PROGRAMS ■ PRACTICES ■ PEOPLE

Non-A, Non-B Hepatitis Is Under Study at NIH and FDA

■ Two teams of Federal scientists have demonstrated for the first time that a transmissible agent which can remain infectious over prolonged periods is responsible for non-A, non-B (post-transfusion) hepatitis. This form of hepatitis has been identified only recently as a disease entity separate from the well-known viral forms—type A (infectious) and type B (serum). The clinical and microscopic similarities of non-A, non-B hepatitis to the previously recognized forms and the new evidence of its transmissibility point strongly to a viral cause.

In independent studies headed by Dr. Harvey J. Alter of the National Institutes of Health's Clinical Center and by Dr. Edward Tabor of the Food and Drug Administration's Bureau of Biologics, chimpanzees inoculated with plasma or serum from patients with either acute or chronic non-A, non-B hepatitis have provided biochemical and biopsy evidence of the disease. The investigators reported in the March 4, 1978, issue of *Lancet* that the ability to transmit hepatitis with chronic phase plasma indicates that there is a chronic asymptomatic carrier state for non-A, non-B hepatitis, just as there is for type B hepatitis.

Development in the early 1970s of sensitive immunological tests to detect the hepatitis B surface (Australia) antigen has enabled scientists to identify most of the blood donors who carry the hepatitis B virus. Application of these tests and the exclusion of commercial donors has led to a dramatic reduction in the incidence of post-transfusion hepatitis. Contrary to physicians' hopes and expectations, however, some post-transfusion hepatitis has continued to appear. Presently, 70 to 90 percent of post-transfusion hepatitis is serologically unrelated to either type A or B viral agents and is tentatively classified as non-A, non-B. It is hoped that the studies of Alter and Tabor and their co-workers conducted with an animal model will lead to the visualization of virus material in liver tissue and the development of a serologic test for non-A, non-B hepatitis, as well as ultimately to the elimination of post-transfusion hepatitis.

Optimum Occupancy Levels for Hospitals Explored

■ A method for determining the maximum average occupancy at which a hospital unit can operate will be developed by the University of Michigan, Ann Arbor, under a 2-year grant from the National Center for Health Services Research, Health Resources Administration. The system will enable hospitals to make optimum use of costly resources while reducing revenue losses resulting from unnecessary bed vacancies.

Walton M. Hancock, principal investigator, will devise a system sensitive to the individual hospital's constraints and policies and applicable to hospital units of 20 to 320 beds. In the system design, account will be taken of the number of beds, the proportion of emergency admissions, the proportion of all elective admissions (scheduled and on-call) that are scheduled, and the average, and the variance of, length of stay. The system will be a further refinement of, and be based on, the admissions scheduling and control system previously developed by the University of Michigan under sponsorship of the National Center for Health Services Research.

Volume 2, Ninth Revision of ICD, Is Available

■ Volume 2 of the Ninth Revision of the International Classification of Diseases, which contains the Alphabetical Index to Volume 1, has been issued. Volume 1, the Tabular List, appeared in 1977 (see January–February 1978 issue of this journal, page 102). The Ninth Revision will come into effect January 1, 1979.

The Alphabetical Index is an essential adjunct to Volume 1 since it contains a great number of diagnostic terms that do not appear in Volume 1. In Volume 1, the terms appearing in a given category are only examples of the content of that category. Volume 2, on the other hand, is intended to contain all diagnostic terms in current use and thus guide coders in assigning the diagnoses they may encounter.

The Alphabetical Index is in three sections. Section I includes diseases, syndromes, signs, symptoms, pathological conditions, injuries, problems, and other reasons for contact with health services—in other words, the kind of information that would be recorded by a physician. The terms in Section II are not medical diagnoses but the external causes of injury (fire, explosion, fall, collision, submersion) and the circumstances under which the injuries occurred (accident, assault, suicide, war, and so forth). Section III is an index-table of drugs and other chemical substances giving rise to poisoning or other adverse effects.

Volume 2 also includes some corrections of Volume 1.

Manual of the International Statistical Classification of Diseases, Injuries, and Causes of Death, Volume 2: Alphabetical Index (ISBN 92 4 154005 2). XII + 659 pages. $15. WHO Publications Center, 9 Sheridan Ave., Albany, N.Y. 12210. (Will be published also in French, Spanish, and Russian.)

New Predominantly Black Medical College in Atlanta

■ A predominantly black medical school opened this fall at Morehouse College in Atlanta, Ga., with grant support from the Department of Health, Education, and Welfare. Of the medical schools now operating, it is the first predominantly black one to open in the United States in this century.

The School of Medicine at Morehouse College accepted its first class of 24 students for a 2-year program in September. This program will be conducted in existing facilities on the campus of Morehouse College (established 1867). The School of Medicine at Morehouse College will expand to a 4-year degree-granting institution in the mid-1980s. In the interim, Meharry, Emory, and Howard medical schools and the Medical College of Georgia have made commitments to accept Morehouse graduates, so that they will be able to complete their degree requirements in any of these institutions.

In fiscal years 1973 and 1974, HEW supported the establishment of the new school with a $2.1 million feasibility study and related activities. Morehouse also received HEW startup grants of $320,000 and $122,500 in fiscal years 1977 and 1978. More recently, the college has also been awarded a $5 million HEW grant to build a basic medical sciences building for the medical school, and the college is conducting a drive for $1.25 million in matching funds to supplement this Federal construction grant.

The School of Medicine at Morehouse College will help make physician services more available to the nation's black population and help provide more primary care physicians for the nation's underserved areas. Currently, in the United States, there is 1 physician for every 585 persons, but only 1 black physician per 4,100 blacks. About 7 percent of the first-year students in the nation's medical schools are black.

Broad New Quality Standards for the Manufacture of Medical Devices

■ The Food and Drug Administration has established broad new quality standards for the manufacture of medical devices, which become effective December 18, 1978. Any plant that fails to comply with the requirements after that date will be subject to regulatory action.

Based on the Medical Device Amendments passed by Congress in 1976, the new requirements apply to all medical devices, ranging from bandages and tongue depressors to pacemakers and heart-lung machines. They also apply to diagnostic products such as pregnancy test kits and tests for blood cholesterol and to foreign manufacturers' devices and diagnostic products that are intended for import into the United States.

The regulations describe in general terms the quality assurance procedures necessary to make safe and effective products. For example, they describe requirements for building maintenance, personnel training, record-keeping, equipment design and maintenance, and packaging and labeling controls. Makers of "critical devices" must meet additional production requirements more stringent than the general controls. (Critical devices are those that are implanted in the body, such as intrauterine devices (IUDs) and artificial blood vessels, or devices used in life-or-death situations, such as heart valves, pacemakers, and respirators.)

Donald Kennedy, Commissioner of Food and Drugs, said: "While the overall record of the devices industry is good, there is clearly room for improvement. Ninety percent of the 232 device recalls monitored by FDA from October 1976 to November 1977 were caused by poor manufacturing practices and could have been prevented." Kennedy said FDA plans to inspect at least 1,600 of the approximately 5,000 medical device manufacturing plants each year to make sure they meet the new requirements.

Known as Good Manufacturing Practices, the regulations were proposed March 1, 1977, and final regulations were published in the Federal Register July 21, 1978.

Foundation of Thanatology Calls for Papers for 1979 Symposium

■ The program committee and the conference committee of the Symposium on Thanatology: Homicide/Non-Criminal Homicide and Inappropriate Medical Deaths/Man-Caused Deaths is calling for position papers for the 25th symposium of the Foundation of Thanatology. The symposium will be held in New York City at the Columbia-Presbyterian Medical Center, 168th St., and Fort Washington Ave., April 17–21, 1979.

Deadline for the papers is March 15, 1979. The program and conference committees suggest that the papers deal with areas pertinent to the writers' own interests in the field of thanatology. They should be approximately 5–20 double spaced pages. Abstracts of the papers, up to 500 words, single spaced, should be submitted by February 5, 1979. These abstracts will be published in the *Archives of the Foundation of Thanatology* and distributed to symposium participants.

For further information, write Ms. Nancy H. Allen, Neuropsychiatric Institute, 760 Westwood Plaza, University of California, Los Angeles, Calif. 90024.

BHM Issues Revised Edition of Area Resource File

■ The Manpower Analysis Division of the Bureau of Health Manpower has issued a revised edition of "The Area Resource File—A Manpower Planning and Research Tool." The Area Resource File (ARF) is a computerized system containing a wide range of health and socioeconomic information that is useful in health systems research, analysis, and planning at local and national levels. Data in the system are retrievable by individual county and groups of counties. The file has become a major data resource for the planning network of Health Systems Agencies and State Health Planning and Development Agencies.

The Area Resource File—A Manpower Planning and Research Tool. DHEW Publication No. (HRA) 78–69. Copies are available from the Executive Secretariat, Bureau of Health Manpower, 3700 East-West Hwy., Hyattsville, Md. 20782.

Surprising Observation On Relationship Between Salt and Hypertension

■ Physicians at the University of Iowa College of Medicine and Hospitals, Iowa City, report that some persons may be very sensitive to the deleterious effects of salt on blood pressure, while others may be resistant to such effects.

The report is the result of studies on young adults at the University of Iowa Clinical Research Center. This center is one of 80 such units located at medical institutions throughout the United States that are funded by the Division of Research Resources of the National Institutes of Health. This clinical research unit within the larger hospital provides specialized patient-centered research facilities to the entire staff of the University of Iowa College of Medicine.

The Iowa studies involved two groups of young adults—one with normal blood pressure and another with slight or early hypertension. For 10 to 30 days, six members of each group followed diets with either high or low amounts of salt.

Because the subjects were studied in the Clinical Research Center, research dietitians could vary subjects' salt intake while keeping all other ingredients in their diets constant. To insure the safety and accuracy of the diets, the blood pressure, body weight, kidney and hormonal functions, and general physical condition of the patients were assessed daily by research nurses and by a physician who specializes in the treatment of hypertension.

As the research neared its conclusion, detailed studies of circulatory control were performed on the patients by cardiologists from the University of Iowa Cardiovascular Research and Training Center. These studies, which were conducted through funding from the National Heart, Lung, and Blood Institute of the National Institutes of Health, helped determine the effect of salt on blood pressure and blood vessels.

According to Dr. Allyn L. Mark, program director for the Clinical Research Center, and Dr. Francois Abboud, director of the Cardiovascular Research and Training Center, the most surprising and important finding of the study was that there was a distinct difference in the effects of a high-salt diet on the patients with normal blood pressure as compared with those having a slightly elevated blood pressure.

"Excessive salt raised blood pressure and constricted blood vessels in patients with slight hypertension, but it relaxed the blood vessels and failed to elevate blood pressures in the individuals with normal blood pressure," Mark said. "This indicates that some individuals may be very sensitive to the deleterious effects of salt on blood pressure, while others seem to be resistant. The research raises the intriguing possibility that sensitivity to salt may be a factor in predisposition to hypertension. This finding may have important implications in the prevention and treatment of hypertension."

Additional research studies evaluating the relationship between salt and hypertension are in progress at the two centers.

Capitation System for Reimbursement of Pharmacists

■ The cost-savings potential of a capitation system for reimbursement of pharmacists will be explored by University of Iowa investigators under a 2-year grant from the National Center for Health Services Research, Health Resources Administration.

G. Joseph Norwood, PhD, principal investigator, will evaluate the cost and impact on quality of care of the capitation system currently used in two Iowa counties to reimburse pharmacists for drugs and services provided Medicaid patients. The system encourages pharmacists to reduce their costs through such measures as switching to nonprescription or generic equivalents when appropriate and increasing the quantity of the drug dispensed to reduce the frequency of dispensing. Under this capitation system, Medicaid recipients select a regular pharmacist for services. The pharmacist then receives a monthly capitation fee based on the number of recipients on his or her rolls—a fee equal to 85 percent of the estimated per capita cost for drugs and for dispensing services. Incentive payments are awarded if the pharmacist's drug and management costs are less than the monthly fee; a differential is paid if the costs exceed the capitation fee. The study is to be completed in 1980.

U.S. Biomedical Scientists Offered Research Fellowships in Sweden and Switzerland

■ In 1979 the Swedish Medical Council and the Swiss National Science Foundation will each make available several research fellowships to qualified U.S. biomedical scientists. These fellowships will provide postdoctoral training in basic or clinical areas of medical research.

Applicants must be U.S. citizens and must have been engaged in independent responsible research in one of the health sciences for at least 2 of the last 4 years. Applicants must also provide evidence of acceptance by a training institution and a preceptor.

Fellowships provide for reimbursement of the round trip tourist air fare for the Fellow and his family. Stipends for the Swedish Medical Research Council Fellowships range from approximately $10,000 to $13,600 per year, depending on the number of years of postdoctoral research experience. The Swiss National Science Foundation stipends range from approximately $15,675 to $18,560, depending on the age and experience of the applicant at the time of the award. In addition, the Swiss National Science Foundation Fellowships provide a dependency allowance for the spouse and dependent children.

Material for applications may be obtained from the Scholars and Fellowships Program Branch, Fogarty International Center, National Institutes of Health, Bethesda, Md. 20014. The deadline for completed applications is January 1, 1979. Applications will be reviewed for scientific merit at the Fogarty International Center and forwarded to Sweden or Switzerland, as appropriate, for final selection and award in late spring or midsummer 1979. All correspondence concerning these fellowships must be clearly marked as "Swedish Medical Research Council Fellowship" or "Swiss National Science Foundation Fellowship."

federal register briefs

Compiled by Charles E. Jackson, Division of Legislation, Health Resources Administration

July 13, 1978, Vol. 43, No. 135, pp. 30127–30130

Mental health projects for Indochinese refugees. The Social Security Administration has announced the availability of national funding for special projects and programs designed to assist Indochinese refugees in resettling in the United States and gaining self-respect.

July 17, 1978, Vol. 43, No. 137, pp. 30648–30685

Designation of health manpower shortage areas. The Health Resources Administration of the Department of Health, Education, and Welfare has published its first list of areas that are eligible to apply for assignment of National Health Service Corps personnel to provide services in or to such areas. These areas are also eligible service areas for Public Health Service loan repayment and scholarships programs, and the entities located in them are eligible to apply for (or receive preference for) certain grant programs under the Public Health Service Act.

July 21, 1978, Vol. 43, No. 141, p. 31868

Federal funding of abortions. The Department of Health, Education, and Welfare has amended its regulations, published February 2 and 3, 1978, governing Federal financial participation in expenditures for abortions funded through various HEW programs. Federal financial participation in abortion would be available if a physician certified that the life of the mother would be endangered if the pregnancy were carried to term, two physicians certified that there would be severe and long lasting damage to the patient if the pregnancy were not terminated, or there was signed documentation by a law enforcement agency or public health service that incest or rape had taken place.

July 21, 1978, Vol. 43, No. 141, pp. 31786–31794

Protection of human subjects. The Department of Health, Education, and Welfare is proposing regulations to implement the recommendations on research involving children drawn up by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The key provisions of those recommendations are that such research can be carried out only if research methods are appropriate, investigators are competent, facilities are adequate, and procedures are designed so that the research will contribute vitally to generalizable knowledge. Risks must be minimized, and whenever possible the research must be performed in connection with necessary diagnosis and treatment. Adequate arrangements must be made for obtaining the assent of the child and the consent or permission of the parents or guardians whenever these are necessary.

July 24, 1978, Vol. 43, No. 142, pp. 32084–32089

Grants to Professional Standards Review Organizations. The Health Care Financing Administration has published a final rule that (*a*) establishes eligibility criteria and other conditions for Professional Standards Review Organizations (PSROs); (*b*) sets forth organizational and application requirements that must be met by an organization seeking to be designated as a PSRO; (*c*) requires that the designation and funding of PSROs be made through a grant mechanism; and (*d*) prescribes the length of the grant period and establishes procedures for the nonrenewal and termination of grants to PSROs. This rule implements sections 1152, 1154, and 1155 (f) 2 and 3 of the Social Security Act. The Secretary of Health, Education, and Welfare is authorized under these provisions to award grants to qualified organizations by which they are either conditionally or fully designated as PSROs. The regulation will replace the procurement contract process presently used with a grant system and will codify and simplify the organizational requirements applicable to PSROs.

July 28, 1978, Vol. 43, No. 146, pp. 32988–32999

Classification procedures for medical devices. The Food and Drug Administration has made a final ruling on the criteria and procedures for classifying medical devices intended for human use in order to provide reasonable assurance of safety and effectiveness.

July 28, 1978, Vol. 43, No. 146, pp. 33042–33178

Proposed revisions to guidelines for recombinant DNA research. The NIH Guidelines for Recombinant DNA Research were first issued in 1976. Proposed revisions to these guidelines are the result of a continuing process of scientific and public exchange.

The probable risks and benefits of recombinant DNA research have been discussed in numerous forums since 1973. Congress has held many hearings on the issues, and proposals have been made to connect the guidelines to Federal regulations and to redefine recombinant DNA research so as to narrow the range of experiments subject to the regulations.

July 31, 1978, Vol. 43, No. 147, pp. 33265–33268

National Health Service Corps. The Public Health Service has proposed regulations prescribing the requirements to be met when assigning National Health Service Corps personnel to public or nonprofit private entities for the purpose of providing health services in or to a health manpower shortage area.

August 8, 1978, Vol. 43, No. 153, pp. 35073–35077

Grants for prevention of lead-based paint poisoning. The Center for Disease Control proposes regulations under which grants would be awarded to State and local governments and private nonprofit organizations to assist them in meeting the costs of comprehensive programs for the prevention of lead-based paint poisoning and to State agencies for the purpose of establishing centralized laboratory services to analyze lead specimens.

August 10, 1978, Vol. 43, No. 155, p. 35552

Report on bioassay of acetohexomide and tolazamide for possible carcinogenicity. The National Institutes of Health has announced that a report is available to the public showing the results of tests of the cancer-causing activity of acetohexamide and tolazamide in rats and mice. Single copies can be obtained from the Office of Cancer Communication, National Cancer Institute, Bldg. 31, Rm. 10A21, National Institutes of Health, Bethesda, Md. 20014.

August 11, 1978, Vol. 43, No. 156, pp. 35698–35699

Kidney transplantation centers. A recently promulgated regulation authorizes temporary approval as renal transplantation centers of pediatric hospitals that do not perform the number of kidney transplants usually required for approval under Medicare. These hospitals may be approved under Medicare if the surgery is performed under the direction and supervision of a qualified kidney transplant surgeon who also performs transplants in an approved renal transplantation center and if certain other conditions are met. The intent of this amendment is to make it possible for pediatric patients to receive kidney transplants more conveniently.

August 18, 1978, Vol. 43, No. 161, pp. 36818–36831

Black lung benefits. Final rulemaking establishes criteria, standards, and procedures for reviewing the claims, both

pending and denied, of coal miners who are totally disabled by black lung disease, as well as the pending and denied claims of the survivors of coal miners who have died while totally disabled by black lung disease.

August 22, 1978, Vol. 43, No. 163, p. 37219

Authorization to protect the confidentiality of subjects involved in research on drug abuse. The Secretary of Health, Education, and Welfare has authorized employees of the University of California to protect the privacy of persons who are subjects of drug abuse research by withholding their names and other identifying characteristics from all persons not connected with that research. The university, however, may not withhold this information from qualified HEW personnel needing it for management purposes, but the persons receiving it must not disclose it.

August 23, 1978, Vol. 43, No. 164, pp. 37469–37473

Prohibition against reassignment of claims by providers and suppliers. The Health Care Financing Administration proposes to prohibit, except in specified situations, a provider, a physician, or other supplier of services from reassigning claims for Medicare reimbursement. A provider who violates this prohibition would be subject to termination of the provider agreement; a physician or other supplier would be subject to revocation of the right to receive assignment from Medicare beneficiaries. The proposal would also deter physicians and other suppliers from violating their assignment agreement (chiefly their agreement to accept the reasonable charge) by making the administrative sanctions conform with those that apply to situations involving prohibited reassignments.

August 24, 1978, Vol. 43, No. 165, pp. 37721–37722

End stage renal disease program. Notice is given of a decision by the Health Care Financing Administration to implement the End Stage Renal Disease (ESRD) Amendments of 1978. The regulations will extend Medicare entitlement based on ESRD to the relatively few patients who were previously ineligible because they were 65 years of age or older, will permit entitlement to begin earlier for patients who receive renal transplants or training in self-dialysis, and will lengthen the duration of Medicare payments following a renal transplant. The regulations will also establish requirements for the certification of self-dialysis facilities and for Medicare reimbursement of the services related to self-dialysis facilities and of the services related to self-dialysis in which the patient performs most of the procedures of the dialysis process at home.

education notes

Seminar on hazardous waste management. The Environmental and Water Resources Engineering Program and the Center for Environmental Quality Management of Vanderbilt University are sponsoring a seminar on hazardous waste management, January 16–18, 1979, in Nashville, Tenn. The seminar will present an overview of the present and anticipated policies on hazardous waste management as they apply to toxics, industrial waste and refuse, including the interrelationships among air, water, and groundwater quality. Specific information will be presented on accurate development of solid waste management tools, including design and management and operation and planning. Special consideration will be given to those waste products that contain materials requiring consideration for isolation and immobilization during disposal.

For information concerning the seminar write Prof. W. W. Eckenfelder, Jr., Vanderbilt University, Box 6222, Station B, Nashville, Tenn. 37235.

Occupational dermatology symposium. A symposium on occupational dermatology, sponsored jointly by the International Contact Dermatitis Research Group, the North American Contact Dermatitis Group, the National Institute for Occupational Safety and Health, and the University of California Hospital, San Francisco, will be held March 26–28, 1979, at the University of California Hospital. The course will succinctly summarize the principles and practices of occupational dermatology, emphasizing the latest relevant advances. Presentations by an international faculty will be aimed at physicians, nurses, and allied health scientists involved in the prevention and treatment of skin diseases. Workshops and field trips are optional.

For information, write Extended Programs in Medical Education, University of California Hospital, San Francisco, Calif. 94143, or call (415) 666-4251.

publications

FEDERAL

The Area Resource File (ARF). A manpower planning and research tool. *DHEW Publication No. (HRA) 78-69. April 1978; 104 pages.*

The Construction and Utility of Three Indexes of Intellectual Achievement: An Intellectual-Development (ID) Index, A Socio-Intellectual-Status (SIS) Index, a Differential-Intellectual-Development (DID) Index. U.S. Children and Youths, 6–17 Years. *DHEW Publication No. (HRA) 78-1348, Series 2, No. 4. September 1977; 26 pages.*

Acute Conditions, Incidence and Associated Disability, United States, July 1975–1976. *DHEW Publication No. (PHS) 78-1548, Series 10, No. 120. January 1978; 66 pages.*

Forced Vital Capacity of Children 6–11 Years, United States. *DHEW Publication No. (PHS) 78-1651, Series 11, No. 164. February 1978; 30 pages.*

Cardiovascular Conditions of Children 6–11 Years and Youths 12–17 years, United States, 1963–1965 and 1966–1970. *DHEW Publication No. (PHS) 78-1653, Series 11, No. 166. April 1978; 47 pages.*

Total Serum Cholesterol Levels of Adults 18–74 Years, United States, 1971–1974. *DHEW Publication No. (PHS) 78-1652, Series 11, No. 205. April 1978; 31 pages (Stock No. 071-022-00611-1).*

Survey of Photocopier and Related Products. *By Kenneth R. Envall. DHEW Publication No. (FDA) 8060. 1978; $2.50 (Stock No. 017-015-00149-1).*

Wavelength Dependence of Ultraviolet Enhanced Reactivation and Induction of Mammalian Viruses. *By Thomas P. Coohill. DHEW Publication No. (FDA) 78-8059. 1978; $4.50; $3 microfiche. National Technical Information Service, Springfield, Va. 22161 (accession No. PB 281 534/AS).*

The Physical Basis of Electromagnetic Interactions With Biological Systems. Proceedings of a workshop held at the University of Maryland, College Park, Md., June 15–17, 1977. *Edited by Leonard S. Taylor and Augustine Y. Cheung. DHEW Publication No. (FDA) 78-8055. 1978; $13, $3 microfiche. National Technical Information Service, Springfield, Va. 22161 (accession No. AD-A051218).*

9th Annual National Conference on Radiation Control. Meeting Today's Challenges, June 19–23, 1977, Seattle,