

Staff Assisted Visit: High Level Disinfection (HLD)

Executive Summary

Purpose

Staff assisted visits are conducted by a team from Industrial Hygiene, Infection Control (IC) and the Sterile Processing Department (SPD) at 0830-0930 every Wednesday at WRNMMC. These unannounced visits rotate through the 12 clinics with HLD capabilities observing the clinic's current practice and record keeping, as well as monitoring compliance with WRNMMC and Infection Prevention and Control's (IPaC's) policies regarding HLD process.

Background

The 12 clinics performing HLD are listed below. In addition, 10 other areas in WRNMMC use medical equipment needing HLD. These 10 areas utilize one of the 12 clinics with reprocessing equipment for HLD.

12 clinics with HLD capabilities	Equipment	Areas who use other clinics for reprocessing
1. GI Clinic* (Clinic #2)	Medivator DSD-201	Anesthesia, Gen Surg Clinic, Breast Imaging
2. PEDS GI Endoscopy	Medivator DSD Edge	
3. Pulmonary Clinic* (Clinic #1)	Medivator CER-2	Respiratory Therapy, CT Surgery
4. ENT Clinic	Medivator CER-2	Speech Path, Allergy Clinic, Radiology Oncology
5. Urology Clinic	Steris/Sterrad	
6. Stone Center	Steris/Sterrad/Autoclave	
7. Cardiology Clinic	TD-100	Anesthesia
8. Women's Health	Trophon	
9. OB Clinic	Trophon	
10. ARC/REI	Trophon	
11. MICC (Mother Infant Child Care)	Trophon	Pre-natal Care
12. Radiology Ultrasound	Trophon	Emergency Dept
*SAV performed		

Five of these clinics reprocess transvaginal ultrasound probes.

- Women's Health Center (WHC)
- OB Clinic/Acute Care Clinic

- Advanced Reproductive Clinic (ARC)
- Mother Infant Child Center (MICC)
- Radiology Ultrasound

Six of the clinics reprocess endoscopes

- ENT
- Pulmonary
- GI Clinic
- PEDS GI Endoscopy
- Urology Clinic
- Stone Center

One clinic reprocesses Transesophageal probes

- Cardiology

Verified on 2/12/15

Significance

According to Muscarella (2014), “the cause of virtually every bacterial and viral pathogen transmission following GI endoscopy was attributed to one or more infection control breaches over the last 30 years” (p. 458). Automated endoscopic reprocessors have made scope cleaning easier for the staff but adherence to reprocessing guidelines is still an issue. In a study by Ofstead, Wetzler, Snyder, & Horton (2010) “observers documented guideline adherence, with only 1.4% of endoscopes reprocessed using manual cleaning methods with automated high-level disinfection versus 75.4% of those reprocessed using an automated endoscope cleaner and reprocessor” (p. 304).

Goals/ Outcomes Desired

During the staff assisted visits, the main goals are to observe the clinic’s current practice and to monitor the clinic’s compliance with WRNMMC and IPaC’s policies regarding the HLD process. Also during the visits, clinic specific issues are addressed, questions are answered, and recommendations are provided to the clinic staff in accordance with standards and recommended practices, manufacturer’s instructions for use and current best practice.

The desired outcomes include:

- Complete documentation of initial and annual competency training of staff assigned to perform HLD in the designated areas (WRNMMC-A1 6230.02, 27 January 2015, p. 5)
- HLD process performed in accordance with manufacturer’s written instructions for use (WRNMMC-A1 6230.02, 27 January 2015, p. 4).
- Accurate and complete documentation of the HLD process (WRNMMC-A1 6230.02, 27 January 2015, p. 6).
- 100% compliance with WRNMMC and IPaC’s policy; HLD/sterilization guidelines for clinics.
- 100% compliance of the clinic’s specific policies and procedures (depending on equipment used).

Clinic #1 (Pulmonary Clinic)

Method and Actions

A staff assisted visit of the Pulmonary Clinic's High Level Disinfectant (HLD) area was performed on 5 February 2015. A Pulmonary clinic service member accompanied the team in the walk through.

Findings

Areas to sustain

- The HLD area was clean and organized.
- There was two Medivator CER-2 found in the room, both are being used.
- One scope buddy was available for use.
- Quick ready reference for staff concerning filter changes and rapicide changes were posted on the wall.
- All chemicals were contained in their original containers and no expired solutions were found.
- Service member did know where to find Instructions For Use (IFUs) for equipment, scopes, chemicals, and test strips involved in HLD process.
- There was a hand washing sink inside the HLD room.
- Storage area was clean, secured, and separated from the HLD area.
- There was one person performing HLD during the staff assisted visit.

Areas to improve

- Work flow from dirty to clean was disrupted. Regulated Medical Waste (RMW) red container in clean section and clean cart in dirty area. (Service member stated nothing dirty goes on clean gray cart but witnessed dirty water splashed on clean cart.)
- Proper personal protective equipment (long cuffed/short gloves, masks with shields, and gowns) was available in the HLD area except eye goggles. Service member did not have face mask during cleaning or eye protection. Service member needed to be reminded to wear mask with splash guard to prevent bloodborne transmission.
- Service member was wearing gloves during cleaning of scopes in water but gloves were not long enough to cover wrists.
- Service member was unaware of Material Safety Data Sheet (MSDS) location.
- Service member could not provide a list of trained and competent personnel from the pulmonary clinic or respiratory therapy authorized to perform HLD in the pulmonary clinic.
- Service member did know how to QA with test strips, but did not know where to document results. Date opened on test strips was not found. Service member did not know when test strips were opened.
- Staff unable to locate documentation showing that Rapicide is neutralized prior to disposal IAW Command SOP.

Incidental Findings

- Pen has wooden tongue depressor attached to it.
- Measuring stick for water depth used in cleaning sink not cleaned every day.
- Towel under yellow bin not changed out every day.
- Transporting scopes from sink to reprocessor left water on floor creating a fall risk.
- The most knowledgeable technicians leave creating a void of subject matter experts.

Recommendations

1. **Flow of room needs to be addressed.** Flow should be from dirty to clean -then out for appropriate storage. (AORN (2014), Recommendation VI, p. 265).3.2 Processing Area, ANSI/AAMI ST58 (2014), p.9)

(Joan Godich, Infection Control, returned to the clinic that afternoon to initiate the following corrective actions and to provide recommendations for improvement to the Clinic's overall HLD process.)

- a. Suggested that signage be created and posted to indicate the room flow.
 - b. Move patient-ready scope cart to clean side of room; move trash can to dirty side of room.
 - c. Add a small work table to place the binder on for documenting in the manual log (in place of using the clean scope cart).
 - d. Label all carts appropriately, clean, dirty, etc. to avoid confusion.
 - e. Remove RMW red container from room.
2. **Proper wear of PPE should be addressed.** (AORN (2014), Recommendation VI, p. 521; 4.4 Personal protective equipment, ANSI/AAMI ST58 (2014), p. 16).
- a. Ensure eye goggles are available and used.
 - b. Replace short gloves with long cuffed gloves by the sink for better availability.
 - c. Reeducate staff on importance of PPE and return demonstration of proper PPE donning.
3. **Staff must know where to find MSDS and the importance of MSDS.** (5.5.2 Health and safety consideration, ANSI/AAMI ST58 (2014), p. 21).
- a. Spot check staff to see if they can locate MSDS.
 - b. Hold an in-service covering content of MSDS.
4. **A list of trained and competent personnel from the pulmonary clinic or respiratory therapy that are authorized to perform HLD should be accessible in the reprocessing area** (4.3.1 Processing personnel, ANSI/AAMI ST58 (2014), p.15). WRNMMC's HLD competency policy states that all health care personnel who perform HLD need to attend IPaC's mandatory training program initially and annually (WRNMMC-AI 6230.02, 2015). Each person must also have documentation of initial and annual competence training (IPaC, 2012).
- a. Verify proper documentation of competency is completed and on file.
 - b. Ensure only trained and competent staff are allowed to reprocess scopes.
 - c. Send new staff through HLD training.
 - d. Maintain accurate and up to date list of HLD trained, competent, and authorized personnel per WRNMMC-AI 6230.02.
5. **Lack of knowledge concerning Q&A of Test Strips and requirements for labeling/dating upon opening.** (AORN (2014), Recommendation XI, p. 523).

(Joan Godich, Infection Control, returned to the clinic that afternoon to initiate the following corrective actions and to provide recommendations for improvement to the Clinic's overall HLD process.)

- a. Re-educated staff and correct process for Q&A of Test Strips and requirements for labeling/dating upon opening. Technicians were not available as they were in a case; however, Clinic LPO was trained by Joan Godich on how to perform Q&A. Reviewed with LPO instructions for how to correctly label Test Strip container upon opening.
 - b. Per instructions for use, a new expiration date needs to be recorded upon opening; test strips are only good for 90 days from opening or mfg exp date on bottle (whichever comes first). Test strips were Q&A'd successfully and the RapiCide solution in the two Medivators was tested and both machines passed the test strip testing. All information was documented in the manual log.
 - c. Existing bottle of test strips was discarded. A new bottle (Q&A passed and labeled/dated appropriately) replaced the discarded bottle.
6. **Track down documentation and remind staff to follow SOP.** Perform spot checks when RapiCide is neutralized. (AORN (2014), Recommendation IX, p. 522).

Incidental Findings

1. **Wood tongue depressor needs to be removed from pen because it cannot be cleaned.** (3.4 Housekeeping procedures, AAMI/ANSI ST79 (2014), pp. 35).
2. **Wipe measuring stick down daily to prevent cross contamination.** (AORN (2014), Recommendation VI, p. 265).
 - a. Add this to a daily room cleaning checklist.
3. **Change out towel daily to prevent harboring of microorganisms.** (AORN (2014), Recommendation VI, p. 265).
 - a. Add this to a daily room cleaning checklist.
4. **Transport scopes using chuxs to soak up water to decrease fall risk.**
5. **Look at hiring actions and military manning to select personnel with experience.** Additionally continuity binder to pass on to new personnel.

**On the spot corrections were made with service member.

(See audit tool: High level disinfection/ sterilization audit tool from WRNMMC)

Clinic #2 (GI Clinic)

Methods and Actions

A staff assisted visit of the GI Clinic's HLD area was performed on 5 February 2015 with IC. A GI Clinic service member accompanied team in the walk through.

Findings

Areas to sustain

- The HLD area was clean but crowded.
- There were six Medivator DSD-201 found in the room; one labeled broken, with an active work order in place. Medivators are very close to the dirty sink.
- There were two doors leading to the HLD area; one side was designated as the "dirty" door (decon area) and the other was the "clean" door (clean side of HLD).
- There were three sinks located on the decon side, against the wall.
- Two scope buddies were available in the decon area.
- PPE were available in the HLD area.
- There was a hand washing sink in the HLD area. There was also an eye wash station.
- Storage area was clean, secured, and separated from the HLD area. Scopes were hanging vertically, no labels (dates disinfected) were observed on the scopes.
- The Intercept indicator test strips were available, labeled with opened and expiration dates.

Areas to improve

- The HLD room is being used as the primary staging area for Regulated Medical Waste (RMW) due to no space in clinic. RDW is picked up daily so it does not accumulate.
- Service member did not document QA test strips results.
- The list of personnel from anesthesia who perform HLD there was not found.

Incidental Findings

- Outside the HLD area, there were cabinets along the wall where the scopes ready for patient use were stored. The cabinet doors were open.
- Sterile items found with compromised sterile packages in reprocessing room cabinets.
- Storage items disorganized on bottom shelf.

Recommendations

1. **Move (RMW) to another area where reprocessing does not take place.** Containment should comply with WRNMMC hazardous waste management procedures (6.3.2, Separation of waste and reusable items at point of use ANSI/AAMI ST58 (2014), p. 26).
 - a. Current solution: RDW is picked up daily so it does not accumulate as a way to decrease risk of cross contamination.
 - b. Elevate concern up chain of command to designate a containment area for RMW in order to comply with WRNMMC hazardous waste management procedures.
2. **Address inadequate documentation of QA test strips.** (AORN (2014), Recommendation XI, p. 523).
 - a. Remind staff on proper documentation and spot check documentation
 - b. Send staff to Infection Control HLD class for refresher training.
3. **A list of trained and competent personnel from the GI clinic and anesthesia that are authorized to perform HLD should be accessible in the reprocessing area** (4.3.1 Processing personnel, ANSI/AAMI ST58 (2014), p.15). WRNMMC's HLD competency policy states that all health care personnel who perform HLD need to attend

IPaC's mandatory training program initially and annually (WRNMMC-AI 6230.02, 2015). Each person must also have documentation of initial and annual competence training (IPaC, 2012).

- a. Verify proper documentation of competency is completed and on file.
- b. Ensure only trained and competent staff are allowed to reprocess scopes.
- c. Send new staff through HLD training.
- d. Maintain accurate and up to date list of HLD trained, competent, and authorized personnel per WRNMMC-AI 6230.02.

Incidental Findings

1. **Keep cabinets closed when not in use to prevent possible contamination and use appropriate storage.** "Flexible endoscopes should be stored in a closed cabinet with venting that allows air circulation around the flexible endoscopes" (AORN, 2014, p. 534).
 - a. Current solution: A meeting is pending this month to have all department chiefs be present for purchasing decision concerning cabinets with ventilation.
2. **Resterilize package if package looks like it was compromised to prevent infection secondary to use of contaminated procedure items** (AORN (2014), Recommendation III, p. 564).
 - a. Leadership made aware and immediate action taken. Items in question were immediately sent to Sterile processing department to be reprocessed.
3. Keep items organized and presentable for better access and accountability.
 - a. Leadership made aware and immediate action taken. Items in question were organized.

(See audit tool: High level disinfection/ sterilization audit tool from WRNMMC)

Report prepared by Maj David Bradley, USUHS CNS Student on 13 February 2015. Report reviewed by WRNMMC HLD Infection Control Nurse Mrs. Joan Godich and Perioperative Clinical Nurse Specialist MAJ Duane Zaricor.

Audit Tools

WRNMMC MEDIVATOR "SELF-AUDIT" - HIGH-LEVEL DISINFECTION

WARD/CLINIC/DEPT. Pulmonary Clinic

AUDIT BY: Maj David Bradley (CNS USUHS Student)/Mrs. Joan Godich (Infection Control Consultant)

Date: 5 February 2015

The HLD room has a neat and orderly appearance.	TRUE	FALSE	
The HLD room is <u>not</u> being used as THE primary staging area for regulated medical waste (RMW), regular trash, or soiled linen holding.	TRUE	FALSE	
There is a distinct separation of "pre-cleaned" items from the "grossly-contaminated" items AND Work Flows from DIRTY to CLEAN to PATIENT READY.	TRUE	FALSE	
EYE WASH is checked per WRNMMC SOP and log is POSTED. Enter date of last eye wash check:			2 Feb 2015
SDS (aka MSDS): There is a current (Material) Safety Data Binder available. Did not know where MSDS was <i>(Please ensure that there is a (Material) Safety Data Sheet for each chemical found in your Clinic)</i>	TRUE	FALSE	
PPE: There is an adequate supply of Personal Protective Equipment (PPE) available in HLD Room <i>Place a "check mark" beside all PPE available (stocked) in the HLD room</i> ___x___ Impervious long-sleeve Gown x___ Fluid-Resistant long-sleeve gown Plastic aprons ___x___ Nitrile gloves/Regular Length Nitrile gloves/LONGER Length ___ Chemical goggle(s) ___x___ Surgical mask x___ Surgical mask w/face shield attached ___ Reusable Face Shield x___ Disposable face shields ___ Other PPE (not listed)	TRUE	FALSE	List OTHER PPE here:
COMPETENT PERSONNEL: There is a list of personnel available with the <i>names of ALL trained & competent staff from YOUR CLINIC that perform HLD</i> . Did not know where list was IF OTHER CLINICS USE YOUR AREA: There is a list of <i>ALL staff FROM OTHER areas using this room</i> . If TRUE, please enter # names on list:	TRUE	FALSE	# names on list TRUE FALSE N/A
SECONDARY CONTAINERS: 1. We only use <i>ready-to-use spray foam</i> for our enzymatic cleaner --no secondary container. 2. We mix concentrated enzymatic cleaner with water & pour into container or sink basin. If "b" is TRUE, answer the following: Our secondary container or sink basin (with enzymatic solution) ARE LABELED WITH: <ul style="list-style-type: none"> The <u>CONTENTS (product) and DATE POURED</u> The <u>NAME of person who filled container/basin</u>. "Hazards" of the chemical are identified (per SDS/MSDS). 	TRUE	FALSE	N/A N/A N/A N/A N/A
Our Clinic uses the: <input checked="" type="checkbox"/> Medivator CER-2 <input type="checkbox"/> Medivator DDS 201 <input type="checkbox"/> Medivator DSD Edge <input type="checkbox"/> Other Current method of pre-cleaning endoscopes: <input checked="" type="checkbox"/> Manual <input checked="" type="checkbox"/> Scope Buddy Enter the date the HLD solution was last changed. 2/2/15 Enter date HLD solution in machine expires (per mfg guidelines). HLD Expires on: 3/2/15 HLD Expiration date is POSTED and visible to the staff. YES NO ALL FILTER CHANGE DUE DATES are CURRENT. YES NO DATES above are DOCUMENTED on either a manual or machine-generated log. There is a PATIENT IDENTIFIER documented for each scope. YES NO Test strip Results (Pass/Fail) are documented <i>appropriately</i> for <u>EVERY</u> load. YES NO All open test strips bottles have QA done & documented before use. YES NO Date opened & new expiration date are written on all open test strip bottles. YES NO			Test strips opened: Not there Test strip QA date: Not there Test strip Exp Date: 11/2015
ALL Rapiocide (Gluteraldehyde base) is <u>NEUTRALIZED PRIOR TO DISPOSAL IAW Command SOP</u> .	TRUE	FALSE	N/A
There is documentation that Rapiocide is neutralized prior to disposal IAW Command SOP.	TRUE	FALSE	N/A

LIST ANY ISSUES HERE AND CONTACT INFECTION CONTROL (301-295-4878): See attached sheet.

WRNMMC MEDIVATOR "SELF-AUDIT" - HIGH-LEVEL DISINFECTION

WARD/CLINIC/DEPT. Pulmonary Clinic

AUDIT BY: Maj David Bradley (CNS USUHS Student)/Mrs. Joan Godich (Infection Control Consultant)

Date: 5 February 2015

Findings

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WRNMMC MEDIVATOR “SELF-AUDIT” - HIGH-LEVEL DISINFECTION

WARD/CLINIC/DEPT. GI Clinic

AUDIT BY: Maj David Bradley (CNS USUHS Student)/Mrs. Joan Godich (Infection Control Consultant)

Date: 5 February 2015

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Observation of scope being processed in GI clinic.

1. Tech pre-cleaned the flexible endoscope at point of use by suctioning water through the channels.
2. Tech transported the scope to the decontamination area in a closed container.
3. Tech filled out data/cleaning form for each flexible scope, logged the model and serial number of the scope, type of procedure the scope was used for and initialed form because he was the employee who would clean the scope.
4. Tech attached the leak-resistant cap and tested the scope for leaks in a basin of water.
5. Tech suctioned water through the channels of the scope.
6. Tech tested for leaks and observed for at least one minute and tested the rubber to ensure that no holes are present in the rubber that may be stretched while bending.
7. Tech placed the scope into the next basin with the cleaning solution diluted to the correct level as described by the manufacturer. Amount of cleaning solution per gallon of water posted per MFU.
8. Tech removed the buttons and placed non disposable buttons aside. Disposable buttons were thrown away.
9. Tech brushed all channels with a brush designed for this purpose and continued this process until the brush no longer appeared soiled.
10. Tech ensured all to brush and flush all ports (not just the biopsy port) according to the manufacturer's instructions. Tech was able to verbalize difference between scopes and the number of ports each had.
11. Tech wiped down the exterior of the scope with a washcloth.
12. Tech placed the endoscope into a third basin with fresh water. Used the air water channel device provided by your manufacturer to flush the air water channels with enzymatic solution, followed by a complete flush with fresh water.
13. Tech tested the Medivator solutions with QA test strips. Strips indicated pass and documented in log book.
14. Tech transported scope /non disposable buttons and loaded Medivator per IFUs. Medivator loading protocol posted including what settings were to be followed.
15. Tech selected appropriate cycle.
16. After completion of cycle, solutions were tested again with QA test strips.
17. Tech put on new gloves and unloaded Medivator.
18. Tech hung scope in cabinet outside of until needed. Storage cabinet was open. Tech explained traffic control is enforced for only staff uses this hallway and there is no other space for these cabinets. Leadership informed me that cabinet issue is being elevated up chain of command.

References

- Association of periOperative Registered Nurses [AORN] (2014). Recommended practices for cleaning and processing flexible endoscopes and endoscope accessories. In K. Retzlaff, I. Llewellyn, & Z. Wiggy (Eds.), *Perioperative standards and recommended practices for inpatient and ambulatory settings* (2014, pp. 473-484). Denver, CO: AORN.
- Infection Prevention and Control [IPaC] (2012). *Walter Reed National Military Medical Center infection prevention and control manual*. Bethesda: Walter Reed National Military Medical Center.
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