FEATURE

Clinical Bulletin

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Considering New Technologies?

Multidisciplinary Risk Assessments Help to Pave the Way

New technologies are being developed that help facilities reduce the chance of infection transmission from reusable medical devices. Unfortunately, published standards can't keep up with the technological advancements due to the lengthy process for updating guidelines and recommended practices. This often puts healthcare providers in a difficult situation.

Healthcare institutions need a path by which to evaluate and adopt new technology and processes that current standards presently do not address. AAMI ST58 states that:

> *"When any product is being considered for use within a facility, it is the responsibility of the intended users to evaluate the product using a systematic process of product evaluation and to establish policies and procedures that reflect this process and that are appropriate to the health care organization"*[1]
>
> - ANSI/AAMI ST58

This is especially true when the healthcare organization is considering a product for which there are no guidelines from AAMI or other similar professional organizations.[1]

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A healthcare institution can adopt a new technology or process that surpasses current published standards, provided the team can provide evidence that they have undertaken a conscientious process of evaluation, generally called a risk assessment (RA), before making the change.[1]

The RA should be multidisciplinary and include representatives from all stakeholders such as central processing, clinical staff, infection prevention and control, risk management and other relevant subject matter experts. For reference, key elements of an RA are summarized in Figure 1 and discussed below.

Addressing technology advancements in the Healthcare field
A checklist for conducting a Multidisciplinary Risk Assessment

- ☐ Establish a Committee
- ☐ Establish a Goal
- ☐ Collect and Analyze Critical Information
- ☐ Explore Health, Safety, Compatibility and Cost issues
- ☐ Test the Product
- ☐ Prepare a Recommendation

Figure 1: Summary of steps involved in a multidisciplinary risk assessment (RA) to provide evidence of a conscientious evaluation process prior to adopting new technologies.[2] Modified from Seavey 2017.

The multidisciplinary RA committee should establish specific goals or outcomes the new technology or processes should address, for instance, the new technology will:

- Decrease the chance of cross contamination,
- Increase efficiency,
- Decrease staff exposure to chemicals,
- Decrease damage to equipment, and/or
- Decrease cost and so on.

After establishing the goals, the committee should gather and review pertinent information including but not limited to:

- The product's FDA 510 (k) clearance letters,
- The device manufacturer literature and written IFU,
- Reviews from key opinion leaders,
- Experiences from current users,
- Model policies for product use,
- Product validation studies,
- Peer reviewed articles and other relevant information.

Instructions for use (IFU) may not include new technology so ensure the technology satisfies all of the other criteria. It is also important to thoroughly review the validation studies and the Food and Drug Administration (FDA) 510K clearance indications for use for the device (if applicable).

It is also helpful to discuss new and emerging technologies with peers who may be familiar with the products. Considerations should emphasize the health and safety of patients and staff, the effectiveness of the product, materials compatibility and of course cost effectiveness.

The RA should include a written report addressing the trial findings that take into account goals, benefits, weaknesses, financial impact, and rationalization for the decisions. A written record provides an easily referenced and clear-cut system for both internal and external process review.

Technology will continue to advance, therefore healthcare facilities should establish internal evaluation policies that include risk assessments that are multidisciplinary and look at the benefits to the patient as well as the facility.

Rose Seavey is President/CEO of Seavey Healthcare Consulting and formerly the Director of the Sterile Processing Department at The Children's Hospital of Denver. Rose served on the AORN Board in 2008-2010. Rose is a past President ASHCSP. She received numerous awards such as AORN's award for Mentorship in 2012 and Outstanding Achievement in Nurse Education in 2001. In addition, she received the national 2013 IAHCSMM award of Honor, the Industry Leadership Award from the Massachusetts chapter and the educator of the year award from the Golden West chapter. She was one of the Who's Who in Infection Prevention in 2006 by Infection Control Today. Ms. Seavey is the author of the book tilted Sterile Processing In Healthcare Facilities: Preparing for Accreditations Surveys, published by AAMI and she serves on several AAMI committees writing standards.

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