South Tees Hospitals NHS
NHS Trust

HOSPITAL INFECTION CONTROL POLICY

Document No: HIC24
***All Sites**

ENDOSCOPE DECONTAMINATION USING AUTOMATED ENDOSCOPE REPROCESSORS

TITLE	Endoscope decontamination using automated endoscope reprocessors policy
SUMMARY	This document provides instruction and guidance to managers and others on how to manage Infection Control in their department All Chiefs of Service, Clinical Directors and Divisional / Departmental Managers throughout the Trust are required to instigate action to ensure the successful implementation of the policy within their area(s) of control.
DATE OF REVIEW	December 2007
APPROVED VIA	HICG 13/07/05, CESC 06/09/05
DISTRIBUTION	For distribution to all wards and departments via Risk Management Ext 2505
RELATED DOCUMENTS	HIC01
AUTHOR(S) / FURTHER INFORMATION	Infection Control Team
THIS DOCUMENT REPLACES	

ISSUED BY:
Chief Executive

ISSUE DATE:
September 2005

24: ENDOSCOPE DECONTAMINATION USING AUTOMATED ENDOSCOPE REPROCESSORS

Infection control policies are being constantly developed and revised. If a policy is referred to and is either not available or not current, please contact the Infection Control Team for advice.

24.1 INTRODUCTION

Endoscopic procedures carry a risk of causing infection. Contamination of endoscopes can occur from previous patients, from failure of the decontamination process (e.g. if the final rinse water is contaminated) or during endoscope storage. Although the risk of infection from endoscopic procedures is probably very low, there is no room for complacency. Patients undergoing endoscopies are often elderly and frail and many are immune-compromised. Infections in this group can have serious adverse consequences. Infections associated with endoscopic procedures could also bring adverse publicity and damage the reputation of the Trust.

Decontamination of endoscopes begins with thorough manual cleaning, with a suitable detergent, which should be performed as soon as possible after the endoscope is used. Following manual cleaning the endoscope is thoroughly rinsed. The endoscope is then disinfected, preferably using an automated endoscope reprocessor (AER). AERs are more effective at disinfecting endoscopes than manual cleaning alone and they are safer for staff because they provide containment of potentially irritant and sensitising disinfectants. This policy describes the procedures which are required to ensure that endoscopes are adequately decontaminated and that the final AER rinse water is safe. The policy is restricted to decontamination of endoscopes using AERs. Any clinical areas using manual processes to decontaminate endoscopes should attempt to develop plans to move towards using AERs. This policy does not cover the procedures required for instruments which are passed into sterile body sites, which generally require heat sterilisation (see HIC 19: Decontamination policy).

24.2 ASSESSING THE RISK FROM ENDOSCOPY

Factors which influence the risk of infection from endoscopy include:

- *The type of endoscopic procedure undertaken*: Procedures such as endoscopic retrograde cholangiopancreatography carry a higher risk than those that do not penetrate mucosal barriers.
- *The infectious agents present in the previous patient's secretions*: Organisms which pose a recognised risk include gram-negative bacteria (including *Pseudomonas aeruginosa*, *Klebsiella* species, *Enterobacter* spp, *Serratia marcescens* and *Salmonella* species), *Mycobacterium tuberculosis*, viruses (including hepatitis B), *Giardia*, *Cryptosporidium* and *Strongyloides*. New variant Creutzfeldt-Jakob (vCJD) also has a theoretical risk of transmission.
- *The effectiveness of the procedure used to decontaminate the endoscope*: Thorough cleaning is essential prior to disinfection in the AER. If a disinfectant is used at too low a concentration or for too short a contact time, then there is an increased risk of subsequent infection.

- *The duration and conditions of storage after endoscope decontamination*: The quality of the rinse water used for rinsing the endoscope is extremely important in preventing contamination (e.g. with *Mycobacterium chelonae* and *Pseudomonas aeruginosa*). Prolonged storage after decontamination is a risk factor for recontamination of the instrument.
- *The individual susceptibility of the patient to infection*: Patients who are immunocompromised are at increased risk of developing infections by organisms which usually are of low pathogenicity, such as environmental mycobacteria.

Two adverse consequences may arise from contamination of endoscopes. Firstly an infection may be transmitted to the patient. Secondly a patient may be incorrectly diagnosed with an infection because of a contaminated sample (e.g. mycobacteria in an bronchoscopy sample). Incorrect diagnosis may lead to the patient receiving inappropriate and potentially harmful drugs.

24.3 CAUSES OF INADEQUATE DECONTAMINATION

The major causes of inadequate decontamination are as follows:

- Inadequate manual cleaning prior to putting the endoscope in the AER
- Hard deposits of organic material on the endoscope surfaces
    - Damaged and deformed surfaces on the endoscope
    - Perforated instrument channels
    - Parts of the instrument not being exposed to the cleaning process due to being closed off by valves or seals
    - Failure to clean hinge joints, recessed surfaces, endoscopic lumens and other intricate areas
    - Ineffective rinsing and final drying procedures
- Contamination of wash-bottles and tubes connected to the endoscope
- Inappropriate and incomplete decontamination methods (e.g. the wrong choice of disinfectant or the wrong contact time)
- Use of disinfectant which is diluted below its effective concentration or which is used beyond its recommended shelf-life
- Design faults in the AER which allow persistent growth of microorganisms on the AER or on the endoscope
- Use of water (or other fluids) which is of poor microbiological quality
- Lack of water filters in the system

24.4 TRACEABILITY OF ENDOSCOPES

Flexible endoscopes have a unique serial number. This number should be recorded in the patient's notes when a procedure is performed. This will facilitate tracing which patients have been exposed to a contaminated device, if there is subsequently any question of potential transmission of infection. If accessories

are used they should be kept together with the endoscope to form a complete and traceable set. Wherever possible, single-use accessories should be used to prevent transmission of infection.

24.5 DECONTAMINATION PROCEDURE

Endoscopes must be decontaminated before the endoscopy list, between each procedure, at the end of the list and prior to inspection, servicing or repair. Staff members carrying out the decontamination procedure must be adequately trained. All operations should be carried out using the protective equipment recommended by the disinfectant manufacturers (e.g. gloves and waterproof garments). No cleaning or disinfectant product should first be risk assessed, under the COSHH regulations 2002 and the safety precautions specified into a suitable safe working procedure.

24.5.1 Initial cleaning of the endoscope

Effective cleaning is essential for the removal of debris. This removes organic matter and ensures better contact between the disinfectant and any remaining microorganisms during disinfection. This is important because disinfectants can act as tissue fixatives and this may cause endoscope lumens to block.

The detergent used for initial cleaning must be approved by the endoscope manufacturer and the AER manufacturer. Single-use detergents are recommended. If a reusable detergent is used then it must be used at the frequency recommended by the manufacturer.

Each channel should be cleaned with a brush (preferably single-use) at least three times before processing in an AER. The brushes used must be specifically designed for cleaning endoscope lumens.

24.5.2 Disinfection of the endoscope using an AER

The AER used to disinfect the endoscope must meet the design standards specified in the NHS Estates' Health Technical Memorandum HTM2030. The AER must be installed and validated according to the manufacturer's instructions. The AER should be used, maintained and serviced in accordance with the manufacturer's instructions. These instructions must be followed in full as otherwise the AER can become a potential source of infectious agents. The following factors have been found to be associated with the contamination of AERs:

- Inadequate cleaning, disinfection or maintenance of the machine
- Static water remaining in tanks or pipework being used by the AER

- The use of a water supply which is of poor microbiological quality
- The use of hard water
- Inadequate pre-cleaning of the endoscope
- Contamination by disinfectant-resistant mycobacteria
- The formation of a biofilm within the machine or pipe work supplying the machine

The disinfectant used in the AER must be approved by the AER manufacturer and the endoscope manufacturer. The disinfectant should be replaced in accordance with the protocol recommended by the disinfectant manufacturer. Advice on the minimum effective concentration and the minimum contact time of the disinfectant should be sought from the disinfectant manufacturer. This enables the AER to be programmed to run for the correct time.

The AER must be disinfected at the frequency recommended by the manufacturer using a disinfectant approved by the AER manufacturer. This is usually performed at least once a day using a pre-programmed self-disinfection cycle. The disinfectant chosen for this purpose should be a different one to that chosen for decontaminating the endoscopes. This minimises the risk of contamination with resistant bacteria. If a change is considered for either the type of disinfectant to be used for decontaminating endoscopes or the type of disinfectant for auto-disinfecting the AER, the procedure outlined in appendix A should be followed. High-level disinfectants must be selected which kill bacteria, viruses and spores under AER operating conditions.

Tanks and fluid pathways in the AER should be drained and left dry when not in use or the fluid pathway should be left in contact with fresh disinfectant solution. This minimises the risk of the AER becoming contaminated.

24.5.3 Using bacteria-free water for final AER rinse water

Filters and ultraviolet light are used to ensure that the final rinse water is free of bacterial contamination. A final filter of bacteria-retentive grade is crucial for removing microorganisms. The pipework, tanks, valves and pumps must be designed to avoid dead legs and areas where microbial growth may proliferate. All fittings and pipe connections must be pharmaceutical-grade sanitary fittings and comply with British Standard BS 6920 part 2. All tanks used for storage of water must be free-draining and cleanable. The water treatment system must undergo routine maintenance and if necessary decontamination to ensure its effectiveness. The Trust has named authorised persons who provide external expert advice on endoscope decontamination. These authorised persons should be used for external audit purposes and should also be consulted whenever major changes are considered to the system.

24.6 ENDOSCOPE STORAGE

After completion of disinfection the endoscope should be purged with 70% alcohol. The endoscopes should then be stored suspended vertically in ventilated storage cabinets to allow circulation of air. They should not be in contact with other endoscopes or with flat surfaces. Ideally the control valves, caps and any other detachable components should be stored separately. It is recognised that an endoscope may need to be stored assembled and available for out of hours emergency use. Before storage, the rubber seals of the suction and air or water valves should be lubricated sparingly with silicone oil or in accordance with the manufacturer's instructions.

Prior to use of an endoscope, which has been stored, it should be reprocessed again if the time since the previous disinfection is greater than 3 hours, according to the manufacturer's instructions.

24.7 MONITORING THE QUALITY OF THE FINAL RINSE WATER

The final AER rinse water should be sterile. However mains water is not sterile and therefore a water treatment system is required to provide water which is free from bacterial contamination. The internal pipework of the AER, intermediate tanks, mains water and poorly maintained filters can all be sources of bacterial contamination. It is therefore important to monitor the final rinse water to ensure it is of adequate quality. Samples should ideally be taken in the morning following overnight processor decontamination to allow the maximum time between decontamination and sampling. The site selected will generally depend on the design of the machine. The sites which should preferably be tested are the rinse water which has circulated through the AER (to identify any build up of biofilm) or the rinse bowl prior to discharge to drain. Both of these sites are representative of the final rinse water, with which the endoscopes are in contact.

The following monitoring is recommended for the final AER rinse water:

- The total viable count of bacteria, in the final rinse water, should be monitored on a weekly basis by culture at 35 - 37^{O}C. The results should be plotted on a graph to enable rapid identification of deviations from the normal results.
- Quantitative testing for *Pseudomonas aeruginosa*, in the final rinse water, should be performed on a weekly basis by culture at 35 - 37^{O}C. The results should be plotted on a graph to enable rapid identification of deviations from the normal results.
- Culture for mycobacteria should be performed periodically. The exact frequency should depend upon whether or not mycobacteria have ever been cultured from that AER previously. The frequency should be determined by consultation between the department which owns the AER,

the consultant microbiologist, the AER manufacturer and the infection control team.

- The frequency of routine endotoxin monitoring is a controversial area. Testing for bacterial endotoxins should occur when the AER is first installed and validated and subsequently if considered necessary following discussions between the department which owns the AER, the consultant microbiologist, the AER manufacturer and the infection control team.

The results from routine monitoring should preferably be reviewed by the external authorised person(s) on a regular basis.

24.9 ACTION TO BE TAKEN ON FINDING CONTAMINATED RINSE WATER

Appendix B details the action which should be taken if any of the above tests on AER final rinse water are positive. It is important to check with the AER manufacturer that the machine's components are compatible with the chlorine solution or any other disinfectant which is used for flushing the system. Filters should be decontaminated or changed when the system needs to be flushed with chlorine. If the initial flush with 1,000 parts per million (ppm) of chlorine fails then the following actions should be considered following discussions with the infection control team and the Estates department:

- Use a second flush with 10,000 ppm chlorine
- Replace as much of the pipework as possible to remove any biofilm
- Consider changing the disinfectant used for flushing the system
- Investigate the mains water supply, hospital tanks and all pipework in the system

If problems persist and the source of the problem cannot be identified, external expert advice may be required. The authorised persons are a useful source of assistance in this situation.

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APPENDIX A

Criteria for changing disinfectant for AERs

1. The proposed change should be discussed with the infection control team
2. A COSHH assessment should be performed and Occupational Health should be informed of the results to ascertain if they have objections.
3. The endoscope manufacturers should be contacted to confirm that the disinfectant is suitable for their equipment.
4. The manufacturer of the AER should be contacted to confirm that the disinfectant is suitable for their equipment.
5. A chemically different disinfectant must be used for cleaning the AER than is used for cleaning the endoscopes.
6. The disinfectant and AER must both be used in accord with the manufacturer's instructions.
7. The decision must be reviewed if routine monitoring of the microbiological quality of the rinse water suggests any deterioration after the change.

APPENDIX B

Figure 1: Action to be taken when contaminated rinse water is discovered