Challenges in the US Approach to Disinfection and Sterilization

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Objectives

• Discuss the challenges of communication between instrument manufacturers and end users (specifically orthopedic instruments)

• Review the controversy surrounding “flash” sterilization

• Identify challenges to providing education, certification and recommended practice standards to healthcare facilities
The Challenge of Loaner Instrumentation
The Current System

• Medical devices designed with little or no consideration for cleaning, disinfection and sterilization
• Although required, cleaning and sterilization instructions are often not provided
• Many instrument sets require extended sterilization time
What We Did At Anderson Hospital

- Established policies/procedures regarding loaner instrumentation
- Met with vendors to explain our expectations
- Improved communication between CSSD and Surgery by huddling and having a “go to” staff member
What is IAHCSMM Doing?

• IAHCSMM established an *Orthopedic Council*
  - Members include CSSD professionals, container manufacturers, orthopedic instrumentation manufacturers, sterilization testing facilities, orthopedic surgeon, educators
Council Goals

• Develop a collaboration between IAHCSMM, Association for the Advancement of Medical Instrumentation (AAMI) and Orthopedic Specialty Manufacturer’s Association (OSMA)
• Provide education to OSMA members
• Collaboratively develop standards regarding packaging and sterilization of loaner instrumentation
The Challenge of “Flash” Sterilization
What is “Flash” Sterilization?

• Performed in the OR for JIT delivery of instruments
• No dry time added to cycle
• Challenges
  – Improper cleaning of instruments
  – Improper cycle selection
  – Aseptic delivery to sterile field
The Joint Commission Position

• Updated position paper presented
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– Identified “issues” with the process such as terminology used to describe the process, the choice of the proper cycle for item(s) sterilized and lack of proper cleaning, C/I/Is and aseptic transport to the sterile field

– Cleaning and decontamination, sterilization and storage or return to the field were identified as the Three Critical Steps of Reprocessing
Current Practice

• Joint Commission surveys of CSSD are surveyor dependant and inconsistent
• Inconsistent adherence to Best Practice Standards from hospital to hospital
• These practices make the process of “flash” sterilization inconsistent
Summit on the sterilization process formerly known as “Flash”

- Associations and Agencies represented
  - Association of Perioperative Registered Nurses
  - The Joint Commission
  - American Dental Association
  - Centers for Medicare and Medicaid Services
  - US Food and Drug Administration
  - Association for the Advancement of Medical Instrumentation
  - Centers for Disease Control and Prevention
  - Others...
Points agreed upon…

• Cycles with no dry time can be effective
• Adequate cleaning, decontamination and rinsing are critical
• Aseptic transfer is critical
• Device manufacturer’s written instructions must be followed
• Personnel involved in reprocessing must be adequately educated and trained
Challenges to providing Education and Certification in CSSD
Current Status

- New Jersey is the only US state that requires certification for CSSD technicians or that CSSD follows best practice standards
- Actively seeking Mandatory Certification legislation in New York, Ohio, California, Arizona, others...
- Adherence to best practice standards is “voluntary”
What is AAMI

• The Association for the Advancement of Medical Instrumentation
• Founded in 1967
• 6000+ members – clinical & biomedical engineers and technicians, researchers, manufacturers, physicians, RNs, educators, CSSD professionals, other healthcare professionals
Why do we need AAMI?

• Recommended Practice implies a consensus of those substantially concerned with its scope and provisions.

• It is not the law – it is the standard of practice that “should” be followed in the US.

• The standards are recommendations for optimum performance levels in the reprocessing of reusable medical devices in a healthcare setting.
How should the AAMI Standards be used?

• They should be used as the basis for establishing policies and procedures in CSSD
• They are used to answer questions regarding cleaning, decontamination, sterilization, transport and storage, etc.
AAMI Standards for Everyone!

• All IAHCSMM educational materials based on AAMI standards
• IAHCSMM provides AAMI education at meetings, in Communiqué, etc.
• AAMI Standards available at ½ price to IAHCSMM members
• AAMI Webinar series provided information to CSSD professionals
Summary

• Under the leadership of the professional association, challenges are being identified and addressed
• Change is slow but sure
• Patient safety remains the primary focus
References

• AAMI ST79:2009
• The Joint Commission
Thank you