

Protecting, maintaining and improving the health of all Minnesotans

To: Health Care Facility Administrators, Medical Directors, Infection Preventionists

From: Minnesota Department of Health

Infectious Disease Epidemiology, Prevention and Control Division

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RE: Inadequate Endoscope Reprocessing

Over the past 18 months, several healthcare facilities have contacted the Minnesota Department of Health (MDH) regarding situations involving inadequate endoscope reprocessing. Any endoscope (e.g., colonoscope, bronchoscope, gastroscope, cystoscope, laryngoscope, etc.) that has not been adequately reprocessed poses a potential risk of infection transmission including hepatitis A virus, hepatitis B virus, hepatitis C virus, HIV, and bacterial pathogens. This memo is intended to remind all health care facilities where endoscopic procedures are performed of the importance of proper and effective endoscope reprocessing. Adequate endoscope reprocessing is essential to ensuring patient safety.

We recommend that health care facilities conduct a thorough assessment of the reprocessing procedures and practices for all endoscopes and endoscopic accessories. This assessment includes, but is not limited to the following:

- 1. Compile a list of all endoscopes and accessories (e.g., probes, needle guides, etc.) used in the facility and ensure that manufacturer reprocessing instructions for each are on-site.
- 2. Review manufacturer reprocessing instructions for all endoscopes and endoscopic accessories used in the facility.
- 3. Ensure that all protocols and procedures for endoscope reprocessing and storage follow manufacturer reprocessing instructions and national guidelines (see resources below).
 - a. Seek assistance from manufacturer representatives or other experts as needed.
- 4. Verify that items currently being reprocessed are intended for reuse (i.e. are not single use devices).
 - a. Follow federal Food and Drug Administration (FDA) requirements for reporting an adverse event if it is determined that a single use device has been reprocessed.

- Ensure that all clinicians who perform endoscopic procedures receive at least annual education on cleaning, disinfecting, and sterilizing procedures for the endoscopes and endoscopic accessories they utilize.
- 6. Ensure that all staff responsible for any aspect of endoscope reprocessing receive education and training, including competency testing, at least annually.
- 7. Perform audits of all aspects of endoscope reprocessing at least annually.
- 8. Ensure that infection prevention consultation is available for all areas of the facility that perform endoscopic procedures.
- 9. Maintain a log of all endoscopy procedures performed including: 1) patient name; 2) medical record number; 3) date of the procedure; 4) procedure(s) performed; 5) all endoscopic accessories used and serial number if available; 6) clinician who performed the procedure; 7) type of endoscope used; 8) endoscope serial number; 9) automated endoscope reprocessor (AER) used (if applicable); and 10) AER reprocessing cycle used. Note: This log will be invaluable in the event that a reprocessing breach is detected to facilitate a thorough investigation.

While the above recommendations address endoscopes, they are applicable to the reprocessing of all critical and semi-critical devices, instruments, and components used in the health care facility.

We are available for consultation in the event that a reprocessing breach is identified. If indicated, we can engage Centers for Disease Control and Prevention (CDC) experts for further consultation and additional laboratory testing as necessary. Please contact us at 651-201-5414 or toll free 1-877-676-5414.

Recommended resources:

Nelson BT, Chennat J, Cohen J, et al. ASGE-SHEA Guideline: Multisociety Guideline for Reprocessing Flexible GI Endoscopes: 2011. Infect Control Hosp Epidemiol. 2011; 32: 528-537.

Centers for Disease Control and Prevention *Outpatient Infection Prevention Guide and Checklist* Available at: http://www.cdc.gov/HAI/settings/outpatient/outpatient-settings.html

Rutala WA, Weber DJ, and the Healthcare Infection Control Practices Advisory Committee (HICPAC). CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Available at: http://www.aami.org/steris/CDC_Disinfection.1108.pdf

Rutala WA and Weber DJ. Reprocessing endoscopes: United States perspective. J Hosp Infect. 2004;56:S27-S39.