Endoscope reprocessing: Why cleaning is vital

Within the healthcare system, an ever increasing number of minimally invasive techniques are now possible. Wolfgang Merkens, Schülke & Mayr GmbH warns that without effective and thorough cleaning, it is not possible to adequately disinfect the endoscope, as disinfection cannot remove gross contamination.

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Endoscopic examination offers a simple, low-risk, and cost-effective means to diagnose and treat a wide range of gastrointestinal disorders. During the procedure, the external surface and internal channels of a flexible endoscopes is exposed to bodily fluids and other potential contaminants, meaning that reprocessing poses particular challenges.

Unlike rigid endoscopes, flexible endoscopes are heat labile devices and cannot be autoclaved. Most are classed as "semi-critical devices" as they come into contact with mucous membranes during use and present a potential infection risk.[1]

The decontamination process involves mechanical and detergent cleaning, followed by high-level disinfection, rinsing, and drying.[2] The cleaning stage when removal of soil and organic matter is undertaken with a suitable detergent, is essential to the efficacy of the disinfection stage.[3]

Infection risks

Although the risk of endoscopy-related transmission of infection is estimated to be very low, more health care-associated infections are related to contaminated endoscopes than to any other medical device.[4]

Endoscopy-related transmission of infections may occur if microorganisms are spread from patient to patient by contaminated equipment or if microorganisms are spread from the gut lumen during endoscopy through the bloodstream to susceptible organs, adjacent tissues, or prostheses. Non-endoscopic transmission of infections within endoscopy units may also occur if microorganisms are transmitted from patients to endoscopy staff.[2]

The narrow lumens and multiple internal channels make the cleaning of flexible endoscopes a complex and difficult task.[4]

It is therefore unsurprising that a report on the top 10 health technology hazards of 2018 ranked 'failure to consistently and effectively reprocess flexible endoscopes' as one of the biggest threats to healthcare delivery and patient health, second only to threats to cybersecurity.[5, 6]

This ranking reflects the increasing awareness and recognition of the risks of endoscopy-associated pathogen transmission.[5, 6] In addition, the annual list of Top 10 patient safety concerns of 2018 ranked 'Device cleaning, disinfection, and sterilization' as number eight.[5, 6]

The failure to follow correct detergent and high level disinfection procedures at any point can result in both a compromised device and compromised patient safety.

A recent study of reprocessing, drying, and storage procedures for endoscopes used for gastrointestinal or non-gastrointestinal purposes at three hospitals in the USA found microbial growth after reprocessing on 71% of endoscopes. Residual fluid was found inside 49% of the endoscopes examined, which was associated with higher ATP levels (an indicator of microbial growth). Stenotrophomonas maltophilia, Citrobacter freundii, and Lecanicillium lecanii/ Verticillium dahliae were all found.

Although the identified microbes were not multidrug resistant; potential pathogens were discovered. Reprocessing and drying practices were noted to be deficient at two of the three centres studied, and all three sites used old, damaged devices, creating rough surfaces that promote residual contamination.[7]

A 2018 Review published in The Lancet reflects the increasing awareness and recognition of the risks of endoscopy-associated pathogen transmission.[8] 32 outbreaks involving almost 400 patients were reported between 2002 and 2007. Although most of these outbreaks were associated with duodenoscope use, others reportedly involved bronchoscopes and urological scopes.[8]

The editorial expressed concern that "this tally is likely to increase over time due to the growing number of minimally invasive techniques now being performed, and their increasing complexity, with the growing threat of multidrug antibiotic resistance giving the matter a real sense of urgency."[8]

Although the risk of infection following a gastrointestinal endoscopy is likely to be low, the absolute risk of infection after an endoscopic procedure remains unclear, and outbreaks reported in the literature probably underestimate the true incidence given the likelihood of under-reporting.[8]

It is notable that due to the increase in demand for endoscopy, many units have had to expand in limited space, with the result that decontamination facilities have frequently had to relocate away from the endoscopy unit. This has necessitated the transfer of used endoscopes to the decontamination facility, which sometimes may be at a different hospital altogether.

During the transfer of used endoscopes to decontamination facilities, the endoscopes and their internal channels must be kept moist. This has added another layer of complexity to the challenge of effective reprocessing.

Pre-cleaning

The BSG stipulates that thorough manual cleaning with a CE marked detergent must be undertaken before the endoscope is placed in the washer disinfector. The manual cleaning stage should include the brushing and flushing of all accessible endoscope channels.[9]

Cleaning is also carried out in the EWD ▶

before high level disinfection. The selected detergent must be compatible with the disinfectant used in the EWD.[9]

Cleaning refers to the removal of soil and organic contamination from a device using the physical action of scrubbing and the chemical action of a detergent. Cleaning removes large numbers of microorganisms, which reduces the levels of organic bioburden on these surfaces. This process is designed to remove organisms rather than kill them.[2]

Cleaning which includes the use of a suitable detergent must always precede surface disinfection, especially surfaces like endoscopes with visible contamination, and helps to ensure the efficacy of the subsequent disinfection step.[10]

If soil and bacterial biofilms are not removed from the endoscope, this will adversely impact on the efficacy of the disinfectant which then increases the risk of nosocomial infection.[3]

HTM 01-06 (2016) warns that some chemicals may damage endoscopes therefore any cleaner selected should be compatible with the range of endoscopes in use, as well as with the EWD. All chemicals used in the EWD process should be CE-marked, which indicates that the manufacturer has verified these products meet EU safety, health and environmental standards.

It is essential that the required concentration can be accurately and reproducibly generated by the dosing system(s) on the EWD. HTM 01-06 (2016) also advises that "users should enquire about the erosive or damaging characteristics of the chemical agents recommended." For example, some detergents have added corrosion inhibitors, as water itself is corrosive if the hardness is less than eight.

Cheaper detergents may contain no corrosion inhibitors at all, or poorer quality ingredients, which in the longer term could lead to damage of the endoscope and/or the automated reprocessor. This damage will take place over a period of time and is not immediately obvious.

Flexible endoscope manufacturers will advise on which chemicals could cause damage to their equipment. Use of such contraindicated chemicals is likely to invalidate any manufacturer warranty as well as potentially cause irreparable, or very expensive, damage to the endoscope.

Detergents - mode of action

Detergents act both as wetting agents - in which the reduction of surface tension allows contact with all surfaces – and also as a solvent and/or dispersant of soil. They can also degrade soil components, making them more soluble and easier to remove. Detergents work by penetrating soil and act to reduce the surface tension (forces which adhere soil to a surface), which allows for the removal of the soil.

Most detergents contain surfactants (Surface Active Agents) which are a class of molecules that function to bind and lift soil. Suspended dirt is easier to remove from the surface by rinsing and surviving microorganisms can be destroyed by disinfection. Some types of surfactants serve as wetting agents to lower the surface tension of the cleaning solution and increase the 'wettability' of water.

Detergent selection

It is important that the correct type of detergent is used for the appropriate application. For cleaning critical equipment, such as endoscopes, the choice is between enzymatic detergents or neutral detergents.

Compared with enzymatic detergents, non-enzymatic detergents can be used across wider temperature ranges and are less affected by pH. Non-enzymatic detergents are also less allergenic, but enzymatic detergents are more effective cleaning agents and are designed to maximise the removal of residues.

Enzymes are proteins that accelerate the rate of a chemical reaction. The enzymes in a detergent break down large molecules, like fats and blood proteins, into smaller ones. Thus enzymatic detergents have an advantage over non-enzymatic ones, although stricter personal protection procedures for staff handling are needed.

The ideal detergent cleansing agent should effectively permeate contaminants that contain proteins, lipids, carbohydrates and various chemical bases and separates the contaminants from the channels without damaging the endoscope.[11] It should also be low-foaming to ensure the maximum contact with the surface with the endoscope.[11]

The removal of soil is an important step prior to the application of a disinfectant, as the greater the degree of soiling remaining on a surface, then the lesser the effectiveness of disinfection. This is because disinfectants are either inactivated by organic residues or the soil creates a barrier which prevents the disinfectant from reaching all of the microbial cells.

The selected detergent must be compatible with the disinfectant used. This is because some detergents leave residues which can neutralise the active ingredient in certain disinfectants thereby reducing the microbial killing properties of the disinfectant.

Additional factors which will influence the choice of a detergent include the process of dilution, the stability of the solution and the cost of using a particular product (these costs should consider storage space, conditions required for use, including staff protection measures and material compatibility).

Switching to an alternative detergent

If a decontamination unit is considering the switch to an alternative detergent or disinfectant, there are many factors to take into account before making a decision.

Switching based on cost savings should not be based on comparative detergent costs alone. The efficacy of the detergent to remove soil and organic matter, material compatibility, concentration, stability, storage life, inclusion of corrosion inhibitors are just some of the factors to consider which will all have an impact on the overall cost.

Care should be taken to ensure that all detergents are compatible with the EWD, and are employed at the correct temperature and concentration. Detergents and disinfectants must be compatible with each other. These chemicals should be type tested to show compatibility with both the EWD and the endoscope.[9]

Conclusions

Endoscopy-associated infection transmission is frequently linked to inadequate reprocessing. Residual organic material and moisture may foster biofilm development inside endoscopes, and an American study found microbial growth in 71% of reprocessed endoscopes examined.

It is well established that it is not possible to effectively disinfect flexible endoscopes which are not clean. Therefore, the cleaning stage with a detergent is a critical stage in removing the microbial burden from an endoscope.

Endoscopy has many major benefits and is an essential component of a gastroenterologist's armamentarium. To maintain this key role, adherence to guidelines for reprocessing, including the selection of appropriate detergents is vital.

The three key steps in the flexible endoscope decontamination process

Step 1 - Manual cleaning and rinsing of all exposed internal and external surfaces
This is undertaken at the sink in the 'dirty' section of the decontamination area where a solution such as gigazyme (enzyamtic) or gigasan ND (non-enzymatic) is used to clean the endoscope including the internal tubing, whilst also manually brushing the channels. This cleaning stage is generally not verifiable.

Step 2 - Automated cleaning
This stage describes the process of initial cleaning of the endoscopes when they are placed in the EWD. A detergent such as thermosept Endocleaner (which contains enzymes and surfactants) may be used as it must be compatible with the disinfectant selected for stage 3. This stage of cleaning is verifiable as the EWD tracks and traces every aspect of cleaning including water temperature, pressure and detergent.

Step 3 – Disinfection
After the EWD cleaning stage, the disinfection process takes place. Again, this is verifiable as all elements are controlled, recorded and reproduced at the same level every time. A peracetic acid based disinfectant such as thermosept PAA (effective against bacteria, mycobacteria, fungi, viruses and spores including *Clostridium difficile* spores) may be used for this critical high level disinfection process.

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