

**Case Study In Brief**

# A Retractable Winged Steel (Butterfly) Needle Performance Improvement Project

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An estimated 384,325 percutaneous injuries occur in hospitals in the United States annually.<sup>1</sup> The Occupational Safety and Health Administration (OSHA), through its 2001 Revised Bloodborne Pathogens Standard,<sup>2</sup> has focused on reducing these workplace injuries, and the Centers for Disease Control and Prevention (CDC) has issued the health care safety challenge<sup>3</sup> to eliminate *preventable* needlesticks sustained by health care workers (HCWs). The number of injuries occurring to HCWs outside the hospital setting is much less well characterized but is also thought to be considerable.<sup>4</sup> These HCWs, like their hospital counterparts, risk occupational exposure to one or more bloodborne pathogens, including hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), through percutaneous injuries.

Blood collection and proper safety needle device use and disposal represent a complex, multistep process requiring significant attention to detail to provide safety to the patient and user. Further compounding this issue is the fact that, as several studies indicate, safety devices and safety procedures do not work alone. Rather, an interdisciplinary approach is necessary, entailing mindfulness of real-life staff behavior and practices and requiring staff involvement in developing and implementing safety programs.<sup>2,5-8</sup>

Several studies emphasize the importance of HCW perceptions of the organizational and safety climates in relation to rates of needlestick injuries and near misses.<sup>9</sup> Furthermore, management involvement contributes positively to the safety climate in HCW compliance with bloodborne pathogen-related protocols.<sup>10,11</sup> It is important to forge a partnership between management and staff, given the fact that phlebotomy procedures are routinely performed with little direct supervision. Without buy-in, use of a new procedure or needle product could be assimilated either partly or even not at all, potentially making the situation worse.<sup>12</sup>

This article describes a performance improvement (PI) project that used an interdisciplinary, systematic approach, including frontline staff input, in identifying, selecting, and

evaluating a safer needle device. Safety winged steel needles (WSNs), also called butterfly needles, which are considered high risk for occupational bloodborne pathogen transmission, were targeted for improvement because they were implicated in a disproportionate number of injuries.

## Initiating the PI Project

### SETTING

Good Samaritan Hospital Medical Center (Good Samaritan) is a 537-bed not-for-profit facility (including a 437-bed hospital and a 100-bed nursing home) that is part of an integrated health system serving Long Island, New York.

### RECOGNIZING THE PROBLEM

In compliance with OSHA's Revised Bloodborne Pathogen Standard, needlestick and other sharps incidents are to be promptly reported for documentation and further medical evaluation and treatment as needed.<sup>2</sup> At Good Samaritan, Employee Health Services forwards the completed exposure incident report, which is similar to the Exposure Prevention Information Network (EPINet™) Needlestick and Sharp Object Injury Report form,<sup>13</sup> to the injured staff member's department. Reported data includes an incident description, the type and name of the sharps device, and whether the safety feature was activated.

In 2001, a laboratory safety officer [M.H.] whose assigned duties included evaluating laboratory staff incidents of occupational exposures to blood and body fluids and making recommendations to minimize recurrence, was appointed. After six months or so, it was noted that WSNs were repeatedly implicated in laboratory phlebotomists' needlestick incidents. Because needlesticks are relatively low frequency, evaluation of aggregate data for two years indicated that WSNs were indeed disproportionately involved, even when compared with the conventional (non-safety engineered) vacuum-tube blood collection needles previously used. Specifically, the WSN needlesticks occurred three times as often—3.4 versus 1.1—per

100,000 devices purchased, correlating well with a large CDC sharps safety device study.<sup>14</sup>

The descriptions of *how* needlesticks occurred were quite sketchy and often only indicated “during venipuncture.” One troubling finding was in some cases the safety feature was documented as “not activated.” This begs the question, “Why not?” This retrospective study led to a Plan-Do-Study-Act (PDSA) PI project to answer this as well as “How?” and “Why?” questions to determine the root cause of the needlestick injuries incurred by the clinical laboratory’s phlebotomy staff. The data included two years of retrospective reports of WSN needlesticks (2000 and 2001) and more than four years of prospective reports (2002–2007).

## Implementing the Project

A team—led by the clinical laboratory safety officer and including the nurse director of the infection control department and the nurse coordinator of the employee health services department working under the auspices of the sharps safety committee—was created.

### PDSA CYCLE 1

**Plan: Collect How and When Data.** To determine a root cause of WSN needlesticks, more detailed needlestick investigation information needed to be collected on precisely how WSN needlesticks occurred and during which phlebotomy procedure steps.

**Do—Intervention: Show and Tell.** As a result of the retrospective study, the investigation of needlesticks was modified. Although not well appreciated at the time, this turned out to be the most critical measure taken in establishing the root cause(s) to implement an effective intervention plan. Each needlestick incident was now followed up by the laboratory safety officer, who used one-on-one interviews with injured staff members to elucidate crucial details regarding the circumstances of the incident. Through open-ended questions and reenactment, staff members demonstrated and described how the needlestick occurred. Later in the project, the laboratory safety officer also interviewed all other hospital staff outside the laboratory who sustained WSN needlesticks, including nursing department staff—registered nurses (RNs) and emergency department (ED) technicians—who also used WSN devices.

Data were analyzed to discover the root cause(s) to determine what intervention, if any, would effectively reduce or prevent them. Were these incidents related to an inherent design flaw, device failure, user error (for example, purposeful failure to activate the safety feature or to activate it improperly), or

other circumstances (for example, sudden patient movement precluding safety feature activation)? The first intervention attempted was retraining.

**Intervention: Retraining for Safety WSN Device.** WSN retraining was provided by the manufacturer to ensure that staff had the correct information to handle the device safely from equipment assembly, use, and safety feature activation, through final disposal. Training regarding the activation of the safety feature made it clear that the basic design of this device’s sheath mechanism requires *manually* pushing the protective sheath up over the used needle or, alternatively, pulling the needle back into the sheath. In either scenario, the operator’s finger(s) are brought towards the used needle. The safety-feature activation training included a demonstration of the single-handed and two-handed methods. Generally, only staff with larger hands and longer fingers managed the single-handed method with any adeptness. The manual sliding-sheath needle guard has since been described as “a challenge” for realistic single-handed activation.<sup>15</sup>

Further complicating this delicate maneuver with the small device in gloved hands is the fact that the user is simultaneously engaged in tending to the patient’s phlebotomy site on needle withdrawal. If two hands are used to activate the safety feature, this series of events would best be accomplished with three hands rather than two.

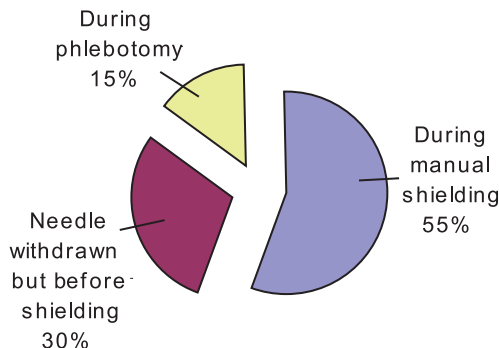
**Study: Failure and Gains.** The Study part of Cycle 1 indicated that the retraining intervention failed to reduce the number of WSN needlesticks after one year of monitoring. However, additional evidence was gained that WSNs were disproportionately involved, as was a better understanding of when WSN injuries occurred (Figure 1, page 102)—and of a putative root cause (through the intervention of interviewing injured staff). The literature supported our experience in terms of the rates and epidemiology of needlesticks with the same WSN device. In separate studies, rates of 3.1/100,000 phlebotomies, 6.41/100,000 WSN devices, and 7.4/100,000 WSNs purchased, respectively, were reported.<sup>14,16,17</sup>

**Act: Need for a “Safer” Sharps Device?** A putative root cause, which was supported by the literature and by the fact that most users were unable to use the single-handed safety feature activation method prompted an interest in exploring the option of a “safer” safety WSN device than the one currently used, leading to the plan for PDSA Cycle 2.

### PDSA CYCLE 2

**Plan: Replace Current Safety WSN with a Safer WSN Device.** An increasing number of safer sharps safety devices

**Time of Injury in Relationship to Safety-Feature Activation for 20 Injuries Associated with Winged Steel Needle with Sliding Sheath Engineered Sharps Injury Prevention Mechanism, October 2001–March 2006**



**Figure 1.** While 15% of the incidents occurred during the venipuncture procedure, 85% occurred during other seemingly problem-prone steps: immediately after needle withdrawal from the vein prior to safety feature activation (30%) and during safety feature activation (55%) involving manually sliding a sheath over the exposed needle.

with newer safety technologies recently came to the market following OSHA's revised Bloodborne Pathogens Standard and subsequent compliance activity.<sup>18</sup> Passive safety-engineered controls in effect before, during, and after the phlebotomy procedure are considered to be most effective.<sup>19</sup> Although there were no *passive* safety WSN devices available, there were several different safety WSN devices employing a variety of *actively* deployed safety features, including those utilizing self-blunting, retractable, sliding-sheath, and hinged recapping needle guard mechanisms.

We compared the devices' operating features in terms of their ability to addressing the majority (85%) of seemingly preventable needlestick injuries, that is, those occurring immediately after needle withdrawal from the vein and during the safety-feature activation step.

**Do: Identify, Select, and Implement a Safer Needle Device.**

Because the current WSN device required most users to use a two-handed technique to activate the safety feature, other devices were examined that would address this concern. Four devices claiming single-handed safety activation were identified and demonstrated by the manufacturers' representatives. The phlebotomy staff chose two devices, one employing a blunting technology, and the other a retractable-needle technology, to undergo full product evaluation on patients. Staff rejected a

third device (employing another sliding-sheath mechanism), which they considered difficult to accomplish using a single-handed activation method, and a fourth device (using a hinged recapping needle guard), which, they believed, placed their fingers unreasonably close to the used needle to activate the safety feature. Moreover, retractable and blunting technologies were found to reduce needlesticks.<sup>14,20</sup>

**Evaluation by Phlebotomists and the Products Committee.**

The facility's product evaluation team, an interdisciplinary team whose members included clinical staff, infection control, risk management, employee health services, and materials management, as recommended by Chiarello<sup>19</sup> and Hatcher,<sup>21</sup> approved the clinical laboratory's request for formal product evaluation pilot studies of the two devices and later expanded the study to include nursing department staff using WSN devices.

**Train and Evaluate.** The first pilot study involved a device with blunting technology, which featured in-vein activation while blood is collected by rotating a third wing on top of the device into position. The needle is essentially "blunted" as a blunt hollow companion tip is extended through the needle beyond the pointed end of the needle. The second pilot study, conducted about six months later, involved a newly introduced device with retractable technology that automatically pulls the needle into the barrel of the device after a button is pushed. This device also features in-vein activation but cannot be deployed *during* the blood collection; it has to be activated *after* blood collection but before needle withdrawal from the vein.

**Training.** The respective manufacturers provided training for the phlebotomists and a sufficient number of devices for several volunteers to evaluate in an approximate two-week period. Pilot study participants were instructed by the laboratory safety officer on completing a standardized WSN product evaluation tool modified from a form available elsewhere.<sup>22</sup> A 5-point Likert rating scale was used, 1 as the highest and 5 the lowest rating.

**User Product Selection:** There was a 100% response rate for both product evaluations—7 for the blunting device and 12 for the retractable device. Theoretically, the blunting device design offered a method to avoid all three identified problem-prone areas of the WSN usage procedure, including during blood collection. However, this device received a lower overall rating (3.6/5.0 versus 1.5/5.0) and substantially lower ratings in respect to patient safety and ease of use, and was rejected by the staff because of these concerns.

The pilot study was replicated for the neonatal intensive care unit (NICU) and emergency department (ED) nursing depart-

ment staff; again with a 100% response rate, the seven staff's ratings averaged 1.6/5.0. The retractable device, which featured in-vein activation and a more reliable single-handed activation mechanism to address the problem-prone steps in the process, was then selected. With support from the directors of the clinical laboratory, infection control, and employee health services, the data, along with volume and pricing information, were presented to the products standardization committee for final approval to add the item to the health system's supply chain purchasing system.

**Finalizing the Choice.** As anticipated, the proposed retractable WSN device met some resistance, given that it was 40% more costly than the existing WSN device. Needlestick safety devices are generally more expensive than conventional (non-safety) devices. Similarly, newly introduced, second-generation active needlestick safety devices are more expensive to purchase than first-generation devices. Cost was found to be a primary obstacle to implementing needlestick safety devices even before the revised Bloodborne Pathogens Standard regulations were adopted.<sup>23</sup> Sinclair et al. determined that cost issues represented the most significant barrier to safety device adoption, driving hospital decision making even more than regulatory compliance activity.<sup>24</sup>

The device's incremental cost could not be justified financially simply by projecting cost savings from incurring fewer reported needlestick injuries. A more in-depth analysis can be performed to account for cost-effectiveness, as described by Chiarello.<sup>19</sup> As illustrated in Table 1 (page 104), it would cost the facility about \$6,717 per injury avoided based on the projected number of reported injuries. This estimate is based solely on reported injuries, so when a 42% national hospital reporting rate (or 58% underreporting rate) is applied to estimate the number of WSN needlesticks (both reported and unreported), the adjusted cost-effectiveness falls to \$2,818.<sup>25</sup>

The resultant reported rate-adjusted cost effectiveness is in concordance with estimates of previously introduced safety needle devices, including the facility's existing manual resheathing WSN when it was first launched.<sup>26</sup>

To further moderate cost issues, OSHA regulations were underscored, including the fact that the revised Bloodborne Pathogens Standard not only mandated using sharps safety devices but also required annual consideration of safer sharps devices and frontline staff involvement in identification, evaluation, and selection of safer sharps devices.<sup>27,28</sup> It was evident that this PI project met both the letter and intent of OSHA's Bloodborne Pathogens Standard regulations.<sup>29</sup>

The demonstration of the efficacy of the retractable WSN

device was considered another potent driver to adoption. Unfortunately, peer-reviewed published data were lacking for this new device. To obtain relevant efficacy data, Good Samaritan was prepared to implement the retractable device in a surrogate pilot study for its integrated health system, including four additional hospitals and three skilled nursing facilities serving the Long Island, New York, region. Unfortunately, concerns about the short-term availability of the product delayed product adoption.

**Adopting the Product.** The year's delay provided the manufacturer the opportunity to address some minor concerns raised by users during the pilot study and others, including visibility of the "flash back" (blood return into the device, indicating blood vessel penetration) and device design and packaging to reduce accidental needle retraction. In addition, the device's cost decreased by nearly 8%. In March 2006, the device was implemented quickly and without issues.

**Study: Collect Postimplementation WSN Needlestick Data.** Initial postimplementation results are promising. In the first nine months, only two needlesticks were reported with the retractable safety WSN (butterfly needle). This represents a rate of 1.5/100,000 retractable WSNs purchased, a 60% decrease from 3.76/100,000 with the formerly used safety manual resheathing WSN. Neither needlestick involved the previously identified high-risk, problem-prone steps that had accounted for 85% of WSN needlesticks. As stated earlier, these "preventable" WSN needlesticks were occurring during the activation of the safety feature and immediately after needle withdrawal from the vein but before activation. The retractable WSN effectively reduced these particular types of needlesticks from 3.19/100,000 WSNs purchased to 0.0/100,000.

Both WSN needlesticks involved laboratory phlebotomists *during* blood collection, reflecting sudden movement, causing the needle to be pulled out of the vein and jostling it into the user's finger or hand. Nursing department staff reported zero WSN needlesticks during the same nine-month period.

As an independent, objective measure of user acceptability, the frequency of activation of the safety feature is also monitored. Ongoing weekly audits of a few phlebotomy sharps containers have shown that 100% of the devices are retracted. Failure to activate the safety feature with the former safety WSN was suggested by anecdotal and physical evidence, as well as by the literature (with none of the reported activation rates exceeding 90%).<sup>5,16</sup>

**Act: Continue Evaluating "Safer" Retractable WSN Device Efficacy.** Data are still collected, monitored, and evaluated to better determine the retractable safety WSN's efficacy.



Table 1. Cost-Effectiveness Analysis of a Proposed Retractable Winged Steel Needle Device\*

Variable	Variable's Value	Variable's Value Adjusted for 42% Reporting Rate <sup>†</sup>
Injuries sustained annually with existing manual resheathing safety winged needle	8	19.1
Projected annual reported injuries after retractable safety winged needle implementation	2	4.8 (if reported)
Projected annual injuries reduction (reported minus projected)	6	14.3 (if reported)
Average cost per injury <sup>‡</sup>	\$650	N/A
Annual cost savings (cost per injury × projected injuries avoided)	\$3,900	N/A
Annualized incremental costs of retractable devices (new safety retractable device unit cost = \$0.34 × 130,000 units purchased)	\$44,200	\$44,200
Net implementation costs (annualized incremental costs minus annual cost savings for avoided injuries)	\$40,300	\$40,300
Cost-effectiveness (cost per injury avoided; net implementation by projected number of injuries avoided)	\$6,717 <sup>§</sup>	\$2,818 <sup>  </sup>

\* Analysis adapted from Chiarello L.A.: Selection of needlestick prevention devices: A conceptual framework for approaching product evaluation. *Am J Infect Control* 23:386–395, Dec. 1995.

<sup>†</sup> As reported in Centers for Disease Control and Prevention, Hospital Infections Program: *The National Surveillance System for Hospital Health Care Workers (NASH): Summary Report for Data Collected from June 1995 through July 1999*. <http://www.cdc.gov/ncidod/hip/NASH/report99.PDF> (last accessed Dec. 15, 2008).

<sup>‡</sup> Estimated costs include source patient/worker lab testing, lost worker time and professional time for treatment, counseling, documentation and follow-up. Treatment costs, e.g., postexposure prophylaxis and lost days of work, are not included.

<sup>§</sup> It will cost this medical center \$6,717 to avoid one reported winged steel needle injury with implementation of the proposed safety device.

<sup>||</sup> It will cost this medical center \$2,818 to avoid one reported or unreported winged steel needle injury with implementation of the proposed safety device.

## Discussion

Although a number of sharps safety device alternatives exist, they vary in design and therefore are not all likely to be equally safe under normal use by various staff members in every environment. Health care organizations should conduct comprehensive studies of their own sharps incidents to determine how and why these occur to make the most effective selection to reduce needlesticks and other sharps injuries.<sup>7</sup>

This PI project to reduce occupational sharps injuries included an interdisciplinary approach to surveillance, annual consideration of safer sharps devices, and most prominently, the involvement of frontline staff in sharps safety device identification, evaluation, and selection.

Data for the 31 months immediately following implementation (March 2006–October 2008) indicate that the retractable WSN safety device significantly reduced reported needlesticks involving WSNs by 88% ( $p < .001$ ) at this hospital, from 3.76 to 0.47 per 100,000 WSNs purchased. During the last 21 months of this period, no needlesticks related to retractable safety WSNs were reported.

Strikingly, the 88% reduction in WSN needlesticks observed with the retractable WSN correlates very well with the large proportion (85%) of reported WSN needlesticks that occurred

during the problem-prone phlebotomy steps identified with the previous WSN device that the retractable device was specifically selected to address. This 88% reduction in WSN needlesticks appears to be directly related to the device's in-vein safety feature activation, in which the contaminated needle is retracted before needle withdrawal and serves as an effective means to avoid needlesticks during the problem-prone phlebotomy steps.

Given these results, the sharps safety committee has not undertaken any additional interventions or changes regarding the retractable WSN blood collection device. Although its continued use should effectively reduce the opportunity of blood-borne pathogen exposure and transmission to health care workers, we look forward to the availability of even safer needle devices. **J**

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