Reprocessing flexible endoscopes

Wolfgang Merkens, Schülke & Mayr GmbH, was invited to address the annual Institute of Decontamination Sciences (IDSc) conference in November 2018. Here, *The Clinical Services Journal* provides highlights from his presentation.

Contaminated endoscopes have been linked to many outbreaks of device-related nosocomial infections, although the actual incidence of endoscopy-related infections is unknown.[1]

Flexible endoscopes are reusable but highly complex devices which require considerable care during the essential decontamination process. Most flexible gastrointestinal endoscopes cannot withstand the conditions used in a steam sterilisation process. So, unlike rigid endoscopes, they cannot be autoclaved yet still present a risk of infection if contaminated during use.[2] This increases the possibility of settlement of biofilm-producing species.[1]

The greatest potential infection risk is through the transmission of microbes from one patient to another using a contaminated endoscope, and studies have suggested that endoscopes are potential vectors for the transmission of *Helicobacter pylori*.[2] Additionally, there is the possibility of transmitting infection to healthcare staff. Healthcare workers are also at potential risk of infection with blood-borne viruses.[2]

Flexible endoscopes which make contact with mucous membranes but do not penetrate sterile areas of the body are therefore generally reprocessed by high level disinfection rather than sterilisation. The term 'high level disinfection' is given to the process which is used to eliminate or kill all vegetative bacteria, mycobacteria, fungi and viruses.

The BSG recommends that a guiding principle for decontamination is that 'any patient must be considered a potential infection risk, and each endoscope and device must be reprocessed with the same rigour following every endoscopic procedure'. [2]

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The choice of disinfectant used in the chemothermal reprocessing of flexible endoscopes in endoscope washer/disinfectors is a key consideration. This article considers the complex process of developing a peracetic acid (PAA) based disinfectant and also examines why not all PAA disinfectants are the same, despite what it may say on the label!

Development considerations

According to the BSG[2], and based on research conducted by Rutala and Weber[3], the ideal chemical high-level disinfectant should have the following qualities: a broad antimicrobial spectrum; prolonged reuse and shelf life; be rapid-acting, noncorrosive, and not harmful to the scope and its parts; non-toxic to humans and the environment; odourless and non-staining; cost effective; and capable of being monitored for concentration and effectiveness.[3]

Looking at each of these requirements in isolation, each one could be developed relatively simply in a single product. For example, achieving a high level of antimicrobial efficacy may be readily achieved, but the end product would not necessarily be compatible with the endoscope.

The challenge for a chemical manufacturer is to achieve as many of the specified desired qualities as possible, whilst conforming with a plethora of regulations and producing all of this in a single product. Simplifying these considerations under four key headings means that a disinfectant manufacturer must be consistent with:

- Growing demands for antimicrobial efficacy
- Regulations, norms and guidelines
- Ensuring material compatibility
- Ensuring patient and staff safety.

The more parameters that need to be met, the more complex the process becomes. Each of these four defined parameters will be examined in relation to developing the best possible PAA-based disinfectant for use in reprocessing flexible endoscopes.

Antimicrobial efficacy

Disinfectants based on peracetic acid are widely used in the UK, as peracetic acid has a strong antimicrobial activity. Depending on its concentration and pH value, it is effective against bacteria including *Helicobacter pylori*, fungi, mycobacteria, viruses including Hepatitis B virus (HBV), and bacterial spores.[4]

Peracetic acid is one of the few powerful antimicrobial agents available for use as a sporicidal agent, which is significant as spores are resistant to several stresses, such as heat, ultra-violet light, and many disinfectants.[5] The oxidising active peracetic acid also helps remove biofilm from endoscopes.

In addition to a broad microbial spectrum, PAA has a short contact time for bacteria, including *Mycobacterium tuberculosis*, fungi, viruses and spores of around 5 minutes. ▶

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This is in contrast to disinfectants based on ortho-phthalaldehyde (OPA) or glutaraldehyde (GDA) which have lengthy contact times of 10 hours for GDA and 32 hours for OPA. The higher the aggressivity of the disinfectant, the shorter the contact time, and conversely a lower aggressivity requires longer contact times for the disinfectant to be effective.

Regulations, norms and guidelines

Before looking at the regulations and directives governing the manufacture of a high level disinfectant, it is essential to consider what constitutes a medical device (MD) and why this is significant in relation to disinfectants.

The Medical Devices Directive 93/42/EEC (MDD) provides guidance on what constitutes a medical device (MD) and is based on the stated intended purpose of the product. According to this EU Directive a medical device is defined as: 'any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s)' which includes 'disinfection of medical devices.'

Products developed for disinfection may come within the remit of the biocides regulations, the medical device regulations or the regulations covering medicinal products for human use, depending upon their intended purpose, composition and the claims made for the products concerned. In general, for a product to be acceptable as a medical device it must be a disinfectant that is specifically indicated for the disinfection of medical devices.

When a flexible endoscope, which is categorised as a medical device (as it is used specifically for diagnostic and / or therapeutic purposes) is being reprocessed a disinfectant with an MD certification must be used during the process.

One of the key questions frequently asked concerns the difference between an MD and a biocide. The MHRA states that biocides are intended as general purpose disinfectants for rooms, hard surfaces etc' and 'are not considered to be medical devices'.[6]

A biocide is approved based on its active substance, so it is only the active ingredient which is approved, not the final complete product, whereas an MD refers to the complete product.

Questions to consider if thinking of switching to a different PAA

- Will the patient be safe?
- Could I end up in court?
- Is the formulation the same?
- Will the endoscopes need expensive repairs
- Will there be an increase in downtime?
- Are any cost savings at the expense of efficacy, material compatibility, contact times?
- Has a full risk assessment involving stakeholders, clinical leads, Estates and Infection Control been conducted?
- Is the risk worth taking?

When developing a disinfectant to conform to the MD Directive, a risk assessment is conducted by the manufacturer to evaluate the intended purpose, the risk to the patient, the risk to the user and to third parties. This must be undertaken before a declaration of conformity to the MD Directive can be received for the product.

Disinfectants conforming to the MDD have a medical traceability system, which is similar to the drug 'track and trace' system. This means that when the manufacturer sends the MD from the warehouse, it is traceable at any point in the life cycle. This is significant as if there is any problem with the MD, it can be readily recalled, whereas there is no possibility of recalling a biocide. There is also a reporting system for medical devices in the event of any problem being encountered. This is not the case for biocides, meaning that MDs offer a far greater degree of safety.

There is a set of agreed regulations which must be followed to bring an MD for cleaning and disinfection to the market. ISO 13485 is an international standard that defines quality management system (QMS) requirements for manufacturers of medical devices. The primary objective of the standard is to facilitate harmonised QMS requirements for regulatory purposes within the medical device sector. It is applicable to all manufacturers of medical devices who have a duty to ensure that devices consistently meet customer requirements and meet all applicable regulatory requirements.

In addition, a company manufacturing a medical device must have established risk management processes that comply with ISO 14971:2007. This standard 'specifies a process for a manufacturer to identify the hazards associated with medical devices… ..to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.' The requirements of ISO 14971 are applicable to all stages of the life-cycle of a medical device.

MDD 93/42 and ISO 13485 and ISO 14971 are the key building blocks underpinning product quality. All need to be in place to ensure the highest quality disinfectant.

Material compatibility

There are a number of considerations that a disinfectant manufacturer needs to consider in terms of producing a product that is compatible with a flexible endoscope. Risk management for medical devices is just one aspect of this.

MDD 93/42 EEC Point 7.3 Part II Annex 1 Risk Management for ISO 14971 states that 'the devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures.' This applies to both the manufacturer of the endoscope and to manufacturers of accessories including cleaner/disinfectants.

When the endoscope and cleaner are used together they must be compatible and the importance of this should not be underestimated. The manufacturer of the cleaner/disinfectant must demonstrate that the products are designed and manufactured in such a way as to be used safely with the materials.

Patient and staff safety

Patient safety is of paramount importance and according to the Medical Devices Directive every patient has 'the right to the best treatment', which includes the right to be examined with a clean endoscope free from viable microbes or biofilm. The chosen disinfectant must be a medical device which is compatible with the endoscope.

Staff safety is also key, and the chosen disinfectant needs to be efficacious against a range of organisms including Hepatitis B virus, Hepatitis C virus and HIV, which potentially pose the greatest risks to staff.

Exposure of staff working in the endoscopy department to disinfectants also needs consideration. Many staff spend years working in an endoscopy department, therefore their exposure to the chemicals used is constant, whereas the patient is potentially only exposed once or twice in their lifetime. This means that exposure is more of a risk to staff than to patients and the impact needs to be

Some questions to consider when selecting a PAA detergent

- Has the manufacturer got the right accreditations?
- Is the chemistry approved and fit for use on medical devices?
- Is there evidence of efficiency / efficacy?
- Is it compatible with flexible endoscopes and EWDs?
- Is it on the flexible endoscope approved list?
- Are there any potential storage issues?

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considered over their entire working life.

The selected disinfectant needs to have the right actives to ensure the spread of Gram-negative bacilli, *Clostridium difficile*, multi-drug resistant organisms (MDROs) and *Helicobacter pylori* is prevented. It should also be remembered that not all disinfectants based on peracetic acid are the same, one cannot be simply switched for another as the results could be markedly different. The quality of the chemicals used must be of the highest standards and conform to all the required regulations, directives and guidelines.

Why all PAA based disinfectants are not the same

Peracetic acid is formulated from acetic acid and hydrogen peroxide dissolved in water, at various concentrations. Commercial solutions contain different concentrations of these three chemicals. Some are promoted as having 'two part chemistry' when in reality they do not have this. A comparable active compound is not the same as having the same formulation. A disinfectant marketed as containing PAA may look like PAA but is not necessarily the same product and is likely to differ in the product details. Even if it appears to contain the same ingredients, the actual formulation may vary considerably.

Some PAA disinfectants have added corrosion inhibitors, as water itself is corrosive if the hardness is less than eight. Cheaper PAA disinfectants 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 takes place over a period of time and is not immediately obvious.

Another area of difference between PAA disinfectants is the product stability and subsequent shelf life of the final product. In addition the duration of contact times may vary between PAA disinfectants. A fast acting PAA with a short but effective contact time means quicker reprocessing, saving valuable time.

The rate and intensity of the reaction between the PAA and the soil on the endoscope shows a wide variation. Although the pH of PAA can be around 2, which is highly acidic, it can be buffered to a pH of 4 or even 8. The temperature at which the PAA is used, together with the pH of the product, has a significant impact on the deactivation of pathogens. For example a PAA used at a temperature of 15˚C and with a pH of 7 will require five times more PAA to deactivate pathogens than a pH of 7 used at a temperature of 35˚C.

Conclusion

Flexible endoscopy is a widely used diagnostic and therapeutic procedure. Contaminated endoscopes may be associated with outbreaks of healthcare-associated infections. Therefore optimum reprocessing is essential. This involves both cleaning and high-level disinfection. Most contemporary flexible endoscopes cannot be heat sterilised and are designed with multiple channels, which are difficult to clean and disinfect. This may lead to the formation of biofilms on the inner channel surfaces.

Developing a high level PAA disinfectant poses many challenges for the manufacturer to ensure a broad spectrum of antimicrobial activity, short contact times, material compatibility and safety for both patients and endoscopy staff. Meeting this challenge will help make the procedure safer from the growing prevalence of many potentially pathogenic organisms.

But it should be remembered that PAA based disinfectants vary considerably from manufacturer to manufacturer, and short term cost savings could be at the expense of longer term damage to equipment, or even worse expose patients and staff to the very real risk of cross-contamination. CSJ

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