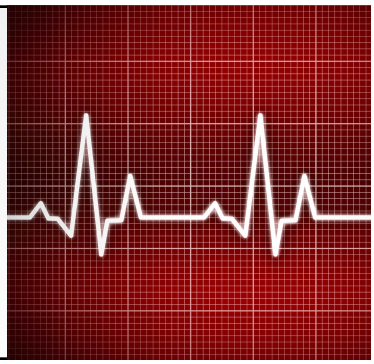
Building an Integrated Medical Device Hygiene Strategy Across the Continuum of Care



J. HUDSON GARRETT JR.
PHD, MSN, MPH, FNP-BC, AS-BC, IP-BC, VA-BC, FACDONA
GLOBAL CHIEF CLINICAL OFFICER
PENTAX MEDICAL-HOYA CORPORATION
ASSISTANT PROFESSOR OF MEDICINE
DIVISION OF INFECTIOUS DISEASES
UNIVERSITY OF LOUISVILLE SCHOOL OF MEDICINE

Objectives

- Review current and future challenges associated with medical device reprocessing
- Discuss evidence-based approaches to ensuring patient safety and infection control related to medical devices
- Review the necessary steps for evidence based product evaluation and industry collaboration to build sustainable patient safety programs of the future

Evolution of US Healthcare Quality

Key challenges in healthcare technology and environment

Technology:

- Procedures that are faster or safer
- Greater cost-effectiveness
- Better access to care
- More information available for care delivery

Unintended Consequences:

- Device design issues
- Environmental real-world issues
- Human factors issues
- Opportunity costs

Opportunities for Improvements:

Definitions:

Medical device: instrument, apparatus, material, or other article, whether used alone or in combination, including software necessary for its application, intended by the manufacturer to be used for human beings for:

- diagnosis, prevention, monitoring treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, or alleviation of or compensation for an injury or handicap;
- investigation, replacement, or modification of the anatomy or of a physiologic process;
- or control of conception

- and that does not achieve its primary intended action in or on the human body by pharmacologic, immunologic, or metabolic means but might be assisted in its function by such means.

Source: US Food and Drug Administration, electronically accessed on September 18, 2016 from http://www.fda.gov/MedicalDevices/default.htm.

Design Challenges

- Long, narrow interior channels (lumens), including those with internal surfaces that are not smooth, have ridges or sharp angles, or are too small to permit a brush to pass through
- Hinges
- Sleeves surrounding rods, blades, activators, inserters, etc.;
- Adjacent device surfaces between which debris can be forced or caught during use
- O-rings
- Valves that regulate the flow of fluid through a device (stopcocks)
- Devices with these or other design features that cannot be disassembled for reprocessing

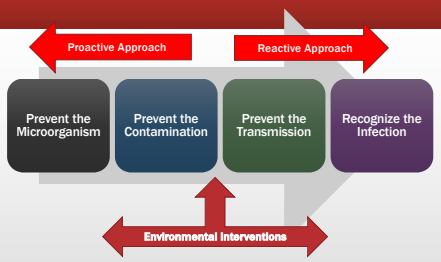
Source: Device Design, US Food and Drug Administration, electronically accessed on September 18, 2016 from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454626.htm#design.

Summary of Key Recent Outbreaks

Scope	Outbreaks	Micro (primary)	Pts Contaminated	Pts Infected	Cause (primary)
Upper GI	19	Pa, *H. pylori*, *Salmonella*	169	56	Cleaning/Dis-infection (C/D)
Sigmoid/Colon oscopy	5	*Salmonella*, HCV	14	6	Cleaning/Dis-infection
ERCP	23	*P. aeruginosa* (Pa)	152	89	C/D, water bottle, AER
Bronchoscopy	51	Pa, Mtb, Mycobacteria	778	98	C/D, AER, water
Totals	98		1113	249	

Source: Kovaleva et al. Clin Microbiol Rev 2013. 26:231-254

Infection Control Imperatives



Designing for Intended Use

- **Manufacturers should consider all intended users when designing medical equipment**

Who Uses the Device?

- Differences in devices from model to model or manufacturer to manufacturer further complicate reprocessing

Equipment Design and Reprocessing

- **The growing complexity of reusable medical equipment complicates optimal reprocessing**

Design Elements Prone to Retaining Biological Material
Lumens with long, narrow interior channels too small to pass a brush through or with ridges, angles, or non-smooth interior
Hinges, O-rings
Sleeves surrounding rods, blades, activators, inserters, etc.
Adjacent device surfaces where debris can get stuck
Valves that regulate flow of fluid through a device (stopcock)
Devices with features that hinder disassembly

FDA Website. Updated August 4, 2015. Accessed October 3, 2016.

Other device-design-related concerns:

- Post-market design changes that do not take into account how the changes impact the ability to properly clean and disinfect the device.
- Lack of communication between manufacturers and/or between manufacturers and device users when medical devices used for reprocessing are modified and instructions are revised.

Source: Device Design, US Food and Drug Administration, electronically accessed on September 18, 2016 from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454626.htm#design.

Reprocessing/Maintenance Program

- Key elements of an after-purchase program
- How to **use** the device safely
- How to **reprocess** the device appropriately
  - List of all steps and staff responsible for each step
  - Design complexities that require special attention
- How to **maintain** the device per manufacturer instructions (including preventive maintenance)

Failing to follow the manufacturer s instructions can damage equipment and increase risk to patients.

Human Factors Approach to Medical Device Hygiene

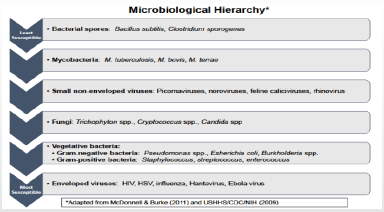
- Systems, staffing, training and oversight
- Environment, equipment, communication, and culture
- Work flow and complexity
- Individual character, condition and capability

Reprocessing challenges at individual facilities

- Staff responsible for steps in the process
- Training available to the staff
- Equipment (e.g. appropriately sized brushes) available for use
- Quality and completeness of the reprocessing instructions provided by the manufacturer
- Access to the manufacturer's instructions.
- Validating competency

Source: Rutala, WA, Weber, DJ, and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008. Centers for Disease Control and Prevention.

Hierarchy of Pathogens



Sources: Rutala, WA, Weber, DJ, and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008. Centers for Disease Control and Prevention.

Consideration of Disinfection Hierarchy Concepts in the Registration of Antimicrobial Products, US Environmental Protection Agency, electronically accessed on September 18, 2016 from: https://www.epa.gov/sites/production/files/2015-09/documents/disinfection-hierarchy-white-paper-draft.pdf.

Infection Prevention Basic Principles for Medical Devices

- Spaulding classification
- Cleaning
- Disinfection
- Sterilization

Source: Rutala, WA, Weber, DJ, and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008. Centers for Disease Control and Prevention.

Effects of Cleaning vs. HLD: Risk Management

- Margin of safety with endoscope reprocessing minimal or non-existent for two reasons:
- Microbial load
  - GI endoscopes contain 10^{7-10}
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - High-level disinfection results in 4-6 $\log_{10}$ reduction
  - Results in a total 6-12 $\log_{10}$ reduction of microbes
  - Level of contamination after processing: 4 $\log_{10}$ (maximum contamination, minimal cleaning/HLD)
- Complexity of endoscope and endoscope reprocessing
- Biofilms-unclear if contribute to failure of endoscope reprocessing

Source: Rutala, WA, Weber, DJ, and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008. Centers for Disease Control and Prevention.

Microbiology

Organisms More Often Associated with Disease:

Gram-negative bacteria

- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Pseudomonas aeruginosa*
- Other Enterobacteriaceae
- *Staphylococcus aureus*
- *Enterococcus*

Source: Rutala, WA, Weber, DJ, and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008. Centers for Disease Control and Prevention.

Ultrasound Transducer Probe Disinfection

Duodenoscope Surveillance Sampling & Culturing

Reducing the Risks of Infection

Source: https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/UCM597949.pdf.

Efficacy of HLD Disinfectants Can be Affected By:

Critical Characteristics

- Concentration and Duration of Contact
- Type and Number of Pathogens
- Surface Areas to Treat
- Temperature of the Environment
- Presence of Soap
- Presence of Organic Materials

Source: Rutala, WA, Weber, DJ, and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008. Centers for Disease Control and Prevention.

FDA's Six Criteria for Reprocessing Instructions

- Labeling should reflect the intended use of the device
- Reprocessing instructions for reusable devices should advise users to thoroughly clean the device
- Reprocessing instructions should indicate the appropriate microbicidal process for the device
- Reprocessing instructions should be technically feasible and include only devices and accessories that are legally marketed
- Reprocessing instructions should be comprehensive
- Reprocessing instructions should be understandable

Source: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff Document electronically accessed on September 19, 2016 from:
http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf

Basic Approach to Medical Device Hygiene

- Stage 1: Strengthening Existing Devices in Market
- Stage 2: Addressing High Risk Components and Accessories
- Stage 3: Terminal Sterilization with Novel Technologies
- Stage 4: Consider Totally Disposable Solutions

Responsibilities

Manufacturers

- IFUs for preprocessing device and device accessories
- Identify materials and equipment needed to reprocess the device (including Parameters)

Clinicians

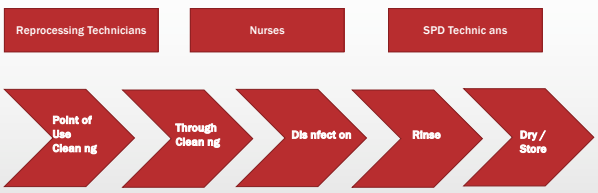
- Facilities
- Equipment
- Easy access to manufacturers IFU
- Ensure IFUs followed
- Third Party Accessories

Source: Device Design, US Food and Drug Administration, electronically accessed on September 18, 2016 from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454626.htm#design.

Staff Education and Training

- Annual and New Hire Competency
- Documentation
- Board Certification
- Components of Required Training:
  - Proper Use/Instructions for Use
  - Indications for Use
  - PPE
  - Disposal
  - First Aid/Safety Data Sheet (SDS)

Reprocessing Overview



Source: Device Design, US Food and Drug Administration, electronically accessed on September 18, 2016 from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454626.htm#design.

Risk recognition (not just for clinical staff!)

- Materials management
- Purchasing
- Biomedical Engineers
- Environmental Services
- Human Factors Engineers

Source: Healthcare Quality and the challenges of medical devices and technology, electronically on September 16, 2016 from www.apicatlanta.org.

Prevention Starts With Purchasing Decisions

Step 1 Determ ne the dev ce s ntended use
- Defined by point-of-care users (eg, physicians, nurses, surgeons, gastroenterologists)
- How, when, where, and what will it be used for?

Step 2 Br ng a the stakeho ders to the tab e
- Relevant clinicians
- Staff from materials management, biomedical engineering, environmental services, infection prevention, and reprocessing

Step 3 Prov de adequate resources for reprocess ng
- Time and equipment
- Training

Medical Device Purchasing Infection Control "Red Flags"-DRAFT

Elements to Avoid	Elements of Concern	Extra Scrutiny Needed for devices & equipment used in:
• Fans • Motors / vibration sources • Condensation sites • Seams and porous surfaces • Other?	• Water reservoirs • Moisture retention • Re-usable tubing • Splash potential • Inaccessible compartments open to the environment • Complex cleaning instructions	• NICU / ICU • Oncology • Transplant • Burn • OR • Sterile processing

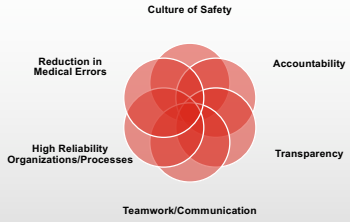
Source: Healthcare Quality and the challenges of medical devices and technology, electronically on September 16, 2016 from www.apicatlanta.org and Centers for Disease Control and Prevention.

Sample Questions to Ponder

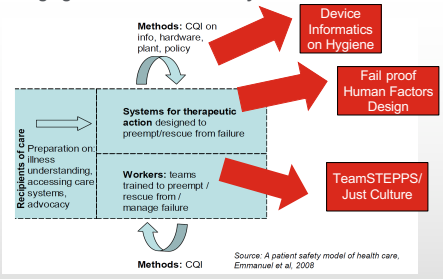
Pre-purchas
Checklis

- Is the item sterile as supplied or does it require sterilization or disinfection before first use?
- Is it compatible with the facility's disinfectants?
- How much time will cleaning and disinfection take?
- How complex is any disassembly and reassembly?
- How can this be integrated into the facility's process?
- Are the manufacturer's reprocessing instructions adequate?

Pillars of Patient Safety



Emerging Model for Patient Safety



Device Hygiene & Infection Control

- Disposable/Single Use Device Functionality
- Advanced High Level Disinfection
- Human Factors Validated IFU
- Reasonable IFU
- Device Sterilization
- Interactive Inservice Support Materials
- Real Time Validation/ATP

Designs that Foster Innovation in Next-Generation Reusable Medical Devices.

- Smooth surfaces, including smooth inner surfaces of the long, narrow interior channels (lumens)
- The ability to disassemble devices with multiple components
- Non-interchangeable connectors for critical connections (For example, tubes used with endoscopes for direct patient connection that cannot be interchanged with tubing used for waste drainage)
- Clear identification of connecting accessories, such as drainage tubing
- Clear indication and identification of components that must be discarded after patient use and cannot be reprocessed or reused
- Disposable components for the hardest to clean areas
- Designs that address how fluid flows through the device, and areas of debris build-up within devices

Source: Device Design, US Food and Drug Administration, electronically accessed on September 18, 2016 from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454626.htm#design.

Future - Collaboration

Additional References

U.S. Food and Drug Administration. Working Together to Improve Reusable Medical Device Reprocessing. Available From: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454626.htm

U.S. Food and Drug Administration. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff. Available from: http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf

Centers for Disease Control and Prevention. (HICPAC). Disinfection of Medical Equipment. Available from: http://www.cdc.gov/hicpac/Disinfection_Sterilization/3_0disinfectEquipment.html

Rutala, WA, Weber, DJ, and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008. Centers for Disease Control and Prevention.

Centers for Disease Control and Prevention. Tracking CRE Infections. Available from: https://www.cdc.gov/hai/organisms/cre/TrackingCRE.html#CREmapNDM

Question and Answer

For more nformat on

Ema judson.gorrell@pentaxmedical.com