Adopting New Technologies by Using a Multidisciplinary Risk Assessment

SAFE PATIENT CARE IS THE MOST IMPORTANT ISSUE TO HEALTHCARE professionals. Technology is ever-changing in the healthcare field and is often an important part of decreasing the risk of infection transmission, improving efficiency and reducing the cost of care; however, despite the potentially significant benefits of new technical advancements, healthcare facilities are often slow to adopt new technology if published national standards and guidelines do not yet address them.

OBJECTIVE 1: DISCUSS ISSUES AND CONCERNS WITH ADOPTING NEW TECHNOLOGY

Standards, guidelines and recommended practices, such as those created by the Association for the Advancement of Medical Instruments (AAMI) and the Association of periOperative Registered Nurses (AORN), are only updated every five years; therefore, they may not address the newest technology and can be a barrier to the adoption of new and emerging technologies.

ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* has been on a continuous maintenance process, however, even with the additional amendments, it can’t possibly keep pace with new technological advancements.

The process of updating AAMI recommendations and subsequent amendments requires stakeholder meetings (including manufacturers’ representatives, laboratories, federal regulatory agencies, and healthcare workers), a public comment period, and then final adoption by the Sterilization Standards Committee. The updating process is arduous and can typically take years, by which time new advancements more than likely have come to market.

In addition to standards not being able to keep up with these new developments, updated manufacturer’s instructions for use (IFU) reflecting these new technologies may not yet be available.

Healthcare facilities need a way to evaluate and adopt newly-developed products and technologies that national standards or device IFU do not presently address. Facilitating an in-house multidisciplinary risk assessment (MDRA) is a better alternative to waiting until the recommended practices and IFU catch up with technological advancements.

Healthcare facilities are held to demanding standards by regulatory bodies such as the US Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS), and accreditation organizations like The Joint Commission (TJC).
OBJECTIVE 2: DESCRIBE HOW TO PERFORM A MULTIDISCIPLINARY RISK ASSESSMENT FOR ADOPTING NEW TECHNOLOGY

When a healthcare facility elects to adopt technology that surpasses current standards, the organization should undertake a rigorous process of evaluation, commonly called a “risk assessment,” before implementing the change. Healthcare facilities should provide evidence discovered by the risk assessment or run the risk of being cited when audited by accrediting agencies. Being cited could result in the loss of certification and accreditation, which could have huge financial consequences for the healthcare institution.

SYSTEMATIC APPROACH FOR MULTIDISCIPLINARY RISK ASSESSMENT

Healthcare providers can evaluate new products that may not be covered by existing standards by following recommendations from AAMI and AORN on conducting an MDRA. These recommendations offer much-needed guidance and clarity for healthcare organizations wanting to implement new technology.

Steps for conducting an MDRA for adopting new products or programs is to establish if there is a need. There are many avenues by which a new product may be brought to the attention of a healthcare institution. It usually starts with a champion, a person who believes in and wants others to know about the product and its benefits. This champion could be a Central Service (CS) technician, a nurse, a surgeon or an infection preventionist.

BUILDING THE COMMITTEE

If adopted, the new technology will more than likely have an impact on other departments in the healthcare system. Therefore, to ensure all stakeholders have a voice in the evaluation and decision processes, an inclusive MDRA committee should be created. It may be impossible to foresee all benefits or risks associated with using a new product unless all of the stakeholders are represented. The committee’s composition will depend on the number of people or departments potentially affected by the technology under evaluation.

The makeup of the product evaluation and selection committee will depend on the product or technology under evaluation. As a general rule, anyone who is going to be impacted by the decision should be represented. “For example, for a product related to steam sterilization, representation could include, but not necessarily be limited to, Infection Prevention and Control, Operating Room, Sterile Processing, Risk Management, and Staff Development/Education.”

If the product under evaluation is a major technology change, every effort should be made to include a champion at the administrative level as well. This person can often be a gap between the “front line” and the C-suite. They are familiar with the organizational political climate and budgetary constraints, and may be helpful in navigating them successfully.

A manufacturer representative should also be considered to be part of the process. He or she brings a wealth of information and product access that can be critical for the evaluation. Manufacturers’ representatives can provide both clinical and technical data related to product research, processing, packaging, disinfection, sterilization, and environmental conservation. Giving this individual an opportunity to be a part of the process can provide the committee with ready access to this information, potentially saving time and resources.

IDENTIFY THE GOALS

Healthcare organizations should not adopt technologies just because they are new and exciting. The new technology should have a clear objective (or goal) to truly advance patient care, improve patient satisfaction, reduce operating costs or make a significant enhancement to current processes. Each of the goals should be established and validated by the committee.

New products or technologies can bring a bit of uncertainty. Even after careful review, unforeseen negative impact can still be possible. Early adoption of new technology can put an organization ahead of its competitors; on the other hand, if the product has hidden issues, the early adoption could eventually
The committee must gather and evaluate important information regarding the new product after the agreed upon goals have been established. The materials and documents to be reviewed should represent a broad range of professional interests and perspectives within the organization. MDRA committees should employ all their resources, from working with the vendor to searching electronic sources and reaching out to others within their professional networks to obtain the critical information.

Depending on the product or technology under review, the informational documents may include:
- Literature from the device manufacturer, including written IFU;
- FDA 510(k) clearance letters;
- Product validation studies;
- Reviews from key opinion leaders (KOL) in the field;
- Experiences from past users;
- Model policies for product use; and/or
- Peer-reviewed articles.

If the product or technology is new to the market, peer-reviewed published articles may not yet be available; therefore, the committee may have to rely on generated data by the product manufacturer and KOLs.

AORN and AAMI’s published guidelines and standards advocate that the device manufacturer’s written IFU be followed. Unfortunately, many IFU are not inclusive or are outdated. For example, a manufacturer’s IFU for a surgical instrument may not include a new sterilization system, although the technology satisfies all of the other criteria noted for consideration in the evaluation. This can put a new technology at a major disadvantage since extensive IFU have not developed at this early point in the product life. Often, medical device manufacturers may demand the new technology have a sufficient installation base (a number of units already in use) to justify using their resources to update their written IFU. Ironically, it is difficult for the new technology to build an installation base without including the device manufacturer’s IFU; therefore, the MDRA team should take that into consideration. The committee should methodically review the validation studies and the FDA’s 510(k) clearance Indications for Use for the device.

Committee members can also pull information from informal sources such as their professional networks. When attending national or local conferences and vendor exhibits, committee members can discuss emerging technologies and collect information that can be useful in the formation of their decisions.

Important information can also be gathered via benchmarking with like healthcare organizations. By identifying gaps between the performance of their organization and that of top performers, the team can more successfully establish whether the new technology can meaningfully reduce these shortfalls.

**OBJECTIVE 3. DEVELOP A CHECKLIST FOR CONDUCTING A MULTIDISCIPLINARY RISK ASSESSMENT**

Whenever new technology is reviewed by a facility, creating a checklist of the important issues to trace the outcomes of that review can be an important tool for tracking the data necessary to make a logical decision.

**IDENTIFYING SAFETY OR HEALTH ISSUES**

When a healthcare facility brings in new technology, it more than likely will affect many people. In order to determine whether this impact will be positive or negative, and whether the organization will be willing and able to embrace the change, the committee should take into consideration issues such as safety, health compatibility and overall cost.

The primary concern should always be the health and safety of patients and staff. In spite of any other benefits, new technology that does not improve, or at least sustain, levels of health and safety should never be adopted. The committee should concentrate on whether the new product has the ability to improve patient care and whether there are any potentially negative impacts on overall safety.

The main question should be, “Does this new technology do what it promises to do?” The most important information about effectiveness will likely come from validation studies, FDA clearance letters, reviews of product use in other healthcare organizations, KOLs, and in-facility trials.

A critical part of the continuous quality improvement (CQI) process is the use of scientific data because there is no data more objective than scientific or quantifiable data. Therefore, scientific information should be given more top priority in the decision-making process.

Another safety issue to consider is whether the product is user friendly. For example, does a new piece of equipment increase or decrease the possibility of human errors due to staff having to make a decision on which button to push?

**IDENTIFYING MATERIAL COMPATIBILITY ISSUES**

One important thing to consider prior to making a decision on new healthcare technology is its compatibility with existing equipment and devices. Consequently, it is imperative that the committee explore whether there are any compatibility issues in integrating the new product into existing devices.
EVALUATING THE PRODUCT’S COST EFFECTIVENESS
When evaluating the cost of adopting a new technology, the initial purchase price should not be the only consideration. The committee must evaluate the total cost cost-effectiveness as it’s a more extensive and telling measure than can be calculated by looking at purchase price alone. The purchase price of a new product may exceed the existing technology; however, the important metric is the cost of operation over the product's lifetime. Here is an example: If a new sterilizer has a shorter cycle time than existing technology CS could turn instruments around more rapidly; thereby, reducing the need to purchase additional sets to match the OR’s schedule.

The committee should ensure they have evaluated all costs to include any other products, such as disposables, that may be needed for the new technology.

PERFORM IN-HOUSE PRODUCT TESTING
Product testing in one’s own facility is always the best form of evaluation. Testing in-house allows the organization to see as realistically as possible how the new technology will affect the everyday procedures in the institution.

In-house testing is best when the facility assigns a testing subcommittee team. Not all products can be tested in house; it often depends not only on the supplier in question, but on the nature of the product itself. Vendors may not be able to make highly technical or physically large products available for trial. When a trial is possible, the testing subcommittee team needs to adhere to the same rigorous and deliberate way the MDRA committee applies the product evaluation process, as a whole.

The trial subcommittee should set and pursue a clear product testing procedure and schedule to ensure that the trial is sound and the results reliable. Common steps in a trial process include but are not limited to:

- Stating the desired outcomes;
- Establishing a time limit for the trial;
- Developing a product evaluation tool;
- Planning and completing any necessary pre-trial training or inservice;
- Conducting the trial;
- Gathering important data;
- Analyzing the data; and
- Determining the degree to which desired outcomes can be met.

Steps may be added or deleted to reflect the needs of the facility or the characteristics of the product.

MAKING A RECOMMENDATION AND CREATING A REPORT
After the assessment period, the MDRA committee should be very familiar with the new product, the technology and the benefits and/or associated issues. Once a decision is made regarding the new technology, the team must share the decision with those responsible for purchasing and associated planning. The best method for sharing this type of information is preparing and distributing a report, along with an executive summary, to highlight the important points. Besides providing a means of information sharing, the report also serves as the documentation and written record of the definitive findings.

The generated report should be methodical, but to the point. The readers should be able to review important information rapidly and plainly to be able to understand how the decision was reached. The report should contain the goals, benefits, weaknesses, financial impact, the decision and the justification for the decision.

CONCLUSION
Healthcare technology will continue to advance in efforts to decrease the risk of infection transmission, improve efficiency and decrease the cost of care. Before new technology is introduced, however, healthcare organizations should establish specific product evaluation policies that include an MDRA.

The gap between the wants and needs of healthcare employees and the C-suite decisionmakers can be a challenge. Improved patient care is always the most important issue; however, how the improvements are measured will often differ with each group. These different measurements can result in communication barriers that could slow down the implementation process.

All team members involved in the MDRA should have the opportunity to speak their opinions and listen to others prior to a final decision. The main question that each team member should answer is, “What is the benefit of the product to our patients?”

REFERENCES
1. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79: 2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, Section 12.
2. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST58: 2013, Chemical sterilization and high-level disinfection in health care facilities (section 5).

RESOURCES