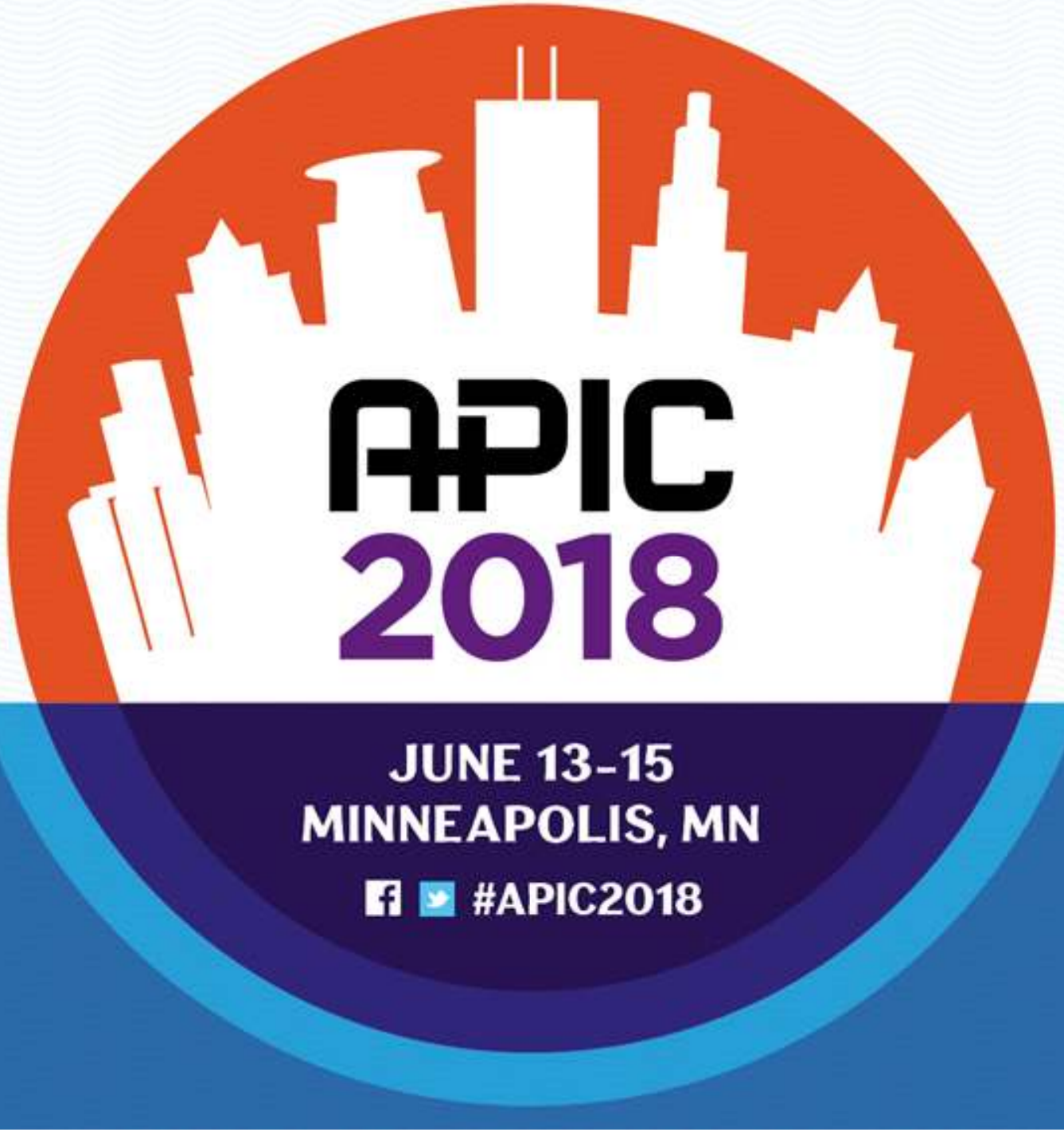
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A Systematic Approach to Adopting New Sterilization Technologies in SPD and the OR

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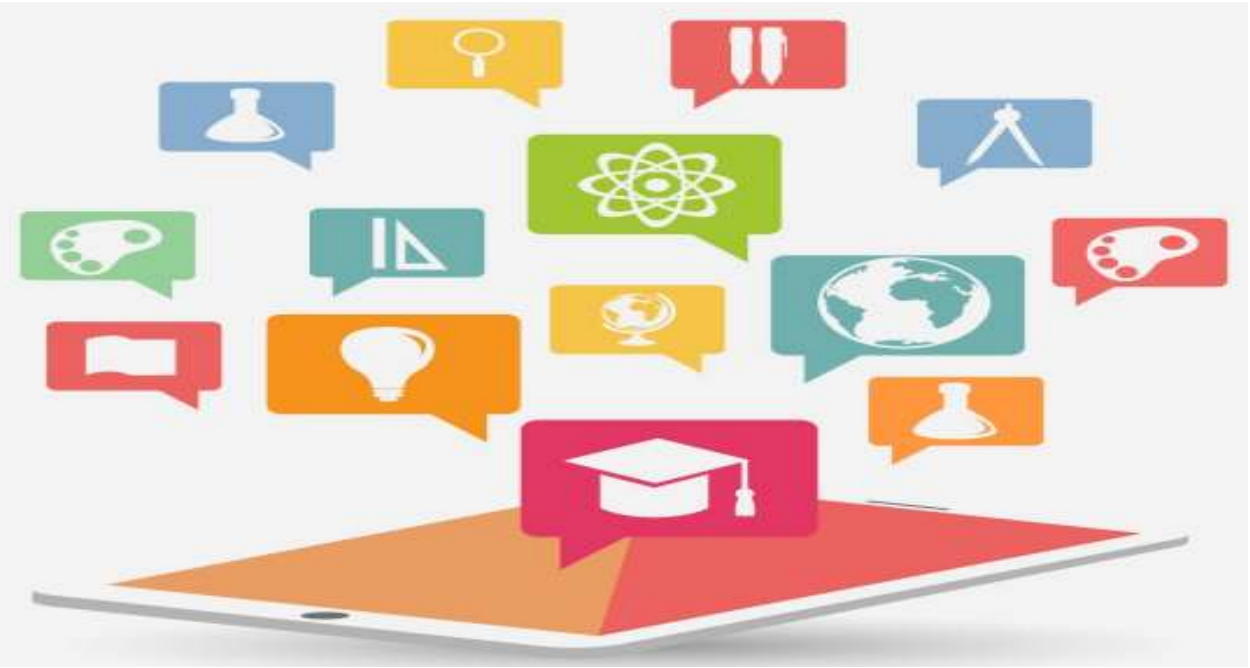
Financial Disclosure

Nothing to disclose for this presentation

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

dopting New Technology
sues and Concerns

Implementation is often delayed, despite the potentially significa
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

eveloping 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

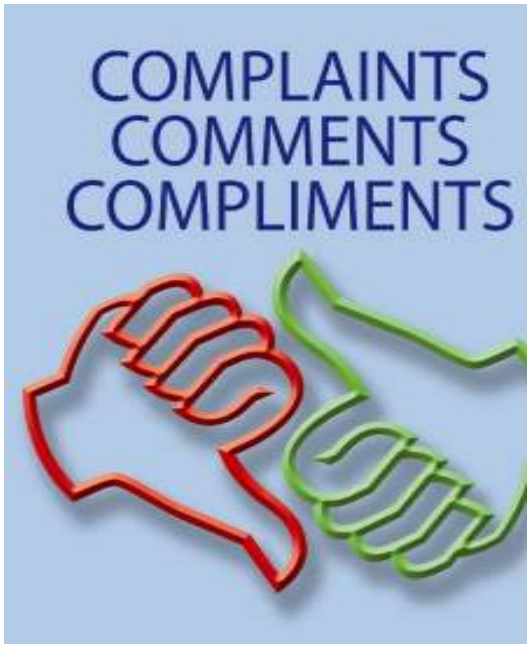
Developing or Updating Standards

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 proce
  - AAMI and AORN - five year cycle
  - CDC Guidelines for Disinfection a Sterilization 2008

- **Even more advancements!**

Follow the IFU”

ccreditation organizations (e.g., CMS, TJC) “ensure practices and procedure
gn with published standards”

ublished standards – follow instructions for use (IFU)

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

ten not updated with new advancements, or

eared from the FDA with only one method

- May not be routine process

Given this gap...

eed an avenue to evaluate and adopt newly developed quipment, products, processes or technology that the urrent 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?

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

ultidisciplinary 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
e responsibility of the intended users to evaluate the product usi
systematic process of product evaluation and to establish
olicies and procedures that reflect this process and that are
ppropriate to the health care organization."

specially true when considering a product **with no guidelines**
om AAMI or other similar professional organizations.

AMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities,
n 15 – New product evaluation)

urpass Existing Standards – ANSI/AAM

ect 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,"

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

AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility nce 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 generat by the product manufacturer and key opinion leaders in the fie

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 trail
- 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

ST79 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* ANSI/AAMI ST79:2010 & 0 &A2:2011 & A3:2012 &A4:2013

ecent Regulatory FDA Guidance Updates

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

leaning, 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

DA 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

https://www.gpo.gov/fdsys/pkg/FR-2017-06-09/html/2017-12007.htm

Recent FDA Guidance Updates con't.

fective 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.

ps://www.gpo.gov/fdsys/pkg/FR-2017-06-09/html/2017-12007.htm

Proactive Planning – It's a Team Sport!

chnology will continue to advance

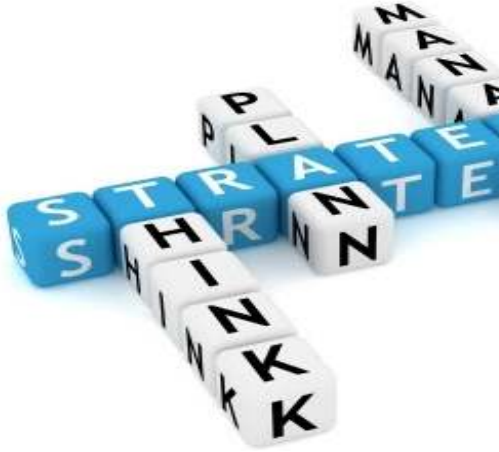
oactive healthcare institutions should establish internal evaluation
icies that include a MDRA.

rmidable challenges between the wants and needs of patient-fac
althcare workers and the C-suite decision making

All want to improved patient care,

Metrics used to measure success often differ, creating:

- ✓a communication barrier, and
- ✓potentially slow the process



ystematic Approach

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 produ under consideration will **enhance the quality** of patient care.

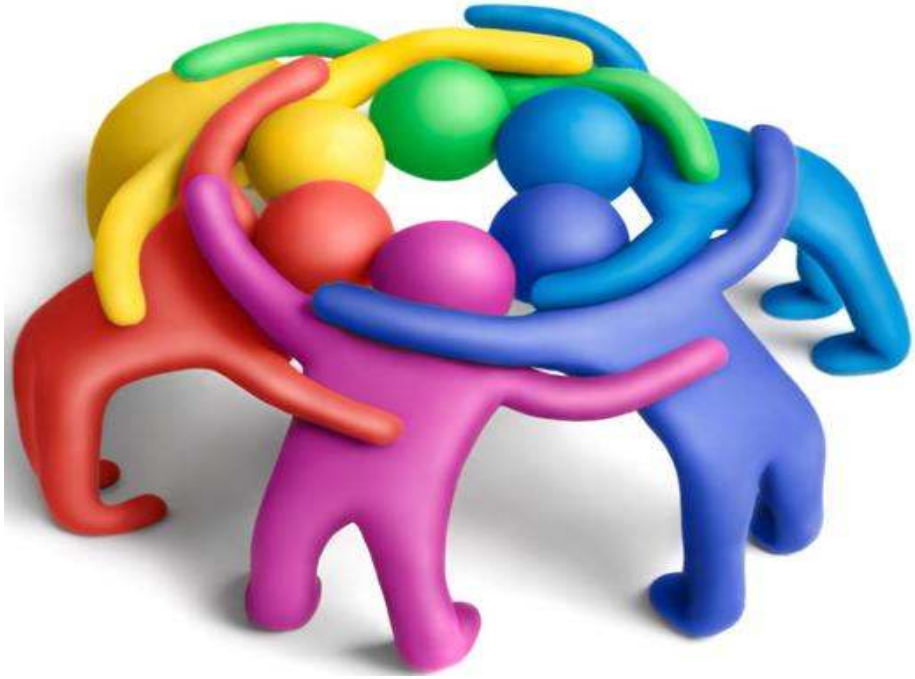
Advance Quality Patient Care

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.

nfection Prevention
s a Shared Responsibility

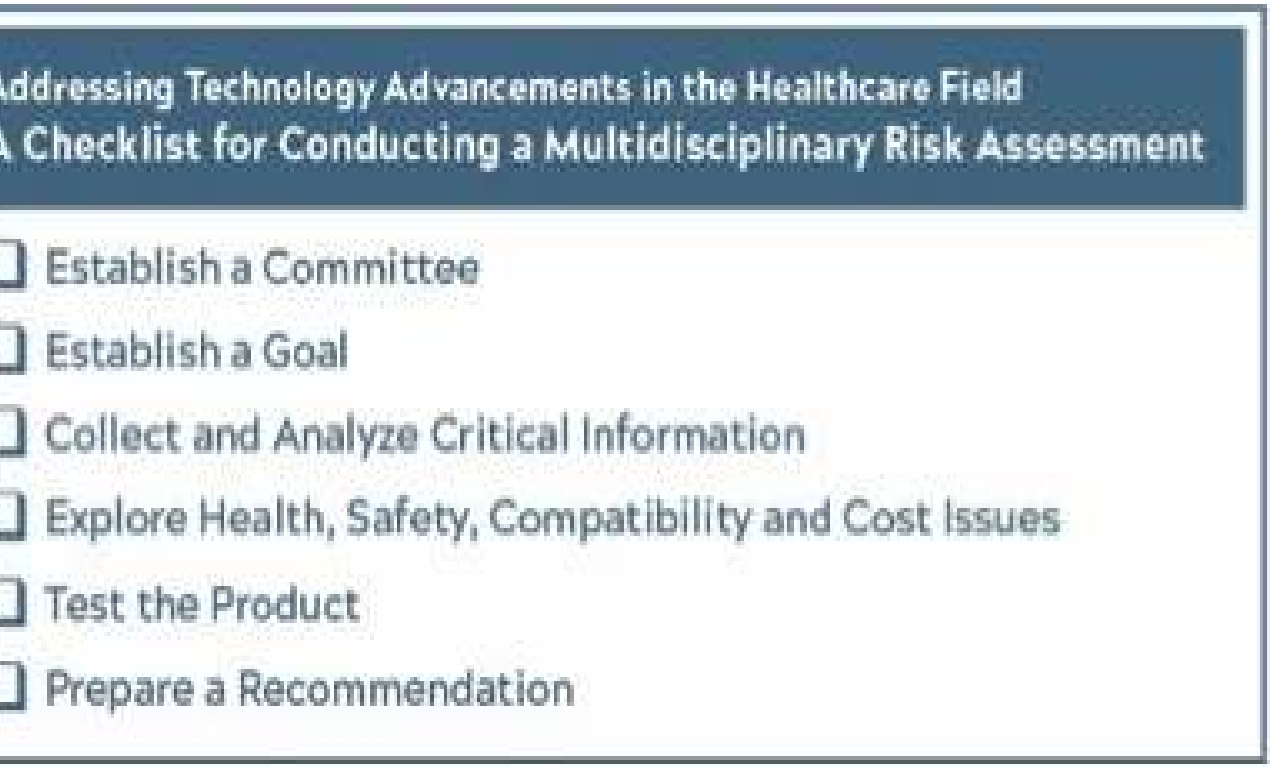
Collaborative coordinated process when considering new technologies

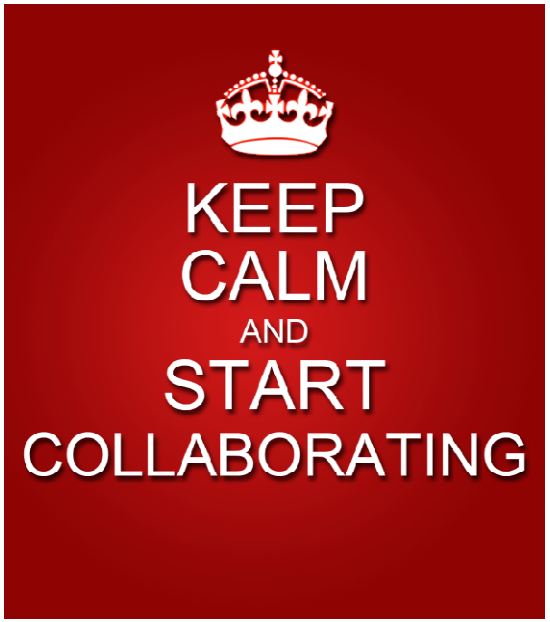


pting New Technology or
cesses using a Multidisciplinary Risk Assessment

Title	Publication	Publish
Systematic Approach to Adopting New Technologies for the Sterile Processing artment (SPD) and Operating Room (OR)	OR TODAY	July/Aug 2017
Systematic Approach to Adopting New Technologies for the SPD and OR	HEALTHCARE PURCHASING NEWS	August,
opting New Technologies in CS Using a Multidisciplinary Risk Assessment. CSMM Communiqué – CHL Lesson Plan	IAHCSMM Instrumental to Patient Care® INTERNATIONAL ASSOCIATION OF HEALTHCARE CENTRAL SERVICE MATERIEL MANAGEMENT	Jan/Feb 2018

ultidisciplinary Risk Assessment Checklis





Spreading knowledge
Preventing infectio

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