edition of the Pharmacy Department Catalog was published and distributed to physicians, dentists, nursing units, and other appropriate individuals.

The Pharmacy Department instituted a practice of receiving and reviewing all research protocols involving the use of drugs, both commercial and investigational. A copy of the protocols, along with a computerized listing of them from each institute, are on file in the pharmacy.

The Chief, Pharmacy Service, served as a member of the newly formed Cardiopulmonary Resuscitation Committee (a subcommittee of the Quality Assurance Committee). This committee is methodically reviewing all procedures and techniques involving CPR in the Clinical Center. The CPR manual was updated and all appropriate drug changes were made by the Pharmacy Department.

IV. Future Objectives

a. Expansion of unit dose drug distribution system to include all Clinical Center nursing units. This involves expanding the program to cover the remaining 10 nursing units (8 NCI and 1 NICHD and 1 NEI) not presently on the system.
b. Development of a computerized intravenous admixture system by pharmacy and MIS personnel to accommodate all phases of centralized intravenous admixture preparation.
c. Expansion of the professional role of the pharmacist to include more clinical functions such as conducting drug histories on newly admitted

patients and providing discharge medication interviews.
d. Feasibility of a satellite intravenous admixture unit in the outpatien clinic will be explored. Currently, intravenous solutions that need to be administered within one-half hour after mixing are being prepared in the clinic.

CENTRAL STERILE SUPPLY SERVICE

I. Missions and Goals

Central Sterile Supply Service provides clean and sterile supplies used in patient care which includes processing, assembling, sterilizing, and issuin of a variety of packs, trays, sets, instruments, and utensils. Also, numerous preprocessed disposable items, both clean and sterile, are procure stored, and issued to patient care areas. The distribution of the supplies is accomplished by a 24-hour mobile exchange cart delivery system.

II. Service Activities (based on 12 months, 7-1-76 thru 6-30-77)

a. Requisitions filled increased 17% with 35,236 requisitions estimated fo 7-1-76 thru 6-30-77.
b. Items issued totaled 4,429,553 with 5,536,941 estimated for July 1, 197 thru September 30, 1977.
c. Number of trays and sets prepared increased 9% with 17,777 estimated fo July 1, 1976, thru September 30, 1977.
d. Turnover rate of personnel was 25%.
e. Acquisition of gravity steam sterilizer for decontamination process.
f. Five full-time permanent employees attended some type of schooling or Upward Mobility program, which represented an average of 20 man-hours per week.

III. Major Progress

a. A heat sensitive chemical indicator strip was incorporated into each item steam sterilized to insure presence of sterilization parameters.
b. The soiled processing area was physically separated from clean productic areas through the use of wall partitions.
c. A Product Review and Standardization Committee, composed of Central Sterile Supply Service, Nursing, and the Procurement Branch, was initiated to evaluate new commercial products.
d. Monthly medical aid inservice education program was initiated.

IV. Future Objectives

a. Revision of stock control methods to facilitate inventory and procuremen activities.
b. Acquisition of additional sterilizing equipment for decontamination process.
c. Replacement of linen wrappers with 2-way crepe paper wrappers for sterile surgical packs.

PHARMACEUTICAL DEVELOPMENT SERVICE

I. Missions and Goals

The Pharmaceutical Development Service (PDS) is responsible for the registration and control of all investigational drugs used for patients in the Clinical Center. This group also develops, formulates, and assays many of the investigational drugs used by physicians in their clinical research studies and prepares a summary of this data for the FDA.

The goals of this group are to provide elegant pharmaceutical products and to assist physicians in their clinical research by supplying services such as drug identity and analyses of in vitro and in vivo samples, setting up single and double-blind studies, maintaining disposition records, and providing drug information.

II. Service Activities (based on 12 months, 7-1-76 thru 6-30-77)

The workload of the Service increased substantially over the last year as follows: 65.5% increase in the number of units formulated, developed, and issued; a 58.7% increase in the number of new investigational drugs processed; 13.7% increase in all requests processed; and a 12.1% increase in investigational drugs registered.

III. Major Progress

The facilities and capabilities of the PDS have been improved through the addition of a few new instruments and the renovation of other equipment. New instruments purchased included a gas-liquid chromatograph equipped with both flame ionization and electron-capture detectors to replace obsolete GLC; a multiple spindle dissolution apparatus which is required for dissolution testing by the USP; a stainless steel freeze-drier; and a glass still in the analytical area to obtain water of a high purity for chemical analysis.

The quality of sterile products prepared was improved by mechanically modifying and adding inline water filters to an existing vial washer.

An intravenous emulsion with a globule size of 2 microns capable of making the liver and spleen opaque which can then be used for computerized scans of the liver has been developed and prepared for the Diagnostic Radiology Department. This unique preparation is a major breakthrough.

The procedure for the Cholestyramine Type II Coronary Intervention Study was changed to decrease order processing time and storage space.

IV. Future Objectives

a. Conduct in vivo testing of clinical dosage forms developed by PDS.
b. Conduct dissolution testing on all oral dosage forms prepared by PDS.
c. Develop a stability testing program for all drugs sealed in unit dose packages.

Problems

Pharmacy Service

a. The Pharmacy needs to complete the unit dose drug distribution system in the Clinical Center. There are currently 335 beds (16 nursing units) o the system and 186 beds (11 nursing units) still to be completed. The sys cannot be completed unless the Pharmacy receives 5 additional positions ab our current on board full-time posisions of 79.
b. There currently is inadequate space to function effectively at our present level of service. We have requested 1000 sq. ft. of additional space and have received 300 sq. ft of space and a commitment to receive an additional 500 sq. ft. in the near future.
c. An inadequate delivery system (pneumatic tube system) for dispatching of medications, due to expansion of the unit dose system, will require messenger service throughout the day as well as in the evenings, which currently is in effect.
d. There is a need to coordinate with the outpatient clinics the schedulin of patient visits in order to alleviate the overburdening of the outpatient pharmacy at specific times each week. For example: on Thursday afternoon between 1 and 4 p.m. the outpatient dispensing unit is deluged with as many as 300 prescriptions to fill in that period of time.

Central Sterile Supply Service

a. Inadequate storage space. Pharmacy has requested: 1,000 sq. ft. of space to remove supplies from the corridors; 1,500 sq. ft. of space in the Central Sterile Supply Service for operational activities; and 2,000 sq. ft of space for the storage of backup supplies.
b. Environmental conditions are such that they lend to rapid accumulation of dust.
c. Antiquated and inadequate sterilizing and cleaning equipment will requi the immediate purchase of new equipment costing approximately $100,000.
d. There is a great time lag between the initiation of work requests and completion of projects by the Engineering Branch.
e. There is a great time lag between submitting Request for Personnal Actic (SF-52) and receiving certificates of eligibles for job interview.

Pharmaceutical Development Service

a. In order to expand our pharmacokinetics studies on the various drugs use in the Clinical Center, two additional full-time employees are needed.
b. There is a severe lack of space in PDS. An additional 600 sq. ft. of space has been requested for operational activities and the storage of investigational drugs.
c. There are long delays in the completion of work requests. For example, renovation of a sterile room was requested and approved two years ago and to date has not been started.

PUBLICATIONS

Chatterji, D. and Gallelli, J.F.: Assay of methotrexate in presence of its decomposition products by high pressure liquid chromatography. Accepted for publication, J. Pharm. Sci.

Chatterji, D., Frazier, A., and Gallelli, J.F.: Thermal and photolytic decomposition of methotrexate in aqueous solutions. Accepted for publication, J. Pharm. Sci.

Chatterji, D., Frazier, A., and Gallelli, J.F.: Identification and quantitation of impurities in methotrexate. Accepted for publication, J. Pharm. Sci.

Daniels, C.E. and Tangrea, J.A.: Use of patient-oriented drug data sheets in counseling patients before discharge. Hosp. Pharm. 12: 230-242, 1977.

Gladding, G.D. and Ballew, T.D.: Proper stock rotation is colored with a positive marking. Hosp., J.A.H.A. 51: 154-155, 1977.

Table I
Pharmacy Department Statistical Data

	1973 (Fiscal)	1974 (Fiscal)	1975 (Fiscal)	1976 (Fiscal)	1977 7-1-76 6-30-77	Est. 1977 (Fiscal) 7-1-76 9-30-77
PHARMACY SERVICE						
Outpatient prescriptions	51,840	57,070	65,998	72,134	77,168	96,461
Inpatient prescriptions	3,087	3,230	2,593	1,559	1,356	1,696
I.V. additives (bottles)	79,793	94,177	89,411	112,845	144,429	180,537
Drug vials reconstituted by I.V. Additive Unit	34,633	39,767	39,015	43,320	44,602	55,752
Sterile compounded items	-	-	4,806	5,247	6,386	7,982
Unit doses dispensed	-	-	83,474	254,103	532,487	665,609
Prepackaged items	24,658	30,857	72,635	365,723	618,165	772,706
Other items (mail-outs, bulk-compounding items, narcotics, requisitions, issues to I.V. area)	240,859	265,300	274,691	282,727	293,885	367,319
PHARMACEUTICAL DEVELOPMENT SERVICE						
Units developed and issued	550,304	581,374	431,972	567,911	939,918	1,174,898
Requests processed	1,193	1,151	1,199	869	988	1,235
Investigational drugs registered	523	587	637	527	591	739
New investigational drugs processed	96	108	126	92	146	182
PHARMACY OFFICER OF THE DAY						
Number of requests for service	9,133	11,866	10,838	13,254	18,754	23,442

	1973 (Fiscal)	1974 (Fiscal)	1975 (Fiscal)	1976 (Fiscal)	1977 7- 1-76 6-30-77	Est. 1977 (Fiscal) 7- 1-76 9-30-77
MAIL-OUT PRESCRIPTIONS						
Number of prescription packages mailed	1,067	1,329	1,478	1,527	1,498	1,872
CENTRAL STERILE SUPPLY SERVICE						
Requisitions filled	17,759	16,422	18,773	24,122	28,189	35,236
Items issued	901,496	979,716	904,848	*2,524,596	4,429,553	5,536,941
Trays and sets prepared	21,566	26,144	15,193	13,068	14,226	17,777

*Due to change in method of tabulating items issued, statistical comparison between FY 1976 and previous years is impossible.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-00001-01 PHA

PERIOD COVERED

July 1, 1976, to September 30, 1977

TITLE OF PROJECT (80 characters or less)

Assay of Methotrexate in Presence of Decomposition Products by HPLC.

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

D. C. Chatterji	Staff Fellow	Pharmacy, CC
J. F. Gallelli	Chief, Pharmacy Department	Pharmacy, CC

COOPERATING UNITS (if any)

LAB/BRANCH

Pharmaceutical Development Service

SECTION

INSTITUTE AND LOCATION

CC, NIH, Bethesda

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
0.6	0.6	

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Two HPLC methods using a strong anion exchange resin column and a perchlorate phosphate buffer as eluent were developed. The method was demonstrated to be useful in the presence of large amounts of thermal and photolytic decomposition products. The applicability of this method in assaying commercial dosage forms was established by comparing with other methods published in the literature.

PHS-6040
(Rev. 10-76)

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-00002-01 PHAR

PERIOD COVERED

July 1, 1976, to September 30, 1977

TITLE OF PROJECT (80 characters or less)

Thermal and Photolytic Degradation of Methotrexate in Aqueous Solutions.

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

D. C. Chatterji	Staff Fellow	Pharmacy, CC
A. G. Frazier	Physical Science Technician	Pharmacy, CC
J. F. Gallelli	Chief, Pharmacy Department	Pharmacy, CC

COOPERATING UNITS (if any)

LAB/BRANCH

Pharmaceutical Development Service

SECTION

INSTITUTE AND LOCATION

CC, NIH, Bethesda

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1	0.6	0.4

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

The chemical kinetics and product analysis of thermal and photolytic degradation of methotrexate (MTX) in aqueous solution was studied. Major degradation products were identified using simple column chromatography and HPLC. These studies led to a mechanism of decomposition of MTX in aqueous solutions. The stability of various commercial dosage forms and one I.V. infusion solution of MTX was studied and found to be acceptable within the recommended storage periods. The impurities commonly present in commercial MTX were found not to be due to degradation products, but were from the synthesis of MTX itself.

PHS-6040
(Rev. 10-76)

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER Z01-CC-00003-01 PHAR

PERIOD COVERED

July 1, 1976, to September 30, 1977

TITLE OF PROJECT (80 characters or less)

Identification and Quantitation of Impurities in Methotrexate.

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

D. C. Chatterji	Staff Fellow	Pharmacy, CC
A. G. Frazier	Physical Science Technician	Pharmacy, CC
J. F. Gallelli	Chief, Pharmacy Department	Pharmacy, CC

COOPERATING UNITS (if any)

LAB/BRANCH

Pharmaceutical Development Service

SECTION

INSTITUTE AND LOCATION

CC, NIH, Bethesda

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
0.8	0.4	0.4

CHECK APPROPRIATE BOX(ES)

☐ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Methotrexate USP, commercial methotrexate, and MTX for investigational use were chromatographed by gradient elution on DEAE cellulose column. In commercial and USP methotrexate, six different peaks (excluding MTX peak) were obtained. Identity of 2 peaks were presented for the first time, using NMR and MS techniques. Percentage purity of MTX samples were found to be of the order of 86% calculated on anhydrous basis. Investigational use MTX showed a completely different spectrum of impurities, although percentage purity of the sample was the same as USP methotrexate, i.e., 86%.

PHS-6040
(Rev. 10-76)

July 1, 1976, through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

REHABILITATION DEPARTMENT

CONTENTS

July 1, 1976, through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

REHABILITATION DEPARTMENT

I. Departmental Mission and Goals

The primary mission of the Rehabilitation Department is to provide physiatric evaluation and treatment, physical therapy, occupational therapy, and speech therapy for patients participating in Institute studies.

An equally important mission of the Department is to support efforts of and collaborate with Institute physicians engaged in research pertaining to evaluation or treatment of rehabilitation problems.

A third mission is to initiate both clinical and basic research independent of the Institutes in rehabilitation of mentally and physically handicapped individuals.

A fourth mission is to advocate and defend the rights of handicapped persons, and to use educational, preventive, and legislative means to accomplish this goal.

II. Department Activities

A. Physical Therapy, Occupational Therapy, Speech Therapy, and physiatric services are presented in Addendum I.

B. Staffing pattern is presented in Addendum II.

C. Patient Care Statistics

Patient care statistics are presented in detail in Tables 1-3 for Physical Therapy, 4-5 for Occupational Therapy Service, Table 6 for physiatrists, and Table 7 for speech therapy.

Not included in the annual report are the Resource Monitoring System statistics which show that the average time spent per patient visit is 30 minutes and that the majority of treatments require skilled therapists, rather than aides.

As of July 25, 1977, patients requiring bronchial drainage and preoperative and postoperative breathing exercises for lung expansion and pulmonary toilet were transferred to the care of the respiratory therapists.

III. Major Progress

A. Services

1. Significant improvement and organization in services were provi to amputees in FY 1977. Specifically, patients are being seen quickly, limbs are being delivered on schedule, the amputee cli is a regular, multidisciplinary patient care activity, and patient follow-up is excellent.

2. Comprehensive management of the arthritic patient has been unde taken by the combined effort of OT, PT, and orthopedic Services Major progress has been made in the following areas: a) standa ization of hand function evaluation, b) standardization of foot evaluations, including some gait evaluation, c) standardization of the postoperative management of patients receiving joint arthroplasty.

3. Provision of a regular, comprehensive program providing speech pathology evaluation and treatment.

4. Development of a program aimed at a non-pharmacologic, non-invasive approach to the management of chronic pain utilizing the transcutaneous nerve stimulator, per-cutaneous nerve stimulator, and biofeedback and relaxation techniques. This program is well underway and is successful in a significant number of patients.

5. The Occupational Therapy Mental Health program was redesigned to provide a consistent program for the five NIMH nursing units to which occupational therapists are assigned. The program focuses on the teaching of skills for independent functioning graded from basic task skills to placement in work therapy and more clearly delineates OT from recreation therapy. Forms for standardized evaluation of psychosocial function and occupational therapy treatment goals were drafted and are in use. Work Therapy evaluation forms also are now used consistently on each of the five NIMH units, and resulted in better documentation of treatment goals and outcome.

B. Research

1. Preliminary evaluation of statistics of the treatment of AKA with osteogenic sarcoma reveals a salutary effect of rigid casting on wound healing and a markedly decreased time between amputation and delivery of limb as compared with those patients not receiving rigid dressing. There is benefit with respect to phantom limb pain and time to final prosthesis (not statistically significant) to the amputee who is ambulated within 24 hours of surgery as compared with those patients whose ambulation is delayed until suture removal.

2. Preliminary evaluation of statistics on patients with psoriatic arthritis receiving psoralen ultraviolet light therapy reveals two subtypes of patients: a) one group shows skin response and joint response to be highly correlated, and these patients have distal, asymmetrical arthritis; b) the other group shows independence of joint and skin response, and these patients have axial arthritis, resembling spondylitis.

3. The Rehabilitation Department in conjunction with the NHLBI Cardiology Branch has developed a musculoskeletal examination for patients with atypical angina that evaluates the contribution of cervical and thoracic spine problems and chest wall pathology to the angina. Preliminary evidence shows that treatment aimed at relieving musculoskeletal problems results in significant amelioration of symptoms and improvement in exercise tolerance in selected patients.

4. Other studies in progress which have not yielded adequate data to report are: a) "Evaluation of the Response of Raynaud's Phenomenon to Biofeedback," b) "Podiatric Evaluation of the Rheumatoid Foot Comparing Accommodative with Corrective Therapy," c) "Evaluation of the Quality of Life Patients with Soft Tissue Sarcomas Receiving Amputation Versus Limb Sparing Local Tumor Resection."

5. Publications:

   a) Clinical Use of Immunosuppressive Drugs: Part II, N. Lynn Gerber & A. D. Steinberg, Drugs, 11:90-112 (1976).

   b) Ribavirin: Efficacy in the Treatment of Murine Autoimmune Diseases, L. W. Klassen, D. R. Budman, G. W. Williams, A. D. Steinberg, N. L. Gerber, Science, 2/25/77, vol 195, pp 787-789.

   c) Therapeutic Studies in NZB/NZW F_1 Mice. V. Comparison of Cyclophosphamide and Chlorambucil: N. L. Gerber, D. Powell, A.D. Steinberg, Arthritis & Rheumatism, July-August 77, vol 20, No. 6, pp 1263-68.

   d) The Hand in Mixed Connective Tissue Disease: R. A. Lewis, J. P. Adams, N. L. Gerber, et al., Hand, in press.

C. Training

The Rehabilitation Department has established a core curriculum for the continuing education of department physical therapists. A similar curriculum is being established for occupational therapists.

IV. Future Objectives

A. Patient Care

1. The Department is generally concerned with providing more comprehensive services, especially in the area of discharge planning, pediatric rehabilitation, rehabilitation of the cance patient, and the rehabilitation of the severely handicapped.

2. Specifically, a major effort is underway to establish reliable methods for evaluating disability and the impact of therapy on disability.

3. In addition, the application of thermoplastic material to a variety of disorders, assessment of efficacy and durability, appropriateness of the use of these materials is a future undertaking of this Department.

4. The need for a swimming pool is significant, and efforts will be made to obtain one.

B. Research

1. A more quantitative, reproducible method to evaluate treatment in hastening or improving rehabilitation of patients is being developed.

2. Another area of particular commitment is to evaluate treatment, prosthetics, and orthotics in a quantitative way as these modalities affect locomotion and upper extremity function. We are interested in evaluating these interventions in a way that would involve analysis of movement, pathomechanics, and the impact of corrective devices on pathomechanics.

C. Training

For Department staff training, we are implementing and evaluating the impact of the core curriculum for therapists. NIH staff training requires continued effort to apprise personnel of Rehabilitation Department activities.

Addendum I. Services Provided by the Rehabilitation Department

A. Physical Therapy Service

1. Tests and measurements

Manual muscle evaluation
Joint range of motion measurements
Electrodiagnostic testing, including chronaxie measurements and strength-duration curves
Progressive resistance exercise evaluation
Girth, length, and volumetric measurements
Quantitative muscle testing
Extremity and spinal joint evaluation
Posture evaluation
Self-care evaluation

2. Heat, including:

Superficial -- hot packs, paraffin bath, whirlpool
Deep -- shortwave diathermy, microwave, ultrasound
General body heat -- Hubbard tank

3. Therapeutic exercise:

General exercise -- passive, active, assistive, and resistive
Muscle reeducation and facilitation techniques
Joint range of motion and articulation
Ambulation training
Pre- and postoperative orthopedic surgery program
Training in self-care activities
Breathing exercises

4. Miscellaneous:

General and local application of ultraviolet light
Bronchial drainage
Cervical and pelvic traction
Application of splints and casts to maintain joints in good anatomical and functional position
Instruction to patients and family in home-care program (application of heat, exercise, use of self-care aids)
Fitting and dispensing canes and crutches
Prescription and procurement of correct shoes, braces, corsets, splints, and prostheses
Measurement for Jobst compression garments
Temperature and EMG biofeedback training
Transcutaneous nerve stimulation (for pain)

B. Occupational Therapy Service

1. Physical and functional restoration:

Basic mobility and functional training of the blind
Design and fabricate upper extremity orthoses
Improve functional endurance
Improve coordination
Infant and early childhood developmental stimulation (includes parent training)
Instruction in joint protection and energy conservation
Maintain or regain joint range of motion
Neuromuscular facilitation and inhibition techniques
Prevention or retardation of hand deformities in rheumatoid arthritis and systemic lupus erythematosus

2. Evaluation and testing:

Developmental testing
Evaluation of adult hemiplegics
Functional hand evaluation
In-depth activities of daily living evaluation, including self-care, homemaking and job
Perceptual motor testing
Record patient's behavior patterns for use in evaluation of patient's reactions in specific research studies (NIMH)
Timed functional activity testing for patients on studies
Upper-extremity motor development testing

3. Psychiatric adjustments:

Provide activities in relation to needs of research studies and report observations of patient's behavior
Aid patient in making acceptable social adjustment
Aid patient in preparing for community living and carrying employment and home responsibilities
Place patient in industrial therapy program as a step toward post-hospital employment

4. Prevocational exploration:

Explore skills, interests, and work habits
Increase work to tolerance
Maintain special skills required by patient's job
Make recommendations on patient's performance and aptitudes for use in vocational planning

C. Speech Therapy Service

1. Evaluation and assessment of: speech articulation, oral-peripheral and oral-motor functioning, voice and vocal pathologies, vegetative oral functions such as swallowing and chewing, oral-sensation, dentition as it affects speech,

linguistic performance, verbal and auditory memory and attention, comprehension of spoken, written and manual communication, academic-educational and pre-academic skills, cognitive functioning as it relates to language, auditory discrimination, and general levels of language development. Individualized remediation strategies are implemented appropriate to the meet the needs of those patients with communication disorders.

D. Office of the Chief

1. Evaluation of Institute patients referred for physical medicine and rehabilitation; prescription and supervision of therapy.

2. Participation in establishing executing research protocols in patient care.

3. Attendance at Institute Rounds: NCI, NIAMDD, NINCDS.

4. Participation in research endeavors with other Institute scientists not involving patients.

5. Supervision of the NIAMDD orthopedic resident.

6. Participation in Clinical Research Panel NIAMDD.

Addendum II Rehabilitation Department Staffing Pattern

Office of the Chief

Chief, Rehabilitation Department	1
Assistant Chief	1*
General Medical Officer	1
Secretaries	3
Clerk-typist, WAE	1
	7

Physical Therapy Service

Chief, Physical Therapy Service	1
Assistant Chief	1
Staff Physical Therapists	5
Physical Therapy Assistants	2
	9

Occupational Therapy Service

Chief, Occupational Therapy Service	1
Staff Occupational Therapists	5**
	6

Speech Therapy Service

Speech Pathologist	1***

* Appointed 8/1/77

** Vacancies filled after 10 and 4 months

*** Part-time employee

PHYSICAL THERAPY SERVICE

Table 1: STATISTICAL REPORT FISCAL YEAR 1977
(July 1, 1976 to October 1, 1977)

INSTITUTE	Number of Different Patients Treated FY 77		Number of Patient Visits FY 77	
	IP	OP	IP	OP
NCI	928	477	4840	1149
NEI	18	0	30	0
NHLBI	139	65	1161	276
NIAID	185	15	785	39
NIAMDD	269	272	2179	1188
NICHD	47	5	164	17
NIDR	13	12	20	16
NIMH	138	0	270	0
NINCDS	937	163	4294	412
TOTALS	2674	100	13,743	3,097

PHYSICAL THERAPY SERVICE

Table 2: COMPARATIVE STATISTICS - Fiscal Years, 1973-1977

FISCAL YEAR	NUMBER OF DIFFERENT PATIENTS TREATED		NUMBER OF PATIENT VISITS	
	Inpatient	Outpatient	Inpatient	Outpatient
1973	1431	456	8528	838
1974	1525	551	8397	1174
1975	1694	586	12,960	2071
1976	2085	796	9016	2155
1977*	2615	966	11,513	2621

* Estimates for July-Sept. 1977

PHYSICAL THERAPY SERVICE

Table 3: NUMBER OF NEW PATIENT ADMISSIONS BY INSTITUTE: COMPARATIVE STATISTICS-FISCAL YEAR 1977*

FISCAL YEAR	NHLBI		NIAMDD		NCI		NIAID		NINCDS		NIMH		NEI		NICHD		NIDR		TOTAL
	IP	OP	IP	OP	IP	OP	IP	OP	IP	OP	IP	OP	IP	OP	IP	OP	IP	OP	
1973	78	16	181	105	243	132	53	6	259	70	50	2	1	0	21	2	9	1	1229
1974	70	20	179	83	241	174	43	2	330	93	32	1	2	0	26	8	7	0	1311
1975	174	21	154	67	277	209	60	3	435	108	32	4	2	1	17	2	9	2	1577
1976	115	16	131	71	387	190	77	10	442	83	34	2	1	1	19	5	3	6	1593
1977*	153	44	170	142	514	291	102	14	648	110	103	0	6	0	39	4	6	6	2380

* Estimates for Jul-Sep. 1977

Table 4: SUMMARY REPORT BY INSTITUTES OF NUMBER OF PATIENTS TREATED, NUMBER OF TREATMENT HOURS* - FISCAL YEAR 1977

INSTITUTES	NUMBER OF DIFFERENT PATIENTS TREATED		NUMBER OF PATIENTS TREATMENTS		NO. OF TREATMENT HOURS	
	IP	OP	IP	OP	IP	OP
NCI	169	27	620	49	406	50
NEI	7	1	40	1	29	1
NHLBI	16	10	71	39	54	39
NIAID	29	13	80	67	76	67
NIAMDD	117	105	594	226	516	208
NICHD	71	55	259	50	228	51
NIDR	-	7	-	3	-	3
NIMH	794	9	10,788	22	13,158	21
NINCDS	471	64	2,143	62	1,848	63
TOTALS	1,774	291	14,595	519	16,315	503

*
Estimates for July-Sept. 1977

OCCUPATIONAL THERAPY SERVICE

Table 5: COMPARATIVE STATISTICS: FISCAL YEAR 1977
PATIENT TREATMENTS AND TREATMENT HOURS*

Fiscal Years	Number of Different Patients Treated		Number of Patients Treatments		No. of Treatment Hours	
	IP	OP	IP	OP	IP	OP
1973	1,583	556	10,129	362	14,121	365
1974	1,195	444	11,332	260	16,119	268
1975	1,220	359	10,622	358	15,805	361
1976	1,411	235	12,052	599	25,373***	625
1977	1,774	294	14,595	519	16,315	503

*
Estimates for July-Sept. 1977

**
The drop in treatment hours from FY 1976 to 77 reflects a decrease in number of staff from 3 mental health OT's to 2 mental health OT's and a stricter definition of what constitutes an O.T. treatment hour and rigidly separating it from recreational activity.

Table 6: NUMBER OF PATIENT EVALUATIONS BY PHYSIATRISTS, FISCAL YEARS 1973-1977

Fiscal Year	Total
1973	900
1974	839
1975	897
1976	848
1977 (estimated J.A.S.)	1494
	+ 131
Including consultant	1625

Table 7: SPEECH THERAPY SERVICE
Fiscal Year 1977

INSTITUTES	TOTAL NUMBER OF PATIENTS TREATED		TOTALS
	IP	OP	
NIAID	16	9	25
NIMH	0	0	0
NINCDS	171	67	238
NCI	20	6	26
NICHD	3	0	3
NHLBI	15	29	44
NIDR	2	16	18
NIAMDD	1	0	1
COURTESY	0	16	16
TOTAL	228	143	371

* Statistics represent period 1/1-9/30/77 (speech pathologist entered on duty 1/1/77, 20 hours/week)

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER 77-CC-A-132

PERIOD COVERED

2 years (beginning June, 1977)

TITLE OF PROJECT (80 characters or less)

Podiatric Evaluation and Treatment of Patients with R.A.

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

N. L. Gerber, M.D., Chief, Rehabilitation Department, CC
Joseph Reed, RPT, Physical Therapy Service, Rehabilitation Department, CC

COOPERATING UNITS (if any)

LAB/BRANCH

SECTION

Rehabilitation Department

INSTITUTE AND LOCATION

Clinical Center, 5D-37

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1/5	1/10	1/10

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

This study is designed to compare the efficacy of 2 different approaches to the management of foot problems in patients with rheumatoid arthritis. Patients will be assigned either conservative treatment with the use of soft inserts to provide comfort in shoes or corrective treatment to try to control abnormalities in foot alignment. Patients will be monitored for progress of disease.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER

PERIOD COVERED
3 years beginning January, 1976

TITLE OF PROJECT (80 characters or less)

Study of Factors Accelerating Rehabilitation in Above-Knee Amputees

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Naomi L. Gerber, M.D., Chief, Rehabilitation Department, CC
William Thorpe, M.D., Surgery Branch, NCI
Physical Therapy Service, Department of Rehabilitation, CC

COOPERATING UNITS (if any)

LAB/BRANCH
Surgery Branch

SECTION

INSTITUTE AND LOCATION
NCI

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1	1/10+ per year	1/2 per year

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

A study evaluating ability of Physical Therapists to apply rigid dressing intra-operatively to above-knee amputees, and evaluation of the benefit to patients who are ambulated immediately postoperatively, when compared with those not ambulated until the wound is healed. Patients are evaluated with respect to wound healing, quality of ambulation, and attitude toward rehabilitation.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER 76-CC-98

PERIOD COVERED
2 years (beginning November 1976)

TITLE OF PROJECT (80 characters or less)

Correlation of Activity of Psoriatic Arthropathy with Psoriasis in Patients Receiving PUVA

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

N. L. Gerber, M.D., Chief, Rehabilitation Department, CC
Werner Barth, M.D., Washington Hospital Center (off site)
John Decker, M.D., ARB, NIAMDD
A. Eric Jones, M.D., Nuclear Medicine, CC
T. Nigra, M.D., Washington Hospital Center

COOPERATING UNITS (if any)

Washington Hospital Center, Rheumatology & Dermatology Section
Nuclear Medicine

LAB/BRANCH
Arthritis & Rheumatism

SECTION

INSTITUTE AND LOCATION
NIAMDD

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
2/3	1/3 per year	

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Study is designed to evaluate the efficacy of psoralen treatment on the arthropathy associated with psoriasis.

Data to date show that there are two types of patients, those with peripheral joint involvement and their joint response parallels the response of the skin to PUVA. Those with axial skeletal involvement do not have a correlation of skin response to treatment with joint response.

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER 77-CC-22

PERIOD COVERED
3 years (February, 1977)

TITLE OF PROJECT (80 characters or less)

Biofeedback in the Management of Raynaud's Phenomenon

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

N. L. Gerber, Chief, Rehabilitation Department, CC
Bernard Frankel, M.D., NINCDS, SN
Dali Patel, M.D., NHLBI-IR
John Decker, M.D., ARB, NIAMDD
Mrs. Cynthia Smith, OTR, Chief, Occupational Therapy Service, CC

COOPERATING UNITS (if any)

LAB/BRANCH

SECTION

INSTITUTE AND LOCATION
NINCDS, NIAMDD, NHLBI

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
1/10	1/20 per year	1/20 per year

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Patients with Raynaud's phenomenon are taught temperature biofeedback and and muscle relaxation using EMG feedback in an attempt to relieve symptoms of Raynaud's phenomenon and control the temperature of the distal digits.

Only 3 patients have received treatment to date. All were able to learn the technique; none had lasting benefit from treatment

SMITHSONIAN SCIENCE INFORMATION EXCHANGE PROJECT NUMBER (Do NOT use this space)	U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE NOTICE OF INTRAMURAL RESEARCH PROJECT	PROJECT NUMBER 77-H-CC-114

PERIOD COVERED

2 years (June, 1977)

TITLE OF PROJECT (80 characters or less)

Chest Wall Syndrome Masquerading as Coronary Artery Disease

NAMES, LABORATORY AND INSTITUTE AFFILIATIONS, AND TITLES OF PRINCIPAL INVESTIGATORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT

Stephen Epstein, M.D., Chief, Cardiology Branch, NHLBI
Naomi Gerber, M.D., Chief, Rehabilitation Department, CC
Lamont Smith, RPT, Rehabilitation Department, CC
Michael Green, MS, Chief, Applied Physics Section, Nuclear Medicine, CC
Stephen Bacharach, Ph.D., Physicist, Applied Physics Section, Nuclear Medici
Jeffrey Borer, M.D., Senior Investigator, NHLBI, CB

COOPERATING UNITS (if any)

Rehabilitation Department, CC

LAB/BRANCH

Cardiology

SECTION

INSTITUTE AND LOCATION

NHLBI

TOTAL MANYEARS:	PROFESSIONAL:	OTHER:
2/5	1/5 to date	1/5 to date

CHECK APPROPRIATE BOX(ES)

☒ (a) HUMAN SUBJECTS ☐ (b) HUMAN TISSUES ☐ (c) NEITHER

☐ (a1) MINORS ☐ (a2) INTERVIEWS

SUMMARY OF WORK (200 words or less - underline keywords)

Patients with chest pain and normal coronary arteries as demonstrated by radionuclide scan are evaluated for non-cardiac, musculoskeletal component to explain chest pain.

Several diagnostic manuevers are performed, and if diagnosis is musculoskeleta problem, patients receive treatment for this.

Follow-up stress test for exercise tolerance will be done to assess efficacy of treatment.

July 1, 1976, through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY OF ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

SOCIAL WORK DEPARTMENT

CONTENTS

July 1, 1976, through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

SOCIAL WORK DEPARTMENT

I. MISSION AND GOALS

The Social Work Department's primary mission and goal is to support the clinical research mission of Clinical Center and to enhance the excellence of medical care. In collaboration with other professionals and disciplines, the department explores in depth the multi-faceted repercussions of chronic illness. In order to pursue these objectives, the staff identifies significant problems of chronic illness and works with patients and their families on an individual basis and through the group modality to help them deal more effectively with the emotional, environmental, and cultural conditions that can enhance or impede the course of treatment. With the support and help provided by the department's staff, patients are assisted to build networks of mutual support with their families, members of the hospital community, and, when they leave the hospital, to bridge the gap between the hospital and their home communities.

An important part of the department's missions and goals is its commitment to share with other social work professionals and with students the insights into medical social work it gains in the unique biomedical research setting of the Clinical Center. Thus, as part of its professional responsibilities, and as a corollary of its primary goals, the Social Work Department's staff participates in a variety of ongoing professional training, and the department carries on an active teaching program of graduate students in cooperation with universities.

Number of Patients Provided with Service in Various Categories

Each month the department reported on the number of patients and their family members served in four principal categories: (1) Preadmission - services to persons before their acceptance as an outpatient or inpatient for admission to a Clinical Center project; (2) Inpatient - services to persons occupying a bed in the Clinical Center; (3) Clinic - services to persons under outpatient treatment who had never been inpatients; and (4) Follow-up - services to those outpatients who had been former inpatients.

SUMMARY OF NUMBER OF PATIENTS SERVED

CATEGORY	FY 1976 Patients Served July 1975 - May 1976		FY 1977 Patients Served July 1975 - May 1976	
	Number	% of Total	Number	% of Total
Preadmission	144	2.0	109	1.4
Inpatient	5,240	71.5	5,513	70.7
Clinic	487	6.6	587	7.5
Follow-up	1,458	19.9	1,593	20.4
TOTAL	7,329		7,802	

For monthly services provided, percent of inpatients covered, and indirect services to clients, see Tables 1, 2, and 3.

II. ACTIVITIES

Group Work

Group work modality continued to expand with the addition of four new groups. In all, 11 groups have been developed by the Social Work staff: (1) The Parkinson's Group (NINCDS); this inpatient group was formed during FY 1976; since January 1977 the Group was extended to include outpatients and their families. (2) The Group Rap Sessions (NIAMDD) were established in FY 74 and continued to be an effective therapeutic medium which helped patients with systemic lupus erythematosus cope with the psychological manifestations of this illness. The group generally consisted of eight patients. (3) The Steroid Group was established in FY 75 and was comprised of six patients with various illnesses whose common bond was steroid treatment. (4) The Sjogren's Group and (5) The Rheumatoid Arthritis Group (NIAMDD) were established in FY 77 for patients and their relatives. Combined, they represented 14 patients. (6) Special Ambulatory Care Patients' Group was started in FY 75 and continued to benefit patients housed in the United Inn Motel. These patients, housed off-campus, are cancer patients who suffer particular anxiety, isolation, and stress. (7) The Parents' Group of the Pediatric Oncology Service with a core group of five, continued for its fifteenth year, but was expanded because of the shift in patient population to include sizeable numbers of young adult patients with their special problems. (8) The 12-West Medicine Branch with 5 or 6 patients began FY 77 for patients with cancer. (9) NCI Surgery Branch Outpatient Group with approximately seven patients weekly began in FY 77 for new cancer surgery patients seen in the Screening Clinic. (10) The Radiation and Medicine Group for relatives of cancer patients began in FY 77 with 5 to 8 patients. (11) The Pediatric Oncology Group continued to meet with parents, patients, social worker and a physician.

Contract/Consultant - Staff Training

In FY 75, the department continued its consultant program to provide training and consultation in group work. Two-hour sessions were provided bi-monthly from September 1976 through June 1977 to 19 staff members and eight University of Maryland students and the department chief. With the staff's developing expertise in using the group modality, the participating staff wished to consolidate its experience with "groups" through writing and publications. As a result two additional hours a month for individual consultation were provided, and participating staff members led patient or family groups, or planned to initiate additional, new groups.

Education

For the second year the department continued its contacts with various colleges and universities; the department continued its collaboration with the graduate program of the School of Social Work and Community Planning, University of Maryland, Baltimore, and supervised eight students during FY 1977.

This training commitment involved the teaching of casework and group work process, introducing the students into this complex setting, work with the University field advisor in bi-monthly conferences, and attendance at meetings of an inter-agency consortium. Nine staff members were involved, and as a result of the educational goals of the department a new "Student Handbook" was prepared by a committee. The department also participated in the Summer Student Program with a total of 11 students, three of whom had graduate degrees from the University of Maryland and the University of Alabama. Supervision was provided by various staff members in the department.

Section Reports

Allergy and Infectious Diseases Social Work Section

The department was fortunate to secure an experienced psychiatric social worker who can serve the considerable number of patients with deep seated psychological problems and, by virtue of her training as a nurse, also can understand the complicated medical aspects of diseases under study. Since her arrival, both the number of patients served and the quality of the service have substantially increased. The additional social work time was used for in-depth exploration of problems that helped more guarded patients to share their concerns and provided meaningful and consistent emotional support during their hospitalization. More time was available for follow through once the patients had left the Clinical Center.

A protocol on insulin resistant diabetes increased the need for social work services. The protocol called for relatively short admissions (7-14 days) which required the social workers to move in rapidly to make a diagnostic assessment and treatment plan; furthermore, the complications that accompany diabetes required considerable support. Patients on this protocol came from

the mid-western part of the United States and from all socio-economic levels, ages, races, and religions. A few had serious psychological problems, apparently unrelated to their diabetes and allergy, but nonetheless interfered with their optimal social functioning.

Regular and intensive casework was necessary for another group of young adult patients whose illnesses were severe or life-threatening. This group of patients, despite their different diagnoses, shared a number of problems: illness had disrupted or radically altered vocational and career plans; illness had upset the normal timetable of their efforts to become self-sustaining adults, or had brought about a regression to earlier adolescent stages which was a source of great concern to both patients and their families; their illnesses necessitated unusually long periods of hospitalization and outpatient treatment. Regular and intensive casework was necessary for these young people and their families; the social worker helped them identify basic family patterns of interaction and understand how illness had cut across them. They were helped in working toward solutions to their difficulties that were at once realistic and emotionally satisfactory.

The presence of a social worker was of particular importance during the termination phase of the Institute Director's protocols which had both practical and emotional repercussions for patients. The social worker reviewed the meaning of this event with all terminated patients, both in terms of losing important relationships with caretakers and in terms of problems in securing alternative medical care. This institutional attention helped to reduce patients' lingering sense of abandonment or rejection.

Arthritis, Metabolism and Digestive Diseases Social Work Section

Patients being followed by the Pediatric Metabolism Service were teenagers and young adults. For this group of patients career choice and marital relationships constituted the main focus of social work intervention.

The main objective of social work staff on the Liver Service was to help defuse the anger against employers of patients who had sustained liver damage as a result of industrial exposure to polyvinyl chloride.

The Social Work Department staff with the Arthritis and Rheumatism Service continued the programs with systemic lupus erythematosus, Sjogren's syndrome, mixed connective tissue disease, collogen disorders, and rheumatoid arthritis. The social worker, as a member of the clinical team, focused on helping the individual patients utilize emotional, physical, and intellectual resources in coping with intrinsic problems endemic in chronic illness.

To better understand and aid in the unit management of steriod-induced central nervous system lupus episodes of psychosis among the systemic lupus erythematosus patients, several interviews were videotaped with patients following their recovery in later months as they reflected on what was helpful or not for them during this psychotic period. The tapes were important learning aids.

The Hematology Branch planned a comprehensive hemophilia diagnostic treatment program in which social work services would again be incorporated into the therapy program as it was several years ago. The group sessions, as well as individual casework services were designed to meet the special needs of this patient group and their families.

Cancer Social Work Section

During this reporting period the National Cancer Institute had a high inpatient census as well as a rapidly expanding outpatient clinic, both with a high incidence of seriously ill and dying patients. This Institute is complex with new configurations and realignments that involve frequent changes in personnel, protocols, patient populations, and disease entities. These conditions required a committed social work staff having utmost flexibility, expertise, and ability to set priorities to meet the multiple challenges.

Comprehensive social work coverage was provided to the 12-bed Unit of the Metabolism Branch. Six patient and family groups were developed for in- and outpatients to meet the needs of the larger number of high-risk patient and family constellations. Of approximately 300 patients who participated in the Radiation Oncology protocols, all new radiation outpatients were seen by a social worker within one week of their initial work-up at the Clinical Center. About 100 of these patients were provided long-term casework services, and an additional 100 were screened and provided brief services as indicated at some point during their treatment program.

From the beginning of FY 77, one worker has seen on an individual or family basis all the patients and families who came to the Surgery Branch clinic for the first time. The purpose of this intervention was to provide an orientation to the Clinical Center and to assess these patients' psycho-social functioning.

As part of the department's ongoing educational commitment, four summer students (graduate) here for a three-month period, were assigned to work in the outpatient clinic to gain more adequate data to more effectively evaluate the needs of patients and families, effective treatment modalities, and the most significant and appropriate points of intervention.

The stress occasioned by the large number of seriously ill and dying patients and the grief experienced by patients, family members, and staff required frequent psychological consultation to assure the highest quality of comprehensive psychosocial and medical care.

Social Work Department staff participated in the regularly scheduled inter-disciplinary meetings on the Pediatric Oncology Unit with a psychiatric consultant. Parallel meetings were held with the nursing staff and social worker on the Surgery Branch. These meetings provided a forum in which to discuss difficult patient problems and staff feelings in this stressful milieu and to arrive at improved ways of coping by staff, patients, and families.

The Cancer Social Work Section met on a bi-monthly basis to make a broad review of the problems of patients and their families and to develop new ways to meet these problems more effectively. These reviews facilitated meeting such problems as: the transfer of all Ewing's Sarcoma patients from the Radiation Branch to the Pediatric Oncology Service. In this instance, families needed help to cope with the change in physicians and the disruption felt by patients transferred to another service. The social work staff worked with families' and patients' anxieties when medical services changed with the change in protocols. Such a change, although necessary, places a strain on patients and their families in addition to that caused by their illness.

Protocols change and new ones are added. An example of the latter is the testicular cancer project begun in FY 77 which will enlist a total of 300 patients in the next three years. The Social Work Department staff, using the group and individual intervention modalities, will have to deal with the chemotherapy regimen and its inevitable devastating side effects, the psychological impact of the diagnosis for these young men, the resultant sterility, and the identity crisis resulting from their impaired sexual functioning. Ongoing emotional support as well as knowledgeable sexual counseling is essential for this group of patients.

Child Health and Human Development Social Work Section

This Institute involved three Branches:the Reproduction, Endocrinology and Pediatric Branch. The major objective for the first two Branches was to continue social work services and coverage which was accomplished through multidisciplinary conferences and constant cooperation with the nursing staff. Psychiatric consultations enabled the staff to discuss frankly their negative feelings about demanding and/or terminally ill patients and in the long-run improved overall patient care.

The Pediatric Branch recruits patients from other Institutes, and these pediatric patients require specialized care. The social work staff member provided service to all these patients and families regardless of diagnosis.

Heart, Lung and Blood Social Work Section

The retirement of the program supervisor and maternity leave of another staff member resulted in an increased burden for the three staff members in this Social Work Section. An effective change was made in social work coverage on Cardiac Surgery and the Diagnostic Cardiology Branch - two workers were assigned to each Service. Patients were divided between the two workers, and an individual patient was followed by one worker throughout his hospitalization. Thus, if a patient became a surgical candidate later, a relationship had already been established. This plan was facilitated by the fact that both workers had participated in twice weekly rounds with the clinical team of all patients. The social worker was the person who provided continuity of service, assisted in the transition from a medical to a surgical unit, and helped prepare the patient insofar as possible for the surgical experience.

In the Molecular Hematology Branch the social worker's main focus was the patients' and relatives' reactions to the severe emotional and physical effects of chronic illness. Patients' and families' depression, anxiety, family and marital conflicts, role reversals, and need for supportive community resources were of central concern.

Other illnesses, such as suspected factitious hypokalemia required a systematic psychological-psychiatric evaluation program to provide a clearer picture of the illness in emotional and physical terms. Social workers could then help patients deal with their self-induced illness.

Neurological and Communicative Diseases and Stroke/Eye Social Work Sections

Because of many changes in personnel in the Neurology Social Work Section, stop-gap measures were necessary to provide coverage on this Service. Primary goals of this Section were: (1) to help patients and families deal more effectively with the social, environmental, and personal problems occasioned by their illness; (2) to enhance the patient's ability to improve his "quality of life"; and (3) to establish closer working relationships among social workers, nurses, rehabilitation personnel, and physicians.

On Medical Neurology, social workers had more visibility and participated in weekly Medical Neurology and Multiple Sclerosis Branches rounds and attended a special weekly meeting with the Medical Neurology associates, nurses, and physical therapists. There were, in addition, weekly grand rounds alternating between the two Units. Teaching rounds were also initiated to provide an opportunity for social workers to make contributions of their expertise to patient care.

The preparation and filming of the Surgical Neurology's Parkinson group as an educational instrument was a rewarding experience for patients and spouses, and most importantly, the group felt exhilarated about making a significant contribution.

Social work responsibilities to the National Eye Institute was on a referral basis. Social workers emphasized coordination of activities with all professional disciplines. The major social work goal was the identification of community and national resources for the visually handicapped so that patients and families would be knowledgeable about the services available to them designed to facilitate their adjustment to visual loss.

III. SPECIAL PROJECTS

NIH Patient Emergency Fund

This fund, administered by the department Chief, continued to serve a crucial need in providing services and emergency funds for Clinical Center patients and families which could not be paid out of Government appropriations. This fund is financed by donations from former patients, family members, friends of patients, and NIH employees.

One special source of income was the annual gift from NIH employees at Christmas time under the "Davis Plan" whereby employees donated to the NIH Patient Emergency Fund in lieu of sending Christmas cards to fellow employees. The Christmas "Davis Plan" drive totaled $6,091.24 for FY 1977.

During the period from July 1976 through June 1977, the five principle areas of expenditures from the Patient Emergency Fund and the amounts spent were:

Special programs (nursing unit parties, supplies, etc.)	$ 4,317.50
Patient transportation	1,073.25
Allowance to relatives to assist with living costs while visiting Clinical Center patients	37,052.68
Patient miscellaneous expenditures (clothing, special devices)	1,707.63
Basic necessities (small weekly spending allowance for patients without funds)	1,327.50
TOTAL AMOUNT SPENT (July 1976 through June 1977)	$45,478.56

The balance in the fund as of July 1, 1977, improved markedly over July 1, 1976; however, compared with the July 1, 1975 balance, much ground remained to be regained.

BALANCE AS OF JULY 1	1977	1976	1975
	$10,000	$ 6,300	$18,400

Patients and family members assisted:

AS OF JULY 1	1977	1976	1975
Total	306	278	425
NCI	154	169	189
Other Institutes	152	109	236

Contributions to the fund (deposits) in 1977 increased significantly over 1976.

1977	1976	1975
$49,000	$35,700	$38,100

Withdrawal from the fund in 1977 declined slightly from 1976.

1977	1976	1975
$45,500	$47,900	$52,600

... average expenditure (withdrawal) per beneficiary (patient or family member).

1977	1976	1975
$150	$172	$124

The weekly cost for room and board averaged about $80.00 to $84.00. The food allowance of $4.00 a day was raised to $5.50 in May 1977, and was based on Clinical Center cafeteria prices. This was in contrast to those patients on the Special Ambulatory Care Program who received a $9.00 a day food allowance in the same period.

See Table 4.

Wig Contract

The contract for Clinical Center patients' wigs continued to be administered through the Social Work Department and approximately 400 wigs, adult and child, costing $30,500, were processed in a 12-month period. Staff members were involved in making the arrangements with the patient and provider, and helped handle their feelings of loss and change in their self-image.

Payment for Burial

In May 1977 the Social Work Department was given the responsibility to decide whether a full or partial contract was required for patient's burial expenses.

IV. MAJOR PROGRESS IN SERVICES, TRAINING AND DEVELOPMENT

Department Reorganization

The department was reorganized to provide for greater efficiency with positions for a deputy chief and two program supervisors who would share administrative and supervisory responsibility for the various Institutes. The department however still faces growing work loads with the ever increasing numbers of outpatients and increasing newly instituted protocols of the Cancer Institute in addition to their ongoing protocols.

Computerized Medical Information System

MIS became operative on several nursing units, and the department was able to begin to evaluate our social work software program and to incorporate needed revisions. Several reports were reviewed to ascertain the quality and utilization of the system. On the whole, reports contained rich information and were redeemed from a "canned" quality by the judicious use of typed comments. Workers used the system without undue difficulty and learned to report economically and fluently. Once Technicon delivers to us the ability to report in a five day period after a patient has been discharged, we expect the system to work smoothly and well for us. A VMT and printer were installed for the Social Work Department.

Participation in Orientation, Training, and Educational Programs

Four major new patient/family groups were added making a total of eleven groups in an expansion of this important social work modality.

Social Work Department staff provided training to Clinical Center Departments and hospital personnel, e.g., the clinical associates, nurses and student nurses, Hematology Section, technologists, Spiritual Ministry, Pharmacy, and Patient Activity Section, as to the psychosocial aspects of various illnesses, work with the dying patient, the needs of infants and parents, and the effects of genetic handicaps upon patients and families.

Committee Representation

There was wider representation on Clinical Center committees which broadened staff's perspective and provided an opportunity to make a contribution within the hospital system. The Social Work Department broadened its contribution within the hospital through wider representation on Clinical Center committees

Training

Eleven staff members participated in professional training courses. Two secretaries attended the Upward Mobility College. Four staff members attended national social work meetings.

Major professional activities of staff members as listed in the Appendix reflected a wide-range of professional expertise among the department's staff members, and recognition by their professional groups at both the local and national level. These activities were essential to keep abreast of changes in the health field and social work practice, and to communicate to others the special social work role in the research setting of the Clinical Center.

On-Call System

To increase the efficiency of coverage by the Social Work Department, as of May 1977, the department staff formalized its "on-call" system for evenings and weekends. Workers were provided beepers, and all inquiries, requests, and subsequent action by the Social Work Department were documented to evaluate the kinds of services rendered.

Licensing

This year the State of Maryland required licensing of social workers "to protect the public by setting standards of qualifications, education, training and experience for those who seek to engage in the practice of social work and by providing high standards of professional performances for those engaged in the profession of social work". Although not required of social workers employed by the Federal government, all staff members with the exception of two who were licensed in New York, either were licensed or their applications were pending.

V. FUTURE OBJECTIVES

1. The outpatient department has never been adequately covered, but with the increased numbers of outpatients, increased professional staff will be required to meet the full-range of responsibilities satisfactorily. During FY 1977, approximately one-third of staff time was devoted to services to outpatients which did not begin to meet the documented need on the Cancer Institute.

2. Improved "accountability" through the Medical Information System, updating the statistical reporting system and developing quality and quantity assurance, including professional review procedures.

3. Continued exploration of strategies for increasing funds for the NIH Patient Emergency Fund.

4. Development of a retrieval mechanism to assemble aggregate data from Medical Information System with which to evaluate program planning for improved patient care.

5. In addition to its monitoring of sample reports, the MIS cadre began to draft a paper on our department's Medical Information System Program which will be of use to the department and the profession as a whole.

6. Increased integration and improvement of the student training program.

7. Publish material about Clinical Center patient and family groups for the 25th anniversary of Clinical Center and the Social Work Department.

8. Long-range goals include social work research relative to the psycho-social dimension of chronic illness.

9. On NICHD Pediatric Branch, interdisciplinary weekly meetings continued to be helpful for optimal planning on behalf of patients. The staff were in the process of addressing the issue of preadmission contact between the unit and new patients and their families who might not know what to expect of an NIH pediatric admission. As a result of these meetings, a booklet is being designed to answer some of the structural and process questions. Also, plans for the future include a regularly scheduled parent group meeting to include all parents whose children are on the Pediatric unit regardless of diagnosis. In addition, specially structured intervention is planned for special diagnostic groups and their families.

VI. STAFF PROFESSIONAL ACTIVITIES OUTSIDE THE CLINICAL CENTER

Mrs. Libby E. Ely

Panelist, Georgetown University School of Nursing and Continued Education, workshop entitled "Health Care of Persons with Lupus Erythematosus", November 11, 1976.

Mrs. Kathryn K. Himmelsbach

Member, NCI Clinical Research Committee Subpanel.

Member, Program Evaluation Committee, American Cancer Society, D.C. Chapter.

Member, Social Workers' Sub-Committee, American Cancer Society, D.C. Chapter.

Member, Board of Directors, American Red Cross, Montgomery County Chapter.

Member, Executive Committee, American Red Cross, Montgomery County Chapter.

Vice-Chairman, Service to Military Families Committee, American Red Cross, Montgomery County Chapter.

Member, Ladies' Board, Georgetown University Hospital.

Member, Washington Hospice Society, Inc.

Panelist, Community Cancer Education Day, Howard University, subject - "Social Work with the Breast Cancer Patient and Family".

Panelist, St. Mary's College Seminarians, Baltimore, Maryland, subject - "Work with Death and Dying".

Panelist, American Cancer Society Second Annual Conference in Human Values and Cancer Patient, Chicago, Illinois, September 8, 1977.

Panelist, Oral Cancer Society, Georgetown University Dental School, sponsored by the American Career Society of D. C., subject - "Medical and Psychosocial Aspects of Head, Neck and Mouth Cancer".

Mrs. Ruth W. Kaneshiro

Member, National Association of Social Work Abstract Committee. Abstracts written for the quarterly journal, Abstracts for Social Work from The Journal of Nervous and Mental Diseases.

Miss Marjorie E. McKinney

Member, Executive Board of Leukemia Society of America.

Miss Barbara A. Murphy

Member, Subcommittee for Social Workers of the Career Development Committee for Health Service Officers.

TABLE I
SOCIAL WORK
INPATIENT COVERAGE BY PERCENTAGE
JULY 1975 through MAY 1976

INSTITUTE	INPATIENT CENSUS	INPATIENTS SERVED	PERCENT COVERAGE
NCI	2,541	1,715	67.5
NHLBI NICHD	2,290	1,885	82.0
NIAID	703	317	45.0
NIAMDD	757	622	82.2
NINCDS NEI	1,053	701	66.6
TOTAL	7,344	5,240	71.4

JULY 1976 through MAY 1977

INSTITUTE	INPATIENT CENSUS	INPATIENTS SERVED	PERCENT COVERAGE
NCI	2,987	1,846	61.8
NHLBI NICHD	2,248	1,743	77.5
NIAID	904	498	55.1
NIAMDD	927	710	76.6
NINCDS NEI	1,237	716	57.9
TOTAL	8,303	5,513	66.4

TABLE 2
NUMBER OF CLIENTS PROVIDED WITH
SOCIAL WORK SERVICES
JULY 1976 through MAY 1977

SW SEC.	(1) CC PATIENT	(1) FAMILY MEMBER	(2) CC PATIENT	(2) FAMILY MEMBER	(3) CC PATIENT	(3) FAMILY MEM.	(4) CC PATIENT	(4) FAMILY MEM.	TOTAL CC PATIENTS	TOTAL FAMILY MEMBER
1976 JUL	6		544		25		118		693	
		2		284		10		44		340
AUG	12		526		30		182		750	
		4		311		10		55		380
SEPT	12		516		87		147		762	
		2		335		37		60		434
OCT	19		495		28		198		740	
		11		352		20		58		441
NOV	6		469		21		147		643	
		1		315		21		45		382
DEC	10		417		20		156		603	
		3		292		12		51		358
1977 JAN	5		485		28		169		687	
				273		22		68		363
FEB	9		501		94		115		719	
		4		311		17		67		399
MAR	16		533		92		119		760	
		5		325		32		44		406
APR	1		494		95		108		698	
		1		318		31		37		387
MAY	13		533		67		134		747	
		1		391		32		50		474
	109		5513		587		1593		7802	
		34		3507		244		579		4364

(1) PREADMISSION Service between acceptance for project and admission.
(2) INPATIENT Person occupying a CC bed at any time during the month.
(3) CLINIC Service where patient has never been an inpatient.
(4) FOLLOW-UP Service to former inpatient.

TABLE 3
GROUP ACTIVITY REPORT
JULY 1976 through MAY 1977

SECTION	RESEARCH ACTIVITIES		PRACTICE-PROGRAM ACTIVITIES		SOCIAL WORK DEPARTMENTAL ACTIVITIES		COMMUNITY AND PROFESSIONAL ACTIVITIES		TOTAL HOURS
	HOURS	%	HOURS	%	HOURS	%	HOURS	%	
NCI	5	.2	1,390	58.9	850	35.6	132	5.4	2,377
NHLBI NICHD	42	3.0	707	51.3	572	41.5	58	4.2	1,379
NIAID NIAMDD	0	0.0	657	53.9	469	38.4	93	7.7	1,219
NINCDS NEI	19	1.6	671	57.9	437	37.7	33	2.8	1,160
TOTAL	66	1.1	3,425	55.1	2,328	38.7	316	5.1	6,135

TABLE 4
NIH PATIENT EMERGENCY FUND EXPENDITURES
JULY 1976 through JUNE 1977

MONTH	SPECIAL PROGRAM	PATIENT TRANSPORTATION	ALLOWANCES TO RELATIVES	PATIENT MISCELLANEOUS	BASIC NECESSITIES	TOTAL WITHDRAWN	TOTAL DEPOSITS
1976 JULY	$ 245.50	$ 13.80	$ 3,397.70	$ 242.97	$ 64.00	$ 3,963.97	$ 1,900.70
AUG.	291.50	106.00	2,596.00	86.00	72.00	3,151.50	1,300.55
SEPT.	306.50	39.00	3,931.52	127.00	89.00	4,493.02	5,566.50
OCT.	310.50	41.25	3,999.84	106.00	117.00	4,574.59	3,698.54
NOV.	336.50	68.00	3,483.00	322.00	249.00	4,458.50	5,648.48
DEC.	451.50	41.50	3,047.50	91.00	154.00	3,812.50	7,553.15
1977 JAN.	314.00	45.55	3,332.00	106.50	163.00	3,961.05	3,296.92
FEB.	347.50	40.20	2,532.00	65.50	132.00	3,117.20	8,035.03
MAR.	449.50	67.85	2,793.00	128.00	130.00	3,568.85	3,889.95
APRIL	370.50	49.00	2,970.00	183.00	47.00	3,619.50	3,181.37
MAY	436.50	451.00	2,279.12	163.86	62.00	3,392.48	2,862.38
JUNE	457.50	110.10	2,664.00	85.80	48.00	3,365.40	2,189.55
TOTAL	$4,317.50	$1,073.25	$37,052.68	$1,707.63	$1,327.50	$45,478.56	$49,123.12

SW-16

RECAPITULATION

Balance brough forward July 1, 1976	$ 6,309.72
Fiscal Year 1977 - Deposits	49,123.12
	$ 55,432.84
Fiscal Year 1977 - Withdrawals	45,478.56
	$ 9,954.28

July 1, 1976 through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

DEPARTMENT OF SPIRITUAL MINISTRY

CONTENTS

July 1, 1976 through September 30, 1977

PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

SUMMARY ANNUAL REPORT OF PROGRAM ACTIVITIES
CLINICAL CENTER

DEPARTMENT OF SPIRITUAL MINISTRY

OVERVIEW

The basic task of the Department was to provide spiritual ministry to patients and their families who welcomed the ministrations of a clergyman and to hold religious services in the hospital. It also included acting as liaison with religious groups not represented by the staff chaplains. Fundamental to this task was the bedside ministry to patients and family members and the religious services held in the fourteenth floor Chapel. Other tasks of the Department included consulting with fellow staff members of the Clinical Center, attending multidisciplinary conferences, membership on research committees, working with the Clinical Center EEO Advisory Committee, participating in educational and orientation seminars, lecturing, and consulting with other clergy and community groups.

As patients and their families experienced the crises of coming to the hospital, being seriously ill, anticipating surgery or other therapies, leaving the hospital, and, for some, facing death, the department endeavored to "rejoice with those who rejoice and weep with those who weep" as a religious friend, guide, and counselor.

Statistics indicated the following average religious preferences of newly admitted patients: Jewish - 7%; Catholic - 26%; Protestant and others - 67%.

STAFF

Chaplain LeRoy Kerney served as Chief of the Department and as a Protestant Chaplain. Chaplain Robert White and Chaplain William Payne were the other Protestant Chaplains.

Father Eugene Linehan, S.J. served in the hospital on a five day basis with Father Michael Griffin and Father Vincent O'Brien serving on days not covered by Father Linehan. Assistance during the day was increased in the new contract to allow for several part-time priests to bring an additional twenty hours of coverage to patients and their families.

Mrs. Emma Ditman, who is certified as a Pastoral Associate provided volunteer service. A small group of seminarians from the School of Theology, Catholic University, came for supervised training during the school year.

Rabbi Maurice Kleinberg, who has served on a half-time basis, retired August 31, 1976. Negotiations were successful in arranging a half-time position at the Clinical Center and a half-time position at St. Elizabeth's Hospital. Rabbi Joseph Levine was appointed to these positions August 1977.

CHAPEL SERVICE

Regular chapel services were held during the year for the major faith groups. Mrs. Frances Viernstein was our Sunday Chapel organist.

These services were:

Protestant: Sunday, 10:00 a.m. Holy Communion Service, the first Sunday of each month.

Catholic: Sunday and weekdays, 11:15 a.m. Daily distribution of Communion to bedridden patients.

Jewish: Friday, 4:30 p.m.

In addition to the regular services, these special services were held:

Protestant: World Wide Communion - 1st Sunday in October
Thanksgiving Day Service
Christmas Carol Service
Christmas Day - bedside visitation
Good Friday Service - (participation by Protestant and Catholic clergy and patients)

Catholic: Holy Days of Obligation Mass
Special Blessing of Throats
Distribution of Ashes - Ash Wednesday

Jewish: Rosh Hashana, Sukkoth, Purim, Shavuoth, Yom Kippur, Chanukah, Passover, Memorial Services

All three faiths extended the ministry of the chapel services by broadcasting the services through bedside speakers for those unable to go to the chapel and by visitation to bedridden patients. Appropriate sacraments were administered as desired.

CHAPEL SERVICE

Daily Catholic Mass provides a great resource for both patients and staff. Noted is the fact that as our Out Patient Clinic develops, so does the attendance at 11:15 service. It supplies for these patients spiritual

nourishment and the sense of Community sorely needed for so many filled with the anxiety of treatment. Today's Liturgy is much richer in terms of Feast Days and the varied Bible Readings so that it contributes mightily to our Catholic Pastoral Care.

Patients, family and staff have remarked that some of their most meaningful worship experiences have occurred during their stay here. In the Clinical Center there is among patients a deeper awareness of a sense of community and caring, and a freedom to express their deepest concerns with the assurance that here they are understood and accepted. Although those who attend may be almost complete strangers prior to worship, they discover the reality of what it means to be part of the body of Christ and the truth of Paul's comment: "If one member suffers, all suffer together; if one member is honored, all rejoice together". (I Cor 12:26) Chaplains find that through our worship together we are continually refreshed and renewed, strengthened and supported, as those who worship together share their concerns, their courage, and their faith.

PASTORAL MINISTRY TO PATIENTS AND THEIR FAMILIES

The department attempted, when possible, to have a staff member visit all patients prior to major surgery, patients who were on the seriously ill list, and families of patients who died. All Catholic patients were contacted through the sacramental ministry of the Catholic chaplain. The Jewish chaplain was able to see all the patients of the Jewish faith. Most of the Protestant patients were visited. Priority was given to the terminally ill, the seriously ill, and those scheduled for surgery. All referrals by staff, relatives and pastors, as well as direct patient requests were seen. Clergymen from the community were called upon to minister to special patients, e.g., patients requesting special rites from clergymen of their own denominations. These included several Greek Orthodox priests who were routinely called to minister to the Greek-speaking patients.

Pastoral problems which the chaplains encountered included: loneliness, grief, fear, guilt, anxiety, loss of spiritual meaning, boredom, identity crisis, and changes in body-image and body-function. Pastoral methods included pastoral conversations, pastoral counseling, sacraments, blessings, prayer, scripture, and worship. On occasion, the chaplains helped patients and their families resolve dilemmas of conscience, conflicts of values, and difficulties in accepting radical therapies.

All members of the staff endeavored to be sensitive to the patient's own understanding of religion for himself, and, in turn, become a resource person for the patient to discover or rediscover his own spiritual strength.

The complex work of a chaplain calls for familiarity with the medical situation, medical knowledge, sensitivity to emotional issues, and work with staff and family, and is illustrated by the following stories:

A patient facing an open heart operation had left her husband and twelve-year-old daughter and was in the process of seeking a divorce. The day of the operation the husband appeared unexpectedly and waited in the solarium

opposite the patient's sister and brother-in-law. They were unwilling to speak to each other. The tension and anger was sensed by others in the solarium.

The twelve-year-old daughter was at her father's house waiting to hear the outcome of her mother's operation.

In talking with the husband and then with the sister the Chaplain sensed a problem if the patient did not survive. The sister had not been permitted to speak to the child (her niece) in the past six months of the estrangement. If her mother died, the child would need the support of her mother's family as well as her father's. On the other hand, if the patient survived, the post-operative period would be more difficult if the present tension and bitterness were not relieved.

Through several discussions with both parties the Chaplain was able to assist them in laying aside their differences temporarily for the sake of the child's welfare and they began to plan together with the Chaplain's assistanc how they might both talk with the child on the telephone once the word came from the doctor.

Through the long day, they gradually and painfully made a kind of peace. Good news came and they all talked to the child. During the days of recuperation the child visited regularly and all the family maintained the truce.

The sister was gratified that she could now have a normal relationship with her niece and the patient and her husband began to verbalize some of their problems and an awareness that they should not let their child become "a football" in their marital dispute.

The Chaplain felt that the patient's recovery was uneventful partly because the tension within the family had been greatly reduced. The husband continue to contact him after the patient's discharge for guidance in the marital dispute.

A social worker requested a Chaplain visit a young boy with a terminal illnes who wanted to talk to a Chaplain. He wanted to read the Bible and pray but didn't know how to do either. He was visited regularly and talked about his concerns, about his loneliness, about death and how he had difficulty going to sleep because he was afraid he wouldn't wake up. The Chaplain shared with him in many ways. He taught him the 23rd Psalm and discussed its meaning, talked about prayer and how one could talk to God just like we talk to each other, and then, after praying together they played checkers and just talked. He also took some pictures of the patient for the patient so that he would have some to send home to his family. The meaning of the relationship was typified in the patient's remark to one of the staff, "That chaplain guy, he really likes me."

A Chaplain became involved with an amputee, who had one thoracotomy and was undergoing a difficult series of chemotherapy treatments. During one treatment procedure the staff informed the patient that the scan had shown a

tumor on his other lung which interrupted the chemotherapy. He was faced with the decision about further surgery. He became very emotional (a reaction which his mother had never seen before) and even said some angry things about God and the patient wondered where he was in all of this. The mother spoke with the chaplain, but the patient avoided him for several days saying he didn't want to talk about it. In one of the conversations with the mother, the chaplain told her that he certainly could understand her son's anger: reading Scripture made it clear that many of God's people became angry with God and even cursed the day they were born. The Chaplain pointed out that it was really only people who had faith who could get angry with God. She told the chaplain later that when she shared this conversation with her son, he smiled for the first time in a long while. It was a revelation to the young man and opened up the possibility for him to deal with his feelings and concerns more openly and honestly.

Pastoral Ministry statistics for two typical months follow:

		Protestant	Catholic	Jewish
Admissions	October 1976	340 (67%)	132 (26%)	37 (7%)
	February 1977	319 (68%)	120 (26%)	28 (6%)
Discharges	October 1976	381 (70%)	122 (23%)	39 (7%)
	February 1977	322 (70%)	116 (25%)	22 (5%)
Pre-Ops	October	67	20	11
	February	67	34	5
Seriously Ill	October	7	0	0
	February	2	2	0
Deaths	October	13	6	0
	February	4	6	0

WORK WITH STAFF

Group seminars with staff members dealt with family, emotional, and treatment problems. Staff attended a number of weekly multidisciplinary meetings.

Frequent, informal consultation with nurses, doctors, and social workers concerning a particular patient's progress and condition was helpful in carrying out an effective plan of pastoral care and visitation.

RESEARCH COMMITTEES

Chaplain Kerney was a member of the National Institute of Mental Health research review committee.

EEO

Chaplain White received an EEO Award for his service as a member and chairperson of the EEO Advisory Committee.

EDUCATION AND TRAINING

Chaplain Kerney participated on a panel on "Terminal Illness" with student nurses.

Chaplain Kerney met with a group of seminarians from Wesley Theological Seminary, a group of college students from Baltimore and two visiting Catholic Sisters from a college in Virginia.

Chaplain White participated in the monthly orientation of new nursing staff conducted by the Nursing Education and Training Department.

Chaplain White participated on a panel on "Death and Dying" in a Clinical Nurse Seminar.

CONSULTATION

Chaplain Kerney served on a committee to evaluate clinical pastoral educatio students at Walter Reed Army Hospital.

Chaplain Kerney served on a nominating committee for the selection of a chaplain at Suburban Hospital, Bethesda, Maryland.

Chaplain Kerney served on a task force of the College of Chaplains, a divisi of the American Protestant Hospital Association to evaluate and recommend changes in the organization.

LECTURES

Chaplain White lectured and led a discussion on "Living With the Dying" at Grace Presbyterian Church in Springfield, Virginia.

Father Linehan spoke to the ecumenical ministerial organization of Rockville on the ministry of the Department of Spiritual Ministry.

Father Linehan lectured to the local Jesuits on "Death and Dying."

Chaplain Kerney lectured and participated on a panel on "Ministry to the Heart Patient" at the Veterans Hospital in Baltimore, Maryland.

PROFESSIONAL MEETINGS AND TRAINING

Chaplain White was an elected commissioner to the annual meeting of the Synod of the Piedmont United Presbyterian Church.

Chaplain White attended a symposium on the Nature of a Humane Society at the University of Pennsylvania.

Chaplain White participated in the Supervisory Training Program course on "Motivational Dynamics."

Chaplain White attended an International Task Force Seminar-Retreat on the North American/Third World Church, Washington, D. C.

Father Linehan attended the Third Annual Institute on Theological Concerns of the Health Apostolate, New York, New York.

Chaplain Kerney attended the annual meeting of the College of Chaplains, a division of the American Protestant Hospital Association, Cincinnati, Ohio.

Chaplain Payne attended a one day lecture/demonstration by Virginia Satir at the University of Maryland.