Product Evaluation of Smoke Evacuation Devices

Adapted from the Centers for Disease Control and Prevention's

Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program

Pages 51-59

The *Workbook for Designing, Implementing and Evaluating a Sharps Injury Prevention Program* has been developed by CDC to help health care facilities prevent needlesticks and other sharps-related injuries to health care personnel. Available at http://www.cdc.gov/sharpssafety/pdf/sharpsworkbook_2008.pdf

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OPERATIONAL PROCESSES

Selection of Smoke Evacuation Devices

Introduction

The process of selecting smoke evacuation devices gives health care 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 surgical smoke. 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 health care facilities.

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.[1] This document outlines an 10-step approach for selecting a product for implementation. The model is most relevant to hospitals, but it can be adapted to other health care settings.

Key Steps in the Product Evaluation Process

1. Organize a product selection and evaluation team
2. Set priorities for product consideration
3. Establish criteria for product selection and identify other issues for consideration
4. Obtain information on available products
5. Obtain samples of devices under consideration
6. Develop a product evaluation survey form
7. Develop a product evaluation plan
8. Tabulate and analyze the evaluation results
9. Select and implement the preferred product
10. Perform post-implementation monitoring

Step 1. Organize a Product Selection and Evaluation Team

Health care organizations should designate a team to guide processes for the selection, evaluation, and implementation of smoke evacuation devices. Many institutions already have product evaluation committees that can fulfill this purpose; others may want to assign this responsibility to a subcommittee of the implementation team. To ensure a successful outcome:

- assign responsibility for coordinating the process,
- obtain input from persons with expertise in or perspectives on certain areas (eg, front-line workers), and
- maintain ties to the implementation team.

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

- **Clinical departments** (eg, Nursing, Surgery, Anesthesiology) and special units (eg, Labor & Delivery, Interventional Radiology) have insight into products used by their personnel and can identify departmental representatives to help with product selection and evaluation.
- **Materials management staff** (purchasing agents) have information about vendors and manufacturers (eg, reliability, service record, in-service support) and can be involved with product purchasing.

It is essential that clinical personnel participate in the evaluation of the 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 gap analysis to determine which device types to consider. To avoid unforeseen compatibility problems, the team should consider only one device type at a time. Additional information regarding the number of devices used or purchased may also be helpful in setting priorities.

Step 3. Establish Criteria for Product Selection and Identify Other Issues for Consideration

Product selection is based on two types of criteria:

- **Design criteria** specify the physical attributes of a device.
- **Performance criteria** specify how well a device functions for its intended patient care and safety purposes.

Step 4. Obtain Information on Available Products

Potential sources of information on available smoke evacuation products include:

- **materials management personnel** 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; and
- **websites** with lists of manufacturers and products.

Step 5. Obtain Samples of Devices under Consideration

Arrangements should be made to contact manufacturers or vendors to obtain samples of products for consideration. After they are obtained, examine 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?
- What type of training and technical support (eg, 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 6. Develop a Product Evaluation Survey Form

The form used to survey health care personnel who evaluate the trial device must collect information needed to make informed decisions for final product selection. The team should try to use readily available forms. This promotes standardization of the evaluation criteria and enhances the ability to compare responses among different health care organizations. If manufacturer-provided forms are used, they should be carefully screened to eliminate potential bias. Product evaluation forms should be easy to complete and score, as well as relevant to in-use performance expectations for patient care and health care 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 (eg, strongly agree, agree, disagree, strongly disagree) helps facilitate scoring. A few specific questions (eg, 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 (eg, noise level).

Additional suggestions for designing or selecting an evaluation form:

- **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**. Health care 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 or group of personnel, information on the respondents (eg, 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 7. Develop a Product Evaluation Plan

Developing a product evaluation plan is necessary to ensure that the form obtains the desired information and documents the process.[2]

- **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 personnel.

- **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.[3,4] Factors to consider include the frequency of device use and the learning curve (ie, the length of time it takes to become comfortable using a product). It is important to balance personnel 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**. Health care 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 personnel and device manufacturer's representatives, is one effective way to provide training. In-house personnel know how products are used in a facility, including any unique applications, and manufacturer's representatives understand the design and use of the safety features. 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, to help reinforce proper use.

Also consider those who might not be able to attend the training (eg, personnel on leave, new students, per diem personnel) 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.[2] This approach eliminates a choice of product alternatives and promotes use of the device undergoing evaluation. 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 pilot tested 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 personnel from completing multiple evaluation forms for the same product.

Step 8. Tabulate and Analyze the Evaluation Results

Compile data from the survey forms. Depending on the number of personnel 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; 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:

- personnel experience with and preference for the conventional device;
- attitudes toward involvement in the product evaluation process;
- influence of opinion leaders;
- personnel opinion of product evaluation team members and manufacturer's 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 that of other groups in the organization. Meet with these groups to understand their issues; it might provide new insights for the evaluation team.

Step 9. 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.

Step 10. Perform Post-implementation Monitoring

After a new device is in use, 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.

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