Special Problems Associated with Reprocessing Instruments in Outpatient Care Facilities

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Disclosure

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Objectives

- Statistics on Outpatient Care in the US
- Three Main Problems with Instrument Reprocessing in Out Patient Care:
  3. Physical Space Problems
     - Improvements achieved without renovation
  2. Training and Education Problems Related to High-level Disinfection
     - IFUs/Validation
     - Industry standardization
     - HLD Education
  1. Lack of Infection Prevention Presence
More patients obtain healthcare in specialty clinics and physicians’ offices in the United States than in hospitals.

- 990 million ambulatory care visits to US physician offices (most specialties)
  - 85% of all adults in the US had contact with a health care professional in the past year
  - 93% of children in the US had contact with a health care professional in the past year
- 126 million outpatient hospital visits (CDC 2011)
Under-reporting of Transmission Associated with Endoscopy

In a CDC survey, 1/3 of respondents reported that their institutions have not used any surveillance methods to identify possible bacterial transmission following certain endoscopic procedures.

Sterilization

Enormous Margin of Safety!

100 quadrillion (10^{-17}) margin of safety

Sterilization kills 1 trillion spores in addition to the washer/disinfector which removes or inactivates 10-100 million microbes.

There is a 1:100 quadrillion chance of the item NOT being sterile.

Rutala
Generally speaking, and particularly compared to HLD, I don’t worry about steam sterilization practices.
High-Level Disinfection
No Margin of Safety
for GI Endoscopes

0 (zero) margin of safety;
Microbial contamination $10^7$-$10^{10}$: compliant with reprocessing guidelines 10,000 microbes after reprocessing:

**Maximum contamination, minimal cleaning** $(10^2)/\text{HLD} (10^4)$

Rutala
I do worry about high-level disinfection practices.
In fact...

**High-level disinfection**

is

the problem with instrument reprocessing today – inpatient and outpatient.
Special Problem #3: Physical Plant Challenges
(or, One Reason Our Outpatient Areas Need Infection Prevention)
Double Sinks: Both clean or both dirty.

We helped them figure this out.
- No sink at all
- Storage of endocavitary probes in processing room

We made it safer.
Before Infection Prevention Assistance...

This is a “clean-to-dirty-to-clean-to-dirty-to-dirty-to-dirty, dirty, dirty, dirty-to-clean” set up.

Critical: rooms must have a dirty-to-clean flow to the best of our ability to make it so.
After Infection Prevention Assistance – it’s all rainbows and unicorns!

They decluttered and established a “dirty-to-clean” flow (mostly).

We helped them figure this out.
Special Problem(s) #2: 
Training, Education, Validation and Standardization 
(or, 4 reasons our outpatient areas need Infection Prevention)
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The quest for a simplified algorithm for HLD
Steps for High Level Disinfection of Equipment Using Glutaraldehyde or OPA

Step 1
Put on PPE: extended cuff nitrile gloves, fluid-resistant gown, eye protection, face shield.

Step 2
Clean the item to be disinfected of all soil/debris using hospital-approved enzymatic detergent per manufacturer's recommendations. Pay special attention to instruments with lumens or other hard-to-reach places.

Step 3
Rinse the item under running tap water and dry completely. Continue to pay special attention to scopes and other instruments with lumens or hard-to-reach places.

Step 4
Perform Quality Control checks on test strips and solution according to test strip manufacturer's instructions and UNCH Infection Control policy.

Step 5
Put the item in the disinfectant chemical, making sure it is completely covered by the solution (completely submerged). Make sure that all channels and lumens are filled with the disinfectant.

Step 6
After appropriate time has passed, remove the item from the solution and rinse well with water according to UNCH Infection Control policy, flushing all lumens and channels very well. If disinfecting a scope, water rinse must be followed by an alcohol rinse and scope must then be thoroughly dried, using medical-grade forced air for all lumens.

Step 7
Perform thorough documentation of cleaning/disinfection procedure on recommended and appropriate log(s). Store equipment in manner that will not re-contaminate, in accordance with UNCH policy and manufacturer's recommendations.

Critical Step: Debris or dried-on/stuck on tissue or fluids that are not cleaned off before disinfection will cause a failure in the disinfection process. These failures can cause infections.

Critical Information: OPA: soak for twelve (12) minutes. Glutaraldehyde: soak for twenty (20) minutes.
The UNCH HLD Workshop has educated over 500 staff in 5 years.
Computer-based training does not work for HLD!
The VALUE in Validation...
Device Validation

• Are HLD chemicals validated by device manufacturer?
• Is the device validated by the manufacturer of the automated endoscope reprocessor (AER)?
• Does the device have lumens?
• Is the sterilizer or AER validated to be efficacious with those lumens?
  – Length, diameter play a role
  – Are here hookups or adapters that must be used to perfuse lumens?
  – Are the correct hookups in use?
Device/Hook-up Validation
Chemical Validation

Revital-Ox™ RESERT® High Level Disinfectant Device Compatibility Matrix

The information in the device guide identifies those cleaned, immersible, reusable, semi-critical medical devices and accessories that have been tested to confirm materials compatibility by STERIS’ Device Testing Program and/or the device manufacturer with Revital-Ox Resert High Level Disinfectant. The devices shown in the guide are ONLY a representation to confirm materials compatibility with a wide range of medical devices. Therefore, not all compatible devices will be listed.

Quick Search — Device by Model Number

Enter Model Number

SEARCH

OR

Step-Through Guided Search

Step 1

Select Manufacturer

Aircraft Medical Limited
Aloka
B&K Medical
Boston Scientific
Care Fusion
Cognexa Medical
ConMed
Custom Ultrasounds
DeVilbiss Healthcare
ESAOTE

Step 2

Select Device Name

Step 3

Select Model Number
No Standardization in the Instrument Reprocessing Industry
Enzymatic Detergents - No Standardization

- Different ratios of detergent to H₂O
- Automated dispensing systems
  - Are they REALLY accurate?
  - Are we checking accuracy?
- Some require certain H₂O temperatures for efficacy
- All must be precisely measured
- All require specific and different soak times
- None are disinfectants – a risk to staff!!
A Plethora of Detergents and Cleaners
HLD Soak Times and Usage: No Standardization

- Most glutaraldehyde is a 20 minute soak time (unheated)
- Revital-ox Resert® is an 8 minute soak time
- OPA is a 12 minute soak time
- Rapicide® HLD glutaraldehyde is only FDA approved to be used heated in an automated endoscope reprocessor (AER)
Test Strips: No Standardization

- Staff may not leave the instrument processing room during wait times
  - 3M Comply™ glutaraldehyde strips
    - 5 minutes – shades of yellow
  - Cidex® glutaraldehyde strips
    - 75 seconds – pass = purple, fail = orange
  - Cidex® OPA strips
    - 90 seconds – pass = purple, fail = teal
  - Revital-Ox® strips
    - 60 seconds – pass dark blue, fail = mottled
  - Rapicide® PA strips
    - 30 seconds – pass black, fail = shades of gray/black
Special Problem #1:
Lack of Infection Prevention Presence
But before we go...

Educate ourselves and become familiar with the process
CMS: Infection Control Worksheet

Two multi-page documents specifically for inspecting infection prevention practices in acute care and ambulatory surgical facilities.

Section 2.B. Injection Practices and Sharps Safety (Medications and Infusates)

Infections are given and sharps safety is managed in a manner consistent with hospital infection control policies and procedures to minimize the prevention of infection and communicable disease including the following:

Note: If possible, questions in this section should be assessed through observation in two separate patient care areas or settings of the hospital.

<table>
<thead>
<tr>
<th>Question</th>
<th>Surveyor Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.B.1. Injections are prepared using aseptic technique in an area that has been cleaned and is free of contamination (e.g., visible blood, or body fluids).</td>
<td>Yes</td>
</tr>
<tr>
<td>2.B.2. Needles are used for only one patient.</td>
<td>Yes</td>
</tr>
<tr>
<td>2.B.3. Syringes are used for only one patient (this includes manufactured prefilled syringes).</td>
<td>Yes</td>
</tr>
<tr>
<td>2.B.4. Insulin pens are used for only one patient.</td>
<td>Yes</td>
</tr>
<tr>
<td>2.B.5. The rubber septum or any medication vial, whether one-use or previously accessed, is removed without access prior to piercing.</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Memorandum Summary

- **ASC Infection Control Surveyor Worksheet Revisions:** The Centers for Medicare & Medicaid Services (CMS) has made minor revisions to the Infection Control Surveyor Worksheet, Exhibit 351 of the State Operations Manual (SOM) for assessing compliance with the Medicare ASC Infection Control Condition for Coverage (CIC).
- **Change:** Revisions were made to bring the worksheet into alignment with current accepted standards of practice; reflect recently released guidance; and improve the clarity of certain questions. The worksheet is used by State and Federal surveyors on all survey activity in

High-Level Disinfection (HLD) and Sterilization BoosterPak

Updated June 2017
Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update

Prepared by: REPROCESSING GUIDELINE TASK FORCE

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This article was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).
American National Standard

ANSI/AAMI ST91:2015
Flexible and semi-rigid endoscope processing in health care facilities
Sept and Oct, 2015 Regulatory Recommendations: Health Care Facilities Need to Immediately Review Medical Device Reprocessing Procedures
Train Staff, Audit Adherence to Steps, Provide Feedback on Adherence

This is an official
CDC HEALTH UPDATE

Distributed via the CDC Health Alert Network
October 2, 2015, 08:00 EST (08:00 AM EST)
CDCHAN-00383

CDC/FDA Health Update about the Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

As a follow-up to HAN 00382 (distributed September 11, 2015), the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) are providing this update to rescind the following recommendation: If healthcare facilities contract maintenance and repair of these devices to third-party vendors, healthcare facilities should verify that these vendors are approved or certified by the manufacturer to provide those services. We are making this change because there are currently no formal standardized programs or processes through which all manufacturers certify third-party vendors. We are also further clarifying that healthcare facilities which hire contractors to perform device reprocessing should verify that the contractor has an appropriate training program (i.e., consistent with what would be required in the healthcare facility) and that the training program includes the specific devices used by the healthcare facility.

Summary
On September 11, 2015, CDC issued HAN 00382 alerting healthcare providers and facilities about the
- Incomplete immersion
- OPA in a cystoscopy clinic
- They did not know...

We helped them figure this out.
Storage Challenges

We helped them figure this out.
Separation Strategies

Clearly distinguishing between clean and dirty items.

What’s dirty and what’s clean?

We helped them figure this out.
What did we do? We helped them figure this out.
Inadequate Space

Yep – here too!
This is **OUR** watch and we cannot do nothing.

Don’t let what you cannot do interfere with what you can do.
• There has never been a time in which we must partner with industry like we must partner today

• Infection Prevention must be engaged at a level not seen before
Thousands of known human infections (and thousands more unknown) are associated with failures in HLD – either human or engineering.

Infection Preventionists are responsible for giving solvable issues our attention immediately.

Industry is responsible for immediately creating engineering controls on devices that make it difficult to infect a patient...such as single use, sterile devices and sheaths.

We are responsible for continuing the pressure on industry to do so.
Our First Step after today (like, on Monday)
Step One...

Tuck ANY HLD Guideline under your arm and

walk into your scope processing room, your instrument processing room, your instrument processing closet and start a conversation.
• IT WAS A MISTAKE for me to ASSUME people who HLD everyday know the right way to do it.

• Your instrument reprocessing sites need your attention and help.
  – They may not know that yet.

• We CANNOT always make it perfect or even consistent with regulations and guidelines.

• We CAN always make it better and safer for our patients and our staffs. I personally guarantee that.

• Just start your first visit. . . the rest will happen for you automatically.

• Fix the worst things first.
IF “Plan A” Didn’t Work.
The alphabet has 25 more letters!
Stay Cool.
Once we, **Infection Prevention**, is fully engaged, the myriad elements and complexities of HLD within our facilities will lead us where they need us to go –
Thank you to Drs. Rutala, Weber, and Sickbert-Bennett and the entire staff of UNC Hospital Epidemiology. Without every one of my colleagues in Chapel Hill, this presentation would not be possible. They have given me all the opportunities I asked for (and some I didn’t).
I must go
my people need me

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