Best Practices: High Level Disinfection of Endoscopes

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Who We Serve

Baptist Health’s service area covers 73% of Kentucky’s population

Baptist at a Glance

- 3.2 million Service Area Population
- $2.33 Billion Revenues
- $3.1 Billion Total Assets
- 2,434/2,026 Licensed/Staffed Beds
- 92,746 Acute Admissions
- 26,428 Outpatient Visits
- 124% Cost Containment
- 155 Days Cash on Hand
- 80 owned acute centers
- 3 managed acute centers
- 124% Cash to Debt
- 34% Debt to Capital

$1.1 Billion Unrestricted Cash
$3.1 Billion Total Assets
12,377 Deliveries
84,239 Discharged Discharges
318,280 Emergency Room Visits
124% Cost Containment
Objectives

Following participation in this program, participants will be able to:

• Assess their current HLD practices and compare with nationally-recognized HLD best practices
• Determine if their HLD work areas and PPE requirements are appropriate
• Develop or revise staff training and competency verification practices
• Perform audits designed to identify the level of staff adherence with established HLD policies and procedures
Baptist Health System Endoscopy Team

- Multidisciplinary Team selected from each of the Baptist Health System Facilities
- Quarterly Audits
- Training program with standardized competencies
- Standardized tools and processes
- Program now includes outlying Baptist Health Medical Group Clinics

Background

- From the Public Broadcasting System (PBS) – “UCLA Medical Center in Los Angeles has told scores of patients they were possibly exposed to a drug-resistant bacterial “superbug” during endoscopy procedures that infected seven patients and may have contributed to two deaths.”

Baptist Health Endoscopy Team

- BHS Endoscopy Team Purpose - The purpose of the Baptist Health System Endoscopy Team is to investigate and evaluate our current practices for processing surgical instruments, flexible and semi-rigid endoscopes and the elevator-type scopes used for endoscopic retrograde cholangiopancreatography (ERCP) procedures to ensure adherence to current and evidence based practices System-wide.
High Level Disinfection vs. Sterilization

- Disinfection is the process of eliminating or reducing harmful microorganisms from inanimate objects and surfaces,
- Sterilization is the process of killing all microorganisms including bacterial spores.

Spaulding Classification System

<table>
<thead>
<tr>
<th>Patient Contact</th>
<th>Examples</th>
<th>Device Classification</th>
<th>Minimum Intervention Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact skin</td>
<td></td>
<td>Non-Critical</td>
<td>Cleaning and/or Low to Intermediate-Level Disinfection</td>
</tr>
<tr>
<td>Massive or minor contamination</td>
<td></td>
<td>Semi-Critical</td>
<td>High-Level Disinfection</td>
</tr>
<tr>
<td>Mucous membranes or non-intact skin</td>
<td></td>
<td>Critical</td>
<td>Sterilization</td>
</tr>
<tr>
<td>Non-intact body, including blood contact</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Survival of Pathogens on Environmental Surfaces

<table>
<thead>
<tr>
<th>Pathogens</th>
<th>Presence on Surfaces</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. Diff</td>
<td>&gt;5 months</td>
</tr>
<tr>
<td>Staphylococci</td>
<td>7 months</td>
</tr>
<tr>
<td>VRE</td>
<td>2 to 36 months</td>
</tr>
<tr>
<td>Acinetobacter</td>
<td>1 to 3 months</td>
</tr>
<tr>
<td>Norovirus</td>
<td>3 weeks</td>
</tr>
<tr>
<td>Adenovirus / Botavirus</td>
<td>3 months</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>1 month</td>
</tr>
<tr>
<td>SARS, HIV</td>
<td>Days to weeks</td>
</tr>
</tbody>
</table>
Standard vs. Recommendation or Guideline

- **Regulation** – principle, rule or law i.e. EPA, FDA, and OSHA.
- **Standard** – established norm determined by opinion, authority, research, and/or theory i.e. AAMI, and the CDC.
- **Recommended Practice** – statements of sound principles of practice that are based upon scientific data and the opinions of experts i.e. IAHCSMM, SGNA and AORN.
- AAMI ST-91 – “A standard or recommended practice is an important reference in responsible decision-making, but it should never replace responsible decision-making.”

Comparison of Standards Matrix

How does a system decide which practices it will adopt?
Review of Selected Standards

- Pre-cleaning at Point of Use, PPE and Transport of Contaminated Scope
- Reusable buttons and water bottles
- Documentation of manual leak test
- Manual clean and rinse – manufacturer IFU
- Cleaning solution changes, water quality, temperature monitoring
- SGNA’s “Safety Stop” after manual steps

Review of Selected Standards

- Storage – drying cabinets, HEPA filtered air, maximum number of days, all accessories with the scope, labeling for storage
- Transport of Clean Scope
- Documentation of cleaning time

Review of Selected Standards

- Environmental Cleaning
- Certification and Competency
- Culturing and requirements for duodenoscope processing
- Drying time
Determination of appropriate number of endoscopes

Analysis of:
• Volume of procedures, by type
• Scheduling patterns, by provider, by day of the week, by type
• Hours when HLD is available
• Ability to comply with established policies, eg, minimum drying time for each type of scope

Personal Protective Equipment

• Glove changes during point of use cleaning, dispose of any contaminated items in the procedure room
• Hair, Jewelry, Fingernails, cover gowns and jackets.

PPE - Processing

• Shoe covers
• Gown
• Long gloves
• Mask and eye protection
• Hair covering
Attire
- Clean uniform
- Shoes

PPE - OSHA
- Shall be provided by the employer when there is a risk of occupational exposure.
- Specialized clothing includes: gloves, masks, goggles and face shields, impervious gowns, surgical caps, hoods, and shoe covers.
- Employer has the obligation to ensure the worker uses PPE
- PPE should be accessible to the worker but stored outside of the room where HLD occurs
- Requirement includes "latex free" for workers with latex sensitivity

Hazardous agents
- Handling procedures
- Storage, signage
- Spill management
- MSDS information
- + or – air pressure requirements
HLD Room Design Considerations

- Scope Decontamination area, sinks, unidirectional workflow
- # hand-washing sinks
- Eye Wash Stations
- Temp/Humidity, Lighting, Air Exchanges
- Square footage

Eye Wash Stations

- OSHA requirement
- Should be hands free and connected to warm water
- Minimum 10 seconds travel time
- Tested weekly-per facility policy and recorded

Room Design Issues

- WHAT IF OUR ORGANIZATION CANNOT AFFORD REMODELING OF THE HLD ROOM, TO MEET RECOMMENDED DESIGN PRACTICE RECOMMENDATIONS (OR REGS)?
  Leaders should identify the potential impact of the current design limitations of the HLD room on:
  - Worker safety
    - Access to an appropriate eye wash station
    - Air quality (removal of hazardous fumes)
    - Access to personal protective equipment (PPE)
    - Worker injuries
Room Design Issues cont.

- Compliance:
  - With pertinent regulations or federal guidance documents (FDA, CDC, OSHA, haz mat handling, etc.)
  - With professional associations’ HLD practice recommendations
  - With the organization’s own HLD policies/procedures
- Efficiency and/or productivity
  - Ability to meet demand (volume of scopes to be processed)
- Possible alternatives: Can HLD activities be transferred to Central Sterile Processing?

Orientation of HLD personnel

- Role of LEAN Team Member(s)
- Full time HLD staff
- Staff who only occasionally are assigned to do HLD

Competency verification

- Full time staff
- Back up staff
Best Practices

- Start at Purchasing – Consult manufacturers’ instructions, are current processors compatible with new scopes?
- Surveillance for detection of infections
- Documentation requirements
- Manufacturer Instructions for Use

Cleaning Verification

Healthmark Endocheck - A color change indicates that blood residue or protein residue remains in the channel, and should be reprocessed.

http://www.healthmark.info/CleaningVerification/EndoCheck/EndoCheckPolicyEDP.pdf

Cleaning Verification Tests

- Boroscope – “Tools such as video boroscopes of an appropriate dimension (length and diameter) may be used to visually inspect the internal channels of some medical devices.”
- https://www.youtube.com/watch?v=t8m7ru1Hk
Identification and Traceability

- Each item or package intended for use should be labeled with a lot control identifier. The lot control identifier should designate:
  a) the identification number or code of the sterilizer, AER, or soaking container;
  b) the date chemical sterilization or high-level disinfection was performed;
  c) the sterilization or high-level disinfection cycle number; and
  d) the patient identifier.

Release of endoscope ST-91

- Product release (endoscope) is an active decision based on evaluation of all available data from the AER Process or high level disinfection process for the particular scope.
- Scopes that do not meet the criteria for release should be clearly identified so that they are not mistakenly distributed.

Auditing Cleaning Processes

- BHS Audits
- Audit tools are available from several sources including toolkit
- Is processing occurring in clinics or in-patient areas?
- AORN – “periodically review and evaluate processing activities to verify compliance or to identify the need for improvement, identify corrective actions directed toward improvement priorities, and take additional actions when improvement is not achieved or sustained.”
- Joint Commission – Risk Assessment from booster pack 2015
Direct Observation Audits

Auditor: Needs subject matter expertise and personal experience in carrying out the activities at focus.

Leadership decisions:

a. Will the auditor interrupt the process when an action is skipped or improperly performed? If they decide that the observer should refrain from making any comments until all steps are completed, the observer must advise the staff person to re-do the activity (in the case of endoscopy processing, the scope would require re-processing from step 1).

b. Will the audit results for a specific employee be used exclusively for QI purposes - or may they also be used performance appraisal and/or disciplinary purposes?

The business case for a system approach to HLD oversight

• Identify subject matter expert(s)
• Conduct baseline gap analysis
• Define scope of services and lines of reporting
• Estimate FTE requirements and other expenses
• Outline anticipated benefits
• Obtain leadership’s support

Response to push back or resistance

• At the entity level
• From work unit managers
• From frontline personnel involved with HLD
• From C-suite leaders
Keeping apprised about the industry

• Reports of outbreaks
• FDA safety advisories or recalls
• Manufacturers’ advisories or notices about changes re: product use or HLD processes
• Follow up actions:
  – Review organizational policies, modify as indicated
  – Educate all affected managers/personnel before putting changes into effect

The HLD Toolkit

• What is its purpose?
• What is contained therein?
• How can its contents be best utilized?

Key Takeaways

• Evidence Based Practice for Flexible and Semi-Rigid Endoscope processing is ever evolving
• Ensure all endoscopes are processed in the same manner
• Audit “Trust but Verify” – Suzanne Massie from Russian Proverb and President Ronald Regan.