

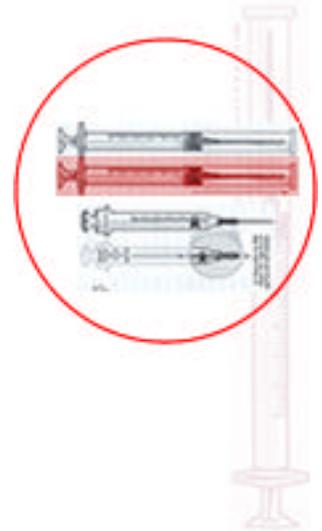
NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries. Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities 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 5: Implement and Monitor the New Device**

### **Background**

Our health-care system is a nonprofit, consumer-governed system that coordinates care and coverage. It provides care to nearly 600,000 people in the Western United States. Our system includes a nationally recognized research center, charitable community foundation, medical centers, specialty centers, and hospitals. In addition, we provide home health care services to our members and skilled nursing services through our long-term care facility. We own and operate our own laboratory. We employ nearly 10,000 staff including an associated 1,050 physician group practice. There is approximately 4,500 clinical staff that uses sharp devices.

Our health system has implemented five safer devices over the last eighteen months. These included a shielded IV catheter, shielded phlebotomy needle, protected disposable scalpel, safety lancet, shielded needle for disposable syringes and a self-sheathing syringe. We had previously implemented a needle-free IV system and shielded butterfly needles. This report provides a description of our safety IV catheter implementation and monitoring process.

### **Implementation Process of IV Catheter**

Step 1: The IV catheter safety evaluation analysis and recommended IV catheter product was presented to the Infection Control Committee for approval. The approval was communicated to the Safety Committee.

Step 2: A product and site-specific communication and training (inservice) implementation process was designed and conducted.

- An article regarding the selection and use of the safety IV catheter was placed in our organization's newsletter that is included with the paycheck. In addition, two medical staff newsletters contained articles describing the sharp injury prevention team and the implementation of the new safety IV catheter.
- A presentation regarding the implementation of the safety IV catheter was given to the hospital management team.

## **Phase 5: Implement and Monitor the New Device**

- Material Management identified all locations using IV catheters. Managers of these departments (hospital, ambulatory and specialty care, home health, long term care) were notified of the change in the IV catheter product by e-mail and that the vendor representative would call to arrange inservice times for their staff. Eighty-five percent of staff using IV catheters were trained during a fifteen-day period of time. Staff who were unable to attend the inservices were trained and competency documented by the charge nurse or manager in their work unit or site.

Step 3: The material management specialists at each site or department were responsible for swapping out the old catheters for the new catheters once inservice training was completed.

Implementation issues:

Our organization was able to obtain sufficient quantities of the IV catheter product. The vendor worked closely with the material management specialists to entirely remove the old product and ensure new product was available.

To determine if the new IV catheter was being used after implementation, several methods were used.

- Materials Management provided data on catheter usage for each department to the Engineering Controls Evaluation Committee.
- Observations by committee members and Infection Control staff occurred informally.
- Infection Control monitored needlestick data.
- E-mail to the Engineering Controls Evaluation Committee chairperson and coordinator were used for comments from staff.

### User Satisfaction

Resistance to use of the catheter did occur with the anesthesia staff. E-mail was the means of communication used by these physicians to convey their concerns regarding use of the IV

## **Phase 5: Implement and Monitor the New Device**

catheters. This method of communication did not facilitate a timely or customer friendly resolution to the concerns raised, as the reason for not wanting to use the catheter needed clarification. After much e-mail had been sent between the parties, the Engineering Controls Evaluation Committee chairperson, coordinator and hospital medical director had a face-to-face meeting and discussed the specific circumstances when a safety IV catheter would not be acceptable and the reasons why the safety catheter could not be used. Safety IV catheters were originally evaluated for peripheral IV starts (which included anesthesia), but not for other uses such as needle cricothyrotomies, arterial and venous lines. The outcome of this meeting was:

- 1) to develop an exemption reporting form (see Appendix 1 original form and Appendix 2 revised form) for staff to petition for use of traditional IV catheters
- 2) to allow the use of traditional IV catheters, which would be ordered non-stock, for use other than peripheral IV's and which had received approval by the Engineering Controls Evaluation Committee
- 3) the Engineering Controls Evaluation Committee would research the availability of safety devices for starting arterial and venous lines and cricothyrotomies.
- 4) Material Management would monitor usage of traditional IV catheters and notify the Engineering Controls Evaluation Committee of departments with increased usage.

Satisfaction with the new IV catheter was determined by use of the exemption form, monitoring of the usage of the new catheter, needlestick data and e-mail from staff. The Engineering Controls Evaluation Committee received only one other exemption request form from pediatrics regarding blood leakage with the 24g IV catheter. No other e-mails were received from staff regarding inability to use the new IV catheters. The needlestick data indicated a decrease in IV catheter accidental parenteral exposures.

### Patient Satisfaction

No monitor was developed to determine patient satisfaction with the new IV catheter device. However, Infection Control nor our customer service department received any customer complaints

## **Phase 5: Implement and Monitor the New Device**

regarding the use of the new device. Infection Control monitored bloodstream infections, of which there were none.

### Management Satisfaction

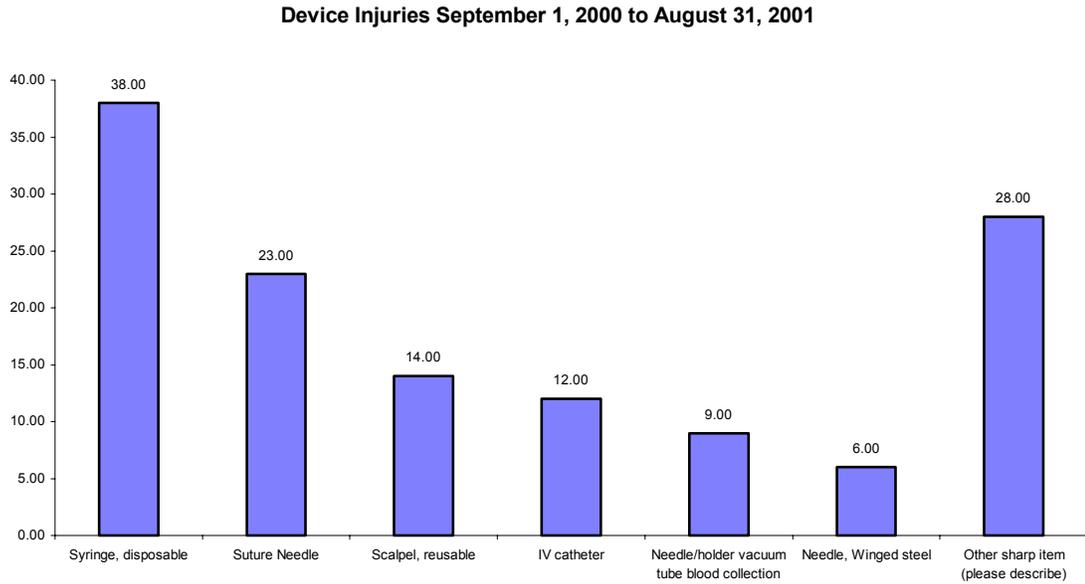
A management satisfaction monitor was not developed for the new IV catheter. However, managers were concerned regarding the increase in supply costs for the new devices. This concern generated the development of a process to notify hospital and statewide finance managers of the cost associated with implementing a new safety device. Material Management developed a spreadsheet that can be used for any new safety device being implemented. The spreadsheet lists by department (using a cost center code) the name of the traditional product, the traditional product price, traditional volume of usage, the name of the new safety product, the new price, the new price with forecasted usage (based upon previous traditional device usage), the projected usage cost for one year and the total organizational traditional product cost per year and the new safety product cost per year. The completed spreadsheet is forwarded to the hospital finance manager who has the responsibility to distribute the information to the statewide finance managers. In addition, to determine the costs of safety devices for the next budget cycle, Material Management creates a projected summary of costs of new safety devices implemented for the current year. Projected new devices to be implemented in the next calendar year are also included.

### Monitoring Effectiveness

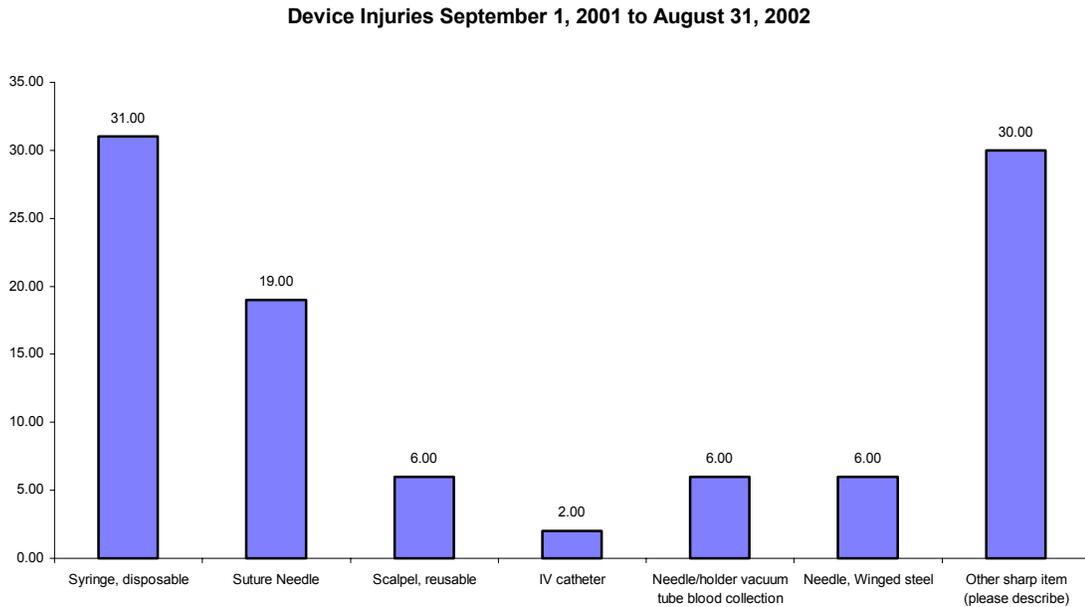
The effectiveness of decreasing accidental parenteral exposures with use of the safety IV catheter was monitored using our needlestick data. The safety IV catheter was implemented during the month of August 2001. IV catheter exposures decreased following implementation of the safety device. The following graphs depict our device injuries for two time periods: one year prior to implementing the safety IV catheter and one year following implementation of the safety IV catheter. Graph 1 represents device injuries September 1, 2000 to August 31, 2001. There were 12 IV catheter exposures during this time period. Graph 2 represents device injuries September 2, 2001 to August 31, 2002 following safety IV catheter implementation. IV catheter exposures decreased by 83 % from the previous year. There were two exposures during this time period.

## Phase 5: Implement and Monitor the New Device

Graph 1:



Graph 2:



The two IV catheter exposures occurred as a result of a traditional IV catheter being used in 2001 and an unactivated safety catheter being improperly disposed of in 2002.

## **Phase 5: Implement and Monitor the New Device**

### **Lessons learned about implementing safer medical devices**

- Planning and preparation for the implementation of the IV catheters with material management, the vendor, and managers ensured a successful transition to the new device. Our implementation was very smooth and successful due to this work.
- Ensure to the best of the organization's ability the removal of the entire old product from the departments.
- Guarantee the vendor has adequate staff to provide the training and problem solving that is needed for new devices. Plan 15 minutes per each staff member for new IV catheter training.
- Ensure a process is in place to train staff not available during the inservice dates and to document competency.
- Development of a communication plan regarding implementation of the new device to the organization in general and to targeted affected staff, including medical staff.
- Develop a process to provide upper management with the comparative cost of the new and old devices prior to implementation.

### **What would we do differently if we were to begin the process again?**

Again, our process went very smoothly due to our planning with the critical team members, i.e. vendor, material management, managers and the Engineering Controls Evaluation Committee. There were several areas that we would have handled differently in hindsight. One area would have been to have a formalized process in place, before implementing the device, for reporting problems with the device or for requesting an exemption for use of a traditional device. Another area would be to communicate information about the new device with the medical staff earlier in the implementation process. This communication would include established problem-solving avenues.

## **Phase 5: Implement and Monitor the New Device**

### **Advice to a similar facility just starting the process**

When concerns regarding a new safety device arise, a thorough risk assessment should be completed. We have found an on-site visit to the department experiencing problems is the most effective method to understand the problem and develop a working relationship with the staff to solve the concern. In addition, when a request for exemption form is completed and received by the Engineering Controls Evaluation Committee, the requester is invited to bring the device to a committee meeting and discuss and demonstrate why the device cannot be used. This has facilitated understanding of the problem by committee members and problem solving that has produced either an exemption being approved, another device found, or a change in product where a sharp is not needed.

### Staff Hours and Costs

<b>Type of Staff</b>	<b>Hours Spent on Phase 5</b>
Management	18
Administrative	60
Front-line	30
Total	108

The vendor spent considerable time inservicing staff on all three shifts in the two hospitals, ambulatory care, specialty care, home health and long-term care. Having the vendor provide training greatly decreased the time needed to be spent by our organizations in training staff. The hours and cost of vendor training and assisting in removal of old product is not included in this report.

**Phase 5: Implement and Monitor the New Device**

**Appendix 1  
Safer Sharps Exemption Request Form**

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Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Brand of Device Involved: \_\_\_\_\_

Select reason device with safety feature cannot be used:

\_\_\_\_\_ Device prevents delivery of optimal patient care

\_\_\_\_\_ No safer device available for this application

\_\_\_\_\_ Patient safety is compromised by use

\_\_\_\_\_ Staff safety is compromised by use

List specific clinical applications for which safer device has been found to be unsafe or ineffective:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Name/Title of Staff requesting exemption  
\_\_\_\_\_

Department/Clinical Location:  
\_\_\_\_\_

\*\*\*\*\*

**REVIEW RESULTS**

**Department of Occupational Health**

Date of Exemption Review: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Exemption Approved: \_\_\_\_\_

Exemption Denied: \_\_\_\_\_

Signature: \_\_\_\_\_

**Medical Directors Office**

Date of Exemption Review \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

**Phase 5: Implement and Monitor the New Device**

Exemption Approved: \_\_\_\_\_

Exemption Denied: \_\_\_\_\_

Signature: \_\_\_\_\_

**Phase 5: Implement and Monitor the New Device**

**Appendix 2**

**Exemption Request To Use Sharp Device Without Safety Feature**

Date: \_\_\_\_\_

Name of staff requesting exemptions: (Print) \_\_\_\_\_ Job Title \_\_\_\_\_  
\_\_\_\_\_

Department: \_\_\_\_\_ Phone: \_\_\_\_\_ Mail Stop: \_\_\_\_\_

Was the person using the product trained prior to its use? YES NO

Device Involved/Size: \_\_\_\_\_

Manufacturer: \_\_\_\_\_

Number of attempts to use device \_\_\_\_\_

Describe in detail the procedure for which the device is used: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Describe why the safety device cannot be used: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

Select reason safety device cannot be used:

- Device prevents delivery of optimal care
- No safety feature available for this device
- Supply unavailable to meet demand
- Staff/co-worker safety
- Other: \_\_\_\_\_
- Patient Comfort
- Patient safety

Proposed resolution: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

