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Guidelines

Guidance for the decontamination of intracavity medical devices: the report of a working group of the Healthcare Infection Society

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SUMMARY

Background: Intracavity medical devices (ICMDs) are used in a wide variety of healthcare settings. The approach to their decontamination and the resources available also differ widely. Their potential for infection transmission is considerable.

Aim: To produce a comprehensive risk assessment-based approach to the decontamination of ICMDs, accompanied by an adaptable audit tool.

Key recommendations:

- All ICMDs should be classified according to the risks of infection transmission they pose.
- The processes used for their decontamination should conform to a basic essential quality requirement, with progression towards a higher quality best practice.
- After each use, all probes should initially be thoroughly cleaned.
- Those probes with mucous membrane contact should be disinfected in a controlled process.
- Manual disinfection would comply with essential quality requirements; validated automated disinfection would constitute best practice.
- Areas of the probe and its associated parts that make contact with an operator's contaminated hand also require decontamination.
- Probes in contact with sterile body tissue should be sterilized; use of sterile barriers alone is unacceptable.
- All those who decontaminate ICMDs should be trained to do so.

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- Decontamination should occur in facilities adequately equipped and allowing a defined dirty to clean flow pathway.
- There should be a documentation system that allows tracking and tracing of each probe to the patients it is used on and each episode of its decontamination.
- That a healthcare provider can supply adequate decontamination should be established before a new ICMD is acquired.
- The process of ICMD decontamination should be regularly audited.

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Introduction

Intracavity medical devices are an essential part of medical practice in a variety of settings. There is a wide range of such devices, principally ultrasound or manometry devices. Surveys in the UK and Europe have revealed a variety of practices for the decontamination of these devices which led to the formation of our working group and production of this guidance [1,2]. Decontamination methods used for other devices (thermal washer-disinfectors and steam sterilization for surgical instruments or automated chemical washer-disinfectors for flexible endoscopes) would not be applicable to ultrasound-based intracavity probes due to their heat sensitivity and inability to be fully immersed.

Intracavity devices can be expensive and delicate. Their expense limits the number of devices that a healthcare provider has, which in turn leads to the requirement for a rapid decontamination procedure to reduce the delay between sequential uses. Whereas manufacturers are required to provide instructions for decontamination of reusable medical devices, these are sometimes insufficiently detailed.

These probes are usually manufactured for a global market. Standards for decontamination may vary among the different geographical user groups. Different regions of the world may have different approaches to requirements for decontamination; global guidance cannot take account of this. To ensure that a device can be decontaminated to local standards, it is essential to obtain information on decontamination prior to its purchase.

The guidance contained in this Healthcare Infection Society working group report is intended to be used by infection prevention and control teams, decontamination leads, and device users/reprocessors to help in their local approach to risk assessment and decontamination of these devices. It cannot give detailed instructions for each type of device but does aim to set out the requirements for decontamination and give guidance on assessing current practices with a view to improving them, if necessary.

Scope

This guidance covers reusable devices used for medical investigations and procedures that are neither amenable to steam sterilization, nor fully immersible and do not have well-established decontamination guidance, such as flexible endoscopes. It will focus on such devices that are used in body cavities or that may have contact with non-intact skin. Examples of such devices are:

- transvaginal ultrasound probes
- transrectal ultrasound probes
- transoesophageal echocardiography probes
- anorectal and oesophageal manometry probes
- sentinel node biopsy probes
- transcranial Doppler ultrasound probes.

Whereas each device – indeed any particular make of device within a category – may have particular requirements or constraints, this guidance outlines generic approaches for device decontamination allowing safe reuse.

Not only the patient contact parts of a device are important; other surfaces (controls, keyboards, electrical connectors, etc.) may have sequential contact with an operator's contaminated gloved hands and the probe. The approach here should be that either there are ways of work that prevent such contact or that these surfaces are decontaminated between patients to the same standard as the probe.

Principles of decontamination

The approach taken within this guidance reflects that of Department of Health (England) decontamination guidance outlined in the Health Technical Memorandum 01 (decontamination) series [3]. The minimum standard should be compliance with essential quality requirements (EQR). EQR is attained when all statutory and regulatory requirements for decontamination have been met. While meeting EQR, device reprocessors should have a plan in place to achieve best practice, defined as measures additional to EQR covering non-mandatory policies and procedures that aim to further minimize risks to patients and generally represent a higher quality assured process than EQR.

The definition of decontamination used in this document is: the sequence of processes including cleaning and microbicidal actions that make a reusable medical instrument safe for reuse. It is important to realize that this is a far wider process than merely, for example, which chemical agent is chosen.

Principles of decontamination applied to intracavity medical devices

Cleaning could be manual, automated or both in sequence. As cleaning is the process that removes both the majority of microbes and organic material that may hamper subsequent microbicidal processes, ensuring efficient cleaning is vital. Both manual and automated cleaning should be done by

trained staff using the correct materials in an environment that facilitates efficient cleaning and prevents recontamination.

Microbicidal action could either be sterilization (the elimination of viable microbes with high-quality assurance) or disinfection (a lower level than elimination of microbes but with quality assurance that ensures that an item is safe without necessarily being sterile). For the majority of applications of ICMDs, sterility is unnecessary; they are used in body cavities. The commonest method of attaining sterility (high-temperature steam) is incompatible with ICMDs. Specialized low-temperature sterilization methods compatible with ICMDs may be expensive and some have long cycle times. Where ICMDs make contact with normally sterile body tissues (e.g. exposed brain), best practice would be to

- clean and dry them thoroughly;
- wrap them in materials that prevent recontamination and that are compatible with the sterilization process;
- sterilize with a process that is compatible with the device. Such processes need to be at a temperature compatible with the devices;
- ensure that staff training in decontamination is in place.

The microbicidal action attained by disinfection may, if the process parameters are adequate and controlled, be adequate to ensure patient safety. Heat disinfection is, like steam sterilization, incompatible with ICMDs. The use of microbicidal chemicals (i.e. disinfectants) is the most appropriate means of making ICMDs safe for reuse, but their selection and use needs to be within a highly controlled process.

The approach to categorization of ICMD decontamination is given in Table I. The level of decontamination should be determined locally for each device.

Although not classified as ICMD, probes that have contact with intact skin such as abdominal ultrasound will also need decontamination. For these, cleaning between uses is normally sufficient. They should be disinfected if there is known or suspected contamination with significantly pathogenic microbes or if a patient is at significantly increased susceptibility to infection. If probes intended for use on intact skin are used on broken skin, they must be disinfected before that use and again before reuse.

Whereas the classical ('Spaulding') approach provides a good starting point for such considerations, intracavity device use often has subtleties that do not make strict conformity to this approach practical [4]. As an example, for transrectal ultrasound-guided prostate biopsy: as the device is used as part of a procedure that enters a normally sterile body area, sterilization would initially seem appropriate. However, this procedure takes place via a highly contaminated body area and the purpose of decontamination is to prevent patient-to-patient transmission of infection. Thus, sterilization of the ICMD in

this situation is of low relevance and practicality (whereas the associated biopsy needle and needle guide are more difficult to decontaminate and are readily available as pre-sterile single-use). By contrast, the use of intracranial probes is an example of when sterilization of the device should occur; here, any microbial contamination is a significant infection risk. Local risk assessments should take account of such constraints.

Combining service provision with adequate decontamination

Adequate decontamination may increase the number of ICMDs required to provide a service. If patients are seen in quick succession, it may need several ICMDs to be in sequential use to allow for decontamination time. This will need to be taken into account when planning the resources required to provide a service.

ICMD covers

There is a perception that ICMD covers in themselves constitute an effective infection prevention intervention. This is not reliably the case for the following reasons:

- (i) ICMD covers may develop holes during use [5–8].
- (ii) Removing covers without contaminating the probe may sometimes be difficult [8].
- (iii) Staff-contaminated gloved hands can make contact with areas of the ICMD or associated equipment not protected by the cover [9].

Unless specifically risk-assessed as reliably providing high-quality assurance patient protection with respect to all these areas, decontamination conforming to the standards detailed in this guidance should occur.

There should be full decontamination after every ICMD use regardless of the use of a cover.

Existing guidance

Some guidance exists but is either very specific, uses very broad principles, or advocates chemical disinfectants that would not be considered safe for use in the UK [4,10–15].

Manufacturers of CE (Conformité Européene)-marked, reusable medical devices are required to provide information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized. In practice this often means giving lists of process chemicals (i.e. detergents and disinfectants) that are compatible with an ICMD but not necessarily those that are suitable for adequate

Table I
Principles of intracavity medical device (ICMD) decontamination

ICMD use	Decontamination	Example of ICMDs
Body cavity/mucous membrane	Clean and disinfect, or single use.	Transrectal Transvaginal Anorectal manometry
Normally sterile body tissues	Sterilization (the use of sterile barriers as a substitute for ICMD sterilization is not acceptable)	Intracranial Sentinel node biopsy

decontamination and sometimes may not be available in all countries that use the device. Many do not describe the whole decontamination process in sufficient detail. Manufacturers' guidance should be incorporated into local procedures but will not, in itself, be adequate to form the whole procedure. BS EN ISO 17664 provides guidance on the information that should be included in the manufacturer's reprocessing instructions when a device is CE-marked as a medical device [16].

The Medicines and Healthcare products Regulatory Agency (MHRA) has produced guidance requiring that 'Healthcare organisations should keep patients, staff and visitors safe and have policies and systems in place to ensure that all reusable medical devices are properly decontaminated prior to use or maintenance, and that the risks associated with decontamination facilities and processes are well managed' [17]. Following an incident of probable transmission of hepatitis B via an ultrasound probe, MHRA issued an alert requiring, among other things, that users of reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes to 'Review, and if necessary update, local procedures for all ultrasound probes that are used within body cavities to ensure that they are decontaminated appropriately between each patient use, in accordance with the manufacturer's instructions' and to 'Ensure that staff who decontaminate medical devices are appropriately trained and fully aware of their responsibilities' [18].

In England HTM 01-06 and in Wales WHTM 01-06 give guidance for the decontamination of transoesophageal echocardiography, transvaginal and transrectal ultrasound probes [13,14]. More detailed guidance has been issued specifically for transoesophageal echocardiography probes [11].

The US Centers for Disease Control and Prevention issued guidance in 2004 that includes decontamination of ICMD but these are addressed comparatively briefly, and disinfectants no longer available in the UK, such as glutaraldehyde, are included for consideration [4].

Facilities for decontamination

The layout of the decontamination facility should allow a defined pathway from 'dirty' to 'clean' i.e. from contaminated to fully decontaminated. This pathway should be linear and not cross back on itself. The reasons for this are two-fold. (i) Surfaces will become contaminated by contact with contaminated instruments; attempts at decontamination of such surfaces can have poor quality assurance. If an instrument at a particular stage of decontamination is put on a surface that has had contact with an instrument at a previous stage of decontamination, that instrument will become recontaminated. (ii) The location of an instrument should signify its place in the progression of the decontamination process. If a facility is used by a number of people, it may happen that a user picks up a clean-looking instrument, assuming it wrongly to have been fully decontaminated. This would not happen if the location of an instrument also signified its stage in the decontamination process. In addition to this, there should be a system in place to indicate which ICMDs are ready for patient use, e.g. documentation accompanying a decontaminated ICMD.

Having a defined and obvious decontamination pathway also facilitates the changing of staff gloves and other personal protective equipment (PPE) so they cannot be vectors of indirect contamination. This also requires staff training, so they know when to wear new PPE and in what stages of the process.

The room should be equipped with a sink for cleaning which is distinct from the dedicated hand wash basin. There should be sufficient work surfaces within the room to allow the progressive flow from dirty to clean to occur reliably. There should also be sufficient storage for the consumables used during the decontamination procedure, e.g. PPE, chemicals, etc., and sufficient capacity for waste disposal.

Best practice would be attained when decontamination takes place in a dedicated room separate from the patient/clinical room. This room would be laid out and equipped for optimal ICMD decontamination. It should be staffed by trained decontamination technicians, releasing radiographers or other clinical staff of this burden. The essential quality requirement could be attained using the same room as the treatment room (for example in outpatients) only if the general principles outlined above can be applied adequately and staff have received adequate training in decontamination of ICMDs.

Cleaning

Cleaning should occur before any blood/body fluid has dried. Ideally this should be immediately following use.

The agent chosen should be:

- compatible with the device being cleaned;
- safe to use;
- effective at removing the soils likely to be present;
- easy to use.

It should be used in a controlled way such that it:

- cleans all surfaces likely to be contaminated (not only patient contact areas but also staff hand contact areas);
- ensures removal of organic matter.

If the detergent is likely to compromise the efficacy of the disinfectant, the detergent should be thoroughly removed by rinsing before disinfection.

Enzymatic detergents suitable for cleaning medical devices, i.e. CE-marked, are available. However, these require prolonged exposure at a specific concentration and temperature to have maximum efficiency and it is doubtful whether there is benefit in this situation from enzyme-containing detergents. In addition, there are health and safety implications if not used correctly [19].

Any checks that the manufacturer recommends (e.g. leak or electrical tests) should take place prior to immersion in fluids.

Verification of cleaning is most practically achieved by visual inspection. This should occur on every surface area of every cleaned item. There should be adequate lighting in the area where this is done. Other methods such as those that detect protein or ATP may be used but only on a low proportion of items cleaned. As contamination may be patchy, a negative result is not necessarily an indicator of thorough cleaning. There is also the problem that the most difficult areas to clean are also the most difficult areas to sample. For these reasons, thorough visual inspection of every item is recommended as the verification method of choice.

Sterilization

If an ICMD is intended for contact with sterile body tissues, sterilization will be required. Low temperature sterilization

methods are available, e.g. ethylene oxide or hydrogen peroxide sterilization systems that should be compatible with ICMDs. The ICMD should be cleaned and dried. It should then be wrapped in a material that is compatible with the sterilization process and that will preserve the sterility of the ICMD until it is used.

Disinfection

Many ICMDs are intermediate-risk items, i.e. in contact with intact mucous membranes, so will require cleaning followed by disinfection.

If chemical disinfection is used, then the following should be considered:

- microbicidal spectrum of the disinfectant
- compatibility of the disinfectant with the device
- contact time required
- method of application
- reproducibility of the process
- staff safety.

It is important that the disinfectant is in contact with all surfaces of the device and that it remains liquid for the recommended contact time. This is more easily achievable with an automated washer-disinfector or by partial immersion in disinfectant. Disinfectant-impregnated wipes that contain an effective disinfectant are widely used but the assurance that all surfaces are in contact with liquid disinfectant for the required time is not easy to achieve as a high-quality assurance standardized process. Therefore, best practice is the use of an automated system or partial immersion, with manual disinfection of any parts that cannot be thus treated. If this is not practical due to the complexity of the device, then wipes may be used. The lack of sufficient devices and requirement for a rapid turnaround should not be seen as the sole reasons for the acceptability of disinfectant wipes.

Low-temperature sterilization may also be an option if the manufacturer's recommended chemical disinfectant is not available.

The role of automated decontamination processes

Unlike flexible endoscopes, ICMDs are not usually fully immersible. Therefore, whereas automated washer-disinfectors provide a good quality of cleaning and disinfection, there will still be a requirement for manual cleaning and disinfection of those parts of an ICMD that cannot be immersed. As parts that cannot be immersed may be intricate (such as the tip-angulation control wheels on a transoesophageal echocardiography probe) and present a distinct challenge to manual cleaning and disinfection, users will have to make a local risk assessment as to what will be gained and lost from using an automated process in addition to manual decontamination.

Systems are available that encase the non-submersible parts of the ICMD to allow an endoscope washer-disinfector to be used. The advice of the ICMD manufacturers should be obtained before using this type of system. Those encased parts of the ICMD and the internal surfaces of the encasing chamber (i.e. those surfaces not exposed to the decontamination

procedure) will require decontamination by manual cleaning and application of compatible disinfectant, as described above.

Emerging technology

New technology specifically for the disinfection of ICMDs is now emerging. However, these systems do not include cleaning as part of the process, so manual cleaning is essential prior to use. The agents used for the disinfection process in these systems are currently either hydrogen peroxide or ultraviolet light. Some will accommodate the entire ICMD (including the non-submersible components) and others only the part of the ICMD in contact with the patient.

Validation of automated disinfection systems for ICMDs

No European standard exists for equipment designed specifically for the decontamination of ICMDs. BS EN ISO 14937 outlines the methods to be followed for characterization of a sterilization process and this could be adapted for disinfection processes as the same principles apply [20]. Validation should be carried out on installation of the decontamination device (including installation qualification, operational qualification, and performance qualification – see below for details) and periodically thereafter, e.g. annually (often called revalidation). If the system uses a chemical disinfectant where adequate concentrations can be detected using an indicator, these could be used more frequently to establish compliance with that process parameter as a form of process monitoring. Chemical indicators exist for hydrogen peroxide-based systems. If a UV light type process is used, then the system should incorporate UV dose measurement for cycle process monitoring. All testing records should be retained according to local policy.

Type testing

Before purchase of any system of this type, prospective purchasers should assure themselves that relevant type testing has been undertaken that includes validation of the process against relevant micro-organisms (such as those listed in Annex A of BS EN ISO 14937) [20].

Test pieces inoculated with micro-organisms could be used but these will not replicate the crevices associated with some ICMDs. Type testing should establish that the disinfection process can successfully inactivate realistic contamination within the most inaccessible areas.

Commissioning checks and tests

These fall under two headings: (i) installation qualification; (ii) operational qualification.

Installation qualification (IQ)

Before any automated decontamination system is used, the manufacturer/supplier should undertake some form of installation qualification. This should ensure that the machine has been supplied and installed correctly, is safe to operate, has been provided with satisfactory services that do not impair the

performance of the machine, and that operation of the machine does not interfere with other equipment.

It would usually involve checking the electrical and any water supplies, testing the alarm functions, and ensuring that the equipment can run through a satisfactory cycle.

Operational qualification (OQ)

This is usually undertaken at the same time as IQ tests. OQ tests establish that the equipment as installed operates within its correct parameters and documents those parameters as reference points for comparison with future assessments. The tests used will vary but should be based on relevant parameters for that particular decontamination process from the OQ tests outlined in the guidance on endoscope washer-disinfectors (Table 1 in HTM 01-01 part D) [21]. OQ tests should include an automatic control test (showing that the parameters indicated and recorded by the equipment show the cycle functioning correctly). It should include verification of the accuracy of the equipment's instrumentation. Correct dosage of any microbicidal component (such as UV light or hydrogen peroxide) should be verified. The set of tests could also include observation that any indicators used function adequately.

Performance qualification (PQ)

This consists of tests designed to prove that the equipment performs satisfactorily using the type of loads intended to be processed. It aims to show that decontamination conditions have been attained throughout the load and the machine's chamber, and to the required standard for the type of load being processed. As with endoscope washer-disinfectors, microbiological tests will usually be required for ICMD decontamination systems that use chemical disinfectants.

To replicate the low soiling that may persist after cleaning, micro-organisms suspended in 0.03% bovine serum albumin should be used. Annex A of BS EN ISO 14937 lists the test micro-organisms that could be used for a PQ test [20]. Where UV light processes are used, microbiological testing is still of value, even when dose measurement systems are fitted, as validation of that dose.

Additional PQ tests for process residues may also be desired to be sure that the process leaves no harmful residues on the processed devices.

Revalidation

After validation and when the machine is passed into service, it should be subject to a schedule of periodic tests at intervals recommended by the manufacturer, to provide evidence that the machine continues to operate within the limits established during installation. As a minimum the machine should be subject to a set of annual tests. These serve to demonstrate that data collected during IQ, OQ and the PQ remain valid.

For these types of process, the tests should normally consist of a repeat of the OQ tests followed by any previously agreed PQ, which would include any microbiological tests.

A suitably resistant micro-organism on a test disc or other suitable test piece, such as self-contained biological indicator systems, should be used in annual revalidation as assurance that combined cycle parameters are still effective.

Cycle parameters

The standard cycle should be used.

Acceptance criteria

The acceptable decontamination level should be that of most European Standard disinfection tests: a 5 log₁₀ reduction for bacteria or a 4 log₁₀ reduction for viruses.

Further advice

Further advice on the validation of automated ICMD decontamination systems can be obtained from an authorizing engineer (decontamination). Many hospitals already retain the services of such an engineer to advise on other matters of decontamination.

Storage and transport

The storage of ICMDs following decontamination is not a critical process. Since they do not have the same potential for bacterial growth as flexible endoscopes, as they do not have lumens, there is no limit on the storage time before the required reprocessing. Nor do they have to be stored in specially ventilated cabinets (as do flexible endoscopes) in order to dry them.

Storage of decontaminated ICMDs should be in an area that will not allow recontamination of processed devices directly or indirectly (i.e. making contact with contaminated surfaces including hands) with blood or body fluid.

Documentation, tracking and tracing

Each ICMD should have a unique identifier and a record kept of the device used on each patient and the method of decontamination. This is important information if a look-back investigation were required, following a decontamination failure or suspected infection transmission.

There should be a means to indicate which devices are ready for patient use and which are awaiting decontamination. Visual examination alone of the device before use is not sufficient.

Assessment tool for ICMD decontamination

The purpose of this tool is to consider areas where intracavity probes are decontaminated, to assess potential hazards, and to identify any local risks with the procedure. The audit tool follows essential requirements leading to 'best practice', which should be followed where possible. Procedures that deviate from best practice must form part of a locally developed risk assessment. Regular audit of decontamination procedures should be performed, at a frequency that can be determined locally.

The initial step in every risk assessment should be establishing the risk level of an ICMD in relation to what body tissues it makes contact with (Table I). The observed current decontamination method can be assessed as either 'unacceptable – action required', 'essential quality requirements fulfilled', or 'best practice achieved' (Table II).

Table II

Assessment of observed intracavity medical device (ICMD) decontamination

Observed process	Assessment
Cover only	Unacceptable – action required
Cover and detergent cleaning	Essential quality requirements fulfilled
All surfaces that make patient or staff hand contact are thoroughly cleaned and exposed to an effective disinfectant for the required contact time	
Use of manual cleaning followed by an automated system that gives an assurance of the decontamination procedure and decontaminates all surfaces of the device that make patient or staff hand contact, or sterilization (if required)	Best practice achieved

This initial assessment will assist in deciding whether further action is required. A more detailed audit tool is given in [Table III](#). This will assist in identifying what action, if any, may be required following audit.

Education and training

Education and training are essential for the decontamination of reusable devices. Where items are reused, it is essential that staff undergo training and retraining at regular intervals to ensure competencies, for example at annual updates. This needs to be included in the induction programme for all new staff undertaking the decontamination process and should be logged as retrievable evidence in staff records. This will make it useful for appraisal and to identify the needs of staff undertaking the decontamination of any reusable device. The level of training provided may vary between staff groups and should be tailored to suit the need of the group. This includes training in basic principles through to advanced training, which may need to be given at a specialist training centre. Training and education requirements should be specified in job plans and sufficient time given to training/education needs during employment.

The education and training should include the following.

The principles of decontamination:

- Appropriate identification of item to be used.
- Consider correct use of personal protective equipment (PPE) before use.
- Correct handling of the device before, during, and after use.
- Correct initial cleaning.
- Appropriate use and hazards of chemicals.
- Appropriate storage of chemicals.
- Appropriate disposal of chemicals and waste.
- Correct rinsing where necessary and drying as necessary.
- Correct storage of the item(s).
- Appropriate means of identifying items requiring repair and appropriate decontamination of items prior to repair or loan.
- Importance of record-keeping for tracking and traceability.

How to undertake a risk assessment:

- How is the item to be used?
- Where is the item to be used?
- Who is to use the item?
- Health and safety requirements.
- Appropriate documentation.
- Training.
- How to identify risks associated with the item and risks associated with not using the item.

Procurement of equipment:

- How is the item to be purchased?
- What level of decontamination is required?
- Are the facilities available or will additional equipment be required?
- Are tracking and tracing requirements met?

Problem solving:

- Critical incidents – how to recognize them.
- Who to inform, what to do, and how to get help.
- Documentation of incidents, e.g. eAIMS (Emergency Analysis Identification and Management System) forms, RIDDOR (Reporting of Injuries, Disease and Dangerous Occurrence Regulations), and COSHH (Control of Substances Hazardous to Health).

There are organizations that provide general decontamination education, including the Institute of Decontamination Sciences, Health Protection Scotland, Steris University (a US organization), and Anglia Ruskin University.

Guidance when procuring new equipment, including replacing or upgrading existing equipment

The manufacturers of ICMDs must be required to provide instructions for the safe and effective processing of equipment. Manufacturers' information should provide details of validated decontamination methods and of what processes are compatible with the equipment. For example, what chemical disinfectants are compatible with the equipment? Are they available locally or nationally? It is most efficient to use processes and disinfection products that are already present and in use in the healthcare facility. This makes training and purchase of consumable items more effective and economic. Therefore, it is also important that manufacturers state that the decontamination processes being considered by the user will not affect equipment warranties or service contracts.

It is essential that a business case based on the manufacturer's recommendations with an assessment of the requirements for cleaning, decontamination or sterilization of ICMDs is built into the procurement process. The failure to do so could result in obtaining equipment that is not fit for purpose. As a result, considerable costs may be incurred during implementation, not included in the original business case.

It is useful to ensure that routine assessment by an infection prevention and control specialist is built into the process, as

Table III
Audit tool for intracavity medical device (ICMD) decontamination

Question	Requirement	Yes	No	Comments
Overall approach to decontamination				
Is the ICMD decontaminated between patients?	Essential			
Does the decontamination process involve cleaning and disinfection (whether or not a cover is used)?	Essential			
Are manufacturer's reprocessing instructions provided and can they be followed?	Essential			
Is the control unit, i.e. monitor, keyboard, etc., decontaminated between patient uses or are separate hands used for ICMD and controls?	Essential			
Is it clear which ICMDs have not been fully decontaminated and which are ready for patient use?	Essential			
Decontamination				
For manual decontamination using chemical disinfectants – are the products (liquid or wipe) used in accordance with the disinfectant manufacturers' instructions?	Essential			
For manual chemical disinfection – are all surfaces of the ICMD, including those in contact with staff hands, cleaned and disinfected?	Essential			
For automated processes, the ICMD is manually pre-cleaned with a compatible detergent in a controlled procedure.	Essential			
For automated processes – the ICMD is manually pre-cleaned, then processed in an automated system, e.g. adapted endoscope washer-disinfector or an alternative process?	Best practice			
For automated processes that do not accommodate the entire ICMD – is there an adequate process in place for cleaning and disinfection for those parts outside the decontamination chamber (cable, socket, etc.)?	Essential			
For automated processes – there is adequate evidence of initial validation followed by periodic verification of the system.	Essential			
For automated processes – there is evidence of a review of the validation documentation by an authorizing engineer (decontamination) or other suitably qualified independent person.	Essential			
Are the manual decontamination detergent and disinfectant contact times controlled?	Essential			
Are the detergent and disinfectant CE-marked for use on medical devices?	Essential			
Storage and transport				
If transporting the ICMD to another area, are containers used to protect the ICMD from damage and/or recontamination?	Essential			
Are the ICMDs stored in a manner that will protect them from direct and indirect recontamination with blood or body fluids?	Essential			
Are clean ICMDs placed on to a clean work surface/tray/holder after decontamination?	Essential			
Is there a clearly defined flow of each probe from dirty through the decontamination processes to fully decontaminated such that no step in the process can be omitted and no fully decontaminated probe could be used in error?	Essential			
Health and safety				
Is appropriate personal protective equipment (PPE) worn during decontamination processes: gloves, apron and visor if risk of splashing?	Essential			
Has hand hygiene competency and compliance been assessed?	Essential			
Spillage kits are readily available if liquid disinfectants are used and staff are aware of how to use them?	Essential			
Facilities				
Is there a separate room for decontamination?	Best practice			
Are there enough ICMDs in the system to allow for adequate decontamination between patients?	Essential			
Is there a separate sink to the hand wash basin for decontamination?	Essential			
Documentation				
Is there a register of all ICMDs kept within the healthcare facility? Who looks after it, e.g. medical engineers?	Essential			
Is there a standard operating procedure (SOP) describing the decontamination procedure for all ICMDs used within the department?	Essential			

Table III (continued)

Question	Requirement	Yes	No	Comments
Is the SOP for decontamination available at the point of decontamination?	Essential			
Is there evidence of regular audit of the decontamination of ICMDs?	Essential			
Does the recording system contain the following information: date, unique ICMD ID, patient ID, operator, method used, confirmation that all stages of the decontamination process took place?	Best practice			
Training				
All staff undertaking decontamination of ICMDs have training in decontamination and have been assessed as competent to carry out this procedure?	Essential			
There is a record of training for each member of staff undertaking ICMD decontamination?	Essential			
There is evidence of regular audit of compliance and updated training records for staff?	Essential			

implications for decontamination requirements may not be immediately obvious. A screening questionnaire (such as that produced by the World Forum for Hospital Sterile Supply Education Group) may be helpful [22]. The assessment of cleaning and decontamination requirements must be included for all new devices, not only items above an arbitrary threshold cost, and must also include items purchased through charitable funds or donated by a charity. For this purpose, a mandatory sign-off procedure, which ensures that an assessment of cleaning and decontamination needs has occurred, is desirable.

Provision for decontamination facilities, equipment, staff time, and consumables must be included in the business case. Decontamination requires designated accommodation, e.g. appropriate sinks for manual cleaning. Consideration on where the item will be used will inform discussions around allocating space for cleaning and disinfection or using a central facility. This may also inform purchasers as to how many items will be required, as turnaround times may be affected by transport to a central decontamination department.

There may be additional staffing requirements. Special equipment for decontamination processing may be required to protect delicate parts or to allow processing with particular agents. Depending on the chemicals needed for decontamination, there may be additional ventilation requirements and exposure restrictions. Thus, an assessment of the COSHH regulations for decontamination products and any possible occupational health requirements is necessary [23].

Operational procedures for the use of intracavity devices must include the decontamination cycle. Depending on the location of decontamination and the time required for turnaround, the number of procedures possible in any clinical session and throughput of patients may be affected by equipment availability.

Training in the decontamination of the intracavity device must be built into the procurement process. The operational policy should also include update training on operation if necessary and cleaning and decontamination. A method of quality assurance in the decontamination process is needed, which must be auditable. ICMDs should be tracked, allowing the device to be followed to patients, operators and decontamination processes. The business case may also need to include provision for tracking and tracing software or extension of existing licences.

Problem-solving

If failures in ICMD decontamination are identified, usually through audit or incident, the following points may help guide actions. However, they are a guide only and cannot cover all varieties of what may go wrong.

- Immediate investigation to assess what may have occurred. This should involve looking at the facilities and talking to the people concerned, rather than assessing written documentation.
- Establish the seriousness of the failure – has it put patients at risk?
- Establish whether particular ICMDs have been involved, the duration of decontamination failure, i.e. whether particular patients at risk can be identified.
- Establish whether the service can continue to be provided: are the defects such that continuing will put patients at risk? If so, can measures be put in place to correct defects and allow resumption of service?
- Is the defect sufficiently serious to warrant a 'serious incident' being declared?
- If patients have been put at risk, in the UK local public health organizations (Public Health England, Health Protection Scotland, Public Health Wales or Public Health Agency for Northern Ireland) should be contacted for help with an assessment, and with the requirement and practicalities for a look-back exercise.

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