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ABSTRACT

OBJECTIVE: To examine a comprehensive approach for preventing percutaneous injuries associated with phlebotomy procedures.

DESIGN AND SETTING: From 1993 through 1995, personnel at 10 university-affiliated hospitals enhanced surveillance and assessed underreporting of percutaneous injuries; selected, implemented, and evaluated the efficacy of phlebotomy devices with safety features (ie, engineered sharps injury prevention devices [ESIPDs]); and assessed healthcare worker satisfaction with ESIPDs. Investigators also evaluated the preventability of a subset of percutaneous injuries and conducted an audit of sharps disposal containers to quantify activation rates for devices with safety features.

RESULTS: The three selected phlebotomy devices with safety features reduced percutaneous injury rates compared with conventional devices. Activation rates varied according to ease of use, healthcare worker preference for ESIPDs, perceived “patient adverse events,” and device-specific training.

CONCLUSIONS: Device-specific features and healthcare worker training and involvement in the selection of ESIPDs affect the activation rates for ESIPDs and therefore their efficacy. The implementation of ESIPDs is a useful measure in a comprehensive program to reduce percutaneous injuries associated with phlebotomy procedures (Infect Control Hosp Epidemiol 2003;24:97-104).

More than 8 million healthcare workers in the United States face a number of occupational risks, including exposure to blood-borne pathogens (eg, human immunodeficiency virus [HIV], hepatitis B virus, and hepatitis C virus) through percutaneous injury.1 The estimated number of percutaneous injuries sustained annually by hospital-based healthcare workers ranges from 311,091 to 463,922.2 Aggregated data from the National Surveillance System for Health Care Workers (NaSH) show that 15% of all reported percutaneous injuries involve phlebotomy procedures (Centers for Disease Control and Prevention [CDC], unpublished data, 2001). Injuries that occur during phlebotomy may carry a higher risk of blood-borne virus transmission. A retrospective case-control study that assessed risk factors for HIV transmission after percutaneous exposure showed that one factor associated with HIV transmission was performance of a procedure in which a needle was placed directly in the infected patient’s vein or artery.3 Of the 56 cases of documented occupational transmission of HIV in the United States, 51 (91%) involved percutaneous injuries,4 and 22 (43%) of these 51 percutaneous injuries occurred during phlebotomy or blood sampling procedures (CDC, unpublished data, 2000). Therefore, to prevent occupational transmission of blood-borne pathogens, high priority must be given to the elimination of percutaneous injuries, particularly those associated with phlebotomy procedures.

This article describes the components of a comprehensive approach to the prevention of percutaneous injuries associated with phlebotomy procedures that was...
undertaken at 10 U.S. hospitals during a multicenter study on the efficacy of engineered sharps injury prevention devices. Included in this approach were enhanced surveillance for percutaneous injuries, education and training of healthcare workers on the use of engineered sharps injury prevention devices, assessment of device use and activation, assessment of the efficacy of selected devices, and determination of healthcare worker satisfaction with the devices.

METHODS

Study Design

The study was conducted from 1993 through 1995 at 10 university-affiliated hospitals in Minneapolis–St. Paul, Minnesota (3 hospitals), New York, New York (1 hospital), San Francisco, California (4 hospitals), and Houston, Texas (2 hospitals). The study consisted of two phases. In the first phase, baseline rates of percutaneous injury during use of conventional devices were collected, and in the second phase, the efficacy of engineered sharps injury prevention devices was assessed. All of the hospitals were to participate in both phases; however, 4 hospitals (2 in Texas and 2 in California) withdrew from the study before the second phase began. Data from these 4 hospitals were included in the analysis of the descriptive epidemiology of percutaneous injuries but not in the assessment of device activation, the calculation of percutaneous injury rates (for conventional or safety devices), or the evaluation of user acceptance of engineered sharps injury prevention devices. For data collection on percutaneous injuries, all of the hospitals used a uniform data collection form that included demographic information, percutaneous injury description, amount of work and rest time injured workers had prior to the injury, workers’ experience with the device causing the injury, and a subjective question to workers regarding the preventability of the exposure.

During phase I of the study (mean duration, 10 months; range, 9 to 12 months), hospitals used conventional phlebotomy devices. During phase II of the study (mean duration, 12 months; range, 6 to 15 months), hospitals attempted to replace the conventional phlebotomy equipment with the chosen engineered sharps injury prevention devices (hospitalwide or in outpatient phlebotomy areas, depending on the hospital), monitored phlebotomy supplies to ensure conventional devices were not in stock, and continued injury surveillance. To assess the impact of engineered sharps injury prevention devices, healthcare workers were surveyed regarding their satisfaction with engineered sharps injury prevention devices and an audit of sharps disposal containers was undertaken to quantify device activation rates.

Survey to Assess Underreporting of Percutaneous Injuries

During both phases of the study, an anonymous survey was distributed to four groups of healthcare workers who routinely performed phlebotomy procedures (ie, phlebotomists and laboratory technicians; nurses on representative medical and surgical wards, intensive care units, and emergency departments; first-, second-, and third-year medical, pediatric, and surgical residents; and third- and fourth-year medical students) to assess the rate of percutaneous injury underreporting to hospital surveillance systems at the six hospitals. Questionnaires were distributed at staff meetings, educational conferences, and nurses’ stations and collected immediately after completion. At one hospital, questionnaires were mailed to medical students who were otherwise inaccessible.

On the anonymous surveys, information was collected regarding occupation, number of injuries sustained in the previous 12 months with needles that had been in contact with a patient’s blood or body fluids, number of injuries reported to the hospital surveillance system, and reasons for not reporting injuries. All injuries, not just those that occurred during phlebotomy, were assessed. Data regarding the average number of phlebotomy procedures performed each day and the average number of days worked each week by the healthcare worker also were collected. Rates of injury reporting were calculated by dividing the total number of injuries healthcare workers recalled reporting by the total number of injuries they recalled sustaining.

Assessment of Preventability

When workers reported an injury, they were asked whether the exposure could have been prevented, and if so, by what mechanism(s). For a subset of injuries, we compared workers’ assessment of preventability with our assessment. Our assessment was limited to percutaneous injuries that involved hollow-bore needles, percutaneous injuries that occurred during or after device use, and percutaneous injuries involving engineered sharps injury prevention devices.

In their preventability assessment, healthcare workers could choose up to nine strategies for prevention (eg, needle safety device, use of puncture- or cut-resistant gloves, improved staffing, improved training in proper technique, and improved compliance with recommended procedures by other staff). For the purposes of our analysis, we classified percutaneous injuries as preventable, not preventable, or undeterminable. A percutaneous injury was considered preventable if it met at least one of the following criteria:
(1) a needle was unnecessary for the procedure; (2) a "safer" needle device was available; (3) a safer work practice could have been used; or (4) there was improper needle disposal. The percutaneous injury was considered not preventable if a needle was necessary, no safer needle was available, a safe work practice was used, and the needle was properly disposed. If the percutaneous injury did not meet any of these criteria, its preventability was considered undeterminable.

Device Implementation

During phase I, each hospital selected the engineered sharps injury prevention devices to be evaluated in phase II of the study; different engineered sharps injury prevention devices were evaluated by different hospitals. Devices were selected by each hospital's product evaluation committee, whose membership included frontline healthcare workers. All engineered sharps injury prevention devices selected for evaluation were vacuum tube blood-collection devices or winged steel (ie, "butterfly") needles used during phlebotomy. The devices chosen for evaluation were resheathable winged steel needles at six hospitals (Safety-Lok, Becton Dickinson Corp., Franklin Lakes, NJ) (Fig. 1); bluntable vacuum tube blood-collection needles at three hospitals (Punctur-Guard, Bioplexus Inc., Tolland, CT) (Fig. 2); and resheathable vacuum tube blood-collection needles at four hospitals (Venipuncture Needle-Pro, Portex, Inc., Keene, NH) (Fig. 3). Before introducing the devices, each hospital conducted a comprehensive training program that included "hands-on" experience with the equipment.

Each device required the worker to activate the safety feature during or after phlebotomy. The Safety-Lok resheathable winged steel needle was activated immediately after use by sliding the sheath forward from behind the needle until it locked, covering the needle. The Punctur-Guard bluntable vacuum tube blood-collection needle was activated after blood filled the vacuum tube and while the needle was still in the patient's vein by forward pressure of the vacuum tube against the adapter end of the needle. This action released a blunted cannula within the lumen of the needle that advanced beyond the needle tip. The Venipuncture Needle-Pro vacuum tube blood-collection needle was activated by pressing a hinged recapping sheath over the needle after withdrawal from the patient’s vein.

Efficacy Evaluation

The rates of percutaneous injury associated with phlebotomy devices for healthcare workers were estimated...
in each of the four groups by dividing the number of phlebotomy-related percutaneous injuries reported to the institution during the study period (adjusted for underreporting by occupation) by the total number of phlebotomy procedures performed. The latter was estimated from survey information regarding the reported daily average number of phlebotomies performed by each worker, the reported days worked per week by each worker, the number of healthcare workers in each occupational group, and the duration of the study period.

**User Satisfaction and Patient Care Impact**

The anonymous device evaluation survey was completed at the end of phase II and collected data regarding training received before using engineered sharps injury prevention devices, user satisfaction with the devices, and the occurrence of patient adverse events during phlebotomy with the devices. Workers could comment on any or all of the engineered sharps injury prevention devices and conventional phlebotomy devices.

**Sharps Disposal Inventory**

At the end of phase II, a representative sample of sharps disposal containers was selected for inspection at each hospital. These containers were located in areas where the engineered sharps injury prevention devices had been implemented. After the contents of the containers were autoclaved for 30 minutes at 121°C to 135°C, auditors used surgical tongs to inspect the contents and to determine the device type of all phlebotomy devices and the safety feature activation status of all engineered sharps injury prevention devices found.

**Statistical Analysis**

For descriptive statistics, data were analyzed using Epi-Info software (version 6.04b; CDC, Atlanta, GA). For analytic statistics, the SAS system (SAS Institute, Inc., Cary, NC) was used. *P* values were obtained from the normal approximation to the binomial distribution. Because estimated rates of phlebotomy-related percutaneous injury by device and occupation were similar in hospitals using the same devices, data were aggregated from those hospitals to permit comparison of percutaneous injury rates for engineered sharps injury prevention devices and conventional phlebotomy devices.

![Image](63x592 to 291x705)

**FIGURE 4.** Distribution of injuries (N = 1,630) by the number of times the injured worker had performed the procedure prior to injury.

**RESULTS**

**Epidemiology of Percutaneous Injuries**

No significant differences in percutaneous injury characteristics were noted among the 6 hospitals that completed both phases and the 4 that participated in only phase I of the study. Therefore, the epidemiology of percutaneous injuries is described using aggregate data from all 10 hospitals. During the study period, 1,630 percutaneous injuries were reported to the surveillance systems at the 10 hospitals. The largest proportion (42%) of the percutaneous injuries were sustained by nursing staff, 26% by physicians, 4% by medical students, 4% by phlebotomists, and 24% by healthcare workers in other occupations. Eighty-three percent of percutaneous injuries occurred during the performance of routine procedures. The majority (79%) of injuries involved exposure to blood, and most were characterized to be of superficial (48%) or moderate (42%) depth. Of the 1,630 injuries, 197 (12%) occurred during phlebotomies. Winged steel needles were involved in 162 (10%) of all percutaneous injuries, and vacuum tube blood-collection needles were involved in 100 (6%).

There was no correlation between being a new staff member or the number of consecutive days and hours worked and the occurrence of percutaneous injury. Of 1,162 employees injured, excluding students and house staff, 1,041 (90%) had at least 1 year of experience in their respective job category. The majority (91%) of reported percutaneous injuries were sustained by healthcare workers who had not worked more than 5 consecutive days, and only 18% were reported by healthcare workers who had been on duty for more than 8 consecutive hours before the exposure. The majority (92%) of percutaneous injuries were reported by healthcare workers who had more than 5 hours of sleep during the previous 24 hours. Further, more than 80% of percutaneous injuries were reported by healthcare workers who said they were familiar with the procedure involved (ie, had performed the procedure more than 25 times) (Fig. 4).

**TABLE 1**

<table>
<thead>
<tr>
<th>Investigators’ Classification of Preventability</th>
<th>No. (%)</th>
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</thead>
<tbody>
<tr>
<td>Preventable (reasons not mutually exclusive)</td>
<td>673 (78)</td>
</tr>
<tr>
<td>By safer needle</td>
<td>388 (58)</td>
</tr>
<tr>
<td>By safer work practice</td>
<td>329 (49)</td>
</tr>
<tr>
<td>Needle unnecessary</td>
<td>187 (28)</td>
</tr>
<tr>
<td>Improper needle disposal</td>
<td>178 (26)</td>
</tr>
<tr>
<td>Not preventable (reasons not mutually exclusive)</td>
<td>46 (5)</td>
</tr>
<tr>
<td>Occurred during needle withdrawal from patient</td>
<td>26 (57)</td>
</tr>
<tr>
<td>Patient moved</td>
<td>18 (39)</td>
</tr>
<tr>
<td>Occurred while inserting needle into patient</td>
<td>8 (17)</td>
</tr>
<tr>
<td>Other</td>
<td>9 (20)</td>
</tr>
<tr>
<td>Undeterminable</td>
<td>142 (17)</td>
</tr>
</tbody>
</table>

*Not involving engineered sharps injury prevention devices, suturing, or cutting, and not limited to phlebotomy procedures.
Assessment of Preventability of Hollow-Bore Percutaneous Injuries

Of the percutaneous injuries they reported, injured healthcare workers believed 1,540 (94%) were preventable. In comparison, 665 (77%) of 861 percutaneous injuries involving hollow-bore needles that were not safety devices were considered preventable by injured healthcare workers. Analysis of these 861 percutaneous injuries by the study investigators indicated 673 (78%) could have been prevented by engineered sharps injury prevention devices or safer work practices (Table 1).

Although both healthcare workers and the study investigators agreed most percutaneous injuries were preventable, only 50% of healthcare workers found injuries preventable for the same reasons as the investigators. Of 46 percutaneous injuries considered preventable by the injured healthcare workers but not by the investigators, 26 (57%) occurred during needle withdrawal from the patient; 18 (39%) when the patient moved; 8 (17%) during insertion of the needle; and 9 (20%) during other steps of the procedure (reasons not mutually exclusive). Seventeen percutaneous injuries were assessed as preventable by the study investigators but not by injured healthcare workers. For 47% of these percutaneous injuries, the investigators considered the needle used by the injured worker to be unnecessary.

Underreporting Survey

The overall response rate for each of the two worker surveys was approximately 75%: 1,697 of 2,157 healthcare workers responded in phase I and 1,246 of 1,705 responded in phase II. The respondents acknowledged reporting 302 (54%) of 563 percutaneous injuries they had sustained during the previous year. Reporting rates varied by occupation: phlebotomists reported 91% of their injuries; nurses, 68%; medical students, 35%; and residents, 31%. Within occupations, underreporting rates were similar among hospitals and between surveys.

Efficacy of Engineered Sharps Injury Prevention Devices

After underreporting was adjusted by occupation, the use of engineered sharps injury prevention devices was associated with a significant reduction in percutaneous injury rates related to phlebotomy procedures performed with the vacuum tube blood-collection devices (Table 2). Both the bluntable phlebotomy needle and the phlebotomy needle with recapping sheath achieved similar reductions in percutaneous injury rates (76% and 66%, respectively; \( P = .003 \)). Although the resheathable winged steel needle also showed a 23% reduction in percutaneous injury rates, this reduction was not statistically significant \( (P = .07) \). Of 41 percutaneous injuries associated with the engineered sharps injury preven-
tion devices under evaluation in this study, 34 (83%) involved winged steel needles and 7 (17%) involved vacuum tube blood-collection needles. Most (59%) of these injuries occurred before activation of the safety feature was appropriate or possible (Fig. 5).

Sharps Disposal Container Audit and User Survey
Of 14,261 phlebotomy devices found in the 504 sharps disposal boxes that were audited, 12,681 (89%) were engineered sharps injury prevention devices. Of 5,255 blunttable phlebotomy needles (Punctur-Guard) identified, 2,984 (57%) had been activated. Of 3,319 phlebotomy needles with a recapping sheath (Needle-Pro) identified, 3,250 (98%) had been activated. There were 4,935 winged steel needles disposed in the containers; 4,065 (82%) had the resheathable feature (Safety-Lok), of which 2,257 (56%) had been activated. Of 694 standard vacuum tube blood-collection needles identified, 143 (21%) were recapped.

One hospital had an activation rate of 17% (84 of 501) for the blunttable vacuum tube blood-collection needle compared with rates of 58% (1,855 of 3,292) and 67% (1,045 of 1,552) for the two other hospitals using the device \((P < .0001)\). A greater proportion (54%) of healthcare workers at the hospital with the lowest activation rate rated the product as more difficult to use compared with the conventional product than at the other hospitals using the device \((P < .0001)\). The majority (69%) of healthcare workers at the hospital with the lowest activation rate reported training on use of the device; healthcare workers at the other five hospitals had rates ranging from 29% to 63% \((P < .001)\). The majority (69%) of healthcare workers at the hospital with the highest activation rate indicated they received individualized training; the highest rate of individualized training at the other hospitals was 29%.

Healthcare Worker Acceptance
During phase II of the study, 1,108 (65%) of 1,705 healthcare workers responded to the survey assessing satisfaction with engineered sharps injury prevention devices. Of 1,879 responses (workers could cite more than one response), 822 (44%) favored one or more safety devices over conventional products, 622 (33%) favored conventional devices, and 435 (23%) were unsure. Of 1,332 responses on ease of use of the engineered sharps injury prevention device compared with the standard device, 968 (73%) said the engineered sharps injury prevention device was easier or much easier to use. Of 1,334 responses to a question about whether the engineered sharps injury prevention device affected the intended procedure, 785 (58%) said it facilitated the procedure or had no effect, 412 (31%) said it made the procedure more difficult, and 137 (10%) were unsure. Of the 412 responses indicating engineered sharps injury prevention devices made the procedure more difficult, 241 (58%) referred to the blunttable phlebotomy needle. Most healthcare workers believed engineered sharps injury prevention devices made the procedures safer to perform: 277 (67%) of 411 for the vacuum tube blood-collection needle with recapping sheath, 252 (52%) of 482 for the blunttable vacuum tube blood-collection needle, and 571 (56%) of 1,017 for the resheathable winged steel needle device.

Healthcare workers had varying preferences for engineered sharps injury prevention devices over conventional devices; 226 (57%) of 397 favored the phlebotomy needle with recapping sheath, 125 (26%) of 482 favored the blunttable phlebotomy needle, and 471 (47%) of 1,000 favored the resheathable winged steel needle compared with the respective conventional devices. Twenty-three percent of respondents had no preference.

DISCUSSION
The Needlestick Safety and Prevention Act was signed into law in November 2000, resulting in revision of
the blood-borne pathogens standard promulgated by the Occupational Safety and Health Administration. The act requires certain employers to document, on an annual basis, consideration and implementation of effective safer medical devices designed to eliminate or minimize occupational exposure. The act also calls on employers to solicit input from healthcare workers when identifying, evaluating, and selecting engineering and work practice controls.

A comprehensive sharps injury prevention program requires organization-wide planning and coordination, use of local data to understand factors contributing to sharps injuries, and the implementation of a combination of prevention interventions. Such interventions include developing a safety culture that has visible support from top-level management; eliminating the use of sharps whenever possible; facilitating procedures for sharps injury reporting to improve the quality of surveillance data; selecting, implementing, and evaluating the impact of engineered sharps injury prevention devices and other engineering controls; promoting safe work practices; and educating and training healthcare workers on techniques for safely performing procedures that involve the use of sharps devices, including the correct method of using engineered sharps injury prevention devices.

This study demonstrated that devices with safety engineering controls can significantly reduce the rates of phlebotomy-related percutaneous injuries among healthcare workers. Although the reduction in percutaneous injury rates with the resheathable winged steel needle did not reach statistical significance, percutaneous injuries associated with winged steel needles occurred at least three times more often than with the vacuum tube blood-collection needle. Therefore, use of resheathable winged steel needles with safety engineering controls may produce the greatest reduction in phlebotomy-related percutaneous injuries. A subsequent study conducted at one of the participating hospitals in New York documented a significant rate reduction (55%; P < .05) in phlebotomy-related percutaneous injuries associated with reintroduction of the resheathable winged steel needle. Of note, 83% of the resheathable winged steel needles surveyed from sharps disposal boxes in that study were activated, compared with only 56% in our study.

Additional reductions in percutaneous injury rates could have been achieved with increased use of engineered sharps injury prevention devices, activation of safety mechanisms, or both. The safety mechanism was not activated in 20% of discarded engineered sharps injury prevention devices during the study period; however, some of the engineered sharps injury prevention devices not activated may not have been used. Because most of the instances in which engineered sharps injury prevention devices were involved in percutaneous injuries occurred when the safety mechanism could not be activated, the preventability of these injuries is uncertain.

Activation rates for engineered sharps injury prevention devices varied according to perceived ease of use, ease of activation, and patient adverse effects; personal preference for devices with safety features; and amount of training healthcare workers had received on use of the devices. These factors, along with perceived risk for occupational infection by healthcare workers and prior experience with engineered sharps injury prevention devices, previously have been reported as affecting activation rates and user acceptability. The high (98%) activation rate of the vacuum tube blood-collection needle with recapping sheath may be due to its safety mechanism design, which makes disposal of the device more difficult if the hinged sheath is not closed, thereby forcing activation.

Our analysis agreed with the assessment of injured healthcare workers that most percutaneous injuries involving conventional, hollow-bore needles were preventable. The high degree of preventability reported by healthcare workers may indirectly reflect their willingness to try safer methods. Because most of these percutaneous injuries theoretically could have been prevented by using safer needles and safer work practices, this underscores the need for additional prevention training and the implementation of safer devices.

The overall and occupation-specific percutaneous injury underreporting rates were similar to those in other reports; phlebotomists and nurses had the lowest underreporting rates, whereas physicians in training (ie, medical students and physicians) had the highest. This finding highlights the need to focus interventions on these groups. There was no correlation between percutaneous injuries and the number of consecutive days or hours worked, or having had fewer than 5 hours of sleep the prior night. However, this study cannot definitively exclude these factors as contributing to the incidence of percutaneous injuries.

This study had several additional limitations. The lack of data on the number of engineered sharps injury prevention devices purchased by category may have limited the ability to calculate percutaneous injury rates. Another limitation is that engineered sharps injury prevention devices did not completely replace conventional products during phase II of the study. For example, approximately one-fifth of all winged steel needles found during the audit were conventional devices, not engineered sharps injury prevention devices. The study also was hindered by lack of data on the use of different phlebotomy devices among different occupations, particularly in the pre-intervention phase. Furthermore, we do not have precise data on the number of phlebotomies performed because these data were derived from self-reported estimates rather than more objective data (eg, number of devices purchased or number of phlebotomy procedures billed). Finally, survey data obtained by asking study participants to remember the average number of phlebotomy procedures performed and the specific percutaneous injuries sustained during a 12-month period may be subject to recall bias.

Percutaneous injuries represent a complex problem that does not lend itself to a simple solution that can be applied to all healthcare facilities. Although engineered sharps injury prevention devices are an important tool in the prevention of percutaneous injuries, they constitute only part of a comprehensive strategy that also incorporates promotion of appropriate work practices to prevent injuries.
and exposure surveillance. Some of the components of the approach described in this article may be impractical or too expensive for many facilities. Nonetheless, multi-tiered interventions have proven effective in achieving significant reductions in percutaneous injuries among healthcare workers. One such intervention documented sustained success during a 7-year postintervention period.\textsuperscript{12,13}

Two points should be emphasized: (1) the data presented here should not be used to select one phlebotomy engineered sharps injury prevention device over another, but rather to select engineered sharps injury prevention devices over conventional products; and (2) for phlebotomy engineered sharps injury prevention devices to be successful, they must be implemented in the context of a percutaneous injury prevention program that includes education of healthcare workers, development of a safety culture, and collection of appropriate surveillance data. Accomplishing long-term reduction in a cost-effective manner presents a formidable challenge to healthcare facilities.

REFERENCES