ASSOCIATION OF OCCUPATIONAL HEALTH PROFESSIONALS IN HEALTHCARE

Spring 2014

Reducing Needlestick Injuries from Active Safety Devices: A Passive Safety-Engineered Device Trial

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Abstract

Background: More than 18 million healthcare workers (HCW) in the United States work in hospitals and other healthcare settings. Precise national data are not available on the annual number of needlestick injuries (NSI) among HCW; however, recent estimates indicate that over 440,000 NSI occur annually. Active safety engineered devices (ASED) are the most widely used type of safety engineered device (SED) at the trial facility. The ASED requires a deliberate activation of the safety feature to re-sheath the needle, while the passive safety-engineered device (PSED) automatically retracts the needle into the barrel of the syringe once medication is delivered, immediately removing the physical hazard. Needlesticks from the ASED used for subcutaneous (SQ) medication administration account for roughly 35% of NSI at the trial facility.

Objective: To evaluate the incidence of NSI among HCW with a new PSED, specifically a SQ retractable needle, compared to the ASED.

Methods: Four medicine nursing divisions and one intensive care unit at a 1,250-bed US teaching hospital participated in a PSED trial between May 2011 and January 2012. Divisions were selected based on their higher than average number of NSI over the previous three years and willingness to participate. The type and size of ASED was selected based on SQ injections (0.5 and 1 ml) being the most frequent NSI in those units. The existing inventories of SQ ASEDs were removed from participating units and replaced with the same size "trial" SQ PSED. Data from HCW self-reported NSI were collected in an electronic data repository and evaluated. A Fisher's exact test was calculated for NSI and employee productive hours.

Results: During the 30-month pre-trial ASED period, 19 NSI were reported with a rate of 2.21 NSI per 100,000 employee productive hours. During the nine-month PSED trial period, one NSI was reported with a rate of 0.42 NSI per 100,000 employee productive hours ($p \leq 0.05$.) Root cause analysis of the single NSI revealed improper use of device as opposed to device failure.

Conclusions: This study confirmed that use of a PSED significantly reduced the SQ NSI rates compared to ASED.

Introduction

The Federal Needlestick Safety and Prevention Act (NSPA) of 2000 required changes in the Bloodborne Pathogens Standard, 1910.1030, an existing Occupational Safety and Health Administration (OSHA) Standard of 1991. The changes required the inclusion of safety medical devices, such as devices with engineered controls designed to eliminate or minimize the risk of occupational exposure to bloodborne pathogens through needlestick and other percutaneous injuries.[1] In addition, employers were required to review and update exposure control plans to reflect changes in technology that eliminate or reduce exposures and implement effective safer medical devices when commercially available for injury prevention.

More than 18 million healthcare workers (HCW) in the United States work in hospitals and other healthcare settings.[2] Precise national data are not available on the annual number of needlestick and other percutaneous injuries among HCW; however, recent estimates indicate that over 440,000 such injuries occur annually.[3] The majority (72%) of reported exposures in the Summary Report for Blood and Body Fluid Exposure Data Collected from Participating Healthcare Facilities from the National Surveillance System for HealthCare Workers (NaSH) involve direct patient care providers, of which 42% are nurses and 30% are physicians, and percutaneous injuries were the most commonly reported route of bloodborne pathogen exposures (82%.)[4] Hollow-bore needles were involved in the majority (55%) of percutaneous injuries reported, and hypodermic needles attached to syringes were the most common type of hollow-bore needle involved in reported injuries. Most injuries occurred during the use of a device (52%) versus after use or disposal of hollow-bore needles, and 56% of percutaneous injuries reported were considered preventable with safer devices available in 26% of exposures.[4]

Currently, there are two types of safety engineered devices (SED) used in healthcare settings. Active safety engineered devices (SED) are the most widely used type of safety device for the delivery of medications and vaccines and require the HCW to manually activate the safety feature on the device. Examples include hypodermic needles with a protective sliding shield or those that must be covered with a plastic toppling shield. PSED require no activation of the safety feature on the device by the user. PSED either instantly retract the needle from the patient into the barrel of the syringe with a push button at the end of the syringe (semiautomatic SED) or automatically cover the needle bevel with a safety shield after use (automatic SED.) By design, semi- and automatic safety devices appear more likely to decrease needlestick injuries (NSI) because they do not require an active sliding motion toward needle points or changing hand positioning for needle coverage prior to disposal.

No studies have been published that directly examined SQ NSI rates after switching from ASED to PSED. Few studies in the literature have focused on SQ syringe PSED versus IV or winged steel needles. Most published studies examined the rates of NSI after the introduction of ASED compared to non-safety devices. In 2010, a large, multicenter observational study by Tosini et al., examined SED-related NSI in 61 French hospitals. In this study, 40 different safety devices were identified, of which 22 were associated with documented NSI; and NSI incidence rates were lowest with fully automatic PSED.[5] One study published the results of a prospective cohort in an 800-bed Australian hospital in 2008. Whitby et al. implemented the use of multiple semiautomatic PSED and observed a significant reduction in hollow-bore NSI compared with the averaged five-year rate prior to implementation of the PSED.[6]

This study provides a direct comparison of SQ NSI rates with the use of an ASED and PSED. The study was conducted at Barnes-Jewish Hospital (BJH,) a 1,250-bed tertiary-care teaching hospital affiliated with Washington University School of Medicine located in Saint Louis, MO. Historically, with the implementation of multiple ASED for subcutaneous (SQ) medication administration, BJH continued to see an increase in NSI despite repeated education efforts.

Methods

A multidisciplinary group, including engineers from one of the ASED manufacturers, conducted an investigation using Lean Six Sigma principles to glean a single root cause for the increasing NSI rates. Even though there appeared to be multiple contributing factors to NSI, further data review indicated SED that required an active motion toward or above the needle point to engage the safety mechanism posed a higher risk of needlesticks. As a result, commercially available alternative SED were investigated, and a PSED that automatically and instantly retracts the needle from the patient into the barrel of the syringe once medication is delivered was trialed. The PSED requires the HCW to push the end of the plunger after medication administration, and requires no change in motion or HCW hand positioning. This was the only device that met our criteria of eliminating the HCW motion toward or above the needle point and was presented to the frontline staff for trial and evaluation.

Four medical nursing divisions and one intensive care unit at the hospital participated in a PSED trial between May 2011 and January 2012. Divisions were selected based on their higher than average number of NSI over the previous three years and willingness to participate. The type of SED was selected based on one-ml SQ insulin and tuberculin syringes being the most frequent device associated with NSI in those units. The existing SQ ASED were removed from participating units and replaced with the same size "trial" SQ PSED. Extensive educational in-services were provided by clinical educators from the PSED manufacturer prior to device utilization for all participating units.

Trial unit nurses completed PSED evaluation questions focused on the passive safety feature, ease of use, device design, hand positioning, patient discomfort, and risk recommendation that were scored on a Likert scale. A five-level scale was used with "1" labeled strongly agree and "5" labeled strongly disagree. Percent of respondents who answered "1-strongly agree" or "2-agree" for each question was calculated.

Data from HCW self-reported NSI were collected in the BJC Occupational Health Database, an electronic data repository of all occupational injuries and exposures, and evaluated. NSI rates were calculated using 100,000 employee productive hours. Our NSI rate denominator included employee productive hours, or "working hours," at 15-minute increments regardless of part- or full-time status or position, collated from human resources data. A Fisher's exact test was calculated for NSI and employee productive hours. Statistical analyses were performed with Epi Info, version 7.0 (Centers for Disease Control and Prevention (CDC,) Atlanta, GA.) Cost impact and cost avoidance, or savings, of a conversion from the ASED to the PSED was completed for BJH, including the four medical nursing divisions and one intensive care unit that participated in the trial.

Results

During the 30-month pre-trial period, 19 NSI were reported with a rate of 2.21 NSI per 100,000 employee productive hours. The 30-month pre-trial period was chosen because that was the time frame the current ASED with a sliding needle shield was being utilized at BJH. During the nine-month PSED trial period, one NSI was reported with a rate of 0.42 NSI per 100,000 employee productive hours (Table 1.) The difference in NSI rates prior to the PSED trial and during the trial period was statistically significant ($p \leq 0.05$.) Introduction of a PSED resulted in a five-fold reduction in SQ NSI per employee productive hours. SQ NSI occurrence decreased nearly 95% during the trial period (Figure 1.) No significant dif-

TABLE 1: NSI Rates Before and During the PSED Trial

	Pre-Trial	Trial
NSI	19	1
Productive Hours	857,895	237,202
Rate*	**2.21**	**0.42**

**per 100,000 employee productive hours*

FIGURE 1: SQ NSI rate in trial divisions (January 2009 – February 2012)

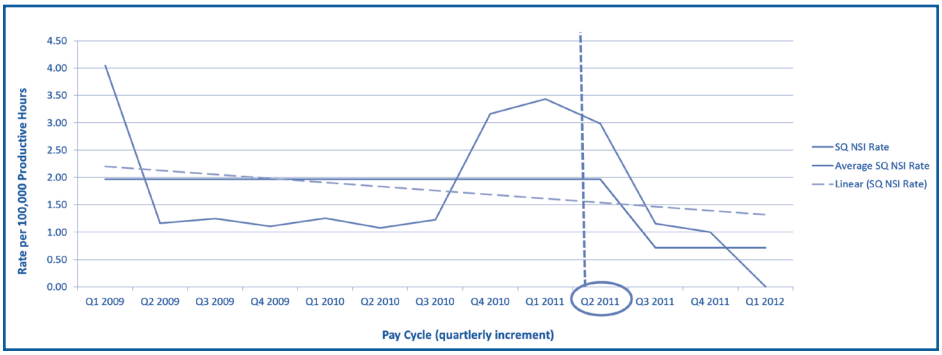

TABLE 2: Purchase cost impact of a conversion to a passive retractable device

Current State: ASED	Qty	Unit Price	Cost	Total
Insulin Syringe 100 unit (29G x 1/2)	37,750	$0.25	$9,437.50	$48,647.75
Insulin Syringe 50 unit (29G x 1/2)	156,841	$0.25	$39,210.25	
Proposed Future State: PSED	**Qty**	**Unit Price**	**Cost**	**Total**
Insulin Syringe 1 ml 100 unit (29G x 1/2)	37,750	$0.30	$11,325.00	$69,356.17
Insulin Syringe 0.5ml 50 unit (30G x 1/2)	156,841	$0.37	$58,031.17	
			Net increase	$20,708.42

TABLE 3: Cost savings of a conversion to a passive retractable device

Current State: ASED	Cost analysis - 2012	Total
Occupational health department	$4,512.00	
Laboratory testing / analysis	$12,251.00	
Exposed employee hours	$9,343.56	$31,706.56
Post-exposure prophylaxis	$5,600.00	
Proposed Future State: PSED*	**Cost analysis - 2012**	**Total**
Occupational health department	$0.00	
Laboratory testing / analysis	$0.00	
Exposed employee hours	$0.00	$0.00
Post-exposure prophylaxis	$0.00	
	Net savings	$31,706.56

**Used appropriately in accordance with manufacturer guidelines*

TABLE 4: Employee evaluation of PSED

Safety Needle Device Survey	% Agreement
1. Use of this product requires you to use the safety feature	82%
2. The safety feature works well with a wide variety of hand sizes	65%
3. The device is easy to handle while wearing gloves	72%
4. The safety feature can be activated using a one-handed technique	80%
5. There is a clear and unmistakable change (audible or visible) that occurs when the safety feature is activated	77%
6. The design of the device suggests proper use	70%
7. It is not easy to skip a crucial step in proper use of the device	63%
8. During the use of this device, the user's hands remain behind the needles until activation of the safety mechanism is complete	68%
9. This device can be used without causing more patient discomfort than the currently used device	52%
10. This device minimizes the risk of user exposure to the patient's blood	73%
11. Would you recommend using this device to minimize your risk of needlestick injury?	70%

ference was seen in hospital-wide NSI rates outside of the trial units, which demonstrate that no additional factors contributed to the NSI decrease (data not shown.)

Root cause analysis of the single NSI occurring during the trial revealed improper use of the device as opposed to device error. The HCW did not push the end of the plunger after medication administration prior to removing the needle from the patient and was consequently "stuck" prior to disposal of the syringe. Thirty-eight percent (60 of 160) of unit nurses completed device evaluations after the nine-month PSED trial. Percent of respondents who answered "1-strongly agree" or "2-agree" on device evaluation questions ranged from 52% to 82% (Table 4.) Most unfavorable responses were around confusion related to a visible tiny air bubble that was incorrectly perceived to interfere with the proper dose volume. Re-education from the manufacturer related to the air bubble and trigger of the safety mechanism mitigated the nurses' concerns. Since engaging the safety mechanism requires additional force on the end of the syringe, or plunger, HCW perception of pain experienced by the patient was also increased with the PSED (question 9;) however, no patient complaints of pain or injury were reported during the trial period. Overall, 70% of nursing staff would recommend using the PSED to minimize their risk of needlestick injury.

Cost impact of a conversion from the ASED to the PSED was completed for BJH, including the four medical nursing divisions and one intensive care unit that participated in the trial. Annual utilization cost for the "current state" ASED device totaled $48,647.75 dollars, and annual cost for the "proposed future state" retractable device totaled $69, 356.17 dollars, for a net annual increase of $20,708.42 (Table 2.)

Cost avoidance, or savings, of a conversion from the ASED to the PSED was also calculated based on: hard costs of occupational health nurse and administrative hours for reported exposures and post-exposure lab testing for bloodborne pathogens; laboratory testing for source patient and employees for up to 12 months of testing; exposed employee hours including only the hours needed to complete the reporting process and any baseline and follow-up laboratory testing; and post-exposure prophylaxis (PEP) including only human immunodeficiency virus (HIV) medication expenses, typically a 28-day regimen. Cost avoidance data did not include soft costs, or those costs that vary by exposure, such as lost work hours outside of exposure reporting and lab testing. For example, sick time, staff coverage, physician consults and visits, HIV PEP side effects, mileage, travel time, legal or attorney fees, and workers' compensation fees were not included. Total cost avoidance of a conversion from an ASED to a retractable device was $68,768.28 (Table 3.)

Discussion

Our study suggests that automatic PSEDs decrease NSI rates when compared to ASED. Our findings are similar to: the results of Tosini et al. in that PSED are most effective for NSI prevention; and results of Whitby et al. in which hollow-bore NSI rates were reduced by 49% when compared with the averaged five-year rate prior to a multiple PSED intervention. By design, PSED eliminate active motion of the HCW to activate the safety feature of the device. If used appropriately, automatic PSEDs eliminate the risk of exposure to bloodborne pathogens because the needle is never

exposed outside of the patient post-use. This conclusion has been validated in the literature with winged steel, or butterfly, needles, [7] and NSI rates have significantly decreased with automatic, passive intravenous (IV) devices.[8]

According to Tuma et al., many factors can impact HCW acceptance of PSED, including HCW involvement in device selection, rate of safety feature engagement, availability and use of devices in the intervention areas, and perceived ease of use.[9] In our experience, repeated, focused education and training within each unit was critical because the trial units had different acceptance levels and device-related concerns. Education and in-services provided before, during and after implementation of SED are necessary, and simultaneous training results in a significant reduction in the number of NSIs based on the four-year prospective study by Adams D et al.[10] HCW evaluation of the design of the device, ease of use, activation of the safety feature, the perceived risk of occupational exposure, and recommendation of use to minimize risk of NSI should all be included in device assessment. Black et al. concluded that broader dissemination of PSED coupled with HCW education and training is essential for a successful bloodborne pathogen exposure and control program.[13]

Ongoing education for effective use of automatic PSED is needed for specific limitations of current PSED on the market. The safety mechanism of the device is not applicable in all medication administration. For example, in percutaneous administration of local anesthetic, the entire syringe contents may not be injected at one time. Since the syringe must be completely emptied for the needle to automatically retract, the HCW must be aware that the needle will not retract with partial or multiple injections. As cautioned by Whitby et al., the one-ml retractable insulin and tuberculin syringes are very similar. While the insulin syringe has an orange cap versus the tuberculin syringe's gray cap, on-going education must be provided to HCW to avoid medication administration errors.[6]

A 2010 publication by Saia et al. examined the estimated cost of post-exposure NSI management, not including potential long-term healthcare costs associated with contracting hepatitis or HIV. Saia calculated that, based on the CDC's expected national annual occurrence of NSI, the financial burden of NSI in the United States would be between $118 million and $591 million.[11] The implementation of safety-engineered needle devices in healthcare, along with education for HCW, may substantially reduce the economic burden of NSI. According to the US General Accounting Office, 29% of NSIs that occur in US hospitals are estimated to be prevented through the implementation of safer devices, and result in an estimated potential cost savings of $34 million to $173 million each year.[11] Phillips et al. discussed the cost savings for implementing safety engineered needle devices after NSPA was enacted in 2000. They calculated that 138,357 needlestick injuries were prevented each year after the NSPA. Using post-exposure management costs estimated from the US General Accounting Office, Phillips calculated a savings range of $69 million to $415 million related to NSI management costs for each year since 2001 in the United States.[12] Our data augments their findings with hospital-specific cost avoidance from a conversion from an ASED to a retractable device.

Limitations of this study include reliance on self-reporting by HCW or voluntary reporting of NSI, and the occurrence of NSI at our institution does not account for underreporting. However, it is unlikely that underreporting varied in the trial units' nursing population before and after implementation of the PSED. If anything, reporting might have been better during the trial due to heightened awareness. Four medical nursing divisions and one intensive care unit in a major teaching institution participated in the trial, and our findings may not be generalizable to other healthcare settings where HCW sustain percutaneous injuries from ASED. The trial time of nine months is also a potential limiting factor compared to previously published data, although we do not expect seasonality with PSED NSI.

No studies have directly examined SQ NSI rates after switching from one type of ASED to PSED. Most NSI studies examined the rates of NSI after the introduction of ASED compared to non-safety devices. Studies selected for inclusion in our review compared hospital-wide SED-related NSI where multiple types of SED were implemented. Few studies in the literature have focused on SQ syringe PSED versus IV or winged steel needles. Our NSI rate denominator included over one million employee productive hours, and 15-minute increments of all employee hours, regardless of part- or full-time status or position, were collated from human resources data. Employee productive hours, or working hours, is an ideal denominator to calculate employee time at risk than other methods in the literature, such as counting the number of nurses employed, full-time equivalents (FTE,) occupied beds, patient days, devices ordered, or devices utilized which may be difficult to calculate accurately.[14,15] Consistent education and device training were provided prior to implementation of both the ASED and PSED in the trial units, and the manufacturers' clinical educators provided the same implementation plan for both the ASED and the PSED.

Conclusion

Our data provide a direct comparison of NSI rates with the use of an SQ ASED and SQ PSED in a major teaching hospital. To increase dissemination of PSED in healthcare settings, the cost impact of PSED must be weighed against the cost avoidance associated with occupational health departments' assessment and counseling post-NSI, laboratory testing of source and HCW, analyses of serologic results, exposed employee off-hours, and post-exposure prophylaxis and subsequent treatment needed. Based on the significant reduction of SQ NSI with PSED, the device was selected for house-wide implementation at BJH.

Acknowledgments
Special thanks to the Evidence-Based Care Team in the Center for Clinical Excellence at BJC HealthCare, managed by Liana Merz, PhD, MPH, for assisting with the literature search and review; and to Dale Reinhold, MCP, Senior Database Analyst for the BJC Occupational Health Database (est. 1997,) for providing study data.

Preliminary data was presented at the Association for Professionals in Infection Control (APIC) 40th Annual Conference in Fort Lauderdale, Florida, in June 2013; and at the AOHP 32nd Annual National Conference in Orlando, Florida, in September 2013.

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Keywords
Needle, stick, injury, exposure, retractable, passive, active, safety, device

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