

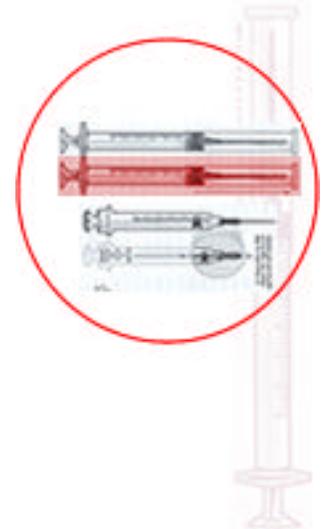
NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries. Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities 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 4: Evaluate Safer Medical Devices

This agency is the largest Community Mental Health/Retardation Center in the United States. The agency provides an array of services for eligible residents of this County in the form of mental health/mental retardation services, early childhood intervention services, crises stabilization, psychiatric emergency services, forensic psychiatry, residential programs, psychiatric rehabilitation services and community outreach. Services for adults, adolescents and children are provided in outpatient clinics, inpatient/residential programs and group homes and in natural environments within the community. Approximately 30,000 consumers are served annually within the various programs and services of this agency.

In Phase 2 of this study, our Sharps Injury Prevention Team (SIPT) identified the devices our agency nurses use most often in the course of their duties. Our focus during the study will be on reviewing and examining the following safer medical devices:

- Phlebotomy needles, especially safer butterfly blood collection sets;
- Vacutainer holders; and
- Safety syringes for injections.

Ten sites were chosen by the SIPT based on the number of consumers/participants seen and who were most likely to have invasive procedures using the above devices in that unit. Six of these sites are outpatient mental health clinics with one community outreach service. Two units are twenty-four hour facilities.

The training occurred both in the SIPT meeting and on the Units by the Project Coordinator, our Infection Control Professional and through vendor demonstrations. The training took approximately one hour at each of the sites. The Project Coordinator was available for consultation and an additional 1-hour training session during the 2nd week of the trial.

The trial lasted 1 month on 5 units and 2 weeks on one of the twenty-four hour units. The four remaining units have been using safety devices of their choice since 12/03 and have submitted evaluation forms. The SIPT met every 2 weeks during the trial and were in frequent contact with the Project Coordinator. Six of the sites had an active SIPT member who acted as Trial Site Leader. The Lead Nurses in the other sites acted as the liaison with the SIPT and Project Coordinator. Trial Site Leaders were responsible for:

- Monitoring the trial process;
- Requesting more supplies from the project coordinator;
- Monitoring forms for accuracy and completeness;
- Managing forms on the unit;
- Answering staff questions and providing onsite instructions as needed;
- Troubleshooting problems and liaison with Project Coordinator as needed; and
- Collecting and sending forms to the project coordinator weekly.

The data was collected at the time of use from consumers/participants who received injection and or phlebotomy procedures using the above devices. The consumers/participants were given the opportunity to complete a satisfaction survey. The survey had 7 questions rated on a 5-point scale. **See attached “Consumer Participant Satisfaction Survey”**.

The nurses in the trial sites were the users and evaluated the devices by completing an evaluation form for each device weekly. There were 17 questions, rated on a 5-point scale. **See attached form” Safety Feature Evaluation Form: Safety Syringes”**. In addition for the Vacuum Tube Blood Collection Systems an 11-question survey was used, and scored on a 5-point rating scale. **See attached form “Safety Feature Evaluation Form: Vacuum Tube Blood Collection Systems”**.

Supervisors were asked to complete weekly evaluation forms on each nurse’s skills using each type of device. The survey has 7 questions and is rated on a 5-point scale. **See attached “Safer Medical Devices Supervisors' Survey”**.

Our team member statistician will assist in the evaluation of the survey tools collected. Given the size of our agency, we have had a proportionately small number of needlestick incidents since the beginning of the 2004 fiscal year on September 1, 2003. The incidents were investigated and analyzed by our Infection Control Professional who is also our Project Coordinator. Education and feedback was provided to the individual nurses at the time of the incidents.

The SIPT reached a consensus that we have enough data due to the tremendous responses from both consumers and users with written and oral feedback that expressed the effectiveness of the device and whether to continue or discontinue the device. We were disappointed in the low responses from the Nursing Supervisors in completing the Supervisors Survey Form. On analysis of this low response we found that the following factors were important:

- Several Supervisors and staff nurses were out on vacation during the trials;
- Nursing Supervisors, not out on vacation, were also users and completed the Device evaluation forms; and
- Lower staffing ratios impacted the Supervisors’ participation.

The SIPT team assured that the devices were being used as planned during this trial by:

- Observation;
- Training and demonstrations; and
- Weekly random visits to trial sites by Project Coordinator.

The nurses were very open to the trials and expressed some concern that certain devices would be difficult to use in their settings. We were able to resolve their concerns by providing additional hands on training and guidance.

There were several lessons that were learned during this process of evaluating safer medical devices. Lessons we learned in the process included:

- The survey tools need to be similar in lay out and design;
- Nurses have different skill levels/abilities in adapting to the new devices;
- Better-defined guidelines are needed for the trial site leaders;
- More frequent contact with Trial Site Leaders to review paperwork and make corrections as needed;
- Include Nursing Supervisors in the process at an earlier stage to increase their participation; and
- Trials should be scheduled in non-peak vacation times.

We were able to resolve the above-identified issues by:

- Providing additional explanation and training regarding completion and processing of forms;
- Providing additional training and supervision on the units by Program Coordinator; and
- Observing nurses drawing blood and giving injections and making recommendations on improving technique.

We were unable to meet weekly due to Agency productivity requirements and time constraints.

If we were beginning this process again we would make sure all survey forms are similar in layout. We would provide a variety of communications options for SIPT members such as conferences calls, Tele-conferencing, e-mail distribution, and on site visits by Project Coordinator in order to maintain consistency in the trial process. We would also involve the Ancillary members from other departments earlier in this phase, (Quality Management and Statistician). We would schedule the trials in non-peak vacation times.

We would encourage other facilities who are beginning this process to:

- Access Internet sites for survey forms.
- Develop trial guidelines early in the process.
- Schedule weekly meetings with key personnel early in the process.
- Elicit management/administrative support prior to trial development.
- If time permits, plan trial to evaluate safer medical devices consecutively rather than concurrently.
- Utilize ancillary SIPT members earlier in trial development.
- Schedule trials during non-peak vacation times.

The roles the SIPT members played in the process were:

- Several licensed nursing staff acted as Trial Site Leaders.
- Nursing staff provided clinical knowledge and expertise.
- Ancillary members provided statistical expertise, assisted in establishing accounting systems, report analysis and medical expertise.
- Nursing staff evaluated various safer medical devices.
- Trial Site Leaders acted as onsite liaison and trial site managers and troubleshooters.
- Survey Tools and forms evaluation and development.
- Report writing and submission.

Staff Hours

Type of Staff	Hours Spent on Phase 4
Ancillary	15 hours
Administrative	57 hours
front-line	101 hours
Total	173 hours

Other, non-labor items:

Item
1. Copies for meetings
2. Safer medical devices
3. Transportation to units

CONSUMER/PARTICIPANT SATISFACTION SURVEY	
Date	Trial Site

For Staff: Please list what safety device was used today for this consumer

Adolescent _____ Child _____ Adult _____ Male _____ Female _____

At your visit today, you had blood drawn and or received an injection. Thinking about those procedures, please rate the following questions.

Circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to your visit today.

During your visit	N/A	Disagree	Agree
1. Convenience of the location of the clinic.	N/A	1-- 2-- 3---	4-- 5
2. Time spent with the nurse was pleasant and beneficial for you.	N/A	1-- 2-- 3---	4-- 5
3. The nurse explained what procedure (s) you were to have today.	N/A	1-- 2-- 3---	4-- 5
4. The nurse you saw today, was careful and competent in drawing your blood.	N/A	1-- 2-- 3--	4-- 5
5. The nurse you saw today, was careful and competent in giving your shot.	N/A	1-- 2-- 3--	4-- 5
6. The procedure today was comfortable for you.	N/A	1-- 2-- 3---	4-- 5
7. The Nurse caring for you was courteous, and respectful.	NA...	1-- 2-- 3---	4-- 5

SAFER MEDICAL DEVICES SUPERVISORS' SURVEY
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Date _____ Site _____

USE THE FOLLOWING SCALE TO RATE THE SAFER MEDICAL DEVICES USED DURING THE SHARPS INJURY PREVENTION STUDY TRIAL.

PLEASE COMPLETE A SEPARATE SURVEY FOR EACH TYPE/BRAND OF SAFER MEDICAL DEVICE USED DURING THE TRIAL.

RECORD THE DEVICE AND BRAND NAME BELOW:

Phlebotomy Device _____

Injection Device _____

PLEASE CIRCLE THE MOST APPROPRIATE ANSWER FOR EACH QUESTION.

During the Trial	N/A	Agree	Disagree
1. The user(s) did not need training for correct operation of this device.	N/A	1-- 2-- 3--- 4-- 5	
2. The design of the device suggests proper use.	N/A	1-- 2-- 3--- 4-- 5	
3. The device is easy to open and use.	N/A	1-- 2-- 3--- 4-- 5	
4. The safer device for injection is compatible with the syringe and needle sizes used at this site.	N/A	1-- 2-- 3-- 4-- 5	
5. The safer medical device used for phlebotomy was easy for user to assemble.	N/A	1-- 2-- 3-- 4-- 5	
6. The potential for needlesticks injuries increased with this device?	N/A	1-- 2-- 3--- 4-- 5	
7. The users stated they liked this device.	NA	1-- 2-- 3--- 4-- 5	

Are there other questions which you feel should be asked regarding the safety /utility of this product?
Are there additional comments you would like to make about this device?

SAFETY FEATURE EVALUATION FORM

SAFETY SYRINGES



Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

DURING USE:

agree.....disagree

1. The safety feature can be activated using a one-handed technique..... 1 2 3 4 5 N/A
2. The safety feature **does not** obstruct vision of the tip of the sharp..... 1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature..... 1 2 3 4 5 N/A
4. This product does not require more time to use than a non-safety device..... 1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes..... 1 2 3 4 5 N/A
6. The device is easy to handle while wearing gloves..... 1 2 3 4 5 N/A
7. This device **does not** interfere with uses that do not require a needle..... 1 2 3 4 5 N/A
8. This device offers a good view of any aspirated fluid..... 1 2 3 4 5 N/A
9. This device will work with all required syringe and needle sizes..... 1 2 3 4 5 N/A
10. This device provides a better alternative to traditional recapping..... 1 2 3 4 5 N/A

AFTER USE:

11. There is a clear and unmistakable change (audible or visible) that occurs
when the safety feature is activated..... 1 2 3 4 5 N/A
12. The safety feature operates reliably..... 1 2 3 4 5 N/A
13. The exposed sharp is permanently blunted or covered after use and prior to disposal..... 1 2 3 4 5 N/A
14. This device is no more difficult to process after use than non-safety devices..... 1 2 3 4 5 N/A

TRAINING:

15. The user **does not** need extensive training for correct operation..... 1 2 3 4 5 N/A
16. The design of the device suggests proper use..... 1 2 3 4 5 N/A
17. It is **not** easy to skip a crucial step in proper use of the device..... 1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/ utility of this product?

SAFETY FEATURE EVALUATION FORM

VACUUM TUBE BLOOD COLLECTION SYSTEMS



Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

- | | agree.....disagree |
|---|--------------------|
| 1. The safety feature can be activated using a one-handed technique..... | 1 2 3 4 5 N/A |
| 2. The safety feature does not interfere with normal use of this product..... | 1 2 3 4 5 N/A |
| 3. Use of this product requires you to use the safety feature..... | 1 2 3 4 5 N/A |
| 4. This product does not require more time to use than a non-safety device..... | 1 2 3 4 5 N/A |
| 5. The safety feature works well with a wide variety of hand sizes..... | 1 2 3 4 5 N/A |
| 6. The safety feature works with a butterfly..... | 1 2 3 4 5 N/A |
| 7. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated..... | 1 2 3 4 5 N/A |
| 8. The safety feature operates reliably..... | 1 2 3 4 5 N/A |
| 9. The exposed sharp is blunted or covered after use and prior to disposal..... | 1 2 3 4 5 N/A |
| 10. The inner vacuum tube needle (rubber sleeved needle) does not present a danger of exposure..... | 1 2 3 4 5 N/A |
| 11. The product does not need extensive training to be operated correctly..... | 1 2 3 4 5 N/A |

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/ utility of this product?