醫療機構即刻重新檢視非拋棄式醫療器械之清潔、消毒、滅菌程序

摘要

美國疾病控制和預防中心（CDC）與美國食品藥物管理局（FDA）提醒醫療機構，為維護民眾健康，應妥善維護、清潔、消毒或滅菌非拋棄式醫療器械。近期醫療機構因為未遵從建議的處理流程導致感染控制疏失，突顯出病人安全的重要漏洞。因此，有使用非拋棄式醫療器械之醫療機構（如：醫院、門診手術中心、門診、和診所等），應立即檢討機構現行處理流程，以確保所有的步驟皆遵守廠商之建議及已經制定與現行標準和指引一致的適當政策和程序。

背景

近日媒體報導數起病人被通知其可能因醫療器械的清潔消毒及滅菌的疏失，以致於感染風險增加的案例。這些報導事件顯示出醫療機構於執行重要醫療物品(critical item)和次重要醫療物品(semi-critical item)的清潔消毒及滅菌處理流程時，並未落實及遵循廠商的建議。因此，醫療機構有必要再次審視機構內部相關的政策和程序，以確保病人安全。

建議

醫療機構應安排具醫療器械清潔消毒及滅菌專業知識之醫療照護專業人士，立即檢視評估機構內的處理流程。這個檢視評估作業是要確保整個清潔消毒及滅菌處理流程的執行能正確完成，其包括：有足夠的時間使工作人員能依循器械製造廠商的建議，執行所有步驟。因此，建議醫療機構執行下列作為：

一、教育訓練

醫療機構應提供所有執行醫療器械清潔消毒滅菌之工作人員相關的教育訓練。

（一）應於下列時機提供教育訓練，並規定相關人員參加：

1.於人員新進擔任該職務時或開始執行相關工作前。

2.至少每年一次。

3.有新技術或設備引進時，包含：廠商修正使用建議時。

（二）工作人員在開始負責執行器械清潔消毒工作前，應該完成相關的測試確認其具備執行能力。

（三）醫療機構應保存目前工作人員的訓練和能力測試證明文件。

（四）如果醫療機構聘請外包廠商執行器械之處理，機構應確認合作廠商有適當的訓練計畫，且訓練計畫內容包含該機構使用的所有器械。

（五）各項器械由廠商提供的使用及處理說明書抄本，應放置於適當位置，使工作人員和查檢人員能隨時方便取得，且說明書內容應包含化學消毒劑的使用說明。

二、查核與回饋

（一）醫療機構應定期查核（監測並記錄）清潔、消毒、滅菌和器械儲存程序的遵從情形。查核應評量所有處理步驟，包括：

1.在使用後、消毒或滅菌程序前，及時執行清潔作業。

2.依照廠商的說明使用消毒劑（例如：稀釋、接觸時間、儲存方式、保存期限）。

3.監測滅菌器的性能（例如：使用化學指示劑和生物指示劑、滅菌週期各項參數的數值、紀錄的適當保存）。

4.監測內視鏡自動化清潔消毒器性能（例如：流速、時間和溫度的列印資料，使用化學指標監測高層次消毒劑濃度）

（二）應針對機構內所有執行非拋棄式醫療器械處理的區域進行查核。

（三）醫療機構應依查核結果，將清潔、消毒和滅菌程序的遵從情形，回饋給工作人員知悉。

三、感染控制政策及程序

（一）醫療機構應安排充足的時間處理非拋棄式醫療器械，以確保所有步驟能夠遵循器械製造廠商的建議執行，包括清潔消毒的器械之乾燥、妥適的存放和運送。需要考慮的事項包括工作的排程與器械的數量，以確保有足夠的時間執行醫療器械的清潔處理與消毒滅菌流程。

（二）醫療機構應有相關指引，以確保醫療照護工作人員能輕易辨別器械已經過清潔消毒，並準備好提供病人使用（如：標籤系統、存放在特定區域）。

（三）醫療機構應有相關政策和程序，說明醫療機構當發現清潔消毒程序錯誤或失敗事件時的應變作為。醫療工作人員應評估錯誤或失敗的原因以及暴露情形，以判定可能的感染風險。應變程序應包含如何辨識、通知、及追蹤可能暴露於錯誤清潔消毒之醫療器械的病人。

（四）每當醫療機構要購買或引進新的器械時，應徵詢感染管制和清潔消毒負責人員的意見，以確保在採購決策和後續實施清潔消毒的適當政策和程序時，會將感染管制相關因素納入考量，並確保機構內已備有處理新進器械所需之設備。

（五）醫療機構應保存清潔消毒程序的相關文件，包括執行清潔消毒設備的維修紀錄（例如：高壓滅菌器、內視鏡自動清潔消毒機，醫用清洗機和清洗機消毒器，水處理系統）、滅菌紀錄（物理、化學和生物指示劑的結果）、和高層次消毒劑測試並適當更換的相關紀錄。

（六）醫療機構應依製造廠商的建議，保養與維修非拋棄式醫療器械及其相關的清潔消毒設備。如果醫療機構委由外包之第三方廠商承攬這些器械或設備的保養及維修，醫療機構應確認這些廠商具備原廠授權或認證，能提供上述服務。

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

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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.
  - 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 (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 (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 (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.ht

m)) should follow the reporting procedures established by their facilities.

[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.

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national and international organizations.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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