New Standards To Prevent Needle-stick Injury

By Jeannette Y. Wick and Guido R. Zanni

Recent legislation revising the Occupational Safety and Health Administration's (OSHA's) regulations on preventing needle-stick injuries (NSI) became mandatory in April 2001 and impacts managed care providers and their members in interesting ways. The most immediate impact requires the consideration of the use of sharps that employ safety features; if alternatives to the use of sharps exist, these too should be employed.

Say "occupational hazard" and most people will envision hard hats, safety glasses, and heavy industrial equipment. But carpal-tunnel syndrome and back strain have largely displaced mangled limbs as occupational hazards. Consequently, workplace hazards don't seem as dangerous. Workers routinely develop healthy respect for certain tools, and circumstances command appropriate precautions. For health care workers, the hypodermic syringe is one such tool.

Federal interventions address all types of sharps (any device that has a needle or sharp device attached to it). Syringes, however, are of most importance to managed care pharmacy. Certain questions arise regarding their use. Why are syringes and needles such a problem? In an era in which cost containment is an increasing challenge, what budget impact will new safety devices have? How will the switch to non-injectable alternatives affect the formulary or the multi-tiered payment

Based on an estimated 800,000 NSI annually, total costs are conservatively put at about \$480 million.

structure? Will legislation, particularly at the state level, eventually extend to outpatient dispensing of syringes? Should these safety devices be covered for members who use injectable drugs at home now?

Unquestionably, syringes and needles save lives and are a staple in our arsenal of medical devices, but we have known for decades that injury with a contaminated needle can transmit disease. For years, our main concern was hepatitis. Today, more than 20 blood-borne pathogens have been transmitted via a needle-stick-related injury. Three are of particular concern: hepatitis B virus, hepatitis C virus, and human immunodeficiency virus. Table 1, page 350, describes the perils associated with each of these.

In 1983, 17,000 workers acquired hepatitis B; today experts estimate that better work practices have reduced the number remarkably—to 800 annually.¹ Better work practices, education, and personal protec-

tive equipment have successfully reduced transmission of all blood-borne pathogens over the past decades. They have, however, reached the limits of their efficacy. Changes in equipment design are now necessary to further decrease NSI.

Federal Mandates

During the past decade, several agencies of the federal government have tried to heighten NSI awareness and have mandated prevention. Beginning this year, the use of safer sharps is no longer discretionary; legislation has been enacted mandating the following, effective April 17, 2001:

- Reduce sharps use if alternatives exist.
- Review and update exposure plans annually.
- Evaluate the effectiveness of safety devices.
- Solicit front-line worker participation in reviewing and selecting safety devices.
- In organizations employing 20 or more workers, maintain a sharps injury log documenting all NSI by worker occupation, device involved, and exposure circumstance.²

Supplementing federal law, 19 states have passed stricter NSI-prevention legislation; 10 more have bills pending. Some actually dictate the type of safety device to be considered.³ These regulatory standards have serious implications for managed care organizations and pharmacies,

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TABLE 1 Blood-borne Pathogens of Significant Concern

Pathogen	Manifestations	Transmission Rate	Treatment
Hepatitis B	Can be asymptomatic, or manifest itself with flu-like symptoms, nausea, anorexia, dark urine, or jaundice. It usually resolves spontaneously, but may be quite severe in its presentation.	6%–30%	The most difficult cases can be treated with interferon, a costly and disagreeable agent.
Hepatitis C (HCV)	Asymptomatic in 75% of cases, but causes between 8,000 and 10,000 deaths from HCV-induced liver disease annually.	about 1.8%	Prevention is the only intervention.
Human immunodeficiency virus (HIV)	Steadily progressive depletion of the immune system followed by opportunistic infection, wasting, and death.	0.3%	A variety of antiviral drugs and supportive measures, costing more than \$12,000 annually.

Source: Wick J. *The other silent epidemic: Prevention and control of hepatitis C*. *Consultant Pharmacist* 1999; 14(7): 721–32.

particularly those that are national in scope. Failure to meet these standards will result in swift and sometimes severe financial penalties.

Occupational Hazards

Every day, 2,100 of our nation's eight million health care workers experience a needle-stick.^{1, 4} Experts have estimated total needle-sticks at between 600,000 and 800,000 incidents annually.^{1, 4, 5} Of these, half (mainly outside the hospital setting) are unreported.^{1, 5}

Nurses experience the greatest number of NSI. They account for 49.7% of reported cases, followed by physicians at 12.6%.⁵ Laboratory personnel, housekeepers, and pharmacists also are at significant risk.¹

Most incidents occur in patient rooms (37%), operating rooms (16%), and emergency departments (7%).⁵ The overall rate for NSI in hospitals is 27 NSI per 100 beds per year.⁵

Using a standard sharp device, NSI are predictable:

- Approximately 38% of NSI occur during needle use; 42% occur after use.¹
- Risk of NSI increases when devices must be taken apart or manipulated.¹
- Needles that are attached to tubing or

are difficult to use increase risk.¹

Five primary activities are associated with NSI: needle disposal, injection administration, blood draw, needle-cap replacement, and trash or dirty-linen removal.⁵

Anatomy of a Needle

To the naked eye, a syringe looks like a simple device: It consists of a barrel, a plunger, and a needle. But these and all sharps must be engineered precisely to ensure that they are sterile, accurate, easy to use, and as painless as possible. In the past 50 years, manufacturing advances have created reliable disposable products that are remarkably inexpensive; traditional syringes cost three to four cents each.

According to the Centers for Disease Control (CDC), approximately 62%–88% of NSI can be prevented by replacing traditional sharps with safer medical devices.⁴ In 1999, the CDC's National Institute for Occupational Safety and Health (NIOSH) issued "Preventing Needle-stick Injuries in Health Care Settings."¹ This alert is user-friendly, and points to the importance of using improved engineering controls in the context of a comprehensive NSI-prevention program. The guidelines stress careful evaluation of all new devices, with extensive

worker involvement in all aspects of the assessment. Accessibility of the device selected and acceptability of any product to the employees who will use it are the cornerstone of any program's design. The reason is clear: Health care workers in different practice locations will have different needs. NIOSH's program guidelines are summarized in Figure 1, page 351.

Newer devices have been developed to bolster safety. The Food and Drug Administration (FDA) suggests five features to protect health care workers, described in Figure 2, page 352. Sharps and syringes are currently described in four ways: (1) Traditional devices offer no protection; (2) Active devices require some action by the health care worker to engage protection—improper use eliminates any protection; (3) Accessory safety devices depend on employee compliance, and although they provide protection, are not considered ideal; and (4) Passive safety devices are ready to use, and protect the user before, during, and after the injection is administered.

Passive devices, because they cannot be circumvented, are preferred by most legislators and employees. They do not hinder patient care and, at the same time, protect workers.^{1, 5}

■ Achieving Compliance with OSHA Reporting Requirements

The Exposure Prevention Information Network (EPINet) at the International Health Care Worker Safety Center in Charlottesville, Virginia, provides assistance and standardized methods for recording NSI and blood and body fluid contacts, consistent with OSHA requirements. EPINet uses a uniform injury-report format that allows easy data entry and analysis. To date, more than 1,500 hospitals use EPINet. Advantages of using EPINet include the analysis of NSI by occupation, device, and procedure. EPINet also evaluates new devices. Participating facilities share data and preventive measures. For additional information about EPINet, call 804-982-0702.³

■ Pharmacy's Role

Pharmacists, whose main exposure to NSI has been in the sterile intravenous hood, often develop a sense of distance from this threat. But their risk of infection is increasing. Managed care pharmacists work in three roles impacted by NSI legislation: as personal work practice, as purchasing decision maker, and as clinical health care provider.

With ample sterile needles at their disposal and few exposures to contaminated sharps, pharmacists who work in the sterile hood may be less vigilant than other health care employees. Consequently, attention to good practices wanes, and NSI occur. Sharps disposal units should be easy to use and replaced frequently. Poor hood technique may result in improper needle disposal, putting others at risk for downstream exposure. For example, when a needle is accidentally thrown in the paper trash, housekeepers and trash-removal personnel are at risk. With no information about the needle, contamination must be assumed. The organization will incur costs of prophylactic treatment and monitoring.

Many pharmacists perceive no risk from clean NSI and do not report them. Reporting NSI, even those resulting from clean needles, helps track the type of device most likely to be involved, or

work practices that contribute to NSI.³

Pharmacists responsibilities are expanding into immunization and administration of chemotherapeutics, radiopharmaceuticals, and other injectables. Managed care has promoted these activities, as they are cost-effective and convenient. For clinicians, use of every available protection is imperative. They must be involved in assessment of proposed safety devices.

■ Patient Protections

In traditional dispensing, safety devices offer certain advantages. Home use of injectable drugs and fluids is increasingly common; pharmacists must help plans decide whether safety devices are a necessity or luxury. People with acquired immunodeficiency syndrome (AIDS), diabetes, cancer, infertility problems, and a host of other conditions inject drugs at home. Doing so avoids hospitalization and saves health care dollars. Although many drugs are self-administered by the patient, some are administered by family members. In the latter situation, safety devices may prevent the spread of infection. In both circumstances, safety devices may protect others from downstream risk. Pharmacists will need to be familiar with various types of sharps, and also with their operation.

As purchasers, pharmacists must be informed of NSI prevention efforts so that products ordered, maintained, and dispensed by the pharmacy meet requirements. In this role, pharmacists represent employers and must implement prevention mandates. The involvement of pharmacists with NSI tracking and analysis minimizes risk. Pharmacists should review local and national NSI data and contribute information from their own facilities. Although EPINet does not track pharmacy-specific NSI, participation in EPINet is advantageous.⁶

■ Implications for Managed Care Plans and Pharmacists

The effectiveness of medical devices with safety features has been clearly established. In addition to NSI reduction fig-

FIGURE 1 NIOSH's Program Guidelines

- Organizations must analyze needle-stick and sharps-related injuries to identify hazards and trends.
- Employers must set priorities and plan strategies relying on local and national information about risk factors and successful interventions.
- Employers must promote and monitor the adequacy of employee training.
- Work practices contributing to needle-stick injuries must be modified.
- Employers must promote safety awareness.
- Employers should establish blameless reporting systems, and conduct follow-up on all needle and sharps-related injuries.
- Employer evaluation of prevention efforts should be followed by performance feedback to all employees.

Source: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. NIOSH Alert: Preventing Needle-stick Injuries in Health Care Settings. DHHS Publication No. 2000-108, 1999.

ures of 62%–88% cited earlier, phlebotomy injuries were reduced by 76% with self-blunting needles, and by 82% with the use of a needle shield. One hospital achieved almost a 90% reduction in NSI with the combined use of safety devices and worker training.⁷

A decision to switch to safety syringes is not budget neutral; recall that a traditional syringe costs about four cents. Safety devices can cost up to 25 cents per device, or approximately \$70,000 per year for the average 300-bed hospital. But consider the alternative. Each uncomplicated NSI costs between \$500 and \$600 for laboratory charges, treatment, and follow-up.⁸ Actual costs are probably higher if lost work time and decreased productivity are considered. Subsequent liability litigation may increase costs. Based on an annual estimate of 800,000 NSI, total annual costs

FIGURE 2 FDA Recommendations for Safety Features

- Safety devices should provide a barrier between hands and needle after use.
- The safety feature should allow or require the worker's hands to remain behind the needle at all times.
- The feature should be part of, not an accessory to, the device; this is called an *integrated device*.
- The feature should work before, during, and after use (to protect downstream workers). This is preferable; it is called a *passive safety system*.
- The feature should be simple and easy to use, requiring little or no training.

Source: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. NIOSH Alert: Preventing Needle-stick Injuries in Health Care Settings. DHHS Publication No. 2000-108, 1999.

for NSI are conservatively estimated to be \$480 million. Data confirm that safety devices prevent injuries; the use of safety devices is a wise business decision and a good preventive measure. Increased facility operating costs get passed on to managed care organizations through per member per month patient costs and upward pressure on premiums.

New federal mandates clearly advocate a multi-faceted approach to preventing NSI, the first step being the use of alternatives where they exist. This has formulary implications if alternative drug-delivery systems are available. In the near future, for example, insulin will be available in an inhaler, which will likely cost more than the injectable form. Additional concerns are raised if alternatives are available but at the second or third tier of a multi-tiered payment plan. Clearly, each organization will have to analyze costs and risks carefully.

The Future

Ultimately, experimental technologies are

expected to reduce the use of sharps over the next few years. Several needle-free injection devices are already in use, and currently there are more than a dozen FDA-approved needle-free injectors.⁹ They are not currently standardized, and can be extremely costly. Some patients experience local reactions, pain, or delayed soreness on a level that is equal to or slightly worse than from a needle.⁹ Advances will improve the utility and cost of needle-free devices.

When multiple or routine samples are needed, alternatives to sharps are a research priority. The newest glucose-testing devices do not require blood. Some drug levels, for example lithium, can be measured in saliva, thus reducing the need for blood samples. For the time being, cost is a barrier to implementation of many of these new techniques.

Conclusion

Science may someday eliminate sharps entirely. History may call them crude and invasive tools. Until then, they remain essential tools of our trade, and emphasis on safe handling is imperative. Transmission of blood-borne pathogens in health care settings is rare, but facts on the low probability of contracting a life-threatening disease from NSI are only comforting when they apply to someone else. ■

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