A Systematic Approach to Adopting New Sterilization Technologies in SPD and the OR

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Objective

Describe a multidisciplinary risk assessment approach for adopting newly developed equipment, products, processes or technology that current standards do not address.
Technological Advancements
Sterilization and High-Level Disinfection

Critically important
• Lengthen and improve quality of life
• Improve patient care
  • effectiveness, and
  • efficiency
• Decrease turnaround time of reprocessed items
• Help compliance with published standards
Adopting New Technology
Issues and Concerns

Implementation is often delayed, despite the potentially significant immediate benefits

✓ wait for updated standards, and
✓ manufacturer’s IFUs reflecting new technologies
  • Companies often do not “work” well together

Skimpy resources provided to non-generating departments, such as Sterile Processing
Standards/Guidelines Can be a Major Barrier

Developing standards is a lengthy rigorous process

- AAMI standards require a consensus review process by all stakeholders:
  - Manufacturers,
  - testing laboratories,
  - regulatory agencies,
  - professional associations,
  - users, and
  - interested parties
Developing or Updating Standards

Comments submitted by working group
- Editorial
- Clinical implications
- Process changes – current research

Review process
- Face to face meetings
- Conference calls

Consensus for a draft document
- Substantial agreement among stakeholders

Committee ballot
- More comments
- Additional review process
Consensus Can Take Years

Draft standard for public review
- Opportunity to review/comment
- Each comment responded to in writing
- If changes: new version subjected to additional ballot and public review

Committee agrees - consensus

Draft submitted to AAMI Standards Board for approval

Submitted to American National Standards Institute (ANSI) for final approval

- Arduous time consuming process
  - AAMI and AORN - five year cycle
  - CDC Guidelines for Disinfection and Sterilization 2008

- Even more advancements!
Follow the IFU”

Accreditation organizations (e.g., CMS, TJC) “ensure practices and procedures align with published standards”

Published standards – follow instructions for use (IFU)

- Device/instrument
- Automatic cleaning equipment
- Chemicals
- Sterilizers etc...

Often not updated with new advancements, or cleared from the FDA with only one method

- May not be routine process
Given this gap...

Need an avenue to evaluate and adopt newly developed equipment, products, processes or technology that the current standards do not address.

Owe it to patients to not delay, if it can:

- Enhance safety,
- Decrease risk of infection transmission,
- Improve efficiency, and/or
- Decrease cost of care
So...what can we do?

Fortunately, there is an alternative to waiting until the guidelines/standards catch up with technological advancements.

Multidisciplinary risk assessment (MDRA)

Collaboration:
- Infection Prevention
- Operating room
- Sterile Processing
- GI Lab
- Physicians
- Risk Management
- Engineering
- Biomed,
- Administration etc.
AAMI New Product Evaluation

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.”

Especially true when considering a product with no guidelines from AAMI or other similar professional organizations.
Surpass Existing Standards – ANSI/AAMI

Elect to adopt technology that exceed existing standards.

Staff must provide evidence that they have undertaken a rigorous process of evaluation, commonly called a “risk assessment,”

If they cannot provide this evidence, run the risk of being cited when audited by accrediting agencies.

ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities, (section 15 – New product evaluation)
Conducting a Product Evaluation

Considerations

• Establish MDRA with representatives from all who will be affected

• Collect and distribute related information such as:
  • FDA clearance
  • Current relevant research
  • Articles published in peer-reviewed journals
  • Manufacturers’ literature and written IFU
  • Experts’ opinions
  • Reports from peers who are using or have trialed the product
  • Evidence review

ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities ANSI/AAMI 2017 Section 15: New Product Evaluation
Peer-reviewed Published Articles

May be rare for technology that is new to the Market—

- Multidisciplinary committee may be reliant on the data generated by the product manufacturer and key opinion leaders in the field.
Other Considerations

Contribution to patient safety
Any legal implications
Cost/value analysis (ROI)
Personnel education
Ease of use of product
Related safety issues
Compatibility of product with existing equipment or products
Environmental impact
Availability of ongoing support and service
Impact on standardization or product inventory

Does it improve patient care?
Product Trial

Time limit for the trial
Identify personnel and departments that should trail
Establish amount of product/devices
Develop evaluation tools
Implement education and demonstrations
Define the desired outcome
Analyze data and compare the actual outcome
Make a recommendation

Recent Regulatory FDA Guidance Updates

Cleaning, Disinfection & Sterilization – 510(k) sterility validation

- **May 28, 1976** Predicated devices already marketed – substantially equivalent

- **Dec. 13, 2016** amendment – req. FDA to publish devices that must include validated IFU

FDA now recognizes there is

- Significant changes in knowledge and technology
- Designs more difficult to clean, disinfect and sterilize
- FDA – Products must be **designed for adequate reprocessing** and safe use

Recent FDA Guidance Updates con’t.

Effective August 8, 2017
IFUs clear and predictable = more efficient review of 510(K)s
✓ must include validation data regarding cleaning, disinfection and sterilization.
   ➢ real world situations

Table 1 – Items that pose a **greater risk** of transmission and infection
   ✓ E.g., endoscopes, arthroscopes, laparoscopic, etc...

Table 2 – Items that pose a **challenge** to adequate reprocessing
   ✓ E.g., lumens, esp. flex. & multi internal lumens, hinges, stopcocks etc.

Proactive Planning – It’s a Team Sport!

Technology will continue to advance.

Proactive healthcare institutions should establish internal evaluation policies that include a MDRA.

Formidable challenges between the wants and needs of patient-facing healthcare workers and the C-suite decision making.

All want to improve patient care,

Metrics used to measure success often differ, creating:

- a communication barrier, and
- potentially slow the process.
Multifaceted process:

✓ Provides a mechanism to foster this cross-level communication,
✓ Allows all team members to have a voice while giving everyone the opportunity to see — by their own distinctive measures— that the product under consideration will enhance the quality of patient care.
Advance Quality Patient Care

Don’t focus on whether or not to adopt a new product, instead the committee should ask:

✓ “What is the benefit of the product to our patients?”
✓ The answer should determine the next steps, allowing HC institutions to maximize time and continue to advance the quality of care for the patients who trust them.
Infection Prevention is a Shared Responsibility

Collaborative coordinated process when considering new technologies
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<td>Systematic Approach to Adopting New Technologies for the Sterile Processing Department (SPD) and Operating Room (OR)</td>
<td>OR Today</td>
<td>July/Aug 2017</td>
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<td>Systematic Approach to Adopting New Technologies for the SPD and OR</td>
<td>Healthcare Purchasing News</td>
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<td>Adopting New Technologies in CS Using a Multidisciplinary Risk Assessment. IAHCSMM Communiqué – CHL Lesson Plan</td>
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Multidisciplinary Risk Assessment Checklist

- 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
Spreading knowledge, Preventing infection.