Patient Safety Alert

Department of Health
An Roinn Sláinte
Männystrie O Poustie
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HEALTH TECHNICAL MEMORANDUM (HTM) 01-06 – MANAGEMENT AND DECONTAMINATION OF FLEXIBLE ENDOSCOPES

For Action:

Chief Executives of HSC Trusts for distribution to:

- Medical Directors
- Directors of Infection Prevention and Control
- Consultant Microbiologists
- Theatre Managers
- Decontamination Leads
- Risk Managers
- Consultant Gastroenterologists
- Governance Leads

Chief Executive RQIA for distribution to:

- Independent Hospitals

For Information:
Distribution as listed at the end of this circular

Related documents:
HSS(SC)3/04 – Decontamination of Reusable Surgical Instruments
https://www.health-ni.gov.uk/sites/default/files/publications/health/HSS%20-%20SC%20-%203-04.pdf

NI/HTM 01-01/01 Periodic testing of Sterile Services Department (SSD) Washer Disinfectors (WD), Ultrasonic cleaners (UC) and Porous load sterilizers (PLS), September 2016
https://www.health-ni.gov.uk/sites/default/files/publications/health/NI-HTM%2001-01-01.pdf

NI/Testing Requirements/01: Water testing and Microbial testing requirements for Decontamination equipment, September 2016
https://www.health-ni.gov.uk/articles/dhssps-decontamination-programme-0

Superseded documents:
PEL (12)13 Choice Framework for local Policy and Procedures, CFPP 01-06

Implementation: Immediate

DoH Safety and Quality Circulars including Patient Safety Alerts can be accessed on:
https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars

Summary

HTM 01-06 takes account of the changes to the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy (ACDP-TSE) Subgroup's general principals on decontamination. HTM 01-06 replaces the guidance document Choice Framework for local Policy and Procedures, CFPP 01-06.

Specific Northern Ireland policy amendments that apply to the revised guidance are outlined in this circular.

Action

Chief Executives of HSC Trusts should:

- Disseminate this circular to all relevant staff.

Chief Executive, RQIA should:

- Disseminate this circular to all appropriate Independent Sector providers.

Background

The major change in this latest version of the guidance is taking account of changes to the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy (ACDP-TSE) Subgroups general principals of decontamination. (See ACDP-TSE's Annex C). In relation to the decontamination of flexible endoscopes, paragraphs C5 and C20 from the Annex state:

Paragraph C5:

For endoscopes, the bedside clean should take place immediately after the procedure has been carried out, and it is recommended that the endoscopes should be manually cleaned according to the manufacturer's recommendations and passed through an Endoscope Washer Disinfector as soon as possible after use.

Paragraph C20:

A routine test for washer disinfectors could be developed to measure the cleaning efficacy at validation and routine testing, such as daily or weekly tests. This method could be based on a process challenge device system that will monitor the optimised wash cycles; the results must be quantifiable and objective.

The ACDP-TSE Annex C guidance is available on the gov.uk website: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/427855/Annex_C_v3.0.pdf.

Health Technical Memoranda (HTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of health and social care.

The revised HTM 01-06 consists of five parts:

Part A: Policy and Management
Part B: Design and installation
Part C: Operational Management

Part D: Validation and verification (including storage/drying cabinets)
Part E: Testing methods

The suite of guidance documents is available:
https://www.gov.uk/government/publications/management-and-decontamination-of-flexible-endoscopes

A summary of the key revisions and specific Northern Ireland policy amendments applicable to the guidance for HSC bodies is detailed at Appendix 1 including requirements for full endoscope decontamination commencing within three hours of use and how HSC Trusts should approach this requirement.

The gov.uk website allows users to register to receive announcements on new publications and revisions to guidance such as Health Technical Memorandum guidance on decontamination. To subscribe to announcements, select Announcements at the bottom of the gov.uk webpage (https://www.gov.uk/government/announcements) and use the filter list to select your area of interest before selecting to receive announcements by email or by feed and complete the subscription process.

Enquiries:

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Yours sincerely

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Deputy Chief Medical Officer

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Appendix 1

List of Key Revisions to the HTM 01-06 Guidance

Part A:

- New Appendix 1: "General principles of decontamination and pathway of a flexible endoscope" to reinforce the importance of the bedside clean and the reduction in time from use of the endoscope on a patient to its route through the decontamination process.

  This outlines a flexible endoscope decontamination timeline which includes for full endoscope decontamination should commence within three hours of use. If there is a delay of more than three hours, it should be assured that the mechanism for keeping the endoscope moist until full decontamination will continue to be effective during this period.

  The pathway from patient use through the decontamination process and finally storage must be planned, controlled, monitored and recorded. Any delays in this process will impair decontamination.

- New Appendix B: decontamination recommendations for ERCP procedures and on-table bile duct exploration (new material and not a requirement of the ACDP recommendations)

Parts B and C**:** These parts remain unchanged

Parts D and E:

- Introduction of process challenge device cleaning efficacy test as a weekly test in the periodic tests. These are recommended to balance the overall testing of routine performance of both the cleaning procedures/washing machines and the consistent washing performance against the verification of the process.

- "Drying cabinets" chapter now retitled as "Controlled environment storage cabinets" and also revised to align with the new British Standard (BS EN 16442), which was not in existence when CFPP 01-06 was published in 2013. Periodic storage cabinet tests also included.

- New chapter on "portable storage systems" now included.

- New advice on tests for residual protein detection introduced.

Northern Ireland Policy Amendments:

The following Northern Ireland policy amendments apply to the HTM 01-06 suite of documents:

1. Health and Social Care providers in Northern Ireland are required to meet “best practice” requirements as outlined in the suite of documents rather than meeting

"essential quality requirements" and to have a plan to meet "best practice" as stated. This has been the consistent policy position in Northern Ireland in respect of "Best Practice" requirements as defined in circular HSS (SC) 3/04.

2. Key requirements of best practice flexible endoscope reprocessing facilities are; centralisation of flexible endoscope decontamination at facility level where practically possible; physical separation of wash/dirty and clean areas; having in place the Medical Devices Quality Management System BS EN ISO 13485: 2003; and operating in a manner consistent with the Medical Devices Regulations 2002.

3. HSC Trusts should review their current flexible endoscope pathways to determine if they can meet the recommended timeline for full endoscope decontamination commencing within three hours of use. If this cannot be met, HSC Trusts should undertake a risk assessment and adopt an appropriate risk management strategy to keep the endoscope moist until full decontamination is commenced.

4. The sizing of endoscope reprocessing facilities should be based on the unit projected throughput profile to determine the full range of equipment required including Endoscope Washer Disinfectors (EWDs), wash sinks etc. required to provide the level of service capacity for the unit, taking into consideration the unit working hours and the equipment downtime required for servicing and maintenance.

5. Northern Ireland addendums to HTMs for the validation and verification testing of Endoscope Washer Disinfectors are outlined in:

    - NI/HTM 01-06/01 (September 2016) - Periodic testing of Endoscope Washer Disinfectors (EWD) and Controlled Environment Storage Cabinets (CESC)

    - NI/Testing Requirements/01 (September 2016) - Water testing and Microbiological testing requirements for Decontamination equipment.

6. It is advised that manual washing sinks in the wash area should be of the adjustable height type to provide ergonomic working conditions for the range of staff carrying out the manual wash process and to ensure that the manual washing of endoscopes are carried out under the appropriate controlled environment i.e. able to be fully immersed, able to be adequately rinsed and detergent concentrations are maintained.

7. Current arrangements for the Department of Health (NI) Authorising Engineer (Decontamination) (AE(D)) assurance function remain unchanged.

8. Northern Ireland readers should refer to the equivalent Northern Ireland legislation and Department of Health (NI) policy and guidance for references to GB Legislation and DoH (NI) policy circulars.