

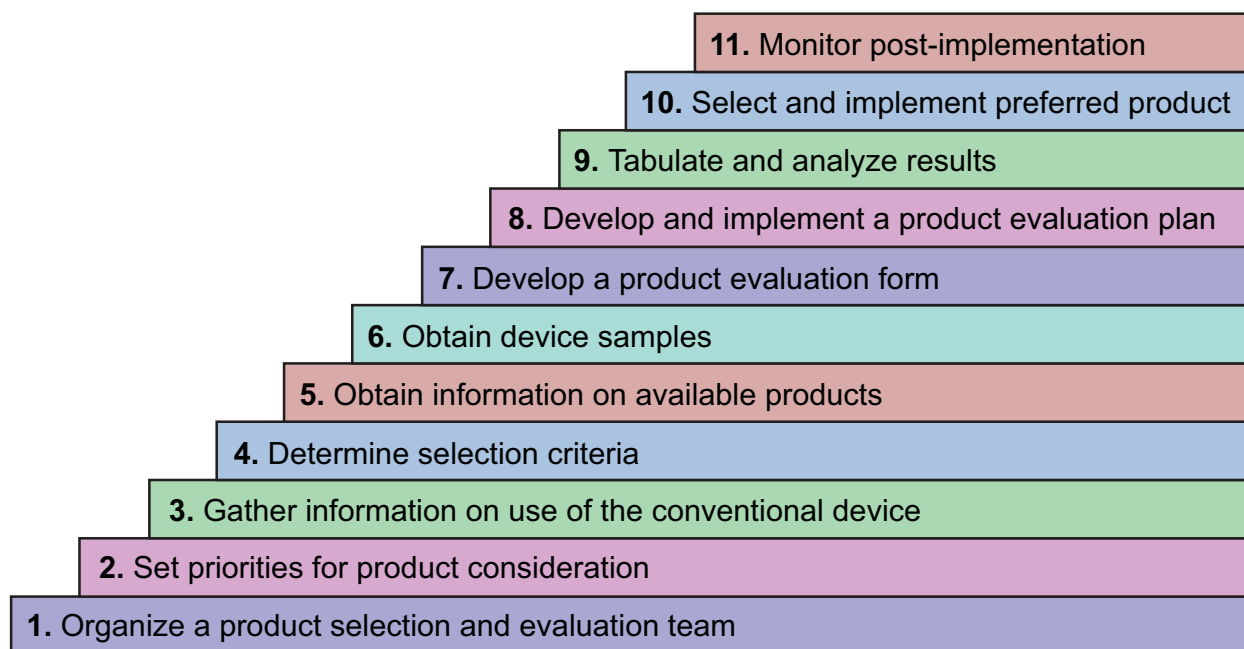
OPERATIONAL PROCESSES

Selection of Sharps Injury Prevention Devices

Introduction

The process of selecting engineered sharps injury prevention devices gives healthcare organizations a systematic way to determine and document which devices will best meet their needs. The selected devices must be acceptable for clinical care and provide optimal protection against injuries. The selection process includes collecting information that will allow the organization to make informed decisions about which devices to implement. The more this process can be standardized across clinical settings, the more information can be used to compare experiences among healthcare facilities.

Key Steps in the Product Evaluation Process



A key feature of the process is an in-use product evaluation. A product evaluation is not the same as a clinical trial. Whereas a clinical trial is a sophisticated scientific process requiring considerable methodological rigor, a product evaluation is simply a pilot test to determine how well a device performs in the clinical setting. Although the process does not need to be complex, it does need to be systematic (93). This *Workbook* outlines an 11-step approach for selecting a product for implementation. The model is most relevant to hospitals, but it can be adapted in other health-care settings. (Guidance for the evaluation of dental devices may be found at <http://www.cdc.gov/OralHealth/infectioncontrol/forms.htm>.)

Step 1. Organize a Product Selection and Evaluation Team

Healthcare organizations should designate a team to guide processes for the selection, evaluation, and implementation of engineered sharps injury prevention devices. Many institutions already have product evaluation committees that may be used for this purpose; others may want to assign this responsibility to a subcommittee of the prevention planning team. To ensure a successful outcome:

- Assign responsibility for coordinating the process,
- Obtain input from persons with expertise in or perspectives on certain areas (e.g., front-line workers), and
- Maintain ties to the prevention planning team.

Key departments and roles to consider when organizing a product selection team include:

- **Clinical departments** (e.g., nursing, medicine, surgery, anesthesiology, respiratory therapy, radiology) **and special units** (e.g., pediatrics, intensive care) have insight into products used by their staff members and can identify departmental representatives to help with product selection and evaluation;
- **Infection control** staff can help identify potential infection risks or protective effects associated with particular devices;
- **Materials management staff** (purchasing agents) have information about vendors and manufacturers (e.g., reliability, service record, inservice support) and can be involved with product purchasing;
- **Central service staff** often know what devices are used in different settings in a facility and can identify supply and distribution issues; and
- **Industrial hygiene staff** (if available) can assess ergonomic and environmental use issues.

Other departments to consult include pharmacy, waste management, and housekeeping.

It is essential that **clinical staff** participate in the evaluation of safety devices. They are the end-users who best understand the implications of product changes. They know the conventional and unconventional ways that different devices are used in clinical care. They can also identify expectations for device performance that will affect product selection.

Step 2. Set Priorities for Product Consideration

The team can use information from the intervention action plan (see *Organizational Processes*) to determine which device types to consider. To avoid unforeseen compatibility problems, teams

should consider only one device type at a time. Consideration of more than one device type might be appropriate if the devices have different purposes (e.g., intravenous catheters and finger/heel-stick lancets). Additional information regarding the number of devices used or purchased may also be helpful in setting priorities.

Step 3. Gather Information on Use of the Conventional Device

Before considering new products for evaluation, healthcare organizations must obtain information on use of the conventional device that it is replacing. Possible sources of information are purchasing and requisition requests. A survey of departments and nursing units might help identify additional issues. Key information to obtain from clinical areas includes:

- Frequency of use and purchase volume of the conventional devices;
- Most commonly used sizes;
- Purpose(s) for which the device is used;
- Other products the device is used with that might pose compatibility concerns;
- Unique clinical needs that should be considered; and
- Clinical expectations for device performance.

If the answers to these questions reveal areas with unique needs, representatives from these areas should be added as ad hoc members of the team.

Toolkit Resource for This Activity:

Survey of Device Use (see Appendix A-11)

Step 4. Establish Criteria for Product Selection and Identify Other Issues for Consideration

Product selection is based on two types of criteria:

- **Design criteria** that specify the physical attributes of a device, including required features for clinical needs and desired characteristics of the safety feature, and
- **Performance criteria** that specify how well a device functions for its intended patient care and safety purposes.

Other issues to consider include:

- **Impact on waste volume.** Some safety features (e.g. extending needle guards added to syringes or single-use blood tube holders) increase the volume of waste and require changes in sharps container use, including container size and frequency of replacement.

- **Packaging.** Changes or differences in device packaging may affect waste volume, ease of opening, and the ability to maintain aseptic technique. Also examine instructional material on or in packaging to determine if it is clear and useful in guiding healthcare personnel through activation of the safety feature.

This *Workbook* includes a tool to help selection teams pre-screen devices using design and performance criteria and the other considerations. This tool also helps facilities document the process to select or reject a particular product.

Toolkit Resource for This Activity:

Device Pre-Selection Worksheet (see Appendix A-12)

Step 5. Obtain Information on Available Products

Potential sources of information on available products with engineered sharps injury prevention devices include:

- **Materials management staff** who have information on product vendors and manufacturers and are also familiar with the service reliability of manufacturers' representatives;
- **Colleagues in other facilities** who can share information on their experiences in evaluating, implementing, or rejecting certain devices.
- **Websites** with lists of manufacturers and products. Some websites include:
<http://www.healthsystem.virginia.edu/internet/epinet/safetydevice.cfm>
http://www.isips.org/safety_products.html
<http://www.premierinc.com/all/safety/resources/needlestick/sharps-lists.jsp>

A comprehensive resource book, "The Compendium of Sharps Safety Technologies", and web site (<http://www.needlesticksafetydevices.com/opportunities.php>) is now available. The book will assist healthcare personnel in selecting and evaluating safer devices. The new reference book, includes extensive descriptions and photos of nearly every available sharps injury prevention device, as of 2005. The Compendium is organized into more than 130 separate categories and is indexed to help healthcare personnel rapidly find and begin evaluation of the precise safety products that they are looking for. A companion website is also available containing the latest information on new safety products.

Peer-reviewed articles in professional journals that describe a facility's experience with a particular type of device and the efficacy of various devices in reducing injuries.

Step 6. Obtain Samples of Devices Under Consideration

Arrangements should be made to contact manufacturers or vendors to obtain samples of products for consideration. Once obtained, look at the devices based on the design and performance criteria and other issues that are important. Consider inviting manufacturers' representatives to present information about their products to the team. Questions for the representatives might include:

- Can the device be supplied in sufficient quantities to support institutional needs?
- Is it available in all required sizes?
- What type of training and technical support (e.g., on-site in-service training, teaching materials) will the company provide?
- Will the company provide free products for a trial evaluation?

Discuss any technical questions related to the product. Based on these discussions, the team should narrow its choices to one or two products for an in-use evaluation.

Step 7. Develop a Product Evaluation Survey Form

The form used to survey healthcare personnel who evaluate the trial device must collect information necessary to make informed decisions for final product selection. Teams should try to use readily available forms. This promotes standardization of the evaluation criteria and enhances the ability to compare responses among different healthcare organizations. If manufacturer-provided forms are used, they should be carefully screened to eliminate potential bias. This *Workbook* includes a generic device evaluation form.

Toolkit Resource for This Activity:

Device Evaluation Form (see Appendix A-13)

Product evaluation forms should be easy to complete and score, as well as relevant to in-use performance expectations for patient care and healthcare personnel safety. The form that is easiest to complete is usually one- or two-pages and allows users to circle or check responses. Use of a graded opinion or Likert-type scale (i.e., strongly agree, agree, disagree, strongly disagree) helps facilitate scoring. A few specific questions (e.g., ease of use, impact on technique, how long it took to become comfortable using the device) should always be asked about any device. Performance questions may be unique to the type of device (e.g., IV catheter, hypodermic syringe/needle), type of safety feature (e.g., sliding shield, retracting needle), or changes in equipment (e.g., single

versus multiple use); these should be added as needed. Additional suggestions for designing or selecting an evaluation form are to:

- **Avoid questions that the product selection and evaluation team can answer.** Unless there is a specific issue, there is no need to include questions that the team can answer about matters such as packaging, impact on waste volume, and training needs.
- **Allow space for comments.** Healthcare personnel should be given an opportunity to comment on a device. Individual comments can provide useful insights and identify areas for further questioning.
- **Include questions about product users.** Unless a product evaluation is confined to a single unit and/or group of staff, information on the respondents (e.g., occupation, length of employment and/or work in the clinical area, training on the new device) is helpful in assessing how different groups react to the new device.

Step 8. Develop a Product Evaluation Plan

Developing a product evaluation plan requires several additional steps, but it is necessary to ensure that the form obtains the desired information and documents the process (128).

- **Select clinical areas for evaluation.** The evaluation does not need to be performed institution-wide, but should include representatives from areas with unique needs. Whenever possible, include both new and experienced staff.
- **Determine the duration of the evaluation.** There is no formula for how long to pilot test a product, although two to four weeks is often suggested (144,146). Factors to consider include the frequency of device use and the *learning curve*, i.e., the length of time it takes to become comfortable using a product. It is important to balance staff interest in the product and the need for sufficient product experience. If more than one device is evaluated as the replacement for a conventional device, use the same populations and trial duration for each product. Make a defined decision on when to abort an evaluation because of unforeseen problems with a device.
- **Plan for staff training.** Healthcare personnel participating in an evaluation must understand how to use the new device properly and what impact, if any, the integration of a safety feature will have on clinical use or technique. Training should be tailored to the audience needs and should include discussion of why the change is being proposed, how the evaluation will proceed, and what is expected of participants. It is important to provide information on the criteria used to evaluate clinical performance and to answer any questions about the interpretation of these criteria.

A team approach, using in-house staff and device manufacturer's representatives, is one effective way to provide training. In-house staff know how products are used in a facility, including any unique applications, but manufacturer's representatives understand the design and use of the safety feature. Give trainees an opportunity to handle the device and ask questions about its use, as well as an opportunity to simulate use of the device during patient care, in order to help reinforce proper use.

Also consider those who might not be able to attend the training (e.g., staff on leave, new students, per diem staff) and how to implement *catch-up* training. One possibility is to identify persons in departments or on nursing units to serve as resources on the devices.

- **Determine how products will be distributed for the evaluation.** Whenever possible, remove the conventional device from areas where the evaluation will take place and replace it with the device under study (128). This approach eliminates a choice of product alternatives and promotes use of the device undergoing evaluation. If the device undergoing evaluation does not meet all needs (e.g., all sizes are not available; the study device can be used for only one purpose and the conventional device has multiple purposes), it may be necessary to maintain a stock of the conventional product along with the product under study. In such instances, provide and reinforce information on the appropriate and inappropriate use of the conventional device. Precede and coordinate staff training with any switch in devices.
- **Determine when and how end-user feedback will be obtained.** Obtain feedback on device performance in two stages. The first stage is informal and occurs shortly after the onset of pilot testing. Members of the evaluation team should visit clinical areas where the device is being piloted and engage in discussions about the device in order to get some preliminary indication of its acceptability for clinical use. These interactions can also reveal problems that might require terminating the evaluation early or providing additional training.

The second stage involves distribution of the product evaluation forms. To avoid recall bias, this should be done as soon as possible after the evaluation period is completed. An active process, such as distributing surveys during unit meetings, may be more reliable than a passive process, where forms are left in the clinical area and filled out at random, and also prevents staff from completing multiple evaluation forms for the same product.

Step 9. Tabulate and Analyze the Evaluation Results

Compile data from the survey forms. Depending on the number of staff involved and survey forms completed, this can be done either by hand or by use of a computerized database. It is useful to score each question in addition to the overall response, particularly if evaluating two or more devices (e.g., hypodermic syringe/needle); responses to each question can be used to compare

devices. In addition, categorize individual comments so they provide a better picture of the clinical experience with the device.

Consider calculating response rates by occupation and clinical area and analyzing data by these variables, if the volume of responses permits. This can help identify differences in opinion that may be influenced by variations in clinical needs.

Several factors can have a positive or negative influence on the outcome of a product evaluation. These include:

- Staff experience with and preference for the conventional device;
- Attitudes toward involvement in the product evaluation process;
- Influence of opinion leaders;
- Staff opinion of product evaluation team members and manufacturers representatives;
- Perceived need for devices with safety features; and
- Patient concerns.

It is possible that one or more of these factors may be influencing opinions if the response of certain groups of personnel to the product change is different from what was expected or differs from other groups in the organization. Meet with these groups to understand their issues; it might provide new insights for the evaluation team.

Step 10. Select and Implement the Preferred Product

The evaluation team should make a product selection based on user feedback and other considerations established by the selection team. Model the process for implementing the selected device after the pilot evaluation process, and coordinate training with product replacement. It may be necessary to implement a product change over several weeks, moving by unit within the hospital.

The team should also consider a back-up plan in case the selected device is recalled or production is unable to meet current demands. Questions to ask include:

- Should a less-preferred product be introduced as a replacement?
- Should the conventional device be returned to stock?
- If the conventional device is still being used for other purposes, should the stock be increased to meet current needs?

These questions are not easy to answer. Furthermore, it is counter to the prevention plan to return to a conventional device once one with a safety feature has been introduced, and it may raise questions among staff. However, in some instances it may be the only option available. Some manufacturers may take back unused devices. It is worth asking the representative that works with the hospital about this option.

Step 11. Perform Post-implementation Monitoring

Once a new device is implemented, assess continued satisfaction with the product through follow-up monitoring and respond to those issues not identified or considered during the evaluation period. In addition, some facilities may wish to assess post-implementation compliance with use of the safety feature. Each product selection team will need to consider the most effective and efficient way to perform post-implementation monitoring.

SAMPLE Cover Letter

Date

Dear (e.g., staff member, healthcare worker, employee):

(Name of organization) is conducting a survey to evaluate a device with an engineered sharps injury prevention feature. Your feedback on this product is important in order to identify safer devices that allow us to better serve our workforce.

Please complete the attached form, which will only take a few minutes. All of your responses are confidential. Once they are collected, there is no connection between your name and the survey you complete. Your responses will be combined with others in order to determine the acceptability of this new device.

If you need help completing this survey or have any questions, please ask _____. When you have completed the survey, please return it to _____. Thank you in advance for providing this information.

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Special Questions about this Particular Device					
[To be added by healthcare facility]	1	2	3	4	5
	1	2	3	4	5
	1	2	3	4	5
Overall Rating					
Overall, this device is effective for both patient/ resident care and safety.	1	2	3	4	5

3. Did you participate in training on how to use this product?

- No (Go to question 6.) Yes (Go to next question.)

4. Who provided this instruction? (Check all that apply.)

- Product representative Staff development personnel
 Other _____

5. Was the training you received adequate?

- No Yes

6. Was special training needed in order to use the product effectively?

- No Yes

7. Compared to others of your gender, how would you describe your hand size?

- Small Medium Large

8. What is your gender?

- Female Male

9. Which of the following do you consider yourself to be?

- Left-handed Right-handed

10. Please add any additional comments below.

THANK YOU FOR COMPLETING THIS SURVEY

Please return this form to: _____