HEPA cabinets to dry and store flexible endoscopes

The rationale for HEPA cabinets is that adequately decontaminated endoscopes stored in this way will remain free of contamination during storage and be ready to use directly from storage without the need for reprocessing.

Health Technology Description

Flexible endoscopes are made of heat-sensitive materials and are routinely decontaminated by high-level disinfection and not sterilisation. After disinfection endoscopes must be stored dry and protected from contamination. The need to reprocess flexible endoscopes taken from storage immediately before use is controversial. British, European and Australian guidelines recommend that endoscopes are reprocessed before the first procedure of the day, whereas US multi-society guidelines do not recommend this procedure for endoscopes that have undergone appropriate decontamination and storage.

Current guidelines recommend that flexible endoscopes are stored in a designated ventilated cupboard and hung vertically to facilitate drip drying of residual moisture. Novel drying and storage cabinets for flexible endoscopes are now available that use a flow of air passed through a High Efficiency Particulate Air (HEPA) filter to ensure thorough internal drying of the endoscope channels during storage. They may also use ultraviolet (UV) light to prevent contamination of the external surfaces of stored endoscopes.

Key points

- Available unpublished evidence from laboratory and field tests is insufficient to clearly differentiate HEPA cabinets from standard storage cabinets with regard to protecting adequately processed endoscopes from contamination during storage.
- Evidence of clinical effectiveness is lacking with regard to whether disinfected flexible endoscopes stored in HEPA cabinets are safe to use without reprocessing.
- To inform evidence-based decision making on HEPA cabinets further studies are needed to provide methodologically robust and clinically relevant information regarding patient safety.
- The cost-effectiveness of HEPA cabinets in relation to current practice has not been formally evaluated.

Epidemiology

The available evidence, largely from case reports, suggests a low but probably underestimated incidence of infection transmitted from contaminated endoscopes to patients. A review of the literature from 1966 to 1992 identified 96 infections transmitted by bronchoscopy and 281 by gastrointestinal endoscopy. The risk of contracting an infection from a contaminated endoscope was estimated at 1 in 1.8 million procedures based on bacterial infections related to endoscopy reported in the US between 1988 and 1992. Between 1990 and 2002 the FDA database of adverse events involving medical devices contained seven possible episodes of pathogen transmission during gastrointestinal endoscopy. The clinical spectrum of reported infections ranges from asymptomatic colonisation to death.
Clinical Effectiveness

A literature search failed to identify published studies evaluating the clinical effectiveness of HEPA cabinets. One published report\textsuperscript{10} was found of data contained in one\textsuperscript{11} of four unpublished evaluations that were obtained through manufacturers of HEPA cabinets.\textsuperscript{11-14} Three evaluations were conducted under laboratory conditions\textsuperscript{10-12;14} and one in an endoscopy unit.\textsuperscript{13}

The laboratory evaluations used test or surrogate endoscopes (pieces of stainless steel) contaminated artificially with known bacteria\textsuperscript{10-12;14} or by exposure to the environment\textsuperscript{11} and assessed cabinet performance of drying, removal of residual bacteria and contamination during storage. In the endoscopy unit endoscopes were hung in a HEPA/UV cabinet immediately after high-level disinfection to assess contamination during storage under normal conditions.\textsuperscript{13} Tests of contamination involved sampling internal and external surfaces of endoscopes or surrogates for viable bacteria before, during and after storage.

The overall conclusion from the laboratory evaluations was that, providing high-level decontamination is effective, flexible endoscopes will be free from bacterial contamination after storage in a HEPA/UV cabinet for 72 hours up to one week.\textsuperscript{10-12;14} Design characteristics varied widely between the studies. Instances of increased contamination were observed and one report recommended reducing the cabinet temperature to avoid a temporary increase in viable bacteria in the first 12 hours of storage.\textsuperscript{10;11} The endoscopy unit test found no overgrowth of harmful bacteria in disinfected endoscopes stored for up to 72 hours, although most of the results related to overnight storage, whether the cabinet HEPA filter and UV were switched on or off.\textsuperscript{13} The report also suggested that there was no difference between storage in the HEPA/UV cabinet and the wooden cupboard routinely used to store endoscopes.\textsuperscript{13}

Limitations in design and reporting and uncertainty around the applicability of the microbiological testing to clinical outcomes warrant careful interpretation of the existing evaluations. Furthermore, published studies of flexible endoscopes hung in ventilated dust proof cupboards for up to one week following high-level disinfection under laboratory conditions\textsuperscript{15} and during normal use in an endoscopy unit\textsuperscript{16} have used similar methods and reported similar findings to the evaluations of HEPA/UV cabinets.

Draft guidance from Health Protection Scotland states that endoscopes can be used without reprocessing following storage for less than 72 hours in a purpose built HEPA filtered cabinet - that being the maximum period validated by the manufacturers.\textsuperscript{17} The British Society of Gastroenterology is to review the evidence in October 2006 before recommendations can be made regarding their use (M Allison, BSG Endoscope Committee Working Party. Personal communication. 26 June 2006).

Potential Risks

Transmission of infection via a contaminated endoscope is a potential risk to patient safety. A recent incident in Northern Ireland necessitated notifying more than 3500 patients and testing almost 1500 exposed to a risk of viral infection.\textsuperscript{18;19} Transmission of infection to health care workers is another potential risk associated with contaminated endoscopes.\textsuperscript{3}

There is no generally accepted way to verify the adequacy of high-level disinfection of an endoscope at the point of use and there is a lack of clinical evidence on the need to subject stored endoscopes to an additional reprocessing cycle before use.\textsuperscript{1} Epidemiologic evidence suggests that virtually all transmission of microorganisms via endoscopes is due to failures in cleaning and disinfection of equipment.\textsuperscript{2;8;9;20} A recent review of endoscope decontamination practice in Scotland found widespread non-compliance with best practice guidance.\textsuperscript{18} Inclusion of a model decontamination map in the report indicating that endoscopes stored for less than 72 hours in a HEPA cabinet can be used without reprocessing was not discussed in the wider context of the review’s findings.\textsuperscript{18}
Economic Implications

No published economic information was identified. HEPA cabinets cost around £7,000 to £10,000 each (Scottish Healthcare Supplies) and store between six and ten endoscopes. Running costs are expected to be low. Less frequent reprocessing of endoscopes would result in a cost saving for individual units depending on how often endoscopes are used. Savings would be expected on staff time, reprocessing consumables and wear and tear on endoscopes.\(^\text{15}\) One manufacturer estimated an annual saving on disinfectant of £7,200 based on one cabinet storing eight endoscopes calculated thus: £3 x 8 x 300 working days.\(^\text{21}\)

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Further information

- Suppliers of HEPA cabinets include [www.afosgroup.com](http://www.afosgroup.com), [www.lancer.co.uk](http://www.lancer.co.uk), and [www.labcaire.co.uk](http://www.labcaire.co.uk).
- For further information about the Evidence Note process, see [www.nhshealthquality.org](http://www.nhshealthquality.org) or email evidencenotes@nhshealthquality.org
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References


