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Learning objectives

1. *Understand the role that Sterile Processing Department managers play in the evaluation and adoption of new technologies.*
2. *Identify the steps of a clinical review.*
3. *Understand the true cost of product changes.*
4. *Perform a financial analysis.*

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SELF-STUDY Series

Incorporating new technologies in the SPD

Thorough product evaluation for optimal patient care

by Heide Ames, Brian Thomas, Joseph Keane, and John Wheeler, RN, BSN, MBA, CNOR, STERIS Corporation

Every healthcare facility strives to provide the highest level of patient care while maintaining fiscal responsibility. Hospitals are continually exposed to new products that promise improvements in patient care delivery or pledge the same care at a lowered delivered cost. How is a facility to know whether it's best to adopt a new technology or replace what they are using with a less expensive product? A systematic process must be in place to evaluate the quality and performance of new supplies and medical devices before they are adopted. This process considers the clinical effectiveness of the product, the risk tolerance of the healthcare facility and the complete cost to the facility of using that product.

Sterile processing departments (SPDs) have a critical connection to patients. Products and procedures used within these departments can have detrimental effects on patients. For example, a non-sterile medical device can lead to a surgical site infection.

SPD managers are expected to provide the business case for any product change and also to defend existing products from less expensive versions that do not provide the same level of performance. The SPD manager is also the negotiator balancing perceived and actual risk with perceived and actual cost. This is a tall order.

How do SPD Managers impact the evaluation of new products?

The information provided by SPD managers can be critical to the successful evaluation and adoption of new products. To see how, let's look at two examples.

Example 1:

In one facility, the SPD manager presented product X for review and adoption by the facility. A clinical review of Product X indicated that there was the potential for a 1% reduction in surgical site infections. The estimated cost to treat those infection cases was \$30,000 annually. This appears to be a significant savings. However, Product X would cost \$40,000 annually to use. The hospital administration decided that it was fiscally

sounder to continue use of the existing product rather than change to Product X, since it resulted in a perceived \$10,000 annual spending increase.

In a different facility, the administration decided that this same Product X was worth the price. After considering the costs associated with the rare event of serious complications from infection, and adding in the "soft" costs associated with increased hospital stays, it was determined that the annual expense to the facility from surgical site infections was closer to \$50,000. With the same product cost, this meant a savings of \$10,000 rather than added expense.

Example 2:

A materials manager identified a sterilization pouch at half the cost of what the facility was currently paying. Following the clinical review, which did not include a trial, the product was adopted. Shortly after starting to use the new pouch, the OR staff began to complain about the pouch shearing when it was opened. The shearing resulted in contaminated instruments, a higher rate of instrument reprocessing, and eventually a return to the previous pouch product.

The impact of the SPD manager

In both examples, the SPD manager played a critical role. In the first example, the SPD manager in the second facility was able to provide his administration with a more complete, facility-wide picture of the true costs of a surgical site infection. This allowed management to have a better understanding of costs associated with infections and the savings the new product would bring.

In the second example, the materials manager failed to test the product to ensure that it worked as required for all affected parties, including the OR. If the trial had been completed first, the productivity and financial losses would have been avoided. Ultimately, it is the SPD manager who must effectively champion or discredit new products being considered for use by the SPD.

The Clinical Evaluation

New products must meet three requirements; performance, safety and budget. It is up to the SPD manager to demonstrate that each requirement has been met. Performance and safety are determined through evaluation of clinical data and a clinical review. These are typically done by a cross-functional clinical review team that includes an infection control professional, an SPD manager, an OR manager and other interested parties as deemed appropriate for the product. For example, medical technicians may be brought in to review equipment.

First step- gather and review data

Obtain data about the product and its performance claims. The manufacturer should provide laboratory reports, technical data, use instructions and any other pertinent information about the new product. Also look for independent test data. Independent data can come from trade journals but has greatest strength from independent certification laboratories and peer-reviewed journal articles. Also consider web sites and chat rooms provided by professional organizations. These will often provide basic information and allow you to query others using the product.

Once the data is compiled, perform a review of the findings. The clinical review team must be given all documentation well in advance of the team meeting to allow time to read and understand the materials. A brief summary of the major points with a recommendation for next steps should also be included by the person requesting the review (champion). During the review meeting, questions to ask include:

- 1) Does the product require FDA clearance? If so, where is the supporting documentation?
- 2) Does this product meet the recognized guidelines and standards for these products?
- 3) What testing has been provided? If laboratory testing only, is there any field testing or a reference you could speak to?
- 4) Do the data reports support what the product's sales person states?
- 5) If a trial was performed, did the product perform as expected during the trial?

Be thorough and ensure that each question is answered. Contradictory data must be reconciled. Companies often have clinical support groups and sales representatives who can help to answer questions on the product's data and applications.

Second Step- compare products

Compare the new product with the old product, if possible. If this is a ground-breaking technology, it may be difficult to make this comparison. However, look-alike and "im-

proved" products should allow for easy comparison. When evaluating a look-alike product, ensure that the same applications are set up for both products. Invite a staff member to give their opinion on the product's ease of use. Be aware of human error; everything from color blindness to English as a second language should be considered.

The same evaluation should be performed when looking at an improved product, with an emphasis on what makes the product better. Look at comparative test data. Determine what recordable activities can be performed to measure this improvement in the facility. If it cannot be measured by the facility it should be verified in some other way.

New ground-breaking technologies are a challenge for any clinical evaluation team to assess. These technologies almost always have no recommendations from guidance organizations and are proprietary. They often replace a well-established function currently being performed. The first reaction is often "Let's see someone else use it first."

Do not be afraid to adopt innovative technologies, but be careful in your preliminary evaluation. Ensure that these technologies have been recognized by FDA for the applications specified by the manufacturer. If there is no guidance from national organizations, look towards international organizations or respected countries already using the technology. What are they doing and why? Make a comparison between what this technology offers and the process or products being replaced. Pay particular attention to how the new product compares to the use applications of the current products.

If the product is so new that it is addressing a need that was never addressed before, the clinical team should evaluate whether that particular need is present in their facility. If it is, review that need and how this product addresses it. For example, if the need is to make high-level disinfection safe, the clinical team would need to review whether high-level disinfection is needed, and if so, what aspects of their current process are unsafe. From there, the new high-level disinfection product would need to demonstrate that it can provide high-level disinfection in a safer manner than what is currently used.

Third Step- evaluate safety

Review the product's safety features. The safety review is more than making the patient safer; this review should also consider hospital personnel, hospital equipment and facilities, and the environment. Does the product under review have ergonomic features? Does it require special containment methods? Is it recyclable

or biodegradable? When all else is equal, it is the additional safety features that will differentiate one product from another.

Products that have unexplainable contradictory test data or cannot provide appropriate supporting information, such as FDA clearance documents, should not receive approval from the clinical committee.

The Trial

A trial is not always possible or necessary. Many products can be adopted without trialing. However, whenever an improved or ground-breaking product can be trialed, it should be. If trialing is not possible, ask for a reference site where staff can observe the product in action.

Hospital trials are not intended to replicate scientific test data performed by manufacturers or test laboratories. Rather, they are intended to provide a level of comfort with the product's use and performance. Trials can take as long as a couple of months, depending on the complexity of the product, but most can be done within two weeks.

Trial Step 1:

Identify the objectives and expected results

This step is most important, since it sets the measurable criteria for comparison. Identify the key comparators and what the passing and failing results will be. Seek expert advice on how the product should be trialed (the manufacturer of the product can usually provide insight). For example, when comparing cleaning detergents, a passing result for a new detergent could be a decrease in instruments requiring re-washing, a decrease in spotting, and/or using less detergent to get the same result. Do not forget to also include a subjective measurement of user satisfaction.

Step 2: Test protocol

Once the objectives are identified, outline how the trial will be conducted, who will do it, and how to document it. Step-by-step instructions should be available during the trial. In addition, the current product and methods should be used simultaneously. Results from both methods should be recorded for review.

Some facilities may wish to replicate test data provided by the manufacturer. Before considering this, ensure that you are using equipment identical to that used by the manufacturer. If this is not possible, ask the product vendor what testing could be performed to verify the data. It is unlikely that a facility will be able to

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Answers	1. a
	2. a
	3. c
	4. b
	5. b
	6. a
	7. b
	8. c
	9. b
	10. b

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duplicate the manufacturer's testing due to the need for specialized equipment.

Step 3: Report on results

The report should answer the following questions: Was each objective met? If not, how and why not? It is important to note that a new product may give a different response but that response may not be wrong. For example, a trial of a Class 5 integrator challenge pack for steam sterilization may show a "failing" result even if the biological indicator is dead. In this case, this result would be expected because a Class 5 integrator measures more of the sterilization parameters than a biological indicator alone, so it is providing additional information.

The Financial Evaluation

As with other businesses, healthcare providers have spending and cost containment requirements placed on them. They must consider new technologies carefully and determine which products will meet all their requirements at an optimal cost.

The financial evaluation ultimately rests with material management, but the SPD manager must encourage the analysis and ask the probing questions to ensure that a thorough evaluation is completed. After all, only the SPD manager understands the implication of product changes in the SPD.

The paramount consideration in the selection of any product related to patient care must be its effectiveness. Competing products have different levels of quality, effectiveness, claims and supporting data that affect the price. If a selection is being made based on price alone, the facility may show a short-term financial benefit, but in many cases, patient care may be negatively impacted over the long term, as well as hospital productivity, safety and efficiency, which can also affect the "bottom line."

In addition, the cost of swapping out a technology before the end of its expected life cycle can be substantial. The expenses for staff training, replacement equipment, and any required modifications could wipe out any projected savings from buying lower cost equipment.

Total cost

What does management evaluate as part of a financial evaluation? The price of the product is one factor, but many products may have additional costs that are not immediately obvious. Complex equipment will require preventive maintenance, servicing parts, accessory equipment (like readers for instrument tracking and incubators for biological indicators), consumable supplies such as cleaning chemistries for washers, and other costs.

Any time there is capital equipment involved, the cost of the equipment will be spread out over a period of time, which is usually the equipment's useful life expectancy. For example, one sterilizer lasts 10 years and cost \$50,000; another sterilizer lasts 20 years and cost \$60,000. In simple terms, the first sterilizer's cost is accounted at \$5,000 per year and the second sterilizer "costs" \$3,000 per year. The second sterilizer is the better deal even though the initial price is higher.

In a second example, both sterilizers cost the same and have the same useful life. However, the first sterilizer, on average, requires \$2,000 in preventive maintenance services while the second sterilizer only requires \$1,000 in services. The second sterilizer proves to be the better deal. When evaluating the total cost of ownership, it is important to look at product cost, necessary accessories cost, required consumable costs on an annual basis, and any service costs that may be required.

"Soft" costs are the hardest to identify and justify. These costs tend to come from productivity and potential costs that may not be realized. For example, if a facility is comparing detergents, there may be a higher instrument reprocessing rate (due to ineffective cleaning) with one product. Repeating the cleaning process means more labor time, slower turn times for instruments and the possible delay of surgeries. The delay in surgery typically has an hourly cost assigned to it that is considered a "soft" cost.

Savings

The SPD is not a revenue-producing department in a hospital, so their financial focus is on savings. The most obvious savings in the SPD come from the total costs associated with a new product. When evaluating the costs of consumables such as detergents or pre-soak chemistries, the cost is calculated over a one-year time frame.

There are other ways to realize savings in the SPD. Just like there are soft costs, there are also "soft savings." For example, evaluate the labor- and time-saving workflow steps that could be made possible with new automated washing or sterilization technology and the process simplification that might be possible as well. Savings in labor and time may allow for reallocation of workers and an increase in productivity. Significant productivity increases can result in additional revenue. For example, by reprocessing items and returning them to surgical inventory faster, the SPD is helping the surgical department complete more cases, which can yield more revenue for the hospital. Also look into ergonomic and safety features on new tech-

nologies that can help the SPD save on workplace injury costs.

Regardless of whether you are evaluating soft cost or soft savings, be realistic in your judgments. Never exaggerate or underestimate the soft savings and costs.

Contracts

Contracts may allow materials managers to obtain the best price for the items they purchase. It can be easy to change a product that is on contract with a company to a different product sold by the same company. However, changing from the contracted company to a different company can be difficult. Your organization should determine when the contract expires, if there are clauses in the contract that allow you to switch to new technologies, or if a percentage of your purchases can be with a different company, for example. A little research can yield a world of information.

Group Purchasing Organizations

Group Purchasing Organizations (GPOs) can be another powerful tool for materials managers. GPO agreements vary greatly, so it is important to know and understand the terms. Members of GPOs have the ability to request that new products be added to the buying list. Be prepared to justify why it should be added and share your clinical review information.

Rebates and other incentives are often tied to GPO contracts. These programs are designed to drive compliance with the GPO product list or develop loyalty with a particular vendor, but are not absolute. For example, switching one product category may not interfere with the program. It's important to include any rebates or other incentives that may be lost or gained by switching products into the cost analysis.

Making a decision

Risk management plays an important role in the final selection of product. Some decisions may be easy – choose the same product, with no change in risk, at a lower cost. Other decisions may require more debate because they involve a different product, with a slightly higher risk, at a lower cost. Other decisions may require a change in the facility's policies and procedures because they are adding a new technology that reduces risk, at a higher cost. Management weighs the options, determines the amount of risk the facility is willing to take and then makes the final decision.

Conclusion

New product evaluation is inevitable in today's ever-changing, technologically advancing world. These evaluations, if approached systematically, can greatly

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benefit the SPD and the quality of patient care provided by the facility.

The evaluation must take into consideration the clinical effectiveness of the product, the total cost to the facility of using that product, and the risk tolerance of the healthcare facility.

Only when a balance among product performance, costs and risk management is achieved can a product change be successful. **HPN**

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CONTINUING EDUCATION TEST — November 2006

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Circle only one answer:

1. When evaluating new products for use in the SPD, it is important to determine true costs of the product for the entire facility, not just the SPD.
 - a. True
 - b. False
2. Ultimately, it is the SPD manager who must champion or discredit new products being considered for use by the SPD.
 - a. True
 - b. False
3. New products must meet three requirements: Performance, safety and _____.
 - a. CEO approval
 - b. GPO availability
 - c. budget
 - d. None of the above.
 - e. All of the above.

4. Which of the following is not one of the steps of a clinical review?
 - a. Obtain data about the product and its performance claims.
 - b. Determine if the product is available through the facility's GPO contract.
 - c. Compare the new product with the old product, if possible.
 - d. Review the product's safety features.
5. When evaluating "ground-breaking" technologies, it is not necessary to ensure that these technologies have been recognized by FDA for the applications specified by the manufacturer since they are new to the market.
 - a. True
 - b. False
6. A safety review should consider the patient, hospital personnel, hospital equipment and facilities, and the environment.
 - a. True
 - b. False
7. Safety of a product is determined by a trial on a test patient.
 - a. True
 - b. False

8. Which of the following should be included when evaluating equipment costs?
 - a. Product cost
 - b. Accessories cost
 - c. Consumables cost
 - d. Service cost
 - e. All of the above
 - f. None of the above
9. Which of the following should be the paramount consideration in the selection of any product related to patient care?
 - a. Total cost of ownership
 - b. Effectiveness
 - c. Quality
 - d. The bottom line
10. An example of soft savings is _____.
 - a. A GPO rebate.
 - b. Labor savings and increased productivity due to automation.
 - c. A lower price on accessories.
 - d. A savings on servicing equipment.

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