

Chapter 33 – Product Evaluation

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ABSTRACT

The healthcare economy demands that institutions carefully and efficiently evaluate medical products. Selected products must be clinically effective, economically efficient for the healthcare organization, and meet patient and employee safety objectives. To ensure that infection prevention aims are considered, infection preventionists must be involved in the product selection process. Device-associated infections are an important focus of infection prevention programs. Similarly, manufacturers seek to improve and design products that prevent healthcare-associated infection in order to increase their market share. It is important that new technology and manufacturer claims be evaluated and cost justified. The Occupational Safety and Health Administration's (OSHA's) emphasis on safety-engineered sharps devices and needleless systems to reduce the risk of occupational exposure bloodborne diseases dictates that product evaluation processes include these products. Additionally, employers are required to solicit input from frontline healthcare workers when selecting safety devices. Processes for product selection should be well defined so that outcome and safety objectives are not lost in the convoluted pathways through group purchasing organizations, cost control systems, and product evaluation committees.

KEY CONCEPTS

- Medical products must be clinically effective, produce desired outcomes, be economically efficient for the healthcare organization, and meet patient and employee safety objectives.
- The Joint Commission (TJC) requires that the healthcare facility's infection prevention goals must include limiting the transmission of infections associated with the use of medical equipment devices and supplies.¹
- New technology and manufacturer claims must be evaluated and cost justified.
- The product evaluation committee (PEC) is expected to select products through an objective and scientific process that considers cost, desired outcomes, patient safety, and infection rates.

- The infection preventionist must participate in the PEC and ensure that products with infection prevention relevance are selected using evidence-based national guidelines or expert consensus.
- When considering the issue of reprocessing of single-use items, the healthcare organization must implement infection prevention activities that are consistent with regulatory and professional standards.¹

BACKGROUND

The evaluation and selection of patient care items is not a new concept in healthcare. Decisions regarding product selection and review have long been delegated to individuals within healthcare facilities. However, infection prevention criteria are not always applied to this review. Interest in product evaluation from an infection prevention perspective was heightened by a nationwide epidemic of bloodstream infections associated with contaminated parenteral products publicized in 1976.² Later, the U.S. Department of Labor Occupational Safety and Health Administration (OSHA) Needlestick Prevention Act underscored the role of the infection preventionist in safety product evaluation.³ Further recognition of infection preventionist expertise by TJC gives responsibility for limiting the transmission of infections associated with the use of medical devices and supplies.¹

Product evaluation has been defined as a “process of appraisal that considers the value and significance of quality, cost, safety, and practitioner choice for product selection.”⁴ Larson and Maciorowski stated that product evaluation should be based on quality, safety, cost, standardization, and service ability.⁵ Rockett stated that product evaluation involved the consideration of cost containment, cost-benefit analyses, and productivity, but the ultimate measure of product success was the impact on patient outcomes.⁶ Elliot and Hollins viewed the product evaluation process as the interface between quality care and cost containment, with a focus on scientific and objective principles and information.⁷

Product evaluation remains an essential function in healthcare facilities. As the healthcare environment is increasingly dominated by managed care and capitated reimbursement, constraints are placed on the amount of funding available to hospitals. At the same time, quality of care and outcome measures are beginning to be used as a basis for reimbursement. Therefore, hospitals have tremendous incentive to control costs and improve outcomes. Healthcare-associated infections (HAIs) are becoming a focus in the product market, as manufacturers develop high-cost products claiming to decrease infections. Infection preventionists must take an active part in the evaluation of products that may affect infection rates to determine whether they are efficacious and thus worth the added cost.⁸

BASIC PRINCIPLES

- The primary objective of a product evaluation program is to select and purchase products that meet specific performance criteria, contribute to good patient outcomes, meet safety requirements, and are cost effective.

- Performance improvement projects related to device-associated infections can contribute to the selection of appropriate devices. Improved outcomes provide the strongest evidence for changing products or using new technology.
- Inventory control can help reduce space requirements and labor costs, but availability of products is critical in the event of bioterrorism or epidemics.
- Group purchase agreements create a system to coordinate the product selections that streamline the process and manage costs for the group.
- The PEC is a multidisciplinary committee appointed by and under the jurisdiction of the administration of the facility or healthcare system to review or evaluate products for use within the facility or healthcare system.
- Healthcare workers and other personnel must be properly trained to use new products or devices before they are put into use to prevent potential problems.
- The infection preventionist is an essential decision maker regarding the reuse of single-use items. The product's decontamination, sterility, and safety must be verified before reuse.

PRODUCT EVALUATION

The Benefits

Systematic Product Review and Value Analysis

A product evaluation process should always begin with the identification of a need. This need may be identified by both clinical and nonclinical personnel. Infection preventionists are key to the need identification process and may lead or contribute to it by attending conferences, reviewing evidence-based and best practices literature, reviewing product materials, networking with colleagues for information, reviewing current guidelines, and critically evaluating clinical studies. All of these sources may provide information about how new products effect clinical outcomes. Nonclinical personnel may identify needs based on contract requirements, the desire to optimize purchasing agreements, the desire to maintain a facility's state-of-the-art status, or because of updated guidelines, regulations, or standards.

Halvorson has suggested the goals of a product evaluation program are to select products that:

- Meet specific performance criteria, including clinical and financial criteria
- Are safe for patients and healthcare workers
- Contribute to positive patient outcomes, such as fewer infections and injuries
- Are cost-effective for both the facility and the patient⁹

Many facilities include product evaluation as a component of a larger, more comprehensive Value Analysis Program. Yokl defines the value analysis process as a strategic, creative, and analytical study of the functions of products, service, and technologies and their value chains.¹⁰

Its objective is to determine the lowest cost of providing an equivalent or better performance of a required function at the lowest possible cost. Value analysis incorporates the studies of functional need, product utilization, and practice efficiency or waste into the product assessment process.

A structured product evaluation program can have a positive effect on patient care and can contribute to the financial health of the organization. In today's healthcare environment characterized by unprecedented financial constraints, healthcare worker shortages, shortened hospital stays, and increased reporting requirements by payers and watchdog organizations, the product selection process is increasingly important. Innovation in the medical product field is continuing to flood the marketplace with technology that rapidly replaces mechanical or manual ways of providing care. And although innovation provides an essential health benefit, the healthcare system is challenged to select and evaluate emerging technologies to ensure their cost benefit. These factors underscore the importance and need for robust product evaluation programs and collaboration across all hospital disciplines.

Product evaluation takes planning, must involve end-users of products, and must be objective and scientific toward the goal of achieving the desired outcomes while containing costs.¹¹ Although committee structure and function must be tailored to the needs and culture of each institution, successful value analysis/product evaluation programs share the following characteristics.

Executive Oversight and Support

- An Executive Champion should be identified and key executives and clinical leaders should support and actively participate in the program.

An Organization-wide Culture that Embraces Product Evaluation

- Supply cost and effectiveness goals should be a part of leader evaluations.
- Organization-wide goals for cost reduction, revenue enhancement, and performance improvement should be established and communicated.

A Data-driven Decision-making Process

- Clinical, quality, and organizational data should be readily available for use in product decision-making processes.
- The product decision process should incorporate a focus on clinical, financial, and/or operational outcomes.
- Postimplementation review must be practiced to ensure success.¹²

Inventory Control

Managing and evaluating inventory are important components of the product evaluation process. Reducing inventory through inventory control methods and systems not only lessens the initial investment of the facility, but also affects space requirements and labor costs necessary to maintain and store the additional products. The just-in-time (JIT) inventory concept, invented in Japan and employed by most product manufacturers today, is a proven method for minimizing inventory associated costs. Just-In-Time inventory management has expanded to healthcare and gained widespread acceptability as a best practice.¹⁰

The goal of hospital inventory control is to maintain availability of critical products while minimizing on-hand inventory and unnecessary costs. Inventory and product costs can be increased unnecessarily by stockpiling practices in hospital departments or through waste and inefficiency in product use. Consideration should be given to these issues during product introduction and evaluation.

Product Standardization

Product standardization eliminates duplication of products and reduces overall inventory, thus saving resources for the facility. Standardization leads to better inventory control, more efficient use of space because fewer products are stocked, less staff training than for multiple products, and fewer errors resulting from increased product familiarity by staff.⁹ However, standardization of products can sometimes be more costly if the same product specifications are used across the organization. Therefore, a customized approach to product selection may be warranted.¹⁰

Occasionally, one product will satisfy all the functional requirements of clinical care without incurring waste, inefficiency, or higher cost than necessary. However, often two or more products may be needed to meet clinical needs. Product standardization should always be a focus of the PEC, but should be considered one of many approaches to achieving a cost-effective product mix in the hospital.

Cost Control Through Competitive Pricing

The average PEC (10 or fewer members) studies about 36 products annually. Larger committees may process up to 50 or more products requests or projects annually.¹³ Product evaluation, market comparisons, and product expense benchmarking may uncover opportunities for the facility to request more competitive pricing, particularly for high-usage items. Product price management is an important tool for controlling product costs. However, facilities should not focus exclusively on price-oriented product evaluations. Conversion costs can be high for product changes when consideration is given to training costs, inventory loss, initial inventory investment, and excessive product use in the learning/implementation phase.¹⁴ Significant differences in price must exist to offset these costs. In addition, further price reductions are difficult to achieve in subsequent years.

Product initiatives focused on utilization, waste, and conformance to clinical requirements are likely to result in higher and more sustainable savings opportunities, although a greater initial investment of time may be required. A general guideline for the PEC is to spend approximately

20% of time and effort on price-related product initiatives and 80% on utilization initiatives in order to achieve maximum value to the organization.¹⁰

Influencing Purchasing Agreements

Membership in group purchasing organizations (GPOs) is a common practice in today's hospitals. One way GPOs provide value to hospital organizations is by negotiating and awarding competitively priced product contracts that can be accessed by the member hospitals. Members also gain efficiencies when the GPO serves as the negotiator and administrator of the contracting process.

GPOs can be structured as national, regional, or local alliances of member hospitals. National and regional GPOs typically incorporate a contracting process that attempts to provide high-quality products with broad clinical acceptability at the best overall value. Member input into product selection is typically obtained indirectly through surveys or directly through participation in councils or task forces. Qualitative and quantitative factors are included in the decision-making process. Audits are an essential part of the post-award process and should be conducted to ensure that suppliers comply with the terms and conditions of the contract.

Regardless of the size and composition, it is important for the PEC to understand and interact with the product selection and contract negotiation process used by the GPO. As an active member of the PEC, the infection preventionist must give input to the GPO contracting process and assist the PEC in determining whether to access the awarded GPO agreement. Infection prevention relevance, personnel, and patient safety issues may differ from hospital to hospital. Therefore, it is always important to evaluate GPO contracts for suitability for implementation at the local level.

Smaller facilities entering into purchasing agreements with larger or academic facilities may benefit from the combined purchasing power of the alliance. This alliance, however, may dictate product selection and availability for the smaller facility because of the greater influence of the larger facility in the product selection process. Care must be taken to consider all practice settings in the selection process in order to provide suitable and cost-efficient options for product purchases.

The Process

Healthcare facilities faced with the challenge of providing cost-efficient healthcare are looking at processes and groups within their facilities to monitor and reduce expenditures. The PEC/value analysis team plays a viable role in this process. The following example provides a comprehensive overview of how a committee can be structured within a healthcare facility. Structure should be designed to be compatible or maximize integration with the systems of care and administration of the facility.

Product Evaluation Committee

Committee Structure and Function

Under ideal circumstances the PEC is a multidisciplinary committee appointed by and under the jurisdiction of the administration of the facility or healthcare system. The committee functions under policies and procedures that are approved by the administration. The PEC is responsible for reviewing, evaluating, and selecting products for use within the facility or healthcare system. Some PECs have the authority to make final decisions on product selection, whereas other PECs recommend products to administrative-level decision makers.

Requests for any new product should be filtered through a PEC, but other events may provide triggers for PEC review. Yokl has suggested exploring the following sources for opportunities for review by the PEC:

- Product line price increases
- Contract expirations
- Product failures or recalls
- GPO offerings
- High dollar spend products
- High utilization products
- Vendor recommendations
- Professional organization publications
- New or revised regulations, standards, or guidelines
- Ideas from new clinical and administrative employees
- Operational and clinical benchmarking with other facilities
- Custom kits or trays¹⁰

Steering Committee

A successful PEC requires support and involvement from hospital administration. This support may begin with the establishment of a steering committee, ideally appointed by the chief executive officer (CEO) of the organization as a means of conveying executive level support. The steering committee is responsible for the overall direction and guidance of the program. The

committee should meet routinely, e.g., monthly or quarterly, to monitor and evaluate the progress of the program and give guidance to meet the program’s mission, goals, and objectives. Suggested members of the steering committee are a senior administrative executive (vice president or chief financial officer), nursing executive, medical executive, quality executive, supply chain executive, finance executive, quality improvement executive, and PEC leader(s). Alternatively, if a standing committee, such as a quality council or performance improvement committee is already in place at the facility, this committee may assume the responsibility of monitoring and managing the PEC.

The product evaluation program should have a mission statement and policies and procedures to guide its actions. All members of the steering committee and PEC should receive an orientation and training in the procedures and processes used by the committee, including attention to ethical considerations involved in product selection, purchasing, and contracting.

Product Evaluation Committees

Depending on the size and complexity of the facility, more than one PEC may be established. The committees may be segmented by service line, product group, or clinical department. Suggested PEC members and roles include:

Position	Roles
Team leader or chairperson	Actively participates in discussions and content of PEC meeting Leads team Develops and follow agenda Schedules meetings Communicates with team members between meetings
Administrative representative	Provides support and guidance on navigating political and administrative challenges Acts as liaison between PEC and other standing committees Keeps executive management team informed on PEC activities Champions PEC program
Physician representative(s)	Provides supporting information on clinical need and product relevance Champions PEC program to medical staff
Facilitator	Coordinates PEC logistics and activities Provides direction on team and project management Maintains PEC focus Manages team dynamics
Recorder/secretary	Documents discussions, ideas, actions, decisions Publishes PEC minutes Maintains PEC history Maintains and publish log of financial impact of PEC decisions
Team members	May serve a dual capacity as project leaders, assembling task forces to work on specific PEC initiatives Represent the facility, not their department Provide clinical expertise and knowledge of literature, best practices, and patient care

Suggested Team Members	Functions
Infection preventionist	Assesses product safety and considers cost and potential infection risks of products
Supply chain/materials management	Works with vendors for product information, provides cost analyses, suggests comparable and competitive products, assists with inventory control
Biomedical engineering	Provides product validation and performance to manufacturers specifications
Clinical educator	Coordinates development of educational materials, inservice training, and on-site support with vendors
Clinical representatives from medical, surgical, critical care, pediatric, and peroperative nursing; respiratory care; laboratory; or other clinical areas as appropriate	Expert product review and evaluation

A facility or hospital system may choose to establish one PEC or multiple specialty PECs. As a general guideline, establishing one PEC for every 300 census beds provides adequate support and structure. To facilitate efficient product review and avoid overlapping jurisdictions, PECs should establish a process to objectively evaluate new products and technology. The following is an example of such a process:

1. The need for a product is identified and the product is introduced to the PEC. A team member may be assigned to lead the product investigation.
2. Functional product specifications are developed.
3. Review of background information to include a market survey of potential products, review of product information from suppliers, review of literature for clinical trials, analysis of costs, and networking with other product users at different facilities.
4. Review of potential safety and infection prevention implications with an infection preventionist.
5. Develop product trial protocol.
6. Conduct product trial.
7. Evaluate trial results.
8. Present to PEC for final decision.⁷

Identifying the need for a product is a concept that is often overlooked. The PEC may literally receive hundreds of new requests each year from staff, clinicians, or department heads who have

identified products they would like to purchase. With few exceptions, these products are not needed, but still need to be investigated and value justified by the PEC. Therefore, all requests for new products may need to be placed on the agenda of the PEC for initial discussion and review. If accepted for further review, a team member can be selected as the project manager. As each team member should manage only one initiative at a time, the PEC may need to develop prioritization criteria for new product requests, based on potential savings, regulatory requirements, safety or infection prevention issues, or perceived clinical need.

The review of background information should include a review of the professional literature, clinical literature, and product information. When reviewing the literature, caution should be exercised in differentiating between company advertising and formal, objective clinical trials.⁷

If clinical need and effectiveness cannot be determined through literature review, a product evaluation/trial may be warranted. Although expensive in terms of resources and time, a carefully designed trial, structured to validate the desired outcomes, may be valuable. The expertise of the infection preventionist is well suited to the development and coordination of these trials. Use of objective criteria for evaluation and attention to analysis of results are important components of the process.

Once the trial is completed and cost and results are analyzed, the PEC will make a decision regarding the acceptance of the product. By utilizing scientific principles in the evaluation process, the cost of the product can be compared with the cost or benefit of the outcome measures to create a rationale for the decision of the PEC. This can also help avoid the perception of the PEC as a cost cutting vehicle that will reduce the quality of the facility's products. Once the committee makes its decision regarding a product, this decision must be documented in the committee's minutes. This documentation must be clear, concise, and easily understood and communicated to the original requestor.

Ensuring Training and Competence

While introducing new products or devices, it is important to ensure appropriate training of personnel to prevent potential problems with application of new technology.³ User error owing to inexperience or lack of knowledge can contribute to adverse patient outcomes, including infection and sharps injuries for the healthcare worker.

Postimplementation surveillance is also important to ensure ongoing competence, proper use, and intended outcomes from the new product. After reviewing several studies of needlestick prevention products, L'Ecuyer et al reported inconsistent results in postimplementation needlestick rates. Several studies found that healthcare workers may not use these devices or may use them incorrectly, thereby increasing the risk of injury to a greater rate than before.¹⁵ The infection preventionist should take an active role in the postimplementation evaluation of products to ensure the risk of HAIs is not increased.¹⁶

Reviewing Practice Guidelines

The product evaluation process should also include the review of relevant practice guidelines from government agencies and professional organizations, such as the Centers for Disease Control and Prevention and the Agency for Healthcare Quality and Research (AHQR). The Association of periOperative Registered Nurses (AORN), in its document, Recommended Practices for the Evaluation and Selection of Products and Medical Devices Used in Perioperative Practice Settings, identifies the following elements for perioperative product review:

1. Products to be evaluated for use in the perioperative setting should be safe, meet identified needs, and promote high-quality patient care.
 - a. Product selection should be based on a collaborative approach and involve various members of the healthcare team.
 - b. Nurses should participate in the clinical evaluation of products.
 - c. Materials management, infection preventionist, laboratory, radiology, biomedical, and manufacturers should act as a resource for information about products to meet clinical needs.
2. A mechanism for product standardization and evaluation should be implemented through a committee that has clearly defined responsibility and authority.
 - a. All departments involved in the selection, purchase, and use of a product should be represented on the committee.
 - b. Goals of product evaluation and standardization processes are to select functional and reliable products that are not economically or environmentally wasteful and do not result in duplication or rapid obsolescence of items.
3. Product evaluation should be based on objective criteria specific to the product or medical device, its function, and its use in the practice setting. Criteria should include, but not be limited to, performance, safety, efficiency, cost, compatibility with other devices or products, efficacy, standardization, quality, ease of reprocessing and sterilization parameters, availability, effect on patient care and environment, and value analysis.
 - a. Baseline clinical acceptability of a product should be determined by comparing its actual clinical performance with a preset standard or desired level of performance.
4. A trial clinical evaluation should be conducted before selection of a product or medical device.
 - a. A facility clinical trial evaluation should be initiated because of an identified need, issue, or concern.

- b. Products should be screened by appropriate committee members before a clinical trial evaluation is conducted.
 - c. All departments and clinical areas affected by a product should be represented in the clinical trial evaluation process.
 - d. Limits should be placed on the scope and time of the evaluation.
 - e. Instruction and demonstration of a product should be conducted before the evaluation process begins.
5. Policies and procedures for the evaluation and selection of products and medical devices should be written, reviewed annually, and made readily available within the practice setting.¹⁷

Selecting Product Evaluation Committee Members

Members and the chair of the PEC should be selected by the facility administration. A position description that outlines the expected contribution and responsibility of the committee should be provided at the time of appointment. Appointees must have a genuine interest in the process to ensure success. Ideally, members should have clinical experience that enables them to make informed product decisions. The chair should be committed to the process, have a working knowledge of facility operations, work well in a committee structure, and possess strong leadership skills. It has been suggested that the chair of this committee be a physician or an individual with a master's degree in business administration so the committee will have the clout necessary to function appropriately. It also has been suggested that the PEC be patterned after the pharmacy's formulary committee and carry the same degree of professional stature and expertise.¹⁸

Membership should be cross-functional by design, in which team members serve dual roles as project managers. This may be necessary in order to complete an optimal number of projects each year to achieve clinical and cost goals. Product evaluation committee members should expect to transition into project managers as the PEC leader assigns them project or products whose evaluation must be planned, trialed, and potentially implemented. They concurrently serve as PEC members, responsible for reviewing reports and findings of other team projects and participating in the approval process for team activities. Projects should be time-based and conducted in an expeditious manner or staff will become disillusioned with the process. Therefore each project team will need administrative support and commitment to facilitate and problem solve when the need arises.

Projects may be more successful if administrators and team leaders are not appointed to lead project teams for which they have ownership of the commodity group or product line to be investigated.

Team members (who may also function as project leaders) will be charged with ensuring that the lowest-cost functional alternative product is selected for use in the facility. In doing so, they will be expected to:

- Represent their facility or unit in deciding on the best solutions for the healthcare organization as a whole
- Share the responsibility for making the PEC a success
- Be an advocate for the PEC process to their peers and their own facilities or unit

Team members should be cooperative, open minded, team oriented, good listeners, and good communicators. They should be analytical thinkers, organized, enthusiastic, reliable, results oriented, open to challenges and change, adaptable, committed to savings opportunities, disciplined, and tenacious.

The role of the PEC is sometimes redefined to use members' time more efficiently. Some healthcare systems use a decentralized approach to identify products and technologies for review, coming often from their centers of excellence, specialty areas, and departments.¹⁹ Decisions are made on a departmental level, and the organization's PEC may be required to address only items whose cost exceeds a preset amount or that affect the majority of patients or personnel. As these changes evolve, the process must allow the infection preventionist to provide the necessary input into decisions related to infection prevention.

Off-Label Use

One role of the PEC that is sometimes overlooked is the awareness and responsibility associated with the off-label use of products. The infection preventionist should play a vital role in the management of this issue.

To fulfill its role in the protection of public health, the Food and Drug Administration (FDA) has implemented a review and approval structure for medical devices. This structure is composed of the Pre-Market Approval (PMA) and Pre-Market Notification (510k) approval processes; guidelines for which are listed in the Federal Food, Drug, and Cosmetic Act. Through these processes, the FDA designates the labeled or indicated use for the product, based on the safety and effectiveness data submitted by the manufacturer. Off-label use is the application of the product for a purpose that is not included in the approved device labeling.

Off-label use can occur in reasonable and studied applications, expressly contraindicated applications, or misapplication based on lack of proper education and training. Despite the existence of potentially valid and valuable reasons for off-label use, inappropriate off-label use is a risk that must be acknowledged, understood, and controlled.²⁰

The PEC and infection preventionist must ensure that labeled indications for a product align with its intended use, prior to introduction for use in the hospital. If approval is sought for off-label

indications or off-label use is discovered for a currently used product, the PEC should initiate a review. Some of the questions to consider might include:

- Is the use supported in the medical literature?
- Is the use contraindicated?
- Is there an approved alternative device available?
- Has the use been carefully reviewed?
- Is training needed for this use?
- Is there a protocol or procedure written for the use?
- If there is a product-related incident, what will be the manufacturer, user, and hospital liability?

One very common off-label product use is the reprocessing of single-use items.

Single-Use Items

The 2009 Joint Commission Standard IC.02.02.01 states that hospitals who reprocess single-use devices must implement infection prevention activities that are consistent with regulatory and professional standards.¹ Therefore, the infection preventionist is an essential decision maker regarding the reuse of single-use items. Product cost is usually the incentive that prompts consideration of reprocessing and reuse of these items. When considering the reuse of single-use items, the healthcare organization should include the infection preventionist, hospital administration, legal counsel, risk management, supply chain administrator, and liability insurance carrier in the decision-making process. Because the facility's sterilization and processing procedures are not consistent with those found in industry and the risk of infection can be great if items are not properly processed, reprocessing through a third-party organization is recommended.

Third-party reprocessing activities are regulated by the FDA, must follow strict guidelines for reprocessing, and in many cases require submission and approval of a 510k submission. Detailed guidelines for submission of reprocessing validation data can be found in the 2006 FDA Guidance Document on the topic.²¹ Submissions must include detailed cleaning, process, process validation, sterilization, functional testing, and product release procedures. This assures the quality and safety of the product and adherence to a predetermined standard.^{22,23}

The infection preventionist should review these processes, actual data collected during these processes, results of FDA inspections of the reprocessing facility, and FDA recall data as part of the product introduction process. A site visit to the reprocessing facility is recommended. Hospital policies should address the hospital's position on reprocessing and specify the devices

approved for reprocessing. Each subsequent request to reprocess a product should be subject to full review by the infection preventionist and the preceding group for approval.

Needles and Sharps

The U.S. Department of Labor issued its final rule in 2001 for Occupational Exposure to Bloodborne Pathogens: Needlesticks and Other Sharps Injuries. The revised Needlestick Safety and Prevention Act authorizes the inclusion of safety-engineered sharps devices to the Bloodborne Pathogens Standard.³ To be compliant with the law, healthcare facilities shall:

- Provide safety-engineered sharps devices and needleless systems to employees to reduce the risk of occupational exposure to bloodborne diseases, and
- Solicit input from employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective safety-engineered products and work practice controls.
- Document the solicitation of input in the Exposure Control Plan.
- Maintain a sharps injury log to record injuries from contaminated sharps. The injury log must contain the type and brand of product involved in the incident, the work area where the incident occurred, and an explanation of how the incident occurred.

The PEC and infection preventionist play essential roles in the evaluation of sharps products. The process will become more robust by the incorporation of the data generated from the requirements of the Standard.

CONCLUSIONS

As economic pressures in healthcare increase, the philosophy of product selection must continue to be objective, scientific, and need-based. Because many elements must be considered when products are being selected for use in the healthcare setting, it is likely that the PEC will continue to play an important role in improving patient outcomes, promoting employee safety, and affecting the organization's bottom line. The infection preventionist brings a unique and vital perspective to the product selection process by mediating pressure on resource utilization (e.g., reuse of medical devices), evaluating and reducing infection risks associated with product change, ensuring patient safety, and providing expertise in clinical literature review.

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SUPPLEMENTAL RESOURCES

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