FDA Issues Safety Alert for Hypodermic Needles on Secondary IV Administration Sets

In late April, the Food and Drug Administration (FDA) issued a Safety Alert warning of the risks of needlestick injuries from the use of hypodermic needles as a connection between two pieces of intravenous (IV) equipment. According to the alert, "The use of exposed hypodermic needles on N administration sets or the use of syringes to access N administration set ports or injection sites are unnecessary and should be avoided. Hypodermic needles should only be used in situations where there is a need to penetrate the skin."

Research shows that N 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 the potential for transmitting bloodborne pathogens. Additionally, healthcare workers sustain needlesticks from exposed needles dangling from unintentionally disconnected secondary medication sets and from needles that protrude from disposal containers. FDA's Device Experience Network has received at least 24 reports describing hypodermic needles that have broken off inside N administration set ports. Injuries to patients may be incurred if these needles travel directly into the patients' bloodstream.

Although the FDA cannot recommend use of specific products, it encouraged healthcare facilities to adopt use of devices that have the following characteristics:

- A fixed safety feature to provide a barrier between the hands and the needle after use; the safety feature should allow or require the worker's hands to remain behind the needle at all times.
- 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 requiring little or no training to use effectively.

Products with these characteristics currently are available. 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 that used a safer technology for N 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% in N-related injuries.[2]

The FDA is interested in information concerning the role of medical devices in the transmission of blood- borne pathogens and encourages healthcare workers to report potential hazards for patients or healthcare professionals to the Product Problem Reporting Program at l-800-6386725.

REFERENCES

1. Jagger J, Hunt EH, Brand-Elnaggar J, Pearson RD. Rates of needlestick injury caused by various devices in a university hospital. *N Engl J Med.* 1988;319:284-288.
2. Chlarello L. Testimony on needlestick prevention technology. Presented before US Congress Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy. Washington, DC; February 7, 1992.

Timetable for OSHA Bloodborne Pathogen Standard

In March, the Occupational Health and Safety Administrations (OSHA) bloodborne pathogen standard took effect. The standard mandates that employers and their workers regard all blood and body fluids as potentially infectious and guard against them. OSHA also is requiring workers to be provided with gowns, gloves, goggles, and other types of protective personal equipment. Workers must have access to vaccinations, training, and follow up if exposure occurs. Certain "work practices" in the handling and management of body fluids are required. The agency also requires that medical records be kept for a total of 30 years, the time necessary to identify the source should an infection occur.

Two deadlines of the three-phase implementation plan already have passed: May 5 was the deadline for every healthcare facility to have written infection control plans; and June 4 was the deadline for training and education programs to have been provided to all potentially exposed workers.

The final deadline is July 6, when hepatitis B immunizations must be provided to all employees at no cost, personal protective clothing and equipment must be provided, engineering and work practice control implements, warning signs and labels displayed, and a record-keeping system established.