The Human Factor of Infection Prevention during Endoscope Reprocessing.
Objectives

• Discuss: Infection Prevention barriers during endoscope reprocessing related to Human Factors.

• Review: Current FDA “Human Factors Guidance” and CDC Health Advisory “Reprocessing Practices”

• Examine: Methods to prevent lapses in Infection Control during endoscope reprocessing.
2015 FDA HF Guidance

Applying Human Factors and Usability Engineering to Medical Devices.

Guidance for Industry and Food and Drug Administration Staff

Documentation issued on: February 3, 2016

US Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Jan 2013-Dec 2014 – FDA received 75 medical device reports encompassing approx 135 patients in the US relating to possible microbial transmission from duodenoscopes
Can all Scopes be cleaned and inspected?
Human Factors and Challenges.

- Complex design of equipment, particularly ERCP and EU
- Reprocessing detailed, multi-step process
- Processing space may be limited
- Time constraints – scope turnaround time

- Regulatory guidelines conflicting and ever-changing
- Flexible endoscopes acquire high levels of bioburden because of the cavities they enter
- Even with full adherence to reprocessing protocols, endoscopes may remain contaminated with pathogenic microorganisms

Regulatory Basis

Medical Devices Final Rule 21CFR Parts 808, 812, and 820 (61 FR 52502)

i.72. "...when designing a device, the manufacturer should conduct appropriate human factors studies, analysis, and tests from the early stages of the design process until that point in development at which the interfaces with the medical professional and the patient are fixed..."
FDA: Priority Device Types

- Duodenoscopes with elevator channels
- Gastroenterology-urology endoscopic ultrasound systems with elevator channels

Any premarket submission for the device should include either a Human Factors test report and data or should provide a detailed rationale that supports the conclusion that human factors data are not necessary.
Cue theme from Jaws
Analysis of Human Factors Validation Test Results

• Analyze qualitatively by aggregating objective and subjective data to:
  • Identify potential use errors.
  • and determine the root causes.

PRACTICE IN REAL LIFE ENVIRONMENTS

• Address use errors and problems through risk management strategies
• Conduct Human Factors (re-)validation testing on the modified user interface elements
Manufacturers Test Participants

Observational Data of participants’ performance of all the critical use scenarios

Minimum number of participants should be 15 for each distinct population.

Product Developers and employees should NOT serve as test participants.

Stating your intention to mitigate the risks by providing “additional training” is not acceptable.
Association for the Advancement of Medical Instrumentation (AAMI)

• Technical Information Report (TIR) 2014, published 01/22/2015
  Human Factors Engineering for Processing Medical Devices

• Identification of potentially challenging use and conditions that can be reasonably anticipated, such as use of gloves, dim lighting, noisy or busy situations, etc., should be included in the testing.
Human Factors
Recommended Report Outline

• Description of Intended device users, uses, interface, environments and training.
• Summary of known use problems.
• Analysis of risks associated with use of the device.
• Summary of preliminary analysis and evaluations.
• Description and categorization of critical tasks.
• Details of **human factors** validation testing.
Human Factors Validation Testing

Demonstrates that the device can be used by the intended users, under expected use conditions, without serious use errors or problems.

Does the user understand what they are asked to do?
Manufacturer’s “Instructions for Use” (IFU)

- “Closely follow...adherence” – FDA
- “Meticulously follow” – AAMI
- “Meticulous adherence to” – SGNA
- “Strict adherence to” – CDC
- “Follow” – TJC
- “Clean according to” - APIC
Setup for Automatically Feeding Water via OFP Pump

- Endoscope with Auxiliary Water Channel
- MAJ-855 Auxiliary Water Tube
- OFP Irrigation Tube
- Green Luer Connector contains an internal one-way valve
- Filter
- Sterilize prior to use. Discard at the end of the day.
- Reprocess after each clinical case
- Sterilize daily

OFP Olympus Flushing Pump
**Interior channels.** When brushing your biopsy/suction and air and water channels, be careful — a brush’s bristles are hard enough to clean the channels, so they are capable of scratching it, too. A brush without rounded ends may scratch the interior channels, which could lead to holes and, eventually, water invasion. In addition, not diluting your enzymatic solution enough can damage the channels.

**Biopsy/suction (work) channel.** As the biopsy forceps or needle irrigator, for example, is moved through this channel, holes or perforations often occur. Taking your time when putting instrumentation into (or when pulling instrumentation out of) it can cut down on this damage.
Automatic Brushing System

Process 1:
- Brush A is inserted in the direction of an endoscope tip from the portion which attaches a suction button.
- Brush A is inserted in the direction of an endoscope tip from the portion which attaches a suction button.

Process 2:
- Brush A brushes a grip.

Process 3:
- Brush A brushes a grip.

Process 4:
- Brush A once returns to a start position, and will be in a standby state.

Process 5:
- Brush A runs in the universal direction and Brush B runs in the direction of an endoscope tip.

Process 6:
- Brush A brushes the universal direction and Brush B brushes an insertion part.
The best way IFU’s are understood

Research shows:

• Break into small manageable tasks
• Use a separate sentence for each step
• Put the steps in order that they should be performed
• No more than 3 actions per step.
• Pictures and graphics are very important.
• Provide Caution statements---what not to do.
What to do with IFUs

• Develop employee competencies that incorporate them

Make sure IFUs are...
• Current/Updated
• Readily available.
• CONSIDER Electronic Versions
  o User-friendly
  o Available for each type of scope
Staff Competencies

- Competencies for staff working with specific HLD processes should be initiated and reviewed:
  - Upon new hire
  - AT LEAST annually
  - **Duodenoscopes**: CDC 2015 recommends “several times a year”
Latest Guidelines

- September 11, 2015 – CDC Health Update –
  - Training
  - Audit and Feedback

- Regularly monitor and document adherence to ALL reprocessing steps
Staff should understand why they document.
Latest Guidelines

• September 11, 2015 – CDC Health Update –

  • Allow adequate time for **ALL** steps of reprocessing per IFU
    o Considerations should be made regarding scheduling of procedures and supply of devices to ensure adequate time is allotted for reprocessing

  • Maintain **documentation** of reprocessing activities
    o Maintenance records for reprocessing equipment (autoclaves, AERs, washer/disinfectors)
    o Sterilization records (physical, chemical and BI results)
    o Records verifying HLD testing/replacement
Documentation should be interpreted the same by all.

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Questions?