

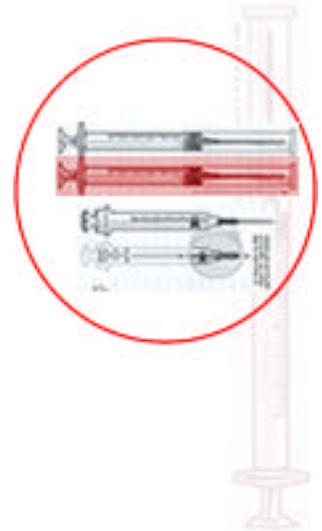
NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries. Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities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



**DISCLAIMER:** Provision of this report by NIOSH does not constitute endorsement of the views expressed or recommendation for the use of any commercial product, commodity or service mentioned. The opinions and conclusions expressed are those of the authors and not necessarily those of NIOSH. More reports on Safer Medical Device Implementation in Health Care Settings can be found at <http://www.cdc.gov/niosh/topics/bbp/safer/>

## Phase 5: Implementation and Monitoring the New Device

### Facility Profile

Privately owned long term care organization that includes nine facilities; with census total of 800 beds. Each facility is unique in that they offer skilled, rehabilitation and intermediate nursing care services as well as services for the mental retarded.

After collating the data from the staff evaluation form from Phase 4, final device purchasing decisions were based upon the following criteria:

1. Staff satisfaction with the device ( product evaluation forms shown in Phase 4)
2. Pricing
3. Manufacturers ability to secure adequate supply

Final Decision was made to purchase the following safe medical devices:

1. Syringes (all sizes)
2. Lancets (blood glucose monitoring)
3. Sharps Disposal Containers (all sizes)

### **Process: Implementation of the Safe Medical Device**



#### **Determine Start Date for Implementation of the Safe Medical Device**

- Start date determined upon manufacturers ability to deliver supply.
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#### **Determine Stop Order and Shipment Date for Old Medical Device**

- Stop orders were coordinated by the Purchasing Department for all facilities.
  - Stop orders of old medical devices were determined by coordinating shipment dates of the new device.
  - In some cases distributors would accept return of old device with credit.
  - Purchase order forms were revised to include the new safe devices.
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#### **Determine Collection Method of Old Medical Device**

- Once the new devices were delivered, old devices were removed from supply shelves and supply selves were restocked with the new safe medical devices.
  - Boxes labeled "old device" were placed in the units with instructions to collect any supplies left on medication carts, emergency carts, treatment carts, etc. These boxes were collected once per day for a period of one week.
  - Maintenance Departments were instructed to replace the old sharps containers with the new containers.
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## **Determine: Communication of Implementation Date, Education and Competency Review**

- Two weeks prior to the implementation of the new safe medical device, notices were posted throughout the units announcing the implementation start date and education/competency dates and times.
- All identified users attended one of the education/competency sessions within that two week period.
- Included in the session was a blood borne pathogens review.
- Each education and competency session lasted 60 minutes.  
\* see attachment 1: education session objective format.
- Each Staff Development Coordinator monitored compliance with the guidelines covered in these sessions. Staff could not return to work until session was completed and competency demonstrated.



## **Determine: Education of New Employees**

- New employee orientation programs were revised to include the new safe medical device education and user competency.
- Education and competency training was placed within the new employee orientation education element for Blood borne pathogen.
- Education criteria were determined according to an employee's potential contact with the new device during employment.



## **Determine: Annual Education/Competency Review**

- Annual blood borne pathogen education and competency training was revised to include the new safe medical device.

## **Determine: Policy and Procedure Implementation**

- Infection Control policy and procedures were revised to include the new safe device.
- The facility's Directors of Nursing was responsible for policy placement and Medical Director Review.

## **Monitoring The New Device**

After implementation of the new device a system was determined to monitor and evaluate the new devices. This monitoring system was based upon the following criteria:

1. User satisfaction
2. User compliance with procedure
3. User needle stick episodes
4. Cost analysis
5. Distributor compliance with supply requirements
6. Review of Policy and Procedure

### **Monitor User Satisfaction**

- User product comment cards are available in each supply room through the units. These cards include patient satisfaction information.  
\*See attachment 2 for example of “User Product Sample Card”
- User product comment cards are collected weekly with supply stocking schedule and forwarded to the Purchasing Director for collation.
- User product comment cards that relate to the new safe medical device are then forwarded to the Safe Medical Device Chairperson for evaluation.
- Each comment is evaluated for product safety, user satisfaction or comment, patient satisfaction, safe medical device act criteria, education needs and manufacturer defects.
- Action Plans are implemented for areas of needed follow-up for the device.
- Action Plans are reviewed and reported quarterly in the Quality Assurance Committee.



### **Monitoring User Compliance With Procedure**

- User compliance is monitored during the initial competency and annual competency review.



### **Monitoring Needle Stick Episodes**

- **All Needle** Stick Episodes are logged and reviewed according to the organizations Exposure Control Policy.
- Needle Stick Episodes that relate to product defect, user compliance with procedure, or lack of safe medical device availability is evaluated and action planned.
- All action plans are reported quarterly to the Quality Assurance Committee.



## **Cost Analysis**

- New Device Product Costs are reviewed annually by the Purchasing Director and reported to the Safe Medical Device Chairperson.
- New Device Product Costs that escalate more than 2% are investigated for product cost comparisons.
- To date, product cost increases have remained under 2%.



## **Distributor Compliance With Supply Demand**

- Every quarter the Purchasing Director monitors and reports distributor compliance with supply demand to the Quality Assurance Committee.
- To date, no incidents of supply and delivery non-compliance have been reported.



## **Policy and Procedure Review**

- Policies and procedures related to the new safer devices are reviewed annually by the policy committee.
- To date one review has taken place with no revisions to the initial policy and procedure.

## **Recommendations and Lessons Learned**

After completion of Phase 5, it was determined that the following processes would be revised.

1. Investigate additional locations of sharp containers prior to implementation. After the implementation of the new sharps containers it was determined that other locations were needed in order to maintain sharps disposal compliance. Although this was accomplished during the implementation phase, it would have been proactive to determine these additional locations during Phase 4: Evaluation of Safer Medical Devices.
2. The final decision for organization product purchase and utilization was made by the Safe Medical Device Committee. The committee neglected to communicate the final decision to the general staff and began the implementation and monitoring phase. Staff Development Educators reported that the general staff requested statistical information regarding the evaluation process and why product choices

were determined. This step has now been included in the process with product analysis reports and final decisions posted for the general staff.

To date all phases of the project for Implementing and Monitoring New Devices is complete. The primary committee team continues to meet quarterly. The continued monitoring and evaluation of the plan is ongoing. The secondary subcommittee meets bi-annually. They continue to report outcomes to the primary committee .

Staffing Hours (approximate)

<b>Type of Staff</b>	<b>Hours Spent on Phase 5 Evaluate Safer Medical Devices</b>
Management	5 hour = Phase 5 meeting Development of Process Development of education objectives 1 hour x each shift x 2 weeks= Staff Development Educators Education and Competency sessions offered for 1 hour each shift x 2 weeks. 2 hours =Staff Development Coordinators education and competency data entry.
Administrative	4 hours = Collation and report of data 2 hours=Product ordering, purchase stop of old product and revision of purchase order
Front Line	1 hour = Education of Evaluation Process and procedure information x each staff user
Total	11 hours= Administrative and Management 44 hours= Each Facility's Staff Development Department 1 hour=Each user identified front line staff

Other, non-labor items

Office supplies
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### Attachment 1

<b>OBJECTIVES</b> List objectives in behavioral terms	<b>CONTENT (Topics)</b> List each topic area to be covered and provide an outline of the content to be presented for each objective	<b>TIME FRAME</b> State the time frame for each objective	<b>FACULTY</b> List the faculty for each objective	<b>TEACHING METHOD</b> Describe the teaching method for each objective
Identify Blood Borne Pathogen Policy	Section 1 A. Infection Control Policies and Procedures B. Infection Control Program C. Infection Control Sub Committee D. Airborne Precautions Contact Precautions Droplet Precautions Standard Precautions Temporary Syndrome Based Precautions E: Genral F. Nursing Section 2 Exposure Control Plan Section 3 Tuberculosis Section 4 Infection Control Data and analysis V. OSHA CDC Compliance Plan	30 minutes		LCD Power Point presentation/Handouts
Identify procedure for safe medical devices	Review procedure for Syringes Lancets Sharps containers IV needles	15 minutes		LCD/Power Pint presentation/ Handouts
Demonstrate competency for safe medical devices	Return demonstration of competency for safe medical devices	15 minutes		Product samples

## Attachment 2

**USER PRODUCT COMMENTS:**

Product Name:  
 Product Serial Number:  
 User Name and Title:  
 User Employee ID:

	Product not available for use Name Product
	Product damaged Forward product with user product card to Central Supply Explain:
	Product seal not intact Forward product with user product card to Central Supply
	Product expired: Forward with user product card to Central Supply
	Safety device did not activate Forward product with user product card to Central Supply
	After or during use, product caused injury, due to malfunction or manufactures defect. Complete medical device injury report Forward with user product card to Central Supply
	Patient complained of excessive pain or discomfort during the use of this product Explain: Forward with user product card to Central Supply
	Procedure for this product is not available on unit.
	I would like further education on this product. Please contact me.

**Other Comments**

**ATTENTION:**  
 USE THE SAFETY BOXES SUPPLIED IN EACH SUPPLY ROOM TO DEPOSIT AND TRANSPORT SHARPS USED OR UNUSED TO CENTRAL SUPPLY.  
 NEVER TRANSPORT SHARPS TO CENTRAL SUPPLY OUTSIDE OF THE PROVIDED SAFETY BOX