ORIGINAL ARTICLE

Effect of the Introduction of an Engineered Sharps Injury Prevention Device on the Percutaneous Injury Rate in Healthcare Workers

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OBJECTIVE. To evaluate the effect of introducing an engineered device for preventing injuries from sharp instruments (engineered sharps injury prevention device [ESIPD]) on the percutaneous injury rate in healthcare workers (HCWs).

METHODS. We undertook a controlled, interventional, before-after study during a period of 3 years (from January 1998 through December 2000) at a major medical center. The study population was HCWs with potential exposure to bloodborne pathogens. HCWs who sustain a needlestick injury are required by hospital policy to report the exposure. A confidential log of these injuries is maintained that includes information on the date and time of the incident, the type and brand of sharp device involved, and whether an ESIPD was used.

INTERVENTION. Introduction of an intravenous (IV) catheter stylet with a safety-engineered feature (a retractable protection shield), which was placed in clinics and hospital wards in lieu of other IV catheter devices that did not have safety features. No protective devices were present on suture needles during any of the periods. The incidence of percutaneous needlestick injury by IV catheter and suture needles was evaluated for 18 months before and 18 months after the intervention.

RESULTS. After the intervention, the incidence of percutaneous injuries resulting from IV catheters decreased significantly ($P < .01$), whereas the incidence of injuries resulting from suture needle injuries increased significantly ($P < .008$).

CONCLUSION. ESIPDs lead to a reduction in percutaneous injuries in HCWs, helping to decrease HCWs' risk of exposure to bloodborne pathogens.

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Bloodborne pathogen exposures are a recognized occupational hazard for health care workers (HCWs).[1-3] Percutaneous injury (PI) from contaminated needles and other sharp instruments (hereafter, "sharps") is the most efficient mode of transmission for occupationally acquired bloodborne pathogen infection[4] and has been associated with increased risk of disease from more than 20 different infectious agents.[5] Bloodborne pathogens of substantial concern include human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). It is estimated that the risk of developing HIV infection after experiencing a percutaneous injury with an HIV-contaminated needle is 0.3%.[6] The risk of being infected with HBV after a percutaneous injury with an HBV-contaminated needle is 23%-37%[7] and the risk of developing HCV infection is 1.8% after a percutaneous injury with an HCV-contaminated needle.[8-11] The risk from exposure of nonintact skin to contaminated blood is unclear but is less than the risk from mucous membrane exposure.[12]

The first cases of occupationally acquired HIV infection were reported in the 1980s.[13] As of December 2001, there have been 57 documented cases attributed to occupational exposure in the United States and 138 more considered possibly occupation-related.[14,15] There is no cure or effective vaccine for acquired immunodeficiency syndrome (AIDS); although postexposure prophylaxis (PEP) is available after HIV exposure and can be effective in reducing seroconversion,[16] there have been documented cases of seroconversion despite receipt of PEP.[17]

National case surveillance data indicate that 14% of HCWs exposed to HIV seroconverted despite receiving PEP.[2] Furthermore, antiretroviral PEP may lead to side effects, as a result of which HCWs may discontinue the medication prematurely or may be unable to work while taking these medications.[17-19] Although a vaccine against HBV is available,[20] not all HCWs avail themselves of the vaccine, and the HBV immune globulin given to nonimmune HCWs as postexposure therapy is 75% effective and does not always prevent HBV infection.[21] There is neither vaccine nor PEP available

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for HCV infection, although early interferon treatment is associated with a higher rate of resolved infection.[22]

Formal efforts to prevent exposure to bloodborne pathogens started in 1985,[23] when the Centers for Disease Control and Prevention (CDC) recommended the use of standard precautions by HCWs. In 1987, this recommendation was updated[24] and in 1991, the Occupational Safety and Health Administration (OSHA) promulgated the Bloodborne Pathogen Standard,[25] of which standard precautions were a cornerstone.[25,26] Even with the introduction of this regulation, PI—including needlesticks—resulting in bloodborne pathogen exposure, which is one of the most common occupational injuries in hospitals,[4] continued to be a concern.[27,28] Recent estimates indicate that 384,325 PIs involving contaminated sharps occur annually among hospital-based HCWs .[29] Since the publication of OSHA's Bloodborne Pathogen Standard, various devices have been developed to help reduce the risk of needlesticks and other sharps injuries.[30-34] OSHA revised the Bloodborne Pathogen Standard in an effort to decrease PIs that lead to bloodborne pathogen exposure. The revised standard requires that employers select safer needle devices as they become available. These revisions, mandated by the Needlestick Safety and Prevention Act, were adopted in October 2001.[4] This act placed safety devices, already in use, under the umbrella of the Bloodborne Pathogen Standard and provided regulatory oversight and stimulus for exploring the more widespread introduction and use of safety devices.

Recent studies indicate that certain types of engineered sharps injury prevention devices (ESIPDs) are associated with significant reductions in PI rates, including devices such as bluntable or resheathable vacuum tube blood collection devices for phlebotomy procedures,[35] and resheathable winged steel needles for intravascular access procedures.[36] The 2001 EPINet report noted a sizeable decrease in the PI rate from 1999 to 2000, from 40 to 34 PIs per 100 occupied beds. This decline was attributed, in part, to the mandated use of safer needle devices.[37] Although an assortment of safety devices has been available for several years, data are sparse with respect to the impact of specific devices on injury reduction.[36] This study was designed to evaluate the effect of introducing an ESIPD, specifically an intravenous (IV) catheter stylet, on the incidence of percutaneous bloodborne exposure among HCWs.

METHODS

Study Design, Setting, and Participants

This controlled, retrospective, interventional, before-after study was conducted over a period of 3 years (from January 1998 through December of 2000) at the affiliate clinics and hospitals of an urban medical center. It was designed to examine the effect of introducing a safer needle device on the incidence of percutaneous bloodborne pathogen exposure. Participants were HCWs at risk for bloodborne pathogen exposure from contaminated needles during the course of their daily work (housestaff, attending physicians, medical students, nurses, nursing assistants, emergency medical technicians, and environmental service workers). These HCWs undergo mandatory annual training on standard precautions for 1.5 hours at a safety fair, including training on reporting procedures for an exposure. HCWs who sustain a needlestick injury are required to report the exposure to the Postexposure Management Program (PEMP), in accordance with hospital policy, and the employee is treated according to CDC guidelines.[38] A confidential log of these injuries is maintained that includes information on the date and time of the incident, the type and brand of sharp involved, and whether an ESIPD was used.

Intervention

The safer needle device chosen for this study was an IV catheter stylet with a safety-engineered feature (a retractable protection shield). It was placed in the clinics and on hospital units in lieu of other IV catheter devices. All other IV catheter devices were removed from the clinics and hospital wards and were no longer available after the beginning of the intervention period (June 30, 1999). Other sharp devices (eg, phlebotomy needles, insulin needles, and tuberculin needles) were replaced by ESIPDs at different rates and did not undergo the rapid transition to safer needle devices that was seen with the IV catheter ESIPDs. Training was provided on the use of ESIPDs at various times during the study period as the devices were introduced. Suture needles, used as the comparison group, were not replaced and were the only sharp device type that remained constant throughout the study period.

Data Collection and Analysis

The data collected for this study were obtained from the Center for Occupational and Environmental Medicine PEMP's 2 computerized database systems, EPINet and a database created with Microsoft Access. These databases contain information pertaining to all sharps-related injuries that HCWs have sustained since 1988. The EPINet database houses information pertaining to sharps-related injuries that occurred after 2000, and the database created with Microsoft Access houses information pertaining to sharps-related injuries that occurred prior to 2000. The HCWs' medical records were used in the event that further clarification was needed.

The types of sharps involved in the incidents were identified and recorded. Only PIs that resulted from suture needles, IV catheters prior to the intervention, and IV catheter ESIPDs after the intervention were used in this analysis. The devices involved in the incidents were identified. The incidence rate of PIs in the study population was evaluated for 18 months before and 18 months after the intervention. Each 18-month interval was further subdivided into three 6-month periods, extending over a period of 3 years from January 1998 to December 2001. The three 6-month periods before and after

TABLE Numbers and Rates of Percutaneous Injuries (PIs) Sustained During 6-Month Intervals of the 18-Month Preintervention and Postintervention Periods

Period, dates	No. of eligible healthcare workers	Intravenous catheter needle		Suture needle	
		No. of PIs	Rate[a]	No. of PIs	Rate[a]
Preintervention					
1/1/98-6/30/98	3,261	8	2.5	5	1.5
7/1/98-12/31/98	3,946	9	2.3	7	1.8
1/1/99-6/30/99	3,954	10	2.5	8	2.0
Postintervention					
7/1/99-12/31/99	4,265	8	1.9	8	1.9
1/1/00-6/30/00	4,292	4	0.9	12	2.8
7/1/00-12/31/00	4,294	1	0.2	26	6.1

[a] No. of PIs per 1,000 healthcare workers.

the intervention were examined and compared for incidence of percutaneous exposure resulting from suture needles and IV catheters (with and without the safety device). The number of HCWs employed during these 6-month periods was also calculated. Data are presented as the number of PIs per 1,000 employees. To determine differences in the incidence rates between the 2 study periods, we used the Fisher exact test. All analyses were performed using SAS statistical software (SAS Institute). *P* values less than .05 were considered statistically significant.

RESULTS

The Table presents the number of PIs and the PI rates for reported incidents attributed to IV catheters and suture needles during the 18-month preintervention period. The injury rate associated with IV needles remained relatively stable over each 6-month period during the 18-month preintervention period, varying from 2.5 to 2.3 PIs per 1,000 HCWs. The injury rate associated with suture needles varied from 1.5 to 2 PIs per 1,000 HCWs. The Table also presents the number of PIs and the PI rates for reported incidents attributed to the IV catheter ESIPD and the numbers and rates for PIs associated with suture needles during the 18-month postintervention period. The rate of PIs that resulted from the IV catheter ESIPD decreased over each consecutive 6-month interval from 1.9 to 0.2 PIs per 1,000 HCWs, whereas the rate of injuries sustained as a result of suture needles increased over each consecutive 6-month interval from 1.9 to 6.1 PIs per 1,000 HCWs.

The Figure illustrates the PI rate during the preintervention and postintervention periods. The number of employees was averaged over each of the 18-month periods to calculate the injury rate. There were 3,720 employees during the preintervention period and 4,284 during the postintervention period. The number of PIs and the rate of PIs sustained from suture needles doubled in aggregate from the preintervention to the postintervention period; the number increased from 20 to 46, and the rate increased from 5.3 to 10.7 PIs per 1,000 HCWs. This increase was statistically significant ($P < .008$). The number of PIs and the rate of PIs sustained from IV catheters and IV catheter ESIPDs decreased from the preintervention to the postintervention period, from 27 to 13 injuries, and from 7.3 to 3 PIs per 1,000 HCWs. This decrease was statistically significant ($P < .01$).

DISCUSSION

This study was designed to evaluate the effect of introducing an ESIPD on the PI rate in HCWs and adds to the literature on the effectiveness of safety-engineered devices in reducing PIs. We assessed the impact of one intervention, the introduction of an IV catheter ESIPD on the PI rate at one urban medical center, by comparing the injury rates associated with another device, suture needles, which were not changed. The data show that the rate of IV catheter–related PIs decreased significantly after the safety device was introduced, whereas the rate of suture needle–related PIs actually increased significantly during the intervention period. The ESIPD used in this study was an IV catheter stylet with a safety-engineered feature (a retractable protection shield), which was placed in the medical center's clinics and hospital wards at the start of the intervention period, as a replacement for all other IV catheter devices. Our results indicate that the PI rate for reported incidents attributed to IV catheter use decreased by 50% between the preintervention and postintervention periods, a statistically significant decrease. Indeed, this rate decreased in a linear fashion over each 6-month period during the postintervention period, yet the rate remained relatively constant during the preintervention period. On the other hand, the percutaneous injury rate attributed to suture needles increased significantly during the postintervention period.

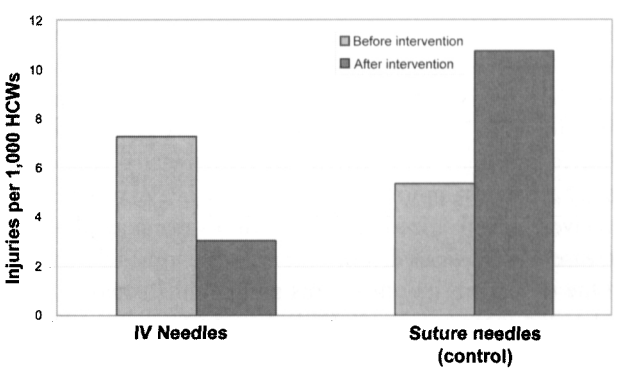

FIGURE. The rate of percutaneous injury among healthcare workers (HCWs) in the 18 months before and after introduction of a safety-engineered intravenous (IV) catheter stylet. Suture needles without protective devices were used as the control.

This study indicates that the use of an IV catheter ESIPD led to a significant reduction in the PI rate in this HCW population, and consequently to a decreased risk of exposure to bloodborne pathogens. As there was no reliable data on the number of IV catheters or suture needles used or purchased during the study period, the incidence of PIs per 1,000 HCWs was used to calculate the rates. The incidence of PIs sustained from suture needles might have been increased because the introduction of ESIPDs led to increased HCW awareness of the importance of PI reporting, resulting in an increased trend in overall reporting. However, this presumptive behavior change in reporting status after the introduction of ESIPDs has not been borne out in other studies.[39]

One might also surmise that the decreased incidence of PIs attributed to the IV catheter ESIPD during the postintervention period was the result of increased compliance with standard precautions. However, the presence of a control group showing the opposite finding makes this assumption unlikely. Another explanation for the increase in the suture needle PI rate in the postintervention period is that the University's PEMP staff may have increased tracking efforts after the introduction of the ESIPDs. This increased tracking, however, should affect reporting of all injuries sustained from all devices, yet the number of reported injuries from the IV catheter ESIPDs did not increase. As the number of employees increased gradually over the years, one might expect the absolute number of injuries to increase in both groups. This did not occur in the intervention group. In addition, there were no changes in the policies and procedures during the intervention period that might account for these results.

The observed linear decrease in IV catheter–related injury rates after the introduction of the ESIPD might also reflect a learning curve. As HCWs became more familiar with the device, they might have been more likely to use it with greater ease and precision. This phenomenon has been observed in other studies, which found that ESIPDs could be even more efficacious in preventing PIs if consistently used correctly.[34-36] Injuries that occur despite the use of an ESIPD may result from mechanical failure of the safety feature, lack of motivation for the HCW to use the device for a variety of reasons (including low perceived risk of injury, inadequate training, and inherent risk in the activation process) or incomplete activation.[31,35,36,40] The likelihood of HCWs activating the safety feature may vary, depending on perceived ease of use, ease of activation, amount of training the HCW received, and perceived risk of infection.[34] Activation rates may, therefore, increase with increased training of HCWs on their use.

One of the limitations of this study is that there is a lack of detailed information available on events surrounding the injuries. For example, it is unclear whether an injury occurred because the device failed to work correctly, the safety device was not activated, or some other reason. Another study limitation is that these data were obtained from only one medical center, affecting the study's generalizeability. The fact that only one brand of IV catheter ESIPD was used also affects generalizeability, as it does not allow comparison of injury rates associated with other brands available for use. Reporting bias is also a concern as, historically, a substantial number of PIs are never reported. Underreporting behavior among HCWs is well-documented in the literature. Recent estimates place the overall rate of underreporting PIs at 43.4%.[29] Underreporting of PIs is also seen in other occupations.[41]

Even in the face of these limitations, our findings are important because they show that the use of IV catheter ESIPDs decreases the incidence of PIs, helping to confirm previous findings[29,36,42] and thus supporting the use of these devices. The Needlestick Safety and Prevention Act[4] gave impetus to the widespread introduction of ESIPDs, which were already available and being used in various settings. Although the cost of safer devices had been a concern for hospitals,[43] ESIPDs have financial benefits that may exceed their cost, as they reduce the needlestick injury rate and the associated medical treatment costs.[44] With increased volume of production, prices have decreased, thus reducing the cost differential.

Further studies are needed to better ascertain what types of ESIPDs will result in the fewest exposures. This information would be useful to healthcare organizations in device selection. Additional studies are also needed to further evaluate the reasons that exposures continue to occur despite the use of ESIPDs. In addition to the factors mentioned earlier, other reasons may include attention failures due to fatigue[45]; organizational factors, such as time pressure due to heavy workload[46-48]; and lack of organizational commitment to safety.[27] It is possible that the reduction in the incidence of PIs as a result of the use of ESIPDs will plateau, because the use of protective equipment alone, without attention to modulating factors, is unlikely to eliminate PIs. Designing targeted interventions to address modulating factors with respect to optimal ESIPD use, assessing the outcomes of these interventions, and instituting those that are proven to work will help to further reduce the incidence of PIs among HCWs.

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