HAZARD NOTICE
By arrangement with the Scottish Executive Health Department

FLEXIBLE AND RIGID ENDOSCOPES:
RISKS FROM INADEQUATE DECONTAMINATION

SUMMARY

Failure to adequately clean and disinfect flexible and rigid endoscopes between uses may increase the risk of transmission of infection between patients. Manual and automatic processes should be reviewed.

BACKGROUND

1. Inadequate decontamination of flexible or rigid endoscopes which are cleaned and disinfected (re-processed) using manual or automated processes could result in an increased risk of transmission of infection between patients. Examples of unsatisfactory practices include:

   a) the use of connection (adaptor) sets that are not designed for a particular endoscope and automated endoscope re-processor (AER),
   b) failure to decontaminate all channels including those that have not been used during the procedure,
   c) failure to manually decontaminate auxiliary channels prior to automated re-processing, where the automated process does not include these channels (e.g. elevator wire channel or auxiliary irrigation channel),
   d) failure to use high level liquid chemical disinfectants for auxiliary channels undergoing manual re-processing.

2. All endoscope channels require to be decontaminated after each procedure, even if they have not been used during that procedure, e.g. auxiliary irrigation channels.

3. Some endoscopes (particularly older models) have channels that are not accessible to automated decontamination processes and these require to be manually cleaned and disinfected.

4. The effective use of an AER requires the endoscope to be connected correctly to the machine, using the designated connection set for that particular model of endoscope. These connection sets are normally supplied by the manufacturer of the AER and are a vital part of the validation of AER/endoscope systems (see Scottish Health Technical Memorandum SHTM 2030 Washer Disinfectors, Part 3 Validation and Verification). Note: microbiological testing is detailed in HTM 2030 but not SHTM 2030.

ACTION

5. This notice should be brought to the attention of all appropriate managers, staff and users, particularly those involved in the use, re-processing, specification or purchase of endoscopes, as well as Senior Infection Control Managers and Consultants in Public Health Medicine (Communicable Disease and Environmental Health) – CPHM(CD&EH).

Suggested Distribution

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SCOTTISH HEALTHCARE SUPPLIES
Gyle Square Edinburgh EH12 9EB
A Division of National Services Scotland for NHS Scotland

CONTACT: RON EUNSON
E-MAIL: ron.eunson@shs.csa.scot.nhs.uk
FAX: 0131 314 0700
WEBSITE: http://www.show.scot.nhs.uk/shs/hazards_safety/adverse.html

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6. The effectiveness of endoscope reprocessing facilities and equipment should be immediately reviewed and assessed. The review team should include specialists in infection control, risk management, health & safety, decontamination and decontamination equipment.

7. The review should focus on the following points:
   a) Endoscope channels that cannot be decontaminated in an AER should be identified. These channels should be manually cleaned and disinfected, following the manufacturer’s instructions, after every use of the endoscope. Both cleaning and disinfection phases are essential and neither should be omitted.
   b) Endoscopes with channels that are not used during every procedure should be identified (e.g. elevator wire channel or auxiliary irrigation channel). These channels should be included in the decontamination cycle (manual or automated) after every use of the endoscope.
   c) Connection sets should be fully compatible with the AER and the endoscopes, as approved by the manufacturer of the AER and the manufacturer(s) of the endoscopes.
   d) All channels of each endoscope should be accessible to the decontamination process and the process should be validated for each type of endoscope.
   e) It should be confirmed that the AER will clean all endoscope channels before disinfecting. If not, the effectiveness of the manual cleaning carried out prior to placing in the AER should be monitored and confirmed.

8. If manual disinfection is required, ensure that:
   a) the correct concentration of disinfectant is used,
   b) the channel is filled and all air is expelled,
   c) contact time is monitored and recorded.

9. If any deficiencies in the above processes are identified, implicated endoscopes should be withdrawn from use until the local infection control team advises on adequate decontamination. If a problem is identified that could raise concerns for public health, the local CPHM(CD&EH) should be contacted.

10. Advice and Instructions For Use provided by manufacturers of endoscopes and AERs should be followed. Any problems with equipment or Instructions For Use should be reported to Scottish Healthcare Supplies.

11. When specifying a new endoscope, and again before purchasing, confirmation should be obtained that the endoscope is compatible with the decontamination process(es) available.

12. Endoscopes should not be put into service without a validated reprocessing procedure.

REFERENCES