(HIV), the cause of acquired immune deficiency syndrome (AIDS). Activities highlighted the role communities played in controlling the epidemic of HIV infections and AIDS. On December 1, 1992, WHO, governmental, and nongovernmental organizations throughout the world held special events designed to increase knowledge and understanding about AIDS and to encourage compassion for persons infected with HIV.

In conjunction with the event, the US Public Health Service designated December 1 as National AIDS Awareness Day. Information about HIV infection, AIDS, and World AIDS Day is available from the Centers for Disease Control and Prevention National AIDS Hotline (CDC NAH) and the CDC National AIDS Clearinghouse (CDC NAC). The CDC NAH provides callers with information about HIV/AIDS, refers callers to services in their community, and places orders for HIV/AIDS publications; the CDC NAC distributes materials and maintains data bases on AIDS service organizations, educational materials, funding sources, and drug trials. The telephone numbers for the CDC NAH are (800) 342-2437 ([800] 342-AIDS); Spanish, (800) 3447432 ([800] 344-SIDA); or deaf service, (800) 243-7889 ([800] AIDS-STTY). For the CDC NAC, the number is (800) 4585231.

States To Adopt Policies for HIV-Infected Healthcare Workers Performing Exposure-Prone Procedures

October 28, 1992, marked the deadline for state public health officials to certify to the Secretary of Health and Human Services that guidelines issued by the Centers for Disease Control and Prevention (CDC) for managing human immunodeficiency virus (HIV) and hepatitis B virus (HBV)-infected healthcare workers performing exposure-prone invasive procedures, or equivalent guidelines, have been implemented in each state. The federal law (section 663 of Public Law 102-141) refers to the CDC's July 12, 1991 "Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures" (any current version of the guideline).

Many states have already applied for a one-year extension until after October 1993, some in anticipation of a revision of the CDC recommendations. However, the CDC has recently indicated that the July 12, 1991, recommendations will not be modified. In a letter to the state public health officers, Dr. William Roper announced that their review of the state guidelines, with respect to their equivalency to the July 12 recommendations, will give appropriate consideration to those states that decide exposure-prone invasive procedures are best determined on a case-by-case basis, taking into consideration the specific procedure as well as the skill, technique, and possible impairment of the infected healthcare worker. The law does not define the term "equivalency." As such, the final decision lies with the CDC.

It is not entirely clear how "equivalency" will be determined; however, experts believe that the CDC may be inclined to allow certain flexibility. In a New *York Times* article on June 6, 1992, Dr. Roper stated that he would be inclined to approve guidelines developed by New York State, which emphasize voluntary testing of healthcare workers, case-by-case evaluation of infection workers to determine if they pose a significant risk to patients, and confidentiality regarding the infection status of any healthcare worker who is determined to be fit for duty. Additionally, the New York State policy requires periodic infection control training, as well as monitoring and enforcement of universal precautions.

The CDC also recently reported on the continuing investigation of patients who have been treated by healthcare workers infected with HIV.[1] These ongoing investigations of more than 15,000 patients have disclosed no further evidence of HIV transmission from a healthcare worker to a patient, beyond the previously reported Florida cluster of HIV transmission in a dental practice.[2] This report from the CDC support the statements in their July 12 recommendations that the risk of HIV transmission from a healthcare worker to a patient is small and that mandatory testing of healthcare workers is not justified.

State health departments will be working with healthcare professional groups, hospital associations, healthcare providers, and others to draft appropriate guidelines, while awaiting any additional changes in interpretation that may arise from the new Clinton administration.

REFERENCES

1. Centers for Disease Control. Update: investigation of patients who have been treated by HIV-infected health care workers *MMWR*. 1992;41:344-346.
2. Ciesielski C. Marlancs D, Ou C-Y, et al. Transmission of human immunodeficiency virus in a dental practice. ***Ann Intern Med.*** 1992;116:798-805.

Update on Safe Medical Device Act

Some hospitals and other "user" facilities, including ambulatory surgical facilities, nursing homes, and outpatient treatment centers, may not be aware that

https://doi.org/10.1017/S0899823X00095258 Published online by Cambridge University Press

they are now required by law, under the Safe Medical Device Act (SMDA), to report certain medical device-related incidents to the manufacturer and/or the Food and Drug Administration (FDA). (Physicians offices are specifically excluded from user facility reporting.) The FDA currently is monitoring the level of reporting by hospitals and other facilities and has indicated that the number of reports coming in are significantly lower than expected. The law requires the FDA to complete a study by August 1994 to determine whether facilities have been complying with the reporting requirements. The FDA has the authority to begin imposing civil penalties of up to $25,000 per occurrence if the study shows that facilities are not complying with the law.

The user reporting provisions of the SMDA, effective in November 1991, requires all user facilities to report incidents in which a medical device caused or contributed to the death, serious illness, or serious injury of a patient of the facility. If the facility has a question about whether an event should be reported, it may contact the FDA in writing at: Food and Drug Administration, Center for Devices and Radiological Health, Division of Product Surveillance (HFZ-340), Medical Device Reporting Inquiries, 1390 Piccard Drive, Rockville, MD 20850. FAX (301) 881-6670.

Reports must be submitted not later than ten working days after sufficient information is obtained to determine that a report is required. Deaths caused by or contributed to by medical devices must be reported to the FDA and to the device manufacturer. Serious injuries or serious illnesses caused by or contributed to by medical devices must be reported to the device manufacturer (if the manufacturer is not known, the report should be submitted to the FDA). Reporting of events caused by user error are not required by the law.

The form to be used for reporting is a preprinted test form developed by the FDA and provided to all user facilities in the FDA's 1991 *Interim Guidance.*

In a June 1992 amendment to the SMDA, Congress modified the definition of a reportable event. Generally, the amendments broaden the scope of events that could be considered reportable and gives the FDA the discretion to designate additional types of adverse events that would not otherwise meet the definition (e.g., concussions, temporary blindness, etc.). The FDA has not yet issued a rule reflecting these amendments, so it is unclear at this time how the changes will impact user reporting requirements. These changes will not become effective until June 1993 or until specific regulations are implemented.

The FDA has prepared and distributed the following materials to assist user facilities in complying with the reporting requirements of the SMDA:

Medical Device Reporting for User Facilities: Questions and Answers Based on the Tentative Final Rule, HHS Publication FDA 92-4247, December 1991.

User Facility Reporting. June 1992 (a quarterly bulletin).

Copies of either document can be ordered by writing to: Office of Training and Assistance (HFZ), Food and Drug Administration, Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857. FAX (301) 227-8067.

The Department of Transportation Delays Rule on Medical Waste

The Department of Transportation (DOT) has delayed the effective date of its final rule concerning regulated medical waste from October 1, 1992, to April 1, 1993. It is hoped that this delay will give the DOT an opportunity to consult with other federal agencies with expertise in this area and formulate a more appropriate and uniform definition of regulated medical waste that reflects the real, rather than aesthetic, health and safety risks to personnel involved in the segregation, handling, and disposal of medical waste.

The DOT's final regulations on the transport of etiologic agents, published in the December 20, 1991, *Federal Register*, changed the definition of "infectious substances" from "cultures and stocks of etiologic agents" to "regulated medical waste" as defined in the former Environmental Protection Agency (EPA) regulations implementing the now-expired Medical Waste Tracking Act (MWTA) demonstration program. This will increase the volume of waste that will have to be handled and paid for as regulated medical waste in most states. Even hospitals that incinerate or treat medical waste on-site will be affected unless their state definition of regulated medical waste is broader than DOT's. The regulation also includes specific requirements for labeling and packaging of waste.

The DOT's final rule marks the fifth agency that has authority over, or is actively involved in influencing, healthcare medical waste activity. The lack of coordination has led to considerable confusion in the field, often resulting in wasteful and unnecessary waste management practices.

The EPA was given the authority to regulate medical waste in the Resource Conservation and Recovery Act (RCRA) of 1976, also known as the Solid Waste Act. Rather than issue regulations, the EPA issued voluntary guidelines in the early 1980s on medical waste management practices. In 1989, EPA was mandated by Congress, under the MWTA, to conduct a two-year demonstration project of medical waste tracking and management in several states. The demonstration program used a definition of medical waste that was broader than the definition used in

https://doi.org/10.1017/S0899823X00095258 Published online by Cambridge University Press