

Needlesticks — Prevention Through Regulation, Technology and Knowledge

a report by

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Needlestick injuries have been an unfortunate healthcare reality for decades. For the past 20 years, the needlestick prevention story has evolved to encompass new legislation, new technologies and an emphasis on sharps safety education among healthcare providers.

Still, the issues remain as to whether these measures are working, what has been learned from history and what can be done to ensure the optimal safety for healthcare workers and the patients they care for.

Every day, millions of healthcare workers are in danger of suffering accidental needlesticks that can expose them to bloodborne pathogens (including HIV, hepatitis B virus (HBV), hepatitis C virus (HCV) and others). Consider the following statistics:

- An estimated 600,000 to 800,000 needlestick and other percutaneous injuries occur among US healthcare workers annually.¹
- At an average US hospital, workers incur approximately 30 needlestick injuries per 100 beds per year.¹
- Studies show that nurses sustain the majority of these injuries and that as many as one-third of all sharps injuries have been reported to be related to the disposal process.²
- As a result of sharps injuries, more than 36 US healthcare workers a year contract HIV, 2,000 workers a year become infected with HCV and 400 contract HBV.³

This article examines the history of national and international regulations concerning needlestick prevention and safety devices, the history and evaluation of safety devices and the direct and indirect costs of exposure and prevention.

A History of Regulation

It has been more than 18 years since the first documented case of needlestick transmission of a bloodborne pathogen was reported. Only two years following that incident, the US Department of Labor Occupational Safety & Health Administration (OSHA) addressed healthcare worker protection from bloodborne pathogens through its Bloodborne Pathogen Standard (1991).

The OSHA mandate was designed to increase clinical education and spur the widespread use of safety devices to prevent needlestick injuries. Several US states also took action themselves. In 1998, California became the first state to mandate that healthcare facilities adopt safer needle devices. In addition, the California law toughened many of the requirements outlined by OSHA, especially in the area of exposure control plans and documentation.

By 1999, Tennessee, Maryland and Texas had enacted legislation similar to that of California's.

In 1999, OSHA revised its 1991 standards to address specifically the need for healthcare facilities to “document the consideration and implementation of appropriate commercially available and effective engineering controls designed to eliminate or minimize exposure” as part of the facility's Exposure Control Plan. While this was not a mandate for the use of safety devices, it was an important first step in that direction.

The same year, the National Institute for Occupational Safety and Health (NIOSH) published *NIOSH Alert: Preventing Needlestick Injuries in Health Care Settings*, admonishing hospitals to adopt measures to protect workers from injuries caused by needles in syringes, intravenous (IV) delivery systems and other related medical devices.³

1. *National Institute for Occupational Safety and Health, NIOSH Alert: Preventing Needlestick Injuries in Health Care Settings, November 1999.*
2. *Occupational Safety and Health Administration (OSHA).*
3. *International Sharps Injury Prevention Society (ISIPS).*

This momentum led to the development and ultimate passage of the Needlestick Safety and Prevention Act (NSPA), which was signed into law in November 2000 and became effective in April 2001. The law required changes in the OSHA Bloodborne Pathogen Standard and encompassed all employers who have employees with occupational exposure to bloodborne pathogens. In addition, NSPA requires that US healthcare facilities involve front-line healthcare providers in the selection and evaluation process of new safer devices and to document the evaluation and adoption of these devices.

Needlestick Safety Goes Global

While needlestick prevention has not topped the international healthcare agenda, the consequences of unsafe injection practices are well understood by international health organisations. As a result, these organisations, such as the United Nations International Children's Emergency Fund (UNICEF) and the World Health Organization (WHO), are adopting many of the standards outlined by the US – in particular the use of single-use safety syringes. The statistics are staggering.

The WHO has estimated that as many as 21 million people a year contract hepatitis, HIV or other lethal viruses from unsafe injection practices. The WHO estimates that 20% to 28% of all HBV infections in China, India and Romania are due to reused syringes. Funding (or lack thereof), local politics and substandard sterilisation practices have placed entire populations in jeopardy – particularly children receiving immunisation injections – and the price of prevention, of supplying these developing countries with safety syringes, is but a fraction of the US\$535 million annual cost of treating the diseases transmitted through syringe reuse.⁴

Safety Devices – A Brief History

The need for safety devices has not been lost on industry. From 1984 to 1996, more than 1,000 patents were issued for safety devices designed to prevent needlesticks.⁵ These devices range from protected needles through sheathes and other devices, to split septum injection port devices, which are designed to replace a standard needle with a blunt plastic cannula and a pre-split septum. Capped and capless valve technology, first introduced in 1989, enabled the injection aspiration or infusion of fluids or medications, including blood, blood products,

lipids or total parenteral nutrition, in a completely needle-free system. Reflux valve systems, which close automatically when the Luer taper is removed, are designed to reduce the risk of air embolism or fluid backflow.

New capless valve technologies that use a positive displacement design expel fluid from the system when the Luer is removed. This positive displacement of fluid helps to prevent blood from backing up into the IV system, reducing catheter occlusions. Again, this device is a swabbable, capless, two-way valve for injection or aspiration of fluids and medications.

Catheter occlusions are one of the most frequent and costly complications in infusion therapy.

Thrombotic occlusions may occur in as many as 25% of all indwelling vascular access devices.⁶ These occlusions add to patient care costs through additional IV restarts and catheter-related infections. In addition, unnecessary IV restarts subject the clinician to potential accidental needlestick injuries. According to Loretta Berger,

“The utilization of positive pressure devices resulted in a significant decrease in the incidence of catheter occlusions, which in turn significantly reduced the cost of patient care.”⁶

A host of safe needles, including syringes and blood collection needles, are available. Most require some sort of user activation to shield and/or blunt the needle tip following use.

Many initial models of safety IV catheters also featured user-activated designs. However, new passive design technology, which does not require user activation and cannot be bypassed, is gaining widespread interest, and there is a growing body of evidence to support the use of passive products.

Evaluation of Safety Devices

With safety devices now spanning the continuum of care, understanding the criteria for evaluating these devices is invaluable. While no single definitive list of criteria has been established, there are four basic criteria that should be addressed. Interestingly, cost is not part of this equation, due to the fact that the NSPA strictly prohibits institutions from citing cost as a factor for failure to adopt sharps safety devices.

4. NAVAN Position Paper: “Safety Devices Sharps Injury Prevention”, Spring 2000.

5. J Jagger, “Reducing Occupational Exposure to Bloodborne Pathogens: Where do we Stand a Decade Later?”, Infection Control Hospital Epidemiology, 1996.

6. L Berger, “The Effects of Positive Pressure Devices on Catheter Occlusions”, Journal of Vascular Access Devices, 1 (Winter 2000), p. 4.

Universal Compatibility

Any needleless system must be compatible with other equipment, including IV tubing, in-line access devices and venous access devices. Since these components may or may not be supplied by the same vendor, it is crucial to evaluate the various sterilisation and safety aspects – such as swabbing versus capping – of each system in use within an institution. Mixed systems may lead to confusion and practice errors.

Ease of Use and Compliance

Ease of use and compliance are intrinsically linked. Ease of use drives compliance, and worker compliance is the single greatest determinant to the overall success or failure of a needlestick prevention programme. To determine ease of use, it is important to understand if the device requires a change in current protocol.

Certain needle-free IV systems, for example, require users to activate a mechanism to render the sharp instrument safe. This added step requires incorporating an additional step into the IV process – a step that can be bypassed or forgotten by a busy clinician. As a result, compliance and overall healthcare worker safety can suffer. Other technologies offer a ‘passive’ design – meaning that the safety mechanism deploys automatically, without the need for user activation. No activation means no change in clinical protocol, and the user cannot bypass the mechanism. As a result, compliance and overall healthcare worker safety are improved.

Infection Control

Going hand-in-hand with sharps injuries data is infection control data. Not every sharp is contaminated. In fact, the vast majority of sharps injuries do not result in the transmission of a bloodborne disease. However, it is imperative that healthcare institutions understand where these exposures occur, the nature of these exposures and whether they are resulting in the transmission of infection. Armed with this data, they can evaluate and improve their sharps safety protocols.

Prevention of Needlesticks

Once a comprehensive needlestick prevention programme has been implemented, continual programme evaluation is essential to determine the impact of the programme on healthcare worker safety and to identify areas that may require improvement. A basic measure for this process is prevention of needlesticks.

Needlestick injuries can occur even when safety devices are being used and, while the OSHA mandates that every healthcare facility maintains a sharps injury log, under-reporting makes it extremely difficult to evaluate device efficacy. Researchers estimate that up to 50% of needlestick injuries may go unreported.⁴

Only by encouraging reporting of all sharps injuries, no matter how minor, can institutions truly evaluate the effectiveness of these devices.

Growing Evidence Supports Passive Design

There is a growing body of evidence to support the use of passive safety devices versus their active counterparts. ‘Active’ design safety needles require the healthcare provider to activate the safety mechanism, which means that it is possible to use the device without the safety mechanism. If the healthcare provider fails to activate the safety mechanism, they can be at risk for accidental needlestick injury from an unsafe needle.

Furthermore, active needles require clinicians to add a step to their normal routines. As a result, training and retraining is often required to ensure maximum compliance with safety standards.

On the other hand, ‘passive’ design safety needles have a safety mechanism that deploys automatically – requiring no user activation. The healthcare provider does not need to take any extra steps to activate the safety mechanism and the mechanism cannot be bypassed. The result is streamlined and simplified training and enhanced compliance. The American Federation of State, County and Municipal Employees (AFSCME) states, in its January 2002 report, *Needle Points: An AFSCME Guide to Sharps Safety*, that “passive features are more effective in preventing needlesticks than devices that rely on an active safety design.”

In 2003, the US Food and Drug Administration (FDA) issued its *Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features*. According to the FDA guidance, desirable characteristics of sharps injury prevention features include devices that work passively (i.e. it requires no activation by the user), a safety feature that is an integral part of the device, a sharps injury prevention feature that cannot be deactivated and remains protective through disposal, a design that enables the user to tell easily whether the sharps injury prevention feature is activated, devices that perform reliably, are easy to use, practical and safe and are effective for patient care.

Finally, in a study presented at the Society of Healthcare Epidemiology of America (SHEA) 2003 Annual Meeting in Arlington, Virginia, researchers from Mount Sinai School of Medicine in New York evaluated a passive design IV catheter for reduction in IV stylet needlestick injuries in the operating room, post-anaesthesia care units, neonatal intensive care unit and paediatric intensive care unit. During the six-month study period, there were no IV stylet needlestick injuries with the use of the passive catheter system (injury rate of 0 per 87,000 usages).

The researchers compared the study data with a 36-month baseline period, where healthcare workers in these units utilised a non-safety IV catheter resulting in 13 stylet needlestick injuries (injury rate of 5.08 per 100,000 usages.) During previous studies, researchers at Mount Sinai evaluated two brands of active design safety IV catheters and found that healthcare workers experienced several needlestick injuries due to non-activation or improper activation of the safety mechanism.^{7,8} In one study, 61% of needlestick injuries were the result of improper activation or non-activation of the safety mechanism, and a sharps audit of disposed needles showed only 79% of safety devices had been activated.⁷

The Bottom Line – Exposure and Prevention Costs

Safer devices, comprehensive protocols, training, evaluation and compliance can help mitigate the risk of needlestick injuries. However, accidents will happen. An immediate, planned response to these accidents will determine the short-term and long-term costs and consequences for the healthcare worker and the institution.

All institutions should have an exposure control plan in place that is understood by all clinical, support and administrative staff. The Centers for Disease Control and Prevention (CDC) has published exposure control guidelines. Any wound should be washed immediately and any mucous membrane flushed with water or saline. The exposure should be reported immediately to a designated department or authority for evaluation and possible intervention. The source patient should be evaluated and any additional testing performed with the patient's consent. The exposed healthcare worker should also be assessed physically and medically, as well as

emotionally. The psychological impact of a needlestick, especially one with the potential for exposure to HIV or hepatitis, can be devastating to the individual, their family and the organisation as a whole. Information on the viruses and medications is often helpful and counselling may be necessary.

Laboratory studies for significant exposures should be obtained and follow-up studies for serious exposures arranged for up to six months – unless it is determined that the source patient posed no risk.

Decisions regarding prophylaxis and treatment should be made with a physician's consultation in conjunction with the healthcare worker and their family. A number of variables can factor into these decisions, including the susceptibility of the healthcare worker to a particular disease, the incidence of the agent in the population, ease of transmission, incubation period and the risks and benefits of prophylactic treatment. This is a complex process. Finally, a resident or local infectious disease specialist should be contacted.

Regardless of the treatment decisions made, follow-up is critical. At two weeks, and again at six months, a physician or infectious disease specialist should examine the healthcare worker. These guidelines are appropriate from a medical, psychological and legal perspective.⁹

Mandates and the Law

OSHA mandates that every healthcare facility where sharps are used is to keep a sharps injury log including details on each injury, with an explanation of how the incident occurred, type and brand of device involved and department or work area in which the exposure incident occurred. An analysis of the information contained in the sharps injury log can be used to identify patterns and prevent future needlestick injuries. A review of the case law underscores the need for healthcare workers to comply with patient care protocols and the use of safe devices. Civil courts are permitting lay people to recover damages more readily for needlestick injuries than healthcare workers. In the case of healthcare workers, the courts have clearly established that workers' compensation is generally the only means for monetary recovery. Furthermore, the courts have limited recovery of

7. M H Mendelson, L Chen and R Solomon, et al., "Evaluation of a Safety IV Catheter", New York, NY: The Mount Sinai Medical Center, 1999.

8. M H Mendelson, L Chen and L Finklestein-Blond, et al., "Evaluation of a Safety IV Catheter Using the Centers for Disease Control and Prevention (CDC) National Surveillance System for Hospital Healthcare Workers Database", New York, NY: The Mount Sinai Medical Center, 2000.

9. D Alan and M D Tice, "Bloodborne Pathogen Exposure and Recommendations for Management", Journal of Infusion Nursing, 25 (64) (Nov/Dec 2002), pp. 55–59.

damages for emotional distress and for the fear of contracting an infectious disease only in cases in which plaintiffs establish that they have actually been exposed to an infectious disease. In most of these cases, the time period for which damages might be recovered for emotional distress and fear of contracting an infectious disease is the time period between the exposure and the time that test results confirm that the patient has not been infected with the disease.¹⁰ The bottom line is that legal recourse for healthcare workers is highly limited. Therefore, they must drive the policies, procedures and product adoption that will minimise their risk of needlestick injuries and ensure that a robust plan is in place should such an accident occur. Needlesticks can impact more than just the individual; they can impact the morale of an entire staff and add stress to an already stressful profession.

Take Charge of Your Safety

NSPA requires front-line healthcare providers to take an active role in the selection and evaluation

process of new, safer devices. Once safety devices are chosen, healthcare workers should take charge of their safety by evaluating current safety protocols, ensuring that these protocols are being followed and reporting any potential accidental needlestick hazards they encounter to employers. Failure to comply with OSHA standards not only puts healthcare providers and patients at risk, it can also result in hefty fines for healthcare facilities.

Conclusion

The dictionary definition of an accident reads in part: “an unfortunate event resulting especially from carelessness or ignorance.” Needlesticks are unfortunate, and they will never be completely eliminated, but, after 20 years of regulations, the advent of new technologies and the emphasis on training and education, carelessness or ignorance should not be part of the equation. As healthcare workers, we have the responsibility to ourselves, our colleagues and our patients to be informed and to inform others, to be careful and to care. ■

10. Kammie Monarch, “Legal Aspects of Infusion Practice: Trends and Issues”, *idem.*, pp. S21, S30.
