State of Montana *Health Alert Network*

DPHHS HAN

Health INFO SERVICE

Cover Sheet

DATE: September 14, 2015

SUBJECT: Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

For LOCAL HEALTH DEPARTMENT reference only

DPHHS Subject Matter Resource for more information regarding this HAN, contact:

DPHHS CDCP
Epidemiology Section
1-406-444-0273

INSTRUCTIONS:

DISTRIBUTE to your local HAN contacts. This HAN is intended for general sharing of information.

- Time for Forwarding: **As Soon As Possible**
- Please forward to DPHHS at hhshan@mt.gov
- **Remove this cover sheet before redistributing and replace it with your own**

DPHHS Health Alert Hotline:
1-800-701-5769

DPHHS HAN Website:
www.han.mt.gov

REMOVE THIS COVER SHEET BEFORE REDISTRIBUTING AND REPLACE IT WITH YOUR OWN

Please ensure that DPHHS is included on your HAN distribution list.

Categories of Health Alert Messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: provides important information for a specific incident or situation; may not require immediate action.
Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.
Information Service: passes along low level priority messages that do not fit other HAN categories and are for informational purposes only.

Please update your HAN contact information on the Montana Public Health Directory

State of Montana *Health Alert Network*

DPHHS HAN

Information Sheet

Date: September 14, 2015

Subject:
Immediate Need for Healthcare Facilities to Review procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

Background:

Events involving patients being notified that they may be at increased risk for infection due to lapses in basic cleaning, disinfection and sterilization are continuing to be reported.

Information:

The failures represent a critical gap in patient safety at a basic easily improvable level that includes reading and following manufacturers reprocessing instructions and either creating or following existing policies and procedures within facilities.

Recommendations:

Healthcare facilities should arrange for a healthcare professional with expertise in device reprocessing to immediately assess their reprocessing procedures. Facility infection prevention and quality improvement programs should prioritize this activity. More detailed information can be found in the attached Centers for Disease Control and Prevention (CDC) Health Advisory.

This is an official

CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
September 11, 2015, 12:15 EDT (12:15 PM EDT)
CDCHAN-00382

Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

Summary
The Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) are alerting healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices. Recent infection control lapses due to non-compliance with recommended reprocessing procedures highlight a critical gap in patient safety**.** Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors' offices) that utilize reusable medical devices are urged to immediately review current reprocessing practices at their facility to ensure they (1) are complying with all steps as directed by the device manufacturers, and (2) have in place appropriate policies and procedures that are consistent with current standards and guidelines.

Background
Recent media reports describe instances of patients being notified that they may be at increased risk for infection due to lapses in basic cleaning, disinfection, and sterilization of medical devices. These events involved failures to follow manufacturers' reprocessing instructions for critical[1] and semi-critical[2] items and highlight the need for healthcare facilities to review policies and procedures that protect patients.

Recommendations
Healthcare facilities should arrange for a healthcare professional with expertise in device reprocessing to immediately assess their reprocessing procedures. This assessment should ensure that reprocessing is done correctly, including allowing enough time for reprocessing personnel to follow all steps recommended by the device manufacturer. The following actions should be performed:

Training

- Healthcare facilities should provide training to all personnel who reprocess medical devices.
  - Training should be required and provided:
    - Upon hire or prior to provision of services at the facility
    - At least once a year
    - When new devices or protocols are introduced, including changes in the manufacturer's instructions for use during the device's life cycle
  - Personnel should be required to demonstrate competency with device reprocessing (i.e., trainer observes correct technique) prior to being allowed to perform reprocessing independently.

---

[1] **Critical items** (e.g., surgical instruments) are objects used to enter sterile tissue or the vascular system and must be cleaned and sterilized prior to reuse.

[2] **Semi-critical items** (e.g., endoscopes for upper endoscopy and colonoscopy, laryngoscope blades) are objects that contact mucous membranes or non-intact skin and require, at a minimum, cleaning and high-level disinfection prior to reuse.

    - Healthcare facilities should maintain current documentation of trainings and competencies.
    - If the healthcare facility hires a contractor for device reprocessing, the facility should verify that the contractor has an appropriate training program and that the training program includes the specific devices the healthcare facility uses.
    - Copies of manufacturers' instructions for operating and reprocessing each type of reusable device should be readily available to staff and inspectors. This file should include instructions for use of chemical disinfectants.

Audit and Feedback

- Healthcare facilities should regularly audit (monitor and document) adherence to cleaning, disinfection, sterilization, and device storage procedures. Audits should assess all reprocessing steps, including:
    - Performing prompt cleaning after use, prior to disinfection or sterilization procedures
    - Using disinfectants in accordance with manufacturers' instructions (e.g., dilution, contact time, storage, shelf-life)
    - Monitoring sterilizer performance (e.g., use of chemical and biological indicators, read-outs of sterilizer cycle parameters, appropriate record keeping)
    - Monitoring automated endoscope reprocessor performance (e.g., print out of flow rate, time, and temperature, use of chemical indicators for monitoring high-level disinfectant concentration)
- Audits should be conducted in all areas of the facility where reprocessing occurs.
- Healthcare facilities should provide feedback from audits to personnel regarding their adherence to cleaning, disinfection, and sterilization procedures.

Infection Control Policies and Procedures

- Healthcare facilities should allow adequate time for reprocessing to ensure adherence to all steps recommended by the device manufacturer, including drying, proper storage, and transport of reprocessed devices.
    - Considerations should be made regarding scheduling of procedures and supply of devices to ensure adequate time is allotted for reprocessing.
- Healthcare facilities should have protocols to ensure that healthcare personnel can readily identify devices that have been properly reprocessed and are ready for patient use (e.g., tagging system, storage in a designated area).
- Healthcare facilities should have policies and procedures outlining facility response in the event of a recognized reprocessing error or failure. Healthcare personnel should assess the cause of the error or failure and the exposure event in order to determine the potential risk of infection. The procedure should include how patients who might have been exposed to an improperly reprocessed medical device would be identified, notified, and followed.
- Individuals responsible for infection prevention and reprocessing at the healthcare facility should be consulted whenever new devices will be purchased or introduced to ensure that infection control considerations are included in the purchasing decision as well as subsequent implementation of appropriate reprocessing policies and procedures and to ensure that the recommended reprocessing equipment is available at the healthcare facility.
- Healthcare facilities should maintain documentation of reprocessing activities, including maintenance records for reprocessing equipment (e.g., autoclaves, automated endoscope reprocessors, medical washers and washer-disinfectors, water treatment systems), sterilization records (physical, chemical, and biological indicator results), and records verifying high-level disinfectants were tested and replaced appropriately.
- Healthcare facilities should follow manufacturer recommendations for maintenance and repair of medical devices that are used to perform reprocessing functions as well as medical devices that are reprocessed. 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.

Additional Information
Examples of relevant guidance include CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 available at http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf; and guidance from the Association for the Advancement of Medical Instrumentation (AAMI), available at http://www.aami.org/standards/index.aspx. Health care administrators should work with their infection prevention personnel and accreditation organizations to ensure that all recommendations are properly implemented to protect patients and personnel.

Problems with medical device reprocessing should be reported to the FDA's MedWatch Adverse Event Reporting program either online at https://www.accessdata.fda.gov/scripts/medwatch/, by regular mail, or by fax. Download the form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm or call 1-800-332-1088 to request a reporting form, then complete and mail to address on the pre-addressed form, or submit by fax to 1-800-FDA-0178. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (see: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm) should follow the reporting procedures established by their facilities.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Categories of Health Alert messages:

Health Alert	conveys the highest level of importance; warrants immediate action or attention.
Health Advisory	provides important information for a specific incident or situation; may not require immediate action.
Health Update	provides updated information regarding an incident or situation; unlikely to require immediate action.

##This Message was distributed to State and Local Health Officers, Public Information Officers, Epidemiologists and HAN Coordinators as well as Clinician organizations##

==========

You have received this message based upon the information contained within our emergency notification data base. If you have a different or additional e-mail or fax address that you would like us to use please contact your State-based Health Alert Network program at your State or local health department.

==========