FDA SAFETY ALERT:
Needlestick and Other Risks from Hypodermic Needles
On Secondary I.V. Administration Sets-
Piggyback and Intermittent I.V.

April 16, 1992

To Hospital Administrators, Directors of Nursing, Risk Managers, and Infection Control Directors:

This is to alert you to the risk of needlestick injuries from the use of hypodermic needles as a connection between two pieces of intravenous (I.V.) equipment[1 2 3]. The use of exposed hypodermic needles on I.V. administration sets or the use of syringes to access I.V. administration set ports or injections sites are unnecessary and should be avoided. Hypodermic needles should only be used in situations where there is a need to penetrate the skin.

The terms "piggyback" or "intermittent I.V." are commonly associated with this equipment configuration. In these procedures, a hypodermic needle is inserted either into a connecting "Y" site on a primary I.V. line ("piggybacking"), or directly into the I.V. access port ("intermittent I.V.").

Research shows that I.V. tubing-needle assemblies have a higher risk of needlestick injury than any other needle devices; needlestick rates more than six times as high as those from disposable syringes have been documented. Although the risk is low, such needlestick injuries have potential for transmitting bloodborne pathogens such as HIV, hepatitis B virus, and hepatitis C virus. Additionally, health care workers (HCWs) sustain needlesticks from exposed needles dangling from unintentionally disconnected secondary medication sets and from needles which protrude from disposal containers. FDA's Device Experienced Network has received at least 24 reports describing hypodermic needles which have broken off inside I.V. administration set ports. Injuries to patients may be incurred if these needles travel directly into the patient's bloodstream.

Although FDA can not recommend use of specific products, we strongly urge that needleless systems or recessed needle systems replace hypodermic needles for accessing I.V. lines. There is no evidence that patient bloodstream infection rates have increased with the implementation of needless systems which have been cleared for marketing. Patient's infection rates, however, should be monitored to ensure appropriate use of these products, as well as minimize risks to patients.

For recessed needle systems, we agree with researchers who have stated that devices with the following characteristics have the potential to reduce the risk of needlestick injuries.

- A fixed safety feature to provide a barrier between the hands and the needles after use, the safety feature should allow or require the worker's hands to remain behind the needle at all times.

- The safety feature as an integral part of the device, and not an accessory.

- The safety feature in effect before disassembly and remaining in effect after disposal, to protect users and trash handlers, and for environmental safety.

- The safety feature as simple as possible, and repairing little or no training to use effectively.

Products with these characteristics are currently available on the market. During 1991, some of these products were evaluated as part of a pilot study by the State of New York. Preliminary analysis of these data from hospitals which used a safer technology for I.V. delivery (i.e., recessed needle or needleless systems), alone or in combination with other safety devices, showed a dramatic decline in sharps-related injuries and reductions of up to 93 percent in I.V.-related injuries.

On December 6, 1991, the Occupational Safety and Health Administration (OSHA) promulgated a final rule which is intended to minimize or eliminate the occupational exposure to bloodborne pathogens. In promulgating the standard, which became effective on March 6, 1992, OSHA concluded that exposures can be minimized or eliminated using provisions which include engineering controls (e.g., use of self-sheathing needles), work practices (e.g., universal precautions), and personal protective clothing and equipment.

FDA is interested in information concerning the role of medical devices in the transmission of bloodborne pathogens, including HIV. We encourage you to report potential hazards for patients and/or health care professionals to the Product Problem Reporting Program at 1-800-638-6725.

I would appreciate your sharing this Safety Alert wit those on your staff who might find it useful, including I.V. teams, nurses, ward supervisiors, employee health programs, and product evaluation committees.

If you have questions, please contact: Thomas Arrowsmith-Lowe, DDS, MPH, Deputy Director, Office of Health Affairs, Center for Devices and Radiological Health, FDA at 301-427-1060.

Sincerely yours,

James S. Benson
Director
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