ORIGINAL ARTICLE

Implementation of an Enhanced Safety-Engineered Sharp Device Oversight and Bloodborne Pathogen Protection Program at a Large Academic Medical Center

Thomas R. Talbot, MD, MPH;[1] Deede Wang, MS, MBA, PMP;[2] Melanie Swift, MD;[3,4] Paul St. Jacques, MD;[5] Susan Johnson, MS, MT(ASCP), CSP;[6] Vicki Brinsko, RN;[2] Valerie Thayer, RN;[4] Teresa Dail, RN;[7] Nancye Feistritzer, DNP, RN;[7] Shea Polancich, PhD, RN[8]

OBJECTIVE. Exposure of healthcare personnel to bloodborne pathogens (BBPs) can be prevented in part by using safety-engineered sharp devices (SESDs) and other safe practices, such as double gloving. In some instances, however, safer devices and practices cannot be utilized because of procedural factors or the lack of a manufactured safety device for the specific clinical use. In these situations, a standardized system to examine requests for waiver from expected practices is necessary.

DESIGN. Before-after program analysis.

SETTING. Large academic medical center.

INTERVENTIONS. Vanderbilt University Medical Center developed a formalized system for an improved waiver process, including an online submission and tracking site, and standards surrounding implementation of core safe practices. The program's impact on sharp device injuries and utilization of double gloving and blunt sutures was examined.

RESULTS. Following implementation of the enhanced program, there was an increase in the amount of undergloves and blunt sutures purchased for surgical procedures, suggesting larger utilization of these practices. The rate of sharp device injuries of all at-risk employees decreased from 2.32% to 2.12%, but this decline was not statistically significant ($P = .14$). The proportion of reported injuries that were deemed preventable significantly decreased from 72.7% (386/531) before implementation to 63.9% (334/523; $P = .002$) after implementation of the enhanced program.

CONCLUSIONS. An enhanced BBP protection program was successful at providing guidance to increase safe practices and at improving the management of SESD waiver requests and was associated with a reduction in preventable sharp device injuries.

Infect Control Hosp Epidemiol 2014;35(11):1383-1390

Needlestick and sharp device injuries are frequent events that can expose healthcare personnel (HCP) to bloodborne pathogens (BBPs), such as human immunodeficiency virus, hepatitis B virus, and hepatitis C virus. In 1991, the Occupational Safety and Health Administration published the Bloodborne Pathogens Standard, which set regulations to protect all US HCP from BBP exposure.[1] HCP blood and body fluid exposures are not uncommon, as reflected in data from facilities participating in the National Surveillance System for Healthcare Workers between 1995 and 2007, which noted more than 30,000 blood and body fluid exposures among HCP in a diversity of practice settings and occupations.[2] Several strategies can be used to prevent sharp device injuries, including the use of safety-engineered sharp devices (SESDs), double gloving for invasive procedures, and blunt sutures during surgical procedures.

Using SESDs is clearly a primary intervention for preventing injuries among HCP.[3] Within the data from the National Surveillance System for Healthcare Workers, 56% of reported injuries were deemed preventable by using safer work practices or technology.[2] In some instances, however, SESDs cannot be utilized because of specific procedural fac-

Affiliations: 1. Department of Medicine, Division of Infectious Diseases, and Department of Health Policy, Vanderbilt University School of Medicine, Nashville, Tennessee; 2. Department of Quality, Safety, and Risk Prevention, Vanderbilt University School of Medicine, Nashville, Tennessee; 3. Department of Medicine, Division of General Internal Medicine, Vanderbilt University School of Medicine, Nashville, Tennessee; 4. Occupational Health Clinic, Vanderbilt University Medical Center, Nashville, Tennessee; 5. Department of Anesthesiology and Department of Biomedical Informatics, Vanderbilt University School of Medicine, Nashville, Tennessee; 6. Environmental Health and Safety, Vanderbilt University Medical Center, Nashville, Tennessee; 7. Hospital Administration, Vanderbilt University Medical Center, Nashville, Tennessee; 8. Department of Community Health, Outcomes, and Systems, University of Alabama at Birmingham School of Nursing, Birmingham, Alabama.

Received April 17, 2014; accepted June 27, 2014; electronically published September 24, 2014.

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https://doi.org/10.1086/678417 Published online by Cambridge University Press

TABLE 1. Vanderbilt University Medical Center Guidance on the Use of Double Gloving for Surgical Procedures

Guideline
Double gloving is necessary for the protection of the healthcare worker to limit exposure to potential sharps injuries and microperforations and a resulting exposure to blood borne pathogens. It is a requirement for all invasive surgical procedures with few exceptions, regardless of physical location of the procedure. The Occupational Safety and Health Administration Waiver Committee at Vanderbilt University Medical Center, in an attempt to balance safety and precision, has exempted the double gloving requirement for the use of 5-0 sutures and smaller during delicate portions of all procedures (where tactile and dexterity requirements are necessary for quality patient care). However, the exemption does not apply to other portions of a procedure when the needle size is greater than the exempted size (eg, during skin closure). Surgical loupes and microscope use alone may not qualify as exemptions to double gloving and must either coincide with the use of the exempted needle size or be considered by the committee in relation to the statement by the American College of Surgeons (ACS). The ACS recommends the universal adoption of the double glove (or underglove) technique in order to reduce body fluid exposure caused by glove tears and sharps injuries in surgeons and scrub personnel. In certain delicate operations and in situations where it may compromise the safe conduct of the operation or safety of the patient, the surgeon may decide to forgo this safety measure.
The designated committee meets regularly to review waiver requests and, upon future review, may amend the above stated exemption as necessary in order to provide a safe working environment.

tors or the lack of a manufactured safety device for the specific clinical use. Additionally, use of double gloving for some delicate microsurgical procedures has been noted to impair tactile sensation and dexterity,[4,5] although this has not been noted consistently.[6] In these situations, a standardized system to examine waiver requests for exemption from expected practices is necessary to systematically review the rationale for use of nonsafety devices or practices and to weigh the risks and benefits of these requests in a formal and standardized manner. In order to enhance existing policies and practices surrounding these issues, Vanderbilt University Medical Center (VUMC) developed a formalized process for waiver requests and standardized guidelines for the use of safe BBP protection practices, with an explicit goal to minimize the usage of nonsafety devices and to maximize adherence to core safe practices by formally assessing any exemption requests to these standards. This article describes this enhanced program and lessons learned through its implementation to provide insight and to serve as a model for other healthcare facilities.

METHODS

VUMC is a large academic health system that includes adult, pediatric, and psychiatric hospitals; on-campus outpatient clinics; and an extensive network of outpatient care sites throughout middle Tennessee. VUMC supports more than 54,000 inpatient admissions, 60,000 surgical procedures, 113,000 emergency room visits, and 1.7 million ambulatory visits annually.[7] In place for several decades, VUMC's BBP protection program is very extensive and includes the following: a rigorous occupational health program that includes identification of personnel at risk for BBP exposure, a hepatitis B immunization program, and convenient on-site sharps injury evaluation and treatment; required annual faculty and employee education that focuses on the risk of BBP transmission, use of SESDs, need for hepatitis B immunization, and detailed warnings about specific practices known to increase injury risk (eg, recapping of devices); engineering controls, including SESDs and readily available sharps disposal boxes in all clinical areas; longitudinal injury rate tracking with ongoing multidisciplinary review of injury trends and individual injury contributors; and a rigorous, comprehensive process for device selection and evaluation.

To address instances in which no SESD was available or where use of available SESDs would hinder clinical care (eg, performing an injection into the posterior oropharynx may be impeded by use of a safety needle with a swing-arm safety lock), a paper-based process to request an SESD waiver was implemented in 2003. This process required providers requesting use of specific nonsafety devices to provide the rationale for their use, to report the availability of any safer alternatives for the procedure, and, if present, to trial such products prior to waiver review. A survey of 5 peer institutions was also required in order to assess for alternatives to nonsafety devices for the specific procedure.

In 2010, VUMC solicited external consultation from Tennessee Occupational Safety and Health Administration surveyors related to better/best BBP protection processes and practices. A formal review of the existing manual waiver process noted challenges to organizing and tracking waiver information over time, an inadequate capacity to report information to end users, and a limited ability for timely decision making. In addition, a need for standardized guidance for core practices—such as the use of double gloving for operative procedure—was also identified. To address these issues, an enhancement of the existing BBP protection program was developed that consisted of 3 major components: (1) formation of an oversight and waiver review committee, (2) establishment of institutional guidance regarding core safe practices created by a subcommittee of the oversight group, and (3) development of an electronic waiver submission platform.

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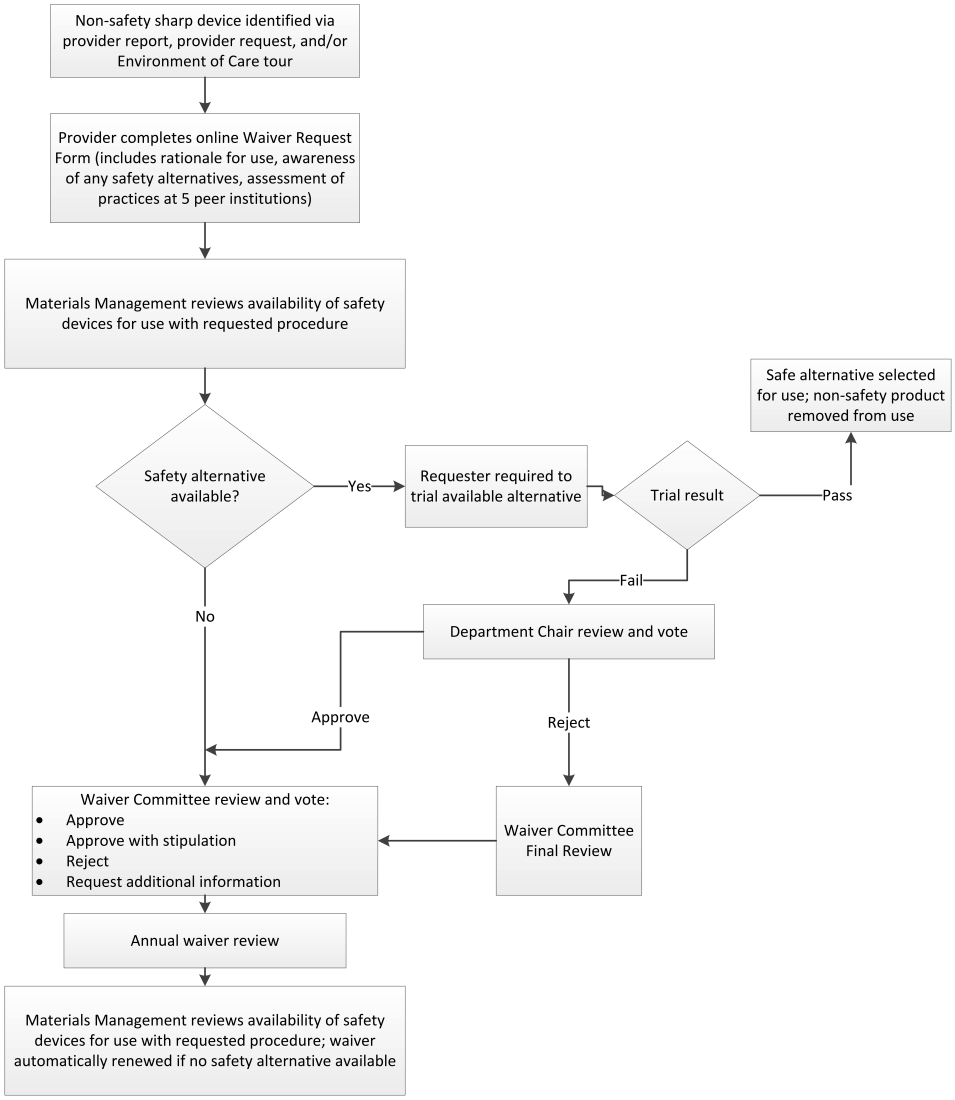


FIGURE 1. Workflow for requests for waiver of safety-engineered sharp devices (SESDs) or exemption from core bloodborne pathogen protection practices: SESD waiver process flow.

Formation of Formal Oversight Committee

The multidisciplinary oversight and waiver review committee was created and charged with providing device waiver oversight and guidance for organizational issues surrounding BBP protection and implementation of core safe practices. The committee was cochaired by experts in quality improvement and infection prevention, with representation from hospital administration, occupational health, perioperative services, surgical departments, anesthesiology, procedural areas, radiology units, materials management, environmental health and safety, and the clinical laboratory. Both adult and pediatric clinical areas were represented, and executive leadership provided support for and actively participated in the initiative.

Standardization of Core BBP Protection Practices

A subcommittee comprised of frontline surgeons and proceduralists was convened to further this goal. Specifically, available literature on the use of double gloves and blunt sutures was reviewed, and a standardized policy was developed that outlined which procedures and practices required the use of these items, unless specific exemptions were identified. As part of the enhanced program, a VUMC statement regarding double gloving was established and integrated into policy (Table 1). Since multiple exemption requests were related to double gloving associated with the use of smaller needle sizes, the task force established logical criteria based on clinical practice that was accepted across the organization. The trigger for exemption of double gloving was established

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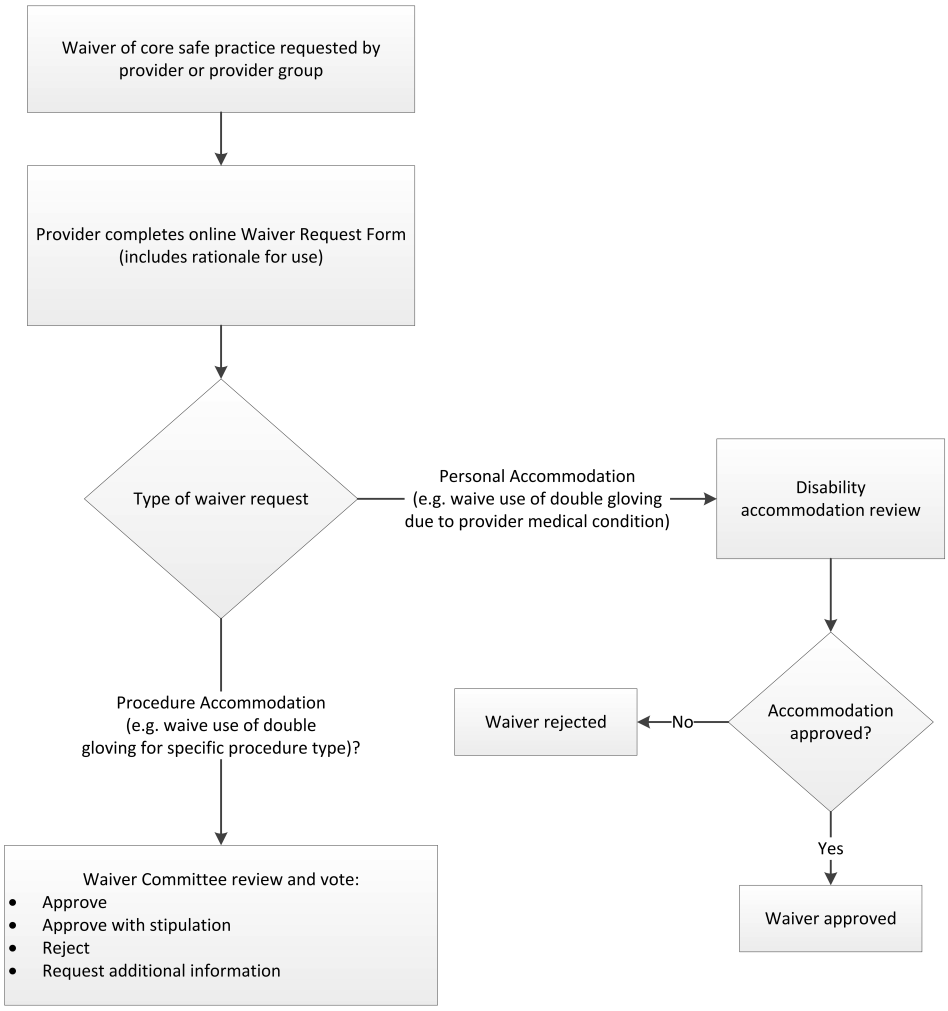


FIGURE 2. Workflow for requests for waiver of safety-engineered sharp devices (SESDs) or exemption from core bloodborne pathogen protection practices: safe practice waiver process flow.

at a needle size of 5-0 and smaller. In addition, there was a challenge associated with balancing the safety of the provider with the safety of the patient, and the double gloving criteria was waived for microsurgical procedures where tactile sensation was a key aspect of safe patient care.

Waiver Process Enhancement

A standardized waiver submission and review process flow was developed for both waivers for nonsafety devices (Figure 1) and waivers for safe practices (eg, double gloving for microsurgical procedures where the surgeon's tactile sensation is an essential part of the procedure; Figure 2). In general, a nonsafety device is identified by provider report or through biannual environment of care rounds of each clinical unit. The requester then submits the waiver using the online tool described below, providing the rationale for the nonsafety device use and the awareness of any alternative safer devices. An alert is then sent to materials management personnel, who investigate for the availability of any SESDs for the specified clinical procedure. If a safety device is identified, the requesting provider and fellow users are asked to formally trial this device prior to waiver review, a step that is essential yet often lacking in device selection.[8] The duration of the trial is dependent on the frequency of device use and lasts at least 2 weeks for high-usage procedures. Completion of a standardized evaluation form is required for all individuals who trial the product. This form includes rankings of the device's performance on several core areas, including ease of device use, impact on procedure time, and ability to open the device and maintain sterility (if applicable). A formal step where the departmental chair reviews each waiver then follows to ensure that the rationale for the nonsafety device is acceptable. Once the materials management and departmental chair reviews are completed, the waiver oversight committee reviews and votes on the request. For instances where no safety alternative is available, the committee chair can determine the waiver

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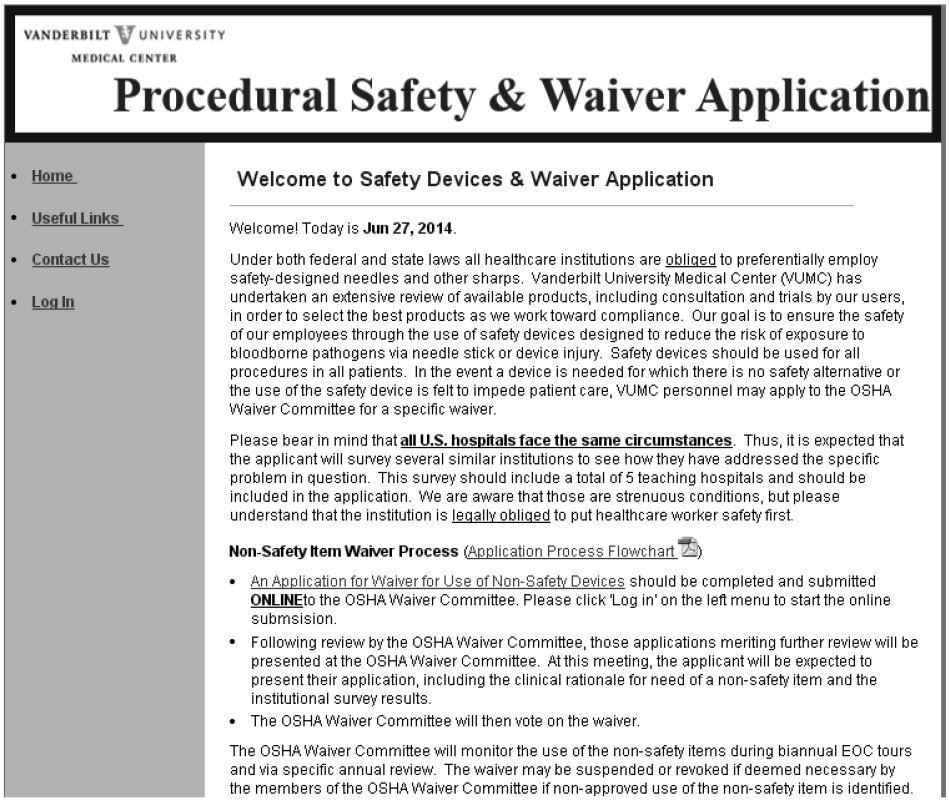


FIGURE 3. User interface for Vanderbilt University Medical Center waiver application.

decision. For other instances, the full committee will review and vote. Nonsafety device waivers are reviewed annually to ensure that no new SESDs have been released on the market and that circumstances surrounding the waiver rationale have not changed.

Waivers of core safety practices may also be requested for a specific procedure or an individual provider. Providers requesting exemptions (eg, waiver for double glove usage because of carpal tunnel injury or other medical condition) submit their request through the waiver process. Individual requests then alert personnel in the disability accommodation office to assess the specific rationale in accordance with the Americans with Disabilities Act standards and to determine whether the waiver is approved.

In order to improve the submission, review, and monitoring of waiver requests, a web-based platform was developed to replace the existing manual process. This tool was designed to provide end user ability to enter and track waiver submissions and to allow oversight committee members the ability to manage, approve, and communicate decisions on submitted waivers electronically (Figure 3). It also serves to track exemptions to the standardized core practices, to provide an infrastructure for research by the materials management department of all available safety devices for a specific use, to support the submission of individual waiver accommodations in compliance with the Americans with Disabilities Act, and to manage annual review of all waivers in order to assess for the development of new SESDs and any unintended consequences of the device waiver. The web-based tool is linked to multiple intranet sites for easy accessibility to the providers and is accessible to environment of care surveyors during their routine inspections to ensure that any identified nonsafety devices have been formally reviewed and waivered. The technical details of the web-based tool development are outside the scope of this article and will not be described in detail.

Impact of the Enhanced Program

An assessment of the impact of the enhanced program was made by examining utilization over time of undergloves (as a marker for implementation of double gloving requirements) and blunt sutures on the basis of volume of product purchased within the institutional inventory management system from 2010 to 2012. In addition, an assessment in the change in sharp device injury rates and in the proportion of total injuries that were deemed preventable upon initial evaluation (defined as an injury that resulted from not using available policies, procedures, devices, or personal protective equipment) were also examined. The injury analysis compared data

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TABLE 2. Breakdown of Nonsafety Sharp Device and Safe Practice Waivers, July 2010–October 2013

Waiver committee decision	No. of waivers
Approved/renewed	49
Approved with stipulation	6
Rejected	2
Withdrawn	4
Pending/requested additional data	3
Total	64

from the preimplementation period (January 1, 2009, through June 30, 2010) with data from the postimplementation period (July 1, 2011, through December 31, 2012). The period from July 1, 2010, through June 30, 2011 was excluded from this analysis because this was the period of implementation of the enhanced program. Analyses were conducted using the 2-sample test of proportion with STATA (ver. 9.0; Stata).

RESULTS

Waiver Utilization/Volume

From July 2010 through October 2013, there were 64 submitted waivers (Table 2). Thirty-eight were for specific products (with 5 related to blunt suture use), while 26 (41%) were related to exemptions from a core practice (eg, double gloving). Most waivers applied to procedures or provider groups who performed the specific procedure, while 3 waivers requested an individual accommodation from use of double gloving because of an underlying medical condition. Thirteen waivers were covered by the institutional statement regarding microsurgery and small needle sizes. Six waivers were approved for a portion of the requested procedure, with a stipulation that the safe practice was required in the event that the procedure conditions changed (eg, exemption of double gloving for laser procedures where no blade is used, with a stipulation that in the event a sharp device is required, double gloving was expected). No safety alternatives were available for 58% (19/33) of the device waivers, while with 3 waivers where an SESD was available, a formal trial of the safer device was performed. Two waivers (3%) were rejected by the committee.

Impact of Enhanced BBP Safety Program

In conjunction with implementation of the enhanced program, there was an increase in the volume of undergloves purchased for surgical procedures that outpaced the slight increase in standard gloves (Figure 4), suggesting an increased utilization of double gloving. Blunt suture utilization, as measured as a percent of the total suture volume purchased, also increased slightly from 16.3% of all sutures purchased in 2010 to 19.1% in 2012 (Figure 4). The rate of sharp device injuries (Figure 5) decreased from 2.32% of all at-risk employees to 2.12%, but this decline was not statistically significant ($P = .14$). The proportion of reported injuries that were deemed preventable decreased from 72.7% (386/531) before implementation to 63.9% (334/523; $P = .002$) after implementation of the enhanced program.

DISCUSSION

An enhanced BBP protection program was successful at providing guidance to increase safe practices such as double gloving and at improving the management of SESD waiver requests. It was also associated with a significant reduction in preventable sharp device injuries. The implementation of the enhanced program was successful for several key reasons. First, there was clear administrative and executive leadership involvement and support for the process. As important was the participation and guidance of frontline proceduralists to assess issues and bring clinical experience to the discussions. In addition, these personnel were able to assist with the implementation of safer practices. Third, clearly defined goals and expectations were established with support from all members of the committee. Finally, the ability to secure and use technology to enhance efficiency was a critical success factor. Having a designated resource for programming and development was central to meeting the aim of implementation

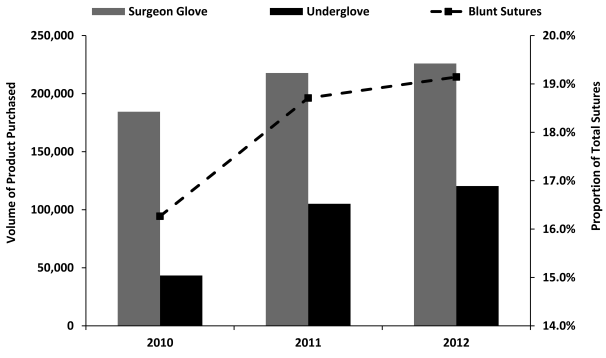


FIGURE 4. Utilization of undergloves and blunt sutures, Vanderbilt University Medical Center, 2010–2012. Blunt suture utilization is noted as the proportion of all sutures purchased that were blunt.

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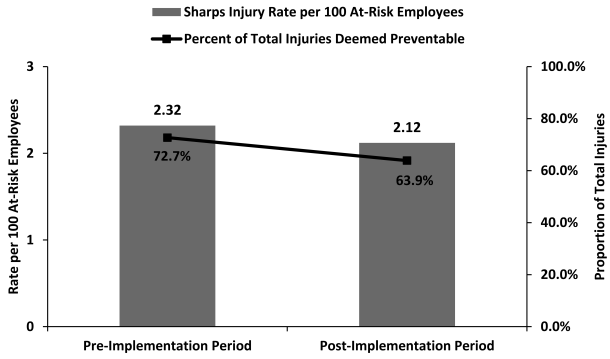


FIGURE 5. Sharp injury rates and proportion of total injuries deemed preventable, before implementation (January 1, 2009–June 30, 2010) versus after implementation (July 1, 2011–December 31, 2012). The period from July 1, 2010, through June 30, 2011, is used as a transition period during which the new program was implemented.

of an electronic process. The web-based tool has provided not only access to data that were difficult to obtain in the manual process but also ease of entry for providers. The waiver application process now takes approximately 1 minute to complete. In addition, the time from waiver submission to final decision decreased from 3–5 months to less than 1 month.

During the implementation of this effort, however, several opportunities for future improvement arose. First, while the number of manufactured SESDs has increased dramatically over the past 25 years,[8] there are still challenges with implementing the use of safety products in all situations because of the lack of manufactured safety alternatives for use with some highly specialized procedures. Second, many procedure kits are manufactured and supplied without a full cadre of safety products, a fact that may not be transparent to the purchaser. There is also a clear need for healthcare facilities and regulatory agencies to partner to prioritize and develop more specific guidance and standardization on the use of SESDs. Ongoing monitoring of the use of available safety devices in actual clinical practice is difficult and cumbersome. There is a need to develop more immediate mechanisms to monitor compliance with safety device protocols. Training of members of the healthcare team to remind each other when the appropriate safety device is available and not used is 1 area of emphasis to ensure greater compliance.

While the rate of total sharp device injuries and the proportion of injuries that were deemed preventable did decrease in conjunction with the implementation of this enhanced program, several important issues should be noted. First, we are unable to directly attribute the reductions to the enhanced program. Second, while rates did decrease, a substantial number of reported injuries were deemed preventable and may not have been impacted by the processes outlined above. Safety engineered sharps are the norm for common nursing procedures, such as injections, intravenous starts, and phlebotomy; thus, the majority of needlestick injuries occur from SESDs,[9] not from unsafe sharps that could be eliminated through the waiver process. Thus, even a robust waiver program must continue to address these important factors as a part of the BBP protection program.

This study has some additional limitations. We used purchasing data as a surrogate of provider utilization, which may not always reflect actual use. In addition, the generalizability of these findings to other facility types that may not have similar informatics resources to develop an online tool may be limited. The development of this waiver process was resource intensive and included personnel, technological, and physical resources. However, having a formal process to examine provider concerns regarding perceived limitations with use of SESDs or safe core practices can ensure a balanced assessment of the reported risks so that safety devices and practices are waivered only when a clear unintended harm is identified. With a clear expectation that SESDs are the default devices used and that waivers to this expectation must undergo formal and standardized review, the onus is on the providers and the institution to thoroughly evaluate every waiver in the same manner. As noted with the described program, a well-integrated multidisciplinary process to obtain and share clear directives on safe practices, device utilization monitoring, injury tracking, and careful review of waiver requests is a key enhancement of HCP and patient safety.

ACKNOWLEDGMENTS

We would like to thank Lorrie Pope and Todd Blakney for their assistance with this project.

Financial support. This program and its study were supported by institutional funds.

Potential conflicts of interest. All authors report no conflicts of interest relevant to this article. All authors submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest, and the conflicts that the editors consider relevant to this article are disclosed here.

Address correspondence to Thomas R. Talbot, MD, MPH, A2200 Medical Center North, 1161 21st Avenue South, Nashville, TN 37232 (tom.talbot@vanderbilt.edu).

https://doi.org/10.1086/678417 Published online by Cambridge University Press

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