

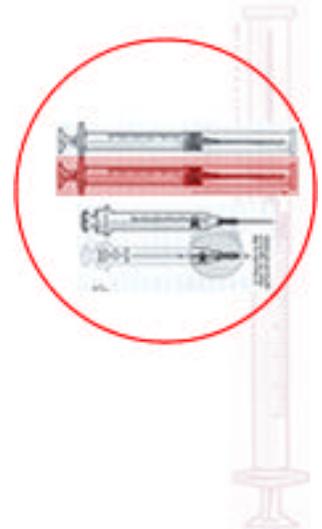
NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries. Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities are required to use safer medical devices.



## SAFER MEDICAL DEVICE IMPLEMENTATION IN HEALTH CARE FACILITIES

### SHARING LESSONS LEARNED

NIOSH has asked a small number of health care facilities to share their experiences on how they implemented safer medical devices in their settings. These facilities have agreed to describe how each step was accomplished, and also to discuss the barriers they encountered and how they were resolved, and most importantly, lessons learned.



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## **Phase 3 -- Identify and Screen Safer Medical Devices**

### **Description of Facility**

Our hospital is licensed for approximately 300 beds and serves a diverse patient population ranging from neonates to geriatric patients. There are three critical care units including a level III+ neonatal intensive care unit (NICU). The hospital has one of the highest volumes of surgical cases in the region. Surgical services are provided through an in-patient general surgical center and two ambulatory surgical centers. A sub-acute unit, a medical-psychiatric unit, and a dialysis unit are on site. Specialty services include Neonatology, Ophthalmology, an Endoscopy Center, and a comprehensive Oncology Service. The community recognizes the OB Service as a center of excellence. Outpatient diagnostic and treatment facilities include a Cardiac Catheter Laboratory, Radiation Oncology, a Diabetes and Nutrition Center, and a Wound Care Center. A community health center offers 7 day a week urgent care services to inner-city residents, in addition to providing care in a number of specialties including pediatrics, and HIV care.

### **Describe the *process* your sharps injury prevention team used in identifying safer medical devices**

A comprehensive analysis of sharps injuries over a six month period showed that safety engineered scalpels were the highest priority for implementation in our facility. The team decided to explore many different sources of information before recommending a particular device for a trial. Surgeon members of the Operating Room (OR) Executive Committee and Value Analysis/Products Committee were asked to perform a preliminary evaluation of the device with regards to clinical efficacy. Of paramount concern was that the safety device would not create new hazards or compromise patient safety. Once the OR Executive and Value Analysis approved the product for clinical evaluation, it could proceed to a trial in the surgical setting.

### **Describe where the sharps injury prevention team obtained information about available devices and what this information included.**

We obtained information through a number of different resources. The team hoped that networking with other infection control professionals through the APIC (Association for Professionals in Infection Control) listserv (<http://www.apic.org/resc/archmain.html>) would provide the best means to communicate with other facilities who had previously engaged in the evaluation of a particular device. In particular, we hoped to find facilities who would give a testimonial for a particular product.

Several internet sites provided lists of sharps injury prevention devices which assisted us with identifying devices for a potential pilot study. One of the most comprehensive lists is maintained by the International Health Care Worker Safety

Center at the University of Virginia. The list is located on the internet at <http://hsc.virginia.edu/medcntr/centers/epinet/safetydevice.html>. Another good list of safety engineered sharps can be found at the National Alliance for the Primary Prevention of Sharps Injuries web site at <http://www.nappsi.org/safety.shtml>.

Vendor fairs sponsored by a regional infection control organization displayed new safety engineered medical devices. The ability to see the devices and pose questions to the manufacturers' representatives proved invaluable as the team sought what products to evaluate and eventually trial.

A reference published by ECRI entitled "*Sharps Safety and Needlestick Prevention - A Resource for Evaluating and Selecting Protective Devices*" is also an excellent reference and aided us in identifying and comparing the available safety scalpel products.

During new employee hospital orientation, staff were encouraged to share success stories regarding safer medical devices that were successfully implemented at other institutions. This provided a unique opportunity for front-line workers to identify and recommend sharps injury prevention devices they may have used in the past. Additional opportunities to solicit frontline worker feedback were provided during infection control rounds on patient care units and during interviews with health care workers in the aftermath of sharps injury exposures.

**List and explain the factors or criteria used in deciding which safer medical devices should be screened for possible pilot testing.**

Factors we considered were the availability of training materials and personnel to provide education and on-going support for the new product, ease of use for safety feature activation, quality of the retraction mechanism, the weight of the scalpel handle compared to a traditional scalpel, the availability of different sizes and shapes of surgical blades, sharpness of the blade, and whether or not the vendor participated in our group purchasing organization (GPO). One of the most important criteria was that the device not cause patients any harm.

**List and explain the factors or criteria used in deciding which safer medical devices to use in a device evaluation.**

There were only 3 products identified which qualified as safety scalpels at the time we were investigating the availability of products. All of them featured a retractable blade which could be activated when the scalpel was passed from person to person during an operative procedure, when the scalpel was placed on a stand outside the operative field, or prior to disposal. Surgeons, nurses, and surgical technicians were given the opportunity to handle all 3 products before proceeding to a clinical trial. This provided the stakeholders a chance to give

specific feedback regarding the potential advantages or disadvantages of each product.

Ultimately our surgeons and nurses do not have a preference to run a pilot study or trial with any one specific product. All three safety scalpels appeared to be quite similar in terms of function and quality of materials. None of the scalpels had safety features or any other material or performance characteristics that clearly differentiated it over the other brands. The decision to select a particular brand for clinical trial was based on three factors: 1.) We were able to identify one other user of the selected product through the APIC listserv who provided a positive testimonial, 2.) The vendor was able to provide assistance with training and management of a pilot study, 3.) The product was easier to acquire because it was available through a group purchasing organization (GPO).

Several forms already existed prior to starting this initiative, however a new form was utilized to streamline the approval process for a safety engineered sharps device (see attachment)

The form is specific for the identification and selection of safer medical devices and will be used in the future for other product trials of sharps and needlestick prevention devices. The form is presented to the Value Analysis/Products Committee in order to provide consistent documentation and establish the rationale for selecting a specific product to pilot.

**What lessons were learned in general during the process of identifying and screening safer medical devices? Describe the difficulties encountered and how problems were resolved.**

We discovered there were no peer-reviewed publications or evaluations of any type for safety scalpels. In addition, because very few hospitals had decided to implement their use, it was very difficult to assess which product(s) had the greatest potential for reducing sharps injuries without compromising patient safety. The project coordinator even contacted a surgeon (see <http://www.orprecautions.com/index.html>) who is a nationally recognized consultant to hospitals engaged in quality improvement activities directed at reducing sharps injury in the surgical setting. The consultant did not favor any one-safety scalpel over another and was not aware of any studies showing safety scalpels were clearly effective in reducing injuries.

**What would you do differently if you were to begin this process again?**

We would ask the surgeons and nurses what practices they thought were most important for reducing occupational exposures, in addition to engineering controls.

**What advice would you offer a similar facility that is just starting this process?**

Establish a collaborative work group with operating room personnel to formally determine what factors and criteria are most important when identifying and selecting devices to trial.

**Please provide any other information you wish to share about the process used or problems encountered in identifying and screening safety devices.** When confronted with a dearth of evidence-based literature, no substantive references, and very little utilization of a particular safety device throughout the country, facilities may want to consider changing their priorities. They could focus on changing work practices in addition to implementing engineering controls for reducing the risk of bloodborne pathogen exposure. They may also consider screening devices for lower priority areas where devices with a proven track record may decrease the risk of bloodborne pathogen exposures even further.

### **Staff Hours and Other Cost Items**

#### **Staff Hours:**

<b>Type of Staff</b>	<b>Hours Spent on Phase 3</b>
Management	8
Administrative	2
Front-line	12
Total	22

#### **Other, non-labor items:**

<b>Item</b>
1. Copying costs