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Active and passive technologies in sharps safety

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Healthcare-associated risk of percutaneous exposure to bloodborne pathogens (BBP) has existed for decades; however, concerns regarding such risk increased significantly after the beginning of the HIV/AIDS epidemic. Although the primary BBPs—hepatitis B virus, hepatitis C virus (HCV), and human immunodeficiency virus (HIV)—may cause significant morbidity and/or mortality, there are equal concerns regarding the severe emotional reaction to exposure even when transmission does not occur. To increase effectiveness and facilitate the best outcomes for healthcare workers (HCWs) and healthcare employers, risk-reduction strategies must be evidence-based.

A variety of studies, designed to determine the number and types of sharps/needlestick injuries experienced by HCWs each year, has been initiated over the past twenty years. Unfortunately, because of underreporting and other complicating variables, the actual prevalence of sharps/needlestick injuries remains unknown.

Estimates provided by the National Institute for Occupational Safety and Health (NIOSH) indicate that between 600,000 and 800,000 sharps injuries occur annually, with the majority of injuries involving primarily nursing and laboratory personnel. NIOSH also references data from the Exposure Prevention Information network (EPInet) system that found HCWs incurring approximately 30 sharps/needlestick injuries per 100 beds per year.[1]

Additional studies revealed that although HBV poses a higher risk of transmission, pre-exposure vaccine and/or post-exposure prophylaxis can reduce the risk of infection.[2] Unfortunately, there are no vaccines available for HCV and HIV, and the effectiveness of prophylaxis has varied.

To ensure that appropriate sharps/needlestick injury prevention interventions were implemented in healthcare settings, federal and state regulatory agencies and legislatures developed a wide range of requirements and guidance documents. The most comprehensive regulatory requirement resulted from the Needlestick Safety and Prevention Act,[3] which required the Occupational Safety and Health Administration (OSHA) to revise the Bloodborne Pathogens Standard.[4]

Primary prevention of sharps/needlestick injury remains the most effective mode for BBP infection prevention. By consistently utilizing safer work practices, disposing of used needles/sharps in appropriate containers and eliminating the use of needles/sharps without improved engineering controls with safety features, the risks for BBP exposure can be reduced.[5] The current availability of more "passive" sharps safety devices provides employers with an opportunity to reexamine existing options and to improve safety device options through enhanced technology.

In combination with other injury prevention strategies, including education of healthcare workers and analysis of percutaneous-injury sources and contributing factors, sharps safety devices have contributed to a significant decrease in specific percutaneous injuries.[6] Although the greatest challenge of sharps injury prevention continues to be the period of "during use" of a sharp device, more passive technology can greatly reduce the injury risk for other risk categories such as after use and before disposal, during disposal, after disposal, etc.

Active vs. passive design

As technology has continued to advance, improvements in safety features and ease of use have also increased. Designing products to effectively advance safety features necessitates a thorough understanding of a product's typical use as well as the many other uses that require special features. This challenge has led to a continuum of devices ranging between those that have "active" designs that require specific safety feature activation and more "passive" designs that require minimal manipulation. To assure that the most passive designs possible are evaluated and implemented, the evaluation processes must initially determine the basic safety feature mechanism and the impact that design may have on the product's use.

Active safety features require specific activation (e.g., buttons to push or barrels to turn, twist, or push forward) and may require two-handed use. Other active safety technology might require adjustments in procedures or techniques to engage the safety feature. Although minor changes in how a device is used—such as advancing a syringe plunger fully to activate a retracting needle—might be viewed as making its safety feature more passive, there may be situations in which the safety feature is not activated due to the product design; for example, not all medication in a syringe is needed, but the needle cannot be retracted without disposing of all remaining medication in order to fully advance the syringe plunger and activate the safety feature. In addition, passive devices can also lead to repetitive ergonomic injuries—for example, if the passive safety feature requires increased pressure to be activated, as is the case in pushing a plunger past the point of completely administering a medication or pushing a Vacutainer tube past the point of puncturing the gasket.

In contrast, truly passive safety designs engage the safety feature without any additional manipulation by the end-user and reliably provide protection with no alteration in either procedures or techniques. Such designs are more technically challenging to manufacture but may significantly improve healthcare worker safety, and they are preferable to more active safety features in most settings. Sharps-disposal boxes that accept any size and shape of sharps device, that have cantilevered lids that automatically deposit the used sharp into the container, and that cannot be opened or permit anything to be disposed of once the container is three-quarters full employ a more passive approach to safety than sharps-disposal containers that require two-handed access. Sharp devices that automatically become shielded when they are removed from a patient (e.g., IV access devices that automatically cover the stylet upon withdrawal) and retracting devices that engage immediately after use are further along the continuum of passive devices.

Product evaluation and selection

Despite efforts to comply with all applicable regulations, healthcare workers (HCW) are at continuing risk of sharps injuries from different types of devices used in both inpatient and outpatient areas. Employers must continue to seek out the best safety solutions through a structured, comprehensive product evaluation and selection process. Evaluations might be time consuming and complex, but they also provide significant impact on a safety program. Continually reviewing the changing technology and identifying the most passive devices in each sharps device category will enhance the outcomes of a safety program and will potentially influence the market availability of truly passive devices.[7]

In order to fully benefit from legislative and regulatory requirements to solicit input from non-managerial employees who are responsible for direct patient care and who are potentially exposed to injuries from contaminated sharps, employers may need to modify the product evaluation process. Frontline staff should be involved in all aspects of identifying, evaluating, and selecting devices and work-practice controls, and the employer should document this in the facility's Bloodborne Pathogen Exposure Control Plan (29 CFR Part 1910 l).

In most successful situations, a work group/committee is formed to identify, review, and evaluate new products. The committee should establish norms on decision-making, either by consensus or by hand vote. Evaluations should be performed in a manner that solicits end-users' input on all equipment.

Several evaluation processes have been described8 with the following common components:

- conducting a thorough literature review on sharp injuries and clinical observations by manufacturers
- identifying all available safety devices
- determining passive versus active safety features among all device categories
- reviewing sharps injury data
- establishing a process for vendor-provided HCW training on devices to be adopted
- clearly defining protocols for:
  - outcomes to be assessed
  - minimum number of devices to be tested
  - length of product evaluation trials
  - identification of potential impact on patients
  - inclusion of all users on all shifts (employees, physicians, per-diem staff)
- developing an evaluation form for the device being considered
- using a defined process for data collation and analysis
- developing a communication plan for any evaluation to be done.

The evaluation committee should establish "go" and "no-go" (i.e., desirable and undesirable) criteria for each type of device; then manufacturers can be asked to provide presentations and product demonstrations to the evaluation committee. Table 1 shows examples of potential "go" and "no-go" criteria.

The evaluation committee should then develop an evaluation tool for all end users. This tool should include all "go" and "no go" criteria for the device to be evaluated, with scoring ranks established prior to the evaluation. A Lickert scale (e.g., 1=strongly disagree, 2=disagree, 3=agree, 4= strongly agree) facilitates more accurate product evaluations.

Other criteria to consider can include the following:

- how difficult the device would be to learn to use,

Table 1. Examples of "go" and "no-go" criteria

1. Safety device is easy to use and requires no changes in technique or procedures.
2. Safety device has a clear, unmistakable audible or visible indication that it has been activated.
3. Safety device has no FDA-related issues (e.g., recalls, rules, pending approvals).
4. Safety device will work on difficult patients.
5. The manufacturer will train end users.

- the device's similarity to other currently used devices,
- its compatibility with other devices,
- its reliability,
- its potential impact on needlestick injuries.

Table 2 provides a sample evaluation tool for end users.

Training

- The user does not need extensive training for correct operation.
- The design of the device suggests proper use.
- It is not easy to skip a crucial step in proper use of the device.

User comments

Providing space for end-users to make additional comments and to answer open-ended questions can be helpful in clarifying subtle differences among various safety devices. Requesting evaluators to rank the importance of the various evaluation criteria also facilitates analysis of the findings by weighting as more significant any questions that end-users identify as extremely important to them. Include such questions as:

- Of the above questions, which three are the most important to your safety when using this product?

Table 2. Sample evaluation tool for end users

During use

- The safety feature can be activated with one hand (if applicable).
- The safety feature does not obstruct vision of the tip of the sharp.
- Use of this product requires use of the safety feature.
- This product does not require more time to use than a non-safety device.
- The safety feature works well with a wide variety of hand sizes.
- The device is easy to handle while wearing gloves.
- This device offers a good view of any aspirated fluid.
- This device will work with all required syringe and needle sizes.
- This device provides a better alternative to traditional recapping.

After use:

- There is clear and unmistakable indication (audible or visible) when the safety feature is activated.
- The safety feature operates reliably.
- The exposed sharp is permanently blunted or covered after use and prior to disposal.
- The device is no more difficult to process after use than non-safety devices.

- Are there other questions that you feel should be asked regarding the safety/utility of this product?[9]
- What did you like best about this product?
- What would you like to see improved with this product?

Results of the evaluation can be used to make the final selection and to modify on-going training that incorporates user concerns.

The role of vendors

Vendors must be prepared to train all HCWs, ensuring that they understand use of the device and answering all questions. There must be enough products available for each person to practice using the device enough that they are comfortable with it before actually using it on a patient.

Coordinating an on-site evaluation

Creating an environment that supports objective evaluation is very important in assessing the effectiveness of a safety device. Any factors that could influence the evaluation should be identified and managed to reduce their impact. Some strategies that may be helpful in coordinating on-site evaluations include:

- removing all comparable devices, leaving only the ones being evaluated. A reserve supply of the usual devices should be secured and available in case of an emergency.
- enabling each participant to use the safety device as many times as established by the evaluation criteria.
- allowing HCWs to complete evaluation forms without outside influence. Although vendors may provide education, they should be barred from any role in the evaluation process. It is imperative that honest feedback be obtained from each of the HCWs regarding how the device performed.

Monitoring and incorporating technology advances

Sharps safety products are constantly changing, necessitating regular reviews of potential options and newer technology. At present, sharps with engineered safety features are available for medication delivery, vascular access, IV administration, blood collection, making punctures/incisions, sampling fluid, blood banking, performing dental procedures, bone marrow collection, and skin closure.

For employers, infection control practitioners, or employee health coordinators, staying current with the latest advances can be challenging. Fortunately, several organizations have met the challenge and provide regular updates to their websites.

Conclusion

Prevention strategies consistent with longstanding infection control principles apply within the sharps safety arena as well. As the CDC identified in the summary to Preventing Occupational HIV Transmission to Healthcare Personnel,[8] there are at least three key areas needed to reduce the risk for occupational transmission of BBP. Each area of activity—administrative efforts, development and promotion of safety devices (incorporating passive technology whenever possible), and monitoring the effects of post-exposure prophylaxis (PEP)—is an essential component that helps to build and maintain a culture of safety within the healthcare setting. Each of these components serves to expand the infection-control principle of routine use of barriers such as washing hands and other skin surfaces and careful handling and disposal of contaminated sharps. When all the principles and activities become a routine part of care delivery, the healthcare environment will be safer for HCWs and patients.

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