

system for easy access to immunization and travel information. The new service provides answers to questions most frequently asked by healthcare professionals and parents.

The FAX materials contain comprehensive and up-to-date information regarding immunizations, including those needed for foreign travel. The system's information ranges from brief summaries suitable for the general public to the detailed ACIP statements for each vaccine.

Much of the material is designed to educate the general public on immunizations that protect children against preventable diseases. Healthcare workers and practitioners may wish to direct interested patients to the system for reference.

To contact the Immunization Voice Information System, call (404) 332-4554 for information specific to immunizations, and select the topic of interest and method of delivery. Or dial direct to the CDC FAX Information Service, (404) 332-4565 and request the immunization directory. For access to the CDC Voice Information System, dial (404) 332-4555 for entry into the CDC-wide voice system, which contains other topics in addition to immunization.

## Severe Isoniazid-Associated Hepatitis Identified in New York

After the identification of a patient in New York who underwent liver transplantation because of severe hepatitis that developed during the use of isoniazid (INH) preventive therapy for latent tuberculous infection, an inquiry into other liver transplant centers in New York identified additional patients who had hepatitis attributed to INH.

Ten patients from New York were identified as being evaluated for liver transplantation because of severe acute hepatitis attributed to INH from January 1991 through May 1993. Of the 10 patients, one received both INH and rifampin. Another had received INH and discontinued its use one month before the onset of hepatitis symptoms because the patient had been exposed to tuberculosis resistant to INH and rifampin. Eight patients were taking INH alone (as therapy to prevent TB) at the onset of the hepatitis. The eight were aged 5 to 68 years; three were aged  $\geq 20$  years. Six were female. Because of the severity of illness, five of the eight patients received a liver transplant; one of these patients died after transplantation. The other three patients died while awaiting a donor liver.

The duration of INH use before the onset of hepatitis symptoms was either known or could be estimated for seven patients and ranged from 21 to 142 days; seven patients continued to take INH for at least 10 days after onset of symptoms. Initial symptoms of hepatitis included fatigue in five patients, nausea in five, abdominal pain in five, and anorexia in

four. All patients had jaundice when they sought medical attention.

Previous reports have described cases of severe or fatal INH-associated hepatitis. One study estimated the risk for hepatitis as 20.7 per 1,000 persons with 4.6% of the cases being fatal. However, in this report neither the number of persons in New York who receive INH preventive therapy each year nor the number who have INH-associated hepatitis are known. Thus, it is unclear whether the number of patients in this report represents an increase in severe or life-threatening INH-associated hepatitis or an improvement in the detection of the problem.

FROM: Severe isoniazid-associated hepatitis-New York, 1991-1993. *MMWR* 1993;42:545-547.

## Long-Term Acyclovir for Genital Herpes Is Safe and Effective

The Acyclovir Study Group now has reported results through the fifth year of their ongoing long-term clinical trial.

After the first year of the study, all patients were offered open-label acyclovir in a dose of 400 mg twice daily. Three hundred eighty-nine patients completed their fifth year of suppressive therapy and 25% of the patients had no recurrence for the entire five years. During each quarter of the fifth year, 86% to 90% of patients had no recurrence. The mean annual number of recurrences declined from 1.7 during the first year of the study to 0.8 during the fifth year of suppressive therapy. A small number of patients (3.3%) needed a dose of 800 mg acyclovir to suppress the outbreaks.

There were no significant changes in white blood cell counts, creatinine, or liver function tests in patients during the fifth year of treatment, and no cumulative toxicity was observed over time.

FROM: Goldberg LH, et al. Long-term suppression of recurrent genital herpes with acyclovir. *Arch Dermatol* 1993;129:582-587.

## MEDWatch Launched to Improve Adverse Events Reporting

The U.S. Food and Drug Administration (FDA) recently announced a program to improve the safety of drugs, biologics, medical devices, infant formulas, dietary supplements, medical foods, and other regulated products by encouraging health professionals voluntarily to report any serious adverse events and product defects.

The new program, called MEDWatch, is a comprehensive approach to FDA's postmarketing surveillance, and is aimed at improving health professionals' involvement by focusing on their reporting.

"Physicians, nurses, and others who care for patients are the first to know when a drug or medical

device does not perform as it should; the sooner they report it to the FDA, the faster the agency can analyze the problem and take corrective action," said FDA Commissioner Dr. David A. Kessler.

An important part of MEDWatch is a simplified reporting form—a self-addressed, one-page form that can be folded and mailed postage-free. In addition, the agency has established a special 24-hour toll-free telephone line, (800) FDA-1088, for adverse event information. Health professionals also will be able to file reports on a computer.

### **Joint Commission to Make Hospital Performance Information Available to Public**

Starting next year, the Joint Commission on Accreditation of Healthcare Organizations for the first time will release information to the public on how hospitals meet specific performance standards. Commission President Dennis S. O'Leary said, "This is a landmark issue for us ... it is very much in line with the reform environment. The change in the Joint Commission's confidentiality and disclosure policy, approved recently by the commissions board, recognizes the accrediting agency's obligation to share information with patients, purchasers, and other stakeholders in healthcare delivery systems."

Under the new policy, standards-compliance ratings in such areas as nursing care, infection control, patient rights, and life safety will be provided on a comparative basis. Also available for comparison will be facilities' overall summary grid scores, which are the basis for accreditation decisions.

Healthcare organizations will be able to review and comment on the data in the Joint Commission performance reports prior to their publication, but official survey reports will remain confidential.

FROM: Trustee magazine. American Hospital Association, July 1993.

### **CDC Clarifies Recommendation for Use of Bleach to Disinfect Needles**

The CDC clarified its April 19, 1993, joint bulletin regarding the use of bleach for disinfecting needles and syringes, including the recommendation for the use of full-strength household bleach. In a letter signed by Dr. James Curran, Associate Director for HIV/AIDS, the CDC explained that it recommended full-strength bleach to disinfect needles and syringes because of the difficulty of cleaning the interior of needles and syringes and the use of needles and syringes for parenteral injection.

This recommendation does not change the recommendations for situations encountered in healthcare settings, such as contamination of environmental

surfaces with blood. The CDC recommendation for disinfecting environmental surfaces continues to include the use of a 1:100 dilution of household bleach (or 1/4 cup bleach to 1 gallon tap water) (See *MMWR* 1993;46:1-18S; August 21, 1987.)

### **Lifetime AIDS Treatment Cost: \$119,274**

The lifetime cost of treating a person with HIV disease, assuming treatment begins immediately after infection and diagnosis, averages \$119,274, Dr. Fred Hellinger of the Agency for Health Care Policy and Research recently reported.

The figure was calculated by multiplying the average monthly cost of care in each of four stages of HIV disease by the average number of months the infected person spends in each stage. Dr. Hellinger's study was based on self-reported interviews and data every three months from 1,164 respondents from March 1991 through August 1992 at 26 sites in 10 cities in the United States. Costs included inpatient care, outpatient visits, home healthcare, long-term care, and drugs, both self-paid and covered by insurance. The survey assumed an average of 10.3 years from infection until progression to AIDS and a 25-month survival time from then until death.

Hellinger said the study was not random and thus the lifetime costs represented the "upper bounds" for the cost of treatment. The study found that the cost of treating a person with AIDS, which has risen rapidly in the past, has fallen as a result reducing the use of inpatient hospital services.

FROM: Hellinger FJ. The lifetime cost of treating a person with HIV infection. *JAMA* 1993;270:474-478.

### **Government Considers Relaxing CLIA Regulations**

The federal government now is looking at proposals for relaxing physician office laboratory regulations under the Clinical Laboratory Improvement Acts (CLIA). Although the Clinton administration vowed to ease some of the more burdensome requirements, it appears that the proposals for easing the rules are driven by the lack of money rather than a desire to limit the burden on physicians. The current plan is to let "low-volume" and "low-risk" labs perform self-assessments rather than submit to on-site surveys by government inspectors.

CLIA set up four categories of labs based on test complexity. It is unclear how the government would define low-risk labs for the purpose of this new proposal. However, it is assumed that the tests they perform would fall into CLIA's "moderately complex" category.

Labs doing high-complexity testing still would be