Disinfection, sterilization and disposables

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Abstract

Medical devices are one way by which healthcare-associated infections can be transmitted. Medical equipment can be categorized based on its risk of spreading infection and these categories aid decisions about whether to decontaminate or dispose of a used medical device. Decontamination is the process by which a reusable device is rendered safe for further use through cleaning and either disinfection or sterilization. It is frequently an automated process which usually involves thermal or chemical techniques and is subject to extensive quality control. Most microorganisms are inactivated or destroyed by disinfection but sterilization is required to eliminate resistant organisms and bacterial spores. Single-use medical devices are now commonplace and avoid the need for decontamination altogether.

Keywords Decontamination; disinfection; disposables; healthcare-associated infection; single-use medical device; sterilization

Royal College of Anaesthetists CPD Matrix: 1E01

Learning objectives

After reading this article, you should be able to:

- define the term 'healthcare-associated infection'
- categorize commonly used anaesthetic equipment based on its potential to transmit infection
- define 'decontamination' and classify the methods by which medical equipment can be decontaminated
- discuss the merits and limitations of single-use medical devices compared to reusable ones
- outline the main steps in the decontamination process for flexible endoscopes

Healthcare-associated infections (HCAIs) are infections that develop following a medical intervention or contact in a healthcare setting. The 2011 Health Protection Agency survey of HCAIs in England revealed an overall prevalence of 6.4%, with the highest rates of HCAIs in critical care (23.4%).[1] HCAIs are estimated to cost the NHS over £1 billion per year and healthcare organizations have a legal responsibility to try to reduce the impact of HCAIs.

Anaesthetic equipment is one route by which HCAIs can spread, and the Medicines and Healthcare Products Regulatory Agency (MHRA) highlighted this in 2011 when they reported on the death of a patient who developed sepsis thought to be a consequence of a contaminated laryngoscope handle.[2] The Association of Anaesthetists of Great Britain & Ireland (AAGBI) addressed the safe use of anaesthetic equipment in their guideline: *Infection Control in Anaesthesia* which supports the increasing trend in the UK towards single-use items, but there is still a need for a reliable system of decontamination for items that are impractical or too expensive to be available in single-use form.

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Classifying the risk of infection

Medical devices vary in their propensity to transmit infection and this influences the choice between single-use or the decision to use a particular decontamination strategy. The Spaulding classification system (developed in 1968) has proved reliable in identifying the risk that a contaminated device poses to patients. Equipment is divided into three categories on the basis of how invasive it is during normal use:

- **Non-critical items (low risk)** – items in contact with normal, intact skin or the environment (e.g. blood pressure cuff, stethoscope). Cleaning or low-level disinfection is usually adequate.
- **Semi-critical items (intermediate risk)** – items in close contact with mucous membranes or non-intact skin (e.g. flexible endoscopes). This category also includes low-risk items which may become contaminated with readily transmissible organisms. They require cleaning followed by high-level disinfection.
- **Critical items (high risk)** – items that penetrate skin or mucous membranes and enter normally sterile tissue (e.g. regional anaesthesia needles, vascular catheters). They must be sterile at the time of use.

Decontamination

Decontamination is the process by which a reusable medical device is rendered safe for further use. It is a combination of either cleaning *and* disinfection or cleaning *and* sterilization. With the exception of low-risk items, it is recommended that all reusable medical items should be processed by a sterile services department (SSD). Figure 1 shows how effective decontamination is a chain of events which relies on adherence to agreed protocols and good communication between hospital departments.

Cleaning

Cleaning is the physical removal of foreign material from an item. It is an essential first step in decontamination because it reduces the *bioburden* (the population of viable infectious agents contaminating a device) and because the persistence of any organic debris (e.g. blood) on an item may prevent disinfectant reaching every surface. Where appropriate, items should be

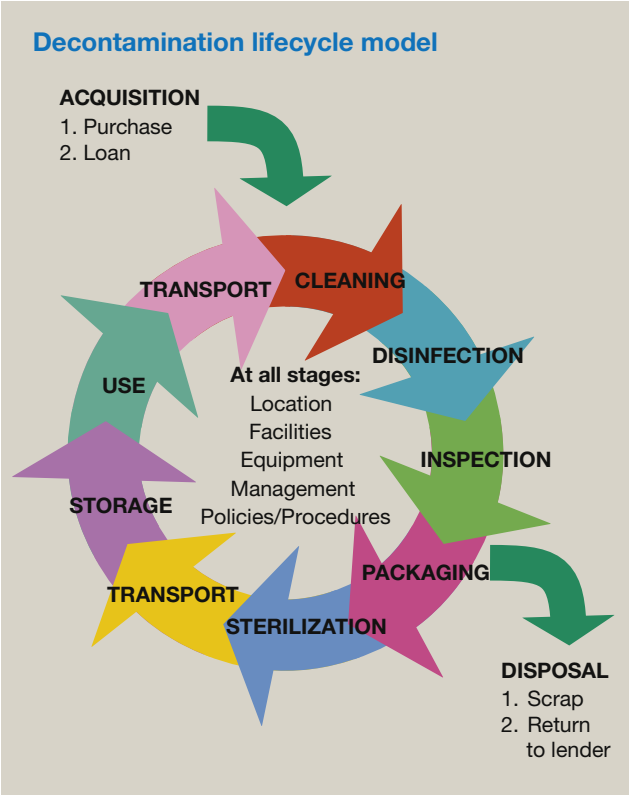

Figure 1

divided into their component parts (e.g. laryngoscope handle and blade) before cleaning to adequately expose all surfaces.

Cleaning can be manual or mechanical. Manual cleaning should only be used when automated cleaning is unavailable as mechanical processes are more amenable to quality control and protect the operator from exposure to chemicals and biohazards. A warm detergent solution is used to manually clean items. The water temperature should be around 35°C as higher temperatures may cause protein deposits to denature thereby creating a protective coating for microorganisms. Common mechanical cleaning methods include hot water disinfectors (discussed below) and ultrasonic cleaners; these usually form part of an automated decontamination process.

Ultrasonic cleaners work at low temperatures and are effective for cleaning delicate instruments. An ultrasound transducer creates numerous microscopic bubbles (cavitations) in a detergent solution. These bubbles collapse with tremendous force and this removes surface contamination without damaging the item itself.

Disinfection

Disinfection is the process by which many or all pathogenic organisms on an item are inactivated. Bacterial spores (Box 1) are not destroyed and cryptosporidia, mycobacteria and some viruses may be resistant depending on the technique chosen. A variety of methods are available, as follows.

Thermal disinfection

Hot water disinfectors combine mechanical cleaning and heat disinfection. A cool rinse and warm detergent wash (<45°C) are followed by hot water disinfection. Water temperatures greater than 65°C are needed to achieve disinfection, so cycles range from 70°C for 100 minutes to 90°C for 1 minute. It is only suitable for devices that can withstand repeated exposure to wet heat.

Pasteurization uses saturated steam below atmospheric pressure at temperatures around 75°C for 10–30 minutes; it is unsuitable for oily/greasy items.

Chemical disinfection

Chemicals are an alternative way to disinfect heat-sensitive equipment but are potentially toxic, flammable or corrosive; they can be divided into *low-level* and *high-level disinfectants*.

Low-level disinfectants (70% alcohol, chlorhexidine, iodophor and sodium hypochlorite) destroy vegetative bacteria and enveloped viruses but non-enveloped viruses, protozoan cysts, mycobacteria and bacterial endospores are more resistant.

High-level disinfectants (aldehydes, hydrogen peroxide, super-oxidized water, chlorine dioxide and peracetic acid) destroy all vegetative bacteria, viruses and fungi. With prolonged exposure they can also destroy bacterial spores and can therefore be used for sterilization. Table 1 gives examples of disinfection and sterilization regimes for common high-level disinfectants.

Bacterial endospores

- ***Vegetative bacteria*** describes bacteria in their active, reproducing state
- ***Bacterial endospores*** (spores) are a method by which some bacteria (e.g. clostridia, bacilli) can survive extreme environmental conditions by forming a copy of their DNA protected by a thick protein coat

Box 1

Immersion in high-level disinfectants — examples of disinfection and sterilization regimes

Disinfectant	Approximate duration of exposure	
	High-level disinfection	Sterilization
>2% Glutaraldehyde[a]	20–90 minutes	10 hours
7.5% Hydrogen peroxide	30 minutes	6 hours
>0.2% Peracetic acid at 50–55°C	Not indicated	12 minutes
0.55% Orthophthaldehyde[a]	12 minutes	Not indicated
Super-oxidized water (650–675 ppm active free chlorine)	10 minutes	Not indicated

ppm, parts per million.
[a] No longer recommended for endoscope decontamination as they fix proteins onto surfaces.

Table 1

Ultraviolet radiation

Ultra-violet light destroys airborne organisms and inactivates organisms on surfaces. It is sometimes used in endoscope storage cabinets to limit recontamination of decontaminated scopes.

Sterilization

Sterilization is any process used to render an object free from all viable microorganisms. In practice this is defined using a sterility assurance level (SAL). A SAL of 1×10^6 indicates that for every 1 million items sterilized, one will remain contaminated. A SAL of 1×10^6 is the standard level at which an item can be considered 'sterile'. Ideally items are wrapped prior to sterilization so that they can be handled and stored afterwards while maintaining sterility. Sterilization can be accomplished via the following methods.

Thermal sterilization

Steam sterilization (autoclave) is a well-defined technique that has been used safely for many years to sterilize most medical devices except for heat-sensitive and lensed instruments. After cleaning and packaging, items are exposed to pure, dry, saturated steam at a set temperature for a specified period of time. Typical cycles include 121°C for 15 minutes or 134°C for 3 minutes.

Dry hot air is an alternative to steam sterilization in which items are exposed to dry heat in an oven for a longer duration of time (e.g. 160°C for 2 hours). It is not recommended in healthcare settings as it is more difficult to reliably control the process.

Chemical sterilization

In addition to prolonged exposure to some high-level disinfectants, the following techniques can be used.

Ethylene oxide (ETO) is a toxic, explosive gas which has been used since the 1950s to achieve sterilization. ETO must be adequately flushed from sterilized equipment after exposure which necessitates extended processing times (often greater than 12 hours).

Hydrogen peroxide gas plasma is generated by vaporizing hydrogen peroxide into a vacuum and exciting the molecules using radiofrequency energy. Highly reactive free radicals are generated which destroy microorganisms at low temperatures (35–45°C) over relatively short cycle times (around 75 minutes). It does not produce toxic emissions but items require special packaging and it has a limited ability to sterilize medical devices with lumens.

Other agents include ozone gas and low-temperature steam mixed with formaldehyde.

Radiation

Gamma radiation is used to sterilize pre-packed, single-use items such as needles and facemasks during their manufacture. It has little role in the sterilization of reusable medical equipment.

Quality assurance

Decontamination services provided by SSDs are extensively regulated and in general, hot water disinfectors and steam autoclaves are preferred because the kinetics of thermal decontamination are reliable and reproducible. A variety of mechanical, chemical and biological indicators can be used to ensure that the specific conditions of the decontamination process have been met, but they do not verify that an item is actually sterile.

- **Mechanical indicators** include thermometers and timers to ensure that autoclaves achieve the set sterilization temperature for an appropriate period of time.
- **Chemical indicators** can be *process indicators* (e.g. tape which changes colour on heating to distinguish processed from unprocessed packages), *performance indicators* (e.g. colour change cards placed in test packages to assess adequacy of steam penetration) or *integrating indicators* which react when multiple conditions (e.g. time, temperature and steam) are met.
- **Biological indicators** are the most accurate method of checking sterilization effectiveness. Commercial test packs contain nonpathogenic, heat-resistant, spore-forming bacteria which can be autoclaved and then cultured. They are not used to routinely monitor steam sterilization.

Chemical decontamination may be less reliable than thermal techniques due to poor chemical storage and preparation or the presence of contaminants which make chemicals less effective. The process may be difficult to monitor and the kinetics of chemical sterilization are less well understood; mechanical devices such as automated endoscope reprocessors help to overcome these difficulties (Box 2).

Disposables

Single-use devices are designed to be used once on an individual patient and then discarded. They are identified by a symbol on the packaging or the device (Figure 2). In practice, many anaesthetic devices are treated as 'single-patient-use' meaning they can be used more than once for the same patient during a

Decontamination of endoscopes

Endoscopes are expensive, heat-sensitive devices requiring high-level disinfection or sterilization, as follows.

- Preliminary cleaning should occur as soon as possible after use. The exterior of the scope is wiped and all channels are flushed with sterile water. The scope should be kept moist prior to decontamination to prevent drying of protein deposits.
- Detachable parts of the endoscope are dismantled and single-use components should be discarded.
- Leak testing should be carried out as per the manufacturer's instructions to ensure the endoscope will not be damaged by immersion in liquid.
- Cleaning of the endoscope's internal and external surfaces is carried out using brushes and an enzymatic detergent.
- High-level disinfection is performed via an automated endoscope reprocessor with liquid disinfectant flushed through all endoscope channels. The process includes rinsing with sterile water before drying with air/70% alcohol.
- Decontaminated scopes should be stored vertically in a ventilated storage cabinet to facilitate drying and prevent recontamination.

Box 2

Figure 2 The universal symbol for a single-use medical device.

clinical episode and then discarded (e.g. a laryngoscope stored in a disinfected tray after intubation).

Single-use devices should be kept in their packaging until the point of use and should be stored separately from reusable devices to prevent confusion. After use, they should be incinerated as medical waste. They should not be decontaminated and reused; in doing so, practitioners assume the complex legal obligations for safety and effectiveness that usually rest with the manufacturer.

Decontaminate or dispose?

Several factors must be considered when deciding between single-use versus reusable equipment and these are summarized in Table 2. Decontamination is a multi-stage process and despite extensive safeguards, there are still opportunities for cross-infection to occur. It has also been demonstrated[3] (Figure 3) that current decontamination practices do not adequately remove protein from reusable medical devices which is relevant to prion diseases (see below).

The AAGBI recommends that single-use devices should be as effective as their reusable counterparts. Previously, single-use plastic laryngoscope blades were found to be a poor substitute for reusable metal blades when difficult airways were encountered. Single-use metal blades have overcome this problem and there is evidence that they may now actually provide better intubating conditions.

The majority of airway equipment in common use nowadays is disposable (e.g. facemasks, tracheal tubes, oro/nasopharyngeal airways) and this eliminates the need for decontamination. However, some anaesthetic equipment warrants special mention as outlined in Table 3. In the future, changing economic and environmental concerns along with new decontamination techniques may reverse this trend towards single-use equipment.

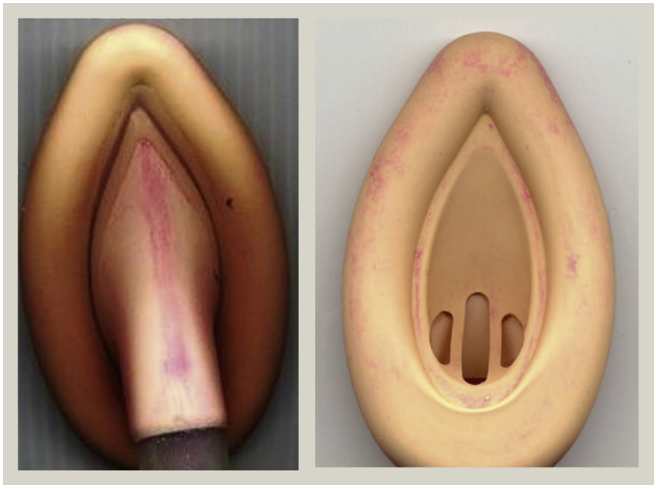

Figure 3 A decontaminated laryngeal mask airway stained with haematoxylin and eosin (H&E) showing significant residual protein deposits.

Prion diseases

Prion diseases are a group of neurodegenerative conditions that are transmissible, progressive and uniformly fatal. They are caused by prions: infectious particles composed of abnormal protein. Prion proteins are extremely hydrophobic and conventional decontamination techniques do not reliably remove them from medical devices.

Prion diseases came to prominence in the 1990s with the emergence of variant Creutzfeldt–Jakob disease (vCJD). Individuals infected with vCJD exhibit prions in lymphoreticular tissue (appendix/spleen/tonsils) whereas in other forms of CJD prions are limited to the brain, spinal cord and posterior eye. To date, 177 cases of vCJD have occurred in the UK and although the peak of the epidemic appears to have passed, prevalence studies suggest that around 1 in 2000 UK adults may be infected with vCJD prions.[4] It is possible there will be future peaks of vCJD

Pros and cons of single-use versus reusable equipment

	Single-use	Reusable
Advantages	• Avoids decontamination altogether • Consistent performance	• May offer improved clinical performance • Likely to be less expensive
Disadvantages	• May be of inferior quality • Likely to be more expensive • Environmental costs of manufacture, transport and disposal • Increased demands for storage space	• Risk of cross-infection • Performance may deteriorate with repeated use • Environmental costs of decontamination • Healthcare workers exposed to chemicals and biohazards during decontamination

Table 2

Infection prevention strategies for some anaesthetic equipment

Equipment	Strategy	Notes
Supraglottic airways	Single-use recommended	Classic LMA can be re-sterilized up to 40 times Destroy if used for tonsillectomy/ adenoidectomy
Bougies	Single-use recommended	Traditional gum elastic bougie may be disinfected and reused up to five times
Laryngoscope blades	Single-use recommended	Blades are 'high-risk' items (often contaminated with blood). Reusable blades should be sterilized by SSD
Laryngoscope handles	Single-use recommended	Reusable handles should be cleaned/ disinfected between patients and sterilized by SSD where possible
Fibreoptic bronchoscopes	Reusable	Decontamination by an automatic system recommended (Box 2). Single-use intubating fibrescopes are now available
Breathing circuits	Disposable	The AAGBI recommends single-use components in a breathing circuit should be changed after each patient use with other components changed daily. Hospitals may instead follow the manufacturer's guidelines (e.g. changing circuits after 7 days while using a new HME filter for every patient) Circuits should be changed sooner if visibly contaminated or after a highly infectious case
Anaesthetic machine/ventilators	Follow manufacturer's cleaning and maintenance policy	Daily decontamination is not necessary. An HME filter is usually placed on the ventilator expiratory port and can be changed in time with the breathing circuit

AAGBI, Association of Anaesthetists of Great Britain and Ireland; HME, heat and moisture exchange; LMA, laryngeal mask airway; SSD, sterile services department.

Table 3

either in these individuals who are currently asymptomatic carriers, or due to transmission from them.

At present there is no treatment for vCJD, no screening test and the natural history and mode of transmission remain uncertain. Four cases have occurred as a result of blood transfusion but there have been no reported transmissions due to contaminated medical devices. The Department of Health offers detailed advice concerning prion disease which takes a 'precautionary approach, seeking to minimize prion transmission within the constraints of current knowledge'.

If a patient with 'definite', 'probable' or 'presumed' vCJD undergoes surgery involving tissues at high or medium risk of vCJD infectivity then consideration must be given to using single-use instruments, quarantining or destroying instruments. In tissues considered to be low risk, instruments can be sterilized and reutilized in a conventional manner.

Previously, tonsillectomy and adenoidectomy were of particular concern to anaesthetists as these tissues are considered 'medium risk' for vCJD transmission and are in close proximity to airway devices. Nowadays nearly all airway management in anaesthesia is accomplished through single-use devices which effectively minimizes this risk but the AAGBI advises that reusable instruments can still be used if needed as the risk of vCJD transmission is extremely small.

There is ongoing research into sterilization techniques which can definitively remove prions. Options include strong alkaline solutions, enzymatic detergents and ozone/hydrogen peroxide plasma techniques. One of these options may be incorporated into existing steam sterilization processes as a cost effective and efficient strategy for the future. ◆

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FURTHER READING

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