WGO-OMGE / OMED

Practice Guideline

Endoscope Disinfection

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1. Key Messages

- Cleaning is the critical step in endoscope reprocessing
- Compliance with endoscope disinfection guidelines is the key factor determining endoscopy safety
- While local circumstances, training and resources may vary, high standards of disinfection must always be maintained

2. Definitions

Cleaning
The removal of blood, secretions or other debris from endoscopes and accessories.

Disinfection
The reduction or destruction of all vegetative microorganisms, mycobacteria, small or non-lipid viruses, medium-sized or lipid viruses, fungal spores, and some but not all bacterial spores to a level appropriate for safe use of endoscopes/accessories in a patient. (Note that this is a definition of high-level disinfection.)

Sterilization
The destruction of all microbial life. Validated processes are used to render a device free from all forms of viable microorganisms. (Note that this definition does not apply to prions.)

Endoscopic accessories
All devices used in conjunction with an endoscope for the purposes of diagnosis or therapy. This definition does not include peripheral equipment.

Single-use accessories (disposables)
Disposable devices provided in a sterile state, ready for once-only use. Once opened a sterile package must be used immediately, as is routine in surgery.

3. Transmission of Infection

3.1 Infection control principles

The following universal rules should always be observed: every patient must be considered a potential source of infection, and all endoscopes and accessory devices must be decontaminated with the same degree of rigor following every endoscopic procedure.

All healthcare personnel in the endoscopy suite should be trained in and adhere to standard infection control procedures for protection of both patients and personnel.

In order to be able to adhere to disinfection guidelines, it is important to understand the prerequisites for development of infection. For a pathogen to be transmitted, all the links in the so-called ‘chain of Infection’ need to be intact. If just one link is interrupted, infection cannot develop. The links in the chain of infection are:

- presence of viable microorganisms
- sufficient number of pathogens to initiate infection
- host susceptibility to infection with the microorganism
- entry of the pathogen through the typical portal (i.e. gastrointestinal pathogens through the gut, blood-borne pathogens through the bloodstream)

Infection control measures which can disrupt the chain of infection include:

- disinfection and sterilization of medical equipment
- proper use of personal protective equipment
- personal hygiene
- engineering controls (ventilation, building design, clean water supply)
- cleaning and disinfection of environmental surfaces
- adequate administrative monitoring and support
- training and continuing education
- adequate written protocols

Although there are few well-designed prospective studies on the incidence of pathogen transmission during gastrointestinal endoscopy and estimates of pathogen transmission based on case reports may underestimate the true incidence of infection, available evidence suggests that pathogen transmission via this routine is an extremely rare event. However, there is evidence in the literature that disinfection techniques are less well adhered to in developing countries.

3.2 Tropical Infections

There is very little evidence available on the risk of transmission of parasitic infections by gastrointestinal endoscopy. To become infective most parasitic agents require progression in a life cycle that takes time, so that they are not immediately infective. Most potentially infective parasites would not survive endoscope reprocessing with mechanical washing, 2% glutaraldehyde and alcohol treatment. There is generally considered to be no risk with respect to helminths, nematodes, platyhelminths, *Anisakis*, or liver flukes such as *Fasciola hepatica.* However, concerns have been raised with respect to the risk of transmission of *Giardia lambliasis*, *Cryptosporidium* species and amebas.

3.3 Cleaning – rinsing – disinfection – sterilization sequence

Compliance with guidelines is the chief factor compromising the safety of endoscope reprocessing. The consequences of failure to follow recommendations may be not only transmission of pathogens, but also misdiagnosis (due to pathological material from one patient being introduced into the next patient), instrument malfunction, and a shortened instrument lifespan.

Most guidelines for endoscope reprocessing prescribe the following six steps:

cleaning → rinsing → disinfection → rinsing → drying → storage

If possible, sterilization should replace the disinfection step, but this is not feasible in the case of flexible endoscopes.

If the reprocessing steps are carried out correctly according to accepted standards, pathogen transmission can be prevented and the endoscope is ready for reuse. If there is any doubt about whether an endoscope has undergone complete reprocessing, it should be subjected to a complete cleaning and disinfection cycle. Once properly reprocessed and stored, another reprocessing cycle should not be necessary.

Cleaning must always be performed prior to disinfection

Ideally, endoscope reprocessing comprises two basic components, which are expanded on in the following sections:

- manual cleaning, including brushing and exposure of all external and accessible internal components to a low-foaming, enzymatic, endoscope-compatible detergent (since enzymatic detergents need at least 15 minutes of contact to be effective non-enzymatic detergents are preferred)

- automatic disinfection, rinsing and drying of all exposed surfaces of the endoscope

Disinfection should be carried out immediately after cleaning

The principal steps in endoscope reprocessing, which should be performed as soon as possible after use, comprise:

- wiping down the insertion tube
- flushing the air/water channels
- aspirating water through the biopsy/suction channel
- dismantling detachable parts (e.g. valves)
- manual cleaning with detergent followed by rinsing
- disinfection and rinsing in an automatic reprocessor
- drying and appropriate storage

3.4 Hierarchy of Standards

3.4.1 Introduction

With the introduction of a hierarchy of standard procedures – optimal, normal and minimal - allowing for alternatives in certain resource-sensitive steps in endoscopy reprocessing, these OMGE/OMED guidelines aim for improved compliance, especially in areas of the world where external factors limit available options (major procedure differences are highlighted in red print).

3.4.2 Principles applying to all standards

Pre-cleaning

- pre-clean immediately

Cleaning

- always perform leak testing and block testing before immersing the endoscope in a detergent or soap solution as this may help prevent expensive repairs later

Rinsing

- always rinse between cleaning and disinfection

Disinfection

- always immerse the endoscope and valves in a disinfectant solution of proven efficacy (see below)
- always irrigate all channels with a syringe until air is eliminated to avoid dead spaces
- always observe the manufacturer's recommendation regarding the minimum contact times and correct temperature for the disinfection solution
- always observe the manufacturer's recommendations regarding compressed air values
- always remove the disinfection solution by flushing air before rinsing
- always determine whether the disinfectant solution is still effective by testing it with the test strip provided by the manufacturer

Final rinsing

- always discard the rinse water after each use to avoid concentration of the disinfectant and thus damage to mucosa
- never use the same container for the first and final rinsing

Drying

- always dry the endoscope properly before storage to prevent microorganism growth in the endoscope channels

Storage

- never store in a transport container

3.4.3 Optimal standard

Pre-cleaning

- clear gross debris by sucking detergent through the working channel (250 ml/min)
- expel any blood, mucus or other debris
- flush the air/water channel and wipe down the insertion shaft
- check for bite marks or other surface irregularities
- detach the endoscope from the light source/videoprocessor
- transport in a closed container to the reprocessing room

Cleaning

- conduct leak testing and block testing
- clean all surfaces, brush channels and valves
- use a disposable brush and disposable swab or tissue
- renew detergent solution for each new procedure
- clean and rinse the container before the next procedure

Disinfection (automatic reprocessing)

- cleaning with appropriate detergent solution
- rinsing
- disinfection
- final rinsing

Drying

- dry with compressed air of defined quality or a 70% alcohol flush

Alcohol must be properly stored as evaporation occurs rapidly on exposure to air - if the concentration is <70% it cannot be reliably used in the drying process

Drying should be performed after each processing cycle and not just before storage

Storage

- disassemble the endoscope in a well ventilated storage cupboard
- ensure the valves are dry and lubricate if necessary
- store separately

3.4.4 Normal standard

Pre-cleaning

- clear gross debris by sucking detergent through the working channel (250 ml min)
- expel any blood, mucus or other debris
- flush the air/water channel and wipe down the insertion shaft
- check for bite marks or other surface irregularities
- detach the endoscope from the light source/videoprocessor
- transport in a closed container to the reprocessing room

Cleaning

- conduct leak testing and block testing
- clean all surfaces, brush channels and valves
- use a disposable or autoclavable brush and disposable swab or tissue
- renew the detergent solution for each new procedure
- clean and rinse the container before the next procedure
- follow the same procedures for all accessories as for endoscope processing

Rinsing

- rinse the endoscope and valves under running tap water of drinking-water quality
- immerse the endoscope and irrigate all channels
- discard the rinsing water after each use to avoid concentration of the detergent and the risk of reduced efficacy of the disinfectant solution
- clean and rinse the container before the next procedure

Disinfection

- immerse the endoscope and valves in a disinfectant solution of proven efficacy (GA, PAA, OPA etc)
- irrigate all channels with a syringe until air is eliminated to avoid dead spaces
- follow manufacturer recommendation for the contact time with the solution
- remove the disinfection solution by flushing air before rinsing

The disinfectant solution should be tested at least every day for efficacy using the manufacturer's test strip

Final Rinsing

- rinse the endoscope and valves under running filtered water
- immerse the endoscope and irrigate all channels
- discard the rinsing water after each use to avoid concentration of the disinfectant and thus damage to mucosa

Drying should be performed after each processing cycle and not just before storage

Drying

- ensure correct final drying before storage
- dry with compressed air or a 70% alcohol flush

Alcohol must be properly stored as evaporation occurs rapidly on exposure to air - if the concentration is <70% it cannot be reliably used in the drying process

Storage

- disassemble the endoscope in a well ventilated storage cupboard
- ensure the valves are dry and lubricate if necessary
- store separately

3.4.5 Minimal standard

Pre-cleaning

- clear gross debris by sucking water through the working channel (250 ml min)
- expel any blood, mucus or other debris
- flush the air/water channel and wipe down the insertion shaft
- check for bite marks or other surface irregularities
- detach the endoscope from the light source/videoprocessor
- transport in a closed container to the reprocessing room

Brush reprocessing must follow the same procedures as for endoscope reprocessing

Cleaning

- conduct leak testing and block testing
- immerse the endoscope in detergent or a soap solution
- clean all surfaces, brush channels and valves with a clean dedicated brush and a clean swab or tissue
- follow the same procedures for all accessories as for endoscope processing

Rinsing

- rinse the endoscope and valves under running tap water (must be drinking-water quality)
- immerse the endoscope and irrigate all channels
- discard the rinse water after each use to avoid concentration of the detergent and the risk of reduced efficacy of the disinfectant solution
- clean and rinse the container before the next procedure

Disinfection

- immerse the endoscope and valves in a disinfectant solution of proven efficacy (GA, PAA, OPA etc)
- irrigate all channels with a syringe until air is eliminated to avoid dead spaces
- contact time with the solution should be according to the manufacturer's recommendation
- disinfection solution should be removed by flushing air before rinsing

The disinfectant solution should be tested at least every day for efficacy using the manufacturer's test strip

Final Rinsing

- rinse the endoscope and valves in drinking-quality or boiled water by immersing the endoscope and irrigating all channels
- discard the rinse water after each use to avoid concentration of the disinfectant and thus damage to mucosa

Drying

- ensure correct final drying before storage
- dry with compressed air or if not available inject air with a clean syringe

Drying should be performed after each processing cycle and not just before storage

Storage

- disassemble the endoscope
- store in a well ventilated storage cupboard
- ensure the valves are dry and lubricate if necessary
- store separately or store the endoscope in a clean closed box with the valves

4. Endoscope Cleaning

4.1 General procedures

Endoscope cleaning consists of the mechanical cleaning of internal and external surfaces. This includes brushing and flushing of internal channels with sterile, filtered or drinking-quality water and detergent.

Preliminary cleaning should be started before the endoscope is detached from the light source/videoprocessor. As soon as the endoscope has been removed from the patient begin reprocessing, observing the following steps:

- clear gross debris by sucking detergent through the working channel (250 ml/min)
- ensure the working channel is not blocked
- irrigate the air and water channels with water checking for blockages
- expel any blood, mucus or other debris
- wipe down the insertion shaft
- check for bite marks or other surface irregularities
- detach the endoscope from the light source/videoprocessor
- transfer the endoscope to a reprocessing room with atmospheric extraction facilities
- conduct a leakage test daily to check the integrity of all channels before reprocessing

The next stage involves the dismantling of detachable parts of the endoscope whereby valves and water bottle inlets are removed and detachable tips taken off the insertion tube. Rubber biopsy valve caps are discarded if breached. Water bottles and suction/air-water valves should be autoclaved.

All exposed internal and external surfaces should then be manually cleaned and rinsed according to the following recommendations:

- use a low-foaming detergent specifically designated for medical instrument cleaning
- use the appropriate dilution according to the manufacturer's instructions
- flush and brush all accessible channels to remove all organic (e.g. blood, tissue) and other residues with a disposable brush-tipped wire designed for this purpose

- use brushes of the appropriate size for the endoscope channel, parts, connectors and openings; bristles should have contact with all surfaces
- repeatedly actuate the valves during cleaning to facilitate access to all surfaces
- clean the external surfaces and components of the endoscope with a soft cloth, sponge or brush
- subject reusable endoscopic accessories and endoscope components to ultrasonic cleaning to remove material from hard-to-clean areas
- dispose of all cleaning items

If some of the above steps are not feasible due to limited resources, consider the following alternatives:

- cleaning with a non-enzymatic detergent
- cleaning very carefully with soap and water of acceptable quality as the minimum standard
- using sterile, filtered, drinking-quality or boiled water

Do not use tap water unless it is of drinking-water quality

4.2 Importance of cleaning

The purpose of cleaning is to remove all inorganic and organic material from the internal and external surfaces of flexible endoscopes. If the manual cleaning, brushing and rinsing steps are not properly carried out, protein debris can harden and lead to formation of biofilm on the biopsy channel of the endoscope. Inadequate cleaning can thus result in material remaining on the endoscope surfaces which prevents disinfection and sterilization fluids or gases reaching all parts of potentially contaminated surfaces. Inadequate sterilization or disinfection may in turn result in transmission of infectious organisms when the endoscope is reused. The intricate design, delicate materials and susceptibility to damage of flexible endoscopes further complicates their decontamination.

All disinfection processes, whether done manually or done automatically in a washer-disinfector, can only be effective if prior cleaning is adequate. Effective disinfection or sterilization of an inadequately cleaned instrument is not possible.

The endoscope should be cleaned with an enzymatic detergent compatible with the endoscope immediately after use and before manual or automated disinfection. Cleaning involves the entire endoscope, including valves, channels, connectors and all detachable parts.

Cleaning is the critical step in endoscope reprocessing.

The approach is the same if the presence of pathological prions (including the prions of Creutzfeld-Jakob disease) is suspected, however attention to detail is more important in this case. Accessible endoscope channels should be brushed with a disposable brush-tipped wire assembly designed for this purpose that has an appropriate length and diameter for each channel. Some guidelines recommend a double-brushing and/or double-cleaning procedure in order to remove all protein particles more efficiently.

4.3 Ultrasonic cleaning

Ultrasonic cleaning of reusable endoscopic accessories and components may be needed to remove material from hard-to-clean areas. The same detergent must be used for ultrasonic cleaning as for manual cleaning. The recommendations are as follows:

- a non-foaming detergent should be used which is appropriate for both manual cleaning and ultrasonic cleaning
- enzymatic detergent solutions should preferably be used
- the specific contact time recommended by the manufacturer for enzymatic detergents should be observed
- inhalation of enzyme-containing detergent aerosols and thus the risk of anaphylactic reactions should be minimized by covering the detergent container

4.4 Detergents

For the cleaning of endoscopes detergents with or without enzymes, and detergents containing antimicrobial substances may be used. Use of non-foaming detergents is recommended. Foaming can inhibit good fluid contact with device surfaces, and prevent a clear field of vision during the cleaning process with a risk of injury to personnel.

The detergent selected should effectively loosen organic and non-organic material so that the flushing action of the detergent fluid and subsequent rinsing water removes the unwanted material.

Detergents may contain the following substances with properties supporting the cleaning action:

- surfactants which reduce surface tension thus facilitating removal of debris
- activated H_2O_2 which effectively loosens debris at room temperature
- proteases which break protein debris into smaller, more soluble subunits
- amylase which catalyses the breakdown of starch
- lipase which breaks up fat-containing debris
- quaternary ammonium compounds, biguanidine, alcohols or aldehydes

Other active substances recommended for cleaning include amine compounds or glucoprotamine, peracetic acid and hydrogen peroxide.

Detergents containing aldehydes should not be used for cleaning as they denature and coagulate protein. Likewise detergents based on amine compounds or glucoprotamine in combination with glutaraldehyde for disinfection should not be used as chemical reactions may result in formation of colored residues.

Enzymatic detergents should be discarded after each use as these products are not microbicidal and will not retard microbial growth. In Europe detergents commonly used may contain antimicrobial substances which reduce the risk infection to reprocessing personnel, but they do not replace disinfection.

Enzymes generally function more effectively at temperatures above room temperature (>20-22°C) and should be used in accordance with the manufacturer's recommendations.

5 Endoscope Disinfection

5.1 General procedures

Disinfection of endoscopes should be performed in dedicated rooms by trained staff at the beginning and at the end of each patient list, as well as between patients. The European practice of disinfecting endoscopes just before patient use is not always practiced or recommended in other countries. However, reprocessing the endoscope immediately after use is a commonly accepted standard. An exception can be made when the endoscope is stored in a clean environment.

Recommendations for effective disinfection with a liquid chemical germicide include:

- using an automatic endoscope reprocessor
- performing disinfection in a dedicated area with atmospheric extraction facilities
- flushing high-level disinfectant or chemical sterilant throughout the endoscope at the correct temperature and for the correct duration
- concluding disinfection by rinsing with sterile or filtered water or alcohol
- drying each endoscope properly with forced air

For the protection of staff during the disinfection procedure the following apparel or equipment is recommended:

- long-sleeved waterproof gowns which are changed between patients
- gloves long enough to cover the forearms
- goggles to prevent conjunctival irritation and protect from splashes
- disposable charcoal-impregnated face masks to reduce inhalation of vapor
- an approved vapor respirator available for spillage or other emergencies

There are various classes of disinfectants available. Chemical sterilants are strong disinfectants that kill all microorganisms, including spores, after prolonged exposure; the exposure times recommended by the manufacturer and in the scientific literature should be adhered to. After shorter exposure periods of up to 45 minutes chemical sterilants kill all microorganisms except large numbers of bacterial spores.

Other disinfectants may be biocidal for mycobacteria, vegetative bacteria, most viruses and most fungi, but do not necessarily kill bacterial spores. Some disinfectants kill most vegetative bacteria, some fungi and some viruses within 10 minutes.

Germicides differ markedly among themselves primarily in their antimicrobial spectrum and rapidity of action.

It is important to note that an alcohol flush should not be used as an alternative to disinfection as alcohol is expensive and hazardous to use.

5.2 Importance of disinfection

5.2.1. Introduction

Flexible endoscopes are exposed to body fluids and other contaminants. Procedural errors in decontamination, defective equipment and failure to follow disinfection guidelines are major factors contributing to transmission of infection during endoscopy. Other important risk factors include inadequate cleaning, use of older endoscopes with surface and working channel irregularities, and contamination of water bottles or irrigating solutions.

Further risks are associated with the design or maintenance of automatic endoscope reprocessors, improper selection of disinfecting agents, inadequate drying and/or storage of endoscopes, and in particular incorrect connectors.

In order to prevent transmission of infections, flexible gastrointestinal endoscopes (as well as other heat-sensitive endoscopes) require proper cleaning and - at a minimum - high-level disinfection following each use. However, some bacterial spores may survive disinfection if present in high numbers. Rigid endoscopes and most reusable accessories can be autoclaved.

Unique features with respect to the disinfection of endoscopic equipment include the external surface, the internal channels for air, water and fluid aspiration, and the accessories.

Any disinfection process can fail if cleaning is inadequate

5.2.2 Efficacy of disinfection

The disinfection process eliminates most, if not all, pathogenic microorganisms with the exception of bacterial spores. Disinfection is usually accomplished by the use of liquid chemicals or wet pasteurization, and its efficacy is affected by the following factors:

- prior cleaning of the object
- organic and inorganic load present
- type and level of microbial contamination
- concentration of the germicide and time of exposure to it
- presence of biofilms
- temperature and pH used for the disinfection process

Some pathogens are more difficult to eliminate in the endoscope disinfection process than others. These pathogens are in decreasing order of resistance to disinfectants/sterilization:

- prions – e.g. Creutzfeldt-Jakob prion
- bacterial spores – e.g. *Bacillus subtilis*
- coccidia – e.g. *Cryptosporidium parvum*
- mycobacteria – e.g. *Mycobacterium tuberculosis, Mycobacterium terrae*
- non-lipid or small viruses – e.g. poliovirus, coxsackie viruses
- fungi – e.g. *Aspergillus* species , *Candida* species
- vegetative bacteria – e.g. *Staphylococcus aureus, Pseudomonas aeruginosa*
- lipid or medium-sized viruses – e.g. HIV, herpes viruses, hepatitis B virus

Examinations via endoscopy should be avoided in patients with suspected or confirmed variant Creutzfeldt-Jakob disease (vCJD). If endoscopy is considered essential in such patients, either a dedicated endoscope should be used or an endoscope nearing the end of its life which can be reserved for use in similar patients.

The vCJD prion is resistant to all forms of conventional sterilization. The risk of transmission of this agent is probably extremely low provided scrupulous attention to is paid to detail in the decontamination procedure after each patient. In particular, all accessible endoscope channels should be brushed with a disposable brush-tipped wire assembly designed for the purpose which has an appropriate length and diameter for each channel.

5.3 Disinfectants

5.3.1 General remarks

The ideal disinfectant is effective against a wide range of organisms, including blood-borne viruses and prion proteins; compatible with endoscopes, accessories and endoscope reprocessors; non-irritant and safe for users; and permits environmentally friendly disposal.

Disinfectants must be used at the correct temperature, and in accordance with the manufacturer's

instructions and current recommendations in the literature. The disinfectants should be tested regularly with test strips and/or kits provided by manufacturers to ensure optimal activity of the products.

Factors influencing the choice of disinfectant include

- dilution process
- stability of the solution
- number of reuses possible
- direct cost
- indirect costs (e.g. appropriate automatic endoscope reprocessor, storage space, conditions for use, staff protection measures)

Glutaraldehyde is one of the most commonly used disinfectants in endoscopy units. It is effective and relatively inexpensive, and does not damage endoscopes, accessories or automated processing equipment. However, health, safety and environmental issues are of considerable concern. Adverse reactions to glutaraldehyde are common among endoscopy personnel, and substantial reductions in atmospheric levels of glutaraldehyde have been recommended. In some countries it has been withdrawn from use.

Alternative disinfectants and the use of automated washer-disinfectors are being reviewed as ways of eliminating or minimizing glutaraldehyde exposure in endoscopy units. New automated disinfection machines use glutaraldehyde in very low concentrations, thus reducing staff exposure. The effectiveness of glutaraldehyde in these machines is maintained by heating acid-based formulations to 45-55°C, and use of fresh materials for each cycle reduces the possibility of contamination and cross-infection.

Orthophthalaldehyde is a more stable alternative disinfectant and has a lower vapor pressure than glutaraldehyde. It is practically odourless, does not emit noxious fumes, and has better mycobactericidal activity than 2% glutaraldehyde. It does not appear to damage the equipment, but like other aldehydes it can stain and cross-link protein material.

Peracetic acid is a highly effective disinfectant which may prove to be a suitable alternative to glutaraldehyde.

Before using alternative disinfectants, information should always be obtained from manufacturers of the equipment as use of an alternative to glutaraldehyde may invalidate guarantees and/or service contracts.

Finally, it should be pointed out that in many countries limited budgets do not permit the use of more expensive alternative disinfectants. In some areas even glutaraldehyde is not affordable, and reprocessing is limited to manual washing with a detergent. In such settings the use of automatic endoscope reprocessors or even disinfectant does not come into consideration.

5.3.2 Glutaraldehyde

The standard method of disinfection is immersion for 20 minutes in a 2% glutaraldehyde (GA) solution. Solutions range in concentration from 2.4 % to 2.6 % and have variable maximum shelf-lives. The maximum shelf-life of an alkaline (activated) 2 % GA solution without surfactants is 14 days.

The advantages of GA are that it is effective, relatively inexpensive, and does not damage endoscopes, accessories or automated processing equipment.

However, there are a number of disadvantages of using GA in particular for medical staff and

patients. GA has irritant and sensitizing properties. It can lead to allergic problems (skin, eyes, ENT), and cause dermatitis, conjunctivitis, nasal irritation and asthma. GA has been found to exhibit cytotoxic and genotoxic potential in cultured human cells. The hazards of GA use for staff are considerable, and toxicity has been suspected in 35 % of endoscopy units and detrimental effects established in 63 %. In patients, residues of GA after insufficient rinsing can cause colitis, abdominal cramps and bloody diarrhea.

Other disadvantages of GA are coagulation of proteins with formation of biofilm, and failure to eliminate all atypical mycobacteria within standard contact times. The latter creates diagnostic problems in bronchoscopy and the risk of cross-infection in immunocompromised patients with for instance organisms of the *Mycobacterium avium* complex. This situation is further complicated by the emergence of glutaraldehyde-resistant mycobacteria.

5.3.3 Orthophthalaldehyde

Orthophthalaldehyde (OPA) is a highly effective disinfectant which contains 0.55% 1,2-benzenedicarboxaldehyde. Studies have shown superior mycobactericidal activity of OPA compared to GA (5-log reduction of mycobacteria in 5 minutes). OPA completely destroys all common viable bacteria within 5 minutes of exposure and partially eliminates *Bacillus* species even from under organic material. It requires longer exposure times to be effective against glutaraldehyde-resistant mycobacteria. It does not produce noxious fumes, requires no activation, and is stable at pH values ranging from 3 to 9. Exposure to OPA vapor may irritate the respiratory tract and eyes. Use in a well-ventilated area and maintenance in tightly sealed containers is recommended.

The chief advantages of OPA are the high level of disinfection within 12 minutes, its long lifespan (two weeks), its non-irritant properties, and the fact that it has APIC and FDA approval.

There are several disadvantages of OPA , and the efficacy and properties of this new disinfectant need to be evaluated further. Little data is available on safe exposure levels and the hazards of long-term exposure. OPA causes coagulation of proteins with biofilm formation.
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Exposure to the agent can lead to staining of linen, clothing, skin, instruments, automatic cleaning devices, etc. due to reaction with amino radicals and thiol radicals. Specific detailed instructions are necessary to ensure adequate rinsing of equipment.

5.3.4. Peracetic acid

Compared to GA, peracetic acid (PAA) has similar or better biocidal efficacy. A contact time of 5 minutes is recommended for the destruction of vegetative bacteria and viruses (HBV, HIV); the sporicidal activity requires immersion for 10 minutes (for 0.35 PAA). A contact time of 10 or 15 minutes and a concentration >0.09 %.

With respect to staff safety, PAA is claimed to cause less irritation than GA, and be safer for the environment. Adverse effects are strongly linked to the pH value of the solution - minimal effects are observed at a pH between 7.5 and 10.0. It would, however, seem unwise to state that PAA can be used safely without adequate ventilation or personal protective measures, especially in manual immersion methods.

PAA has the ability to remove hardened material in biopsy channels resulting from use of GA, as demonstrated by surface spectroscopy. In its long history of use in the food industry and medicine, development of microorganism resistance has not been reported; its broad spectrum of activity suggests that microorganisms are unlikely to develop resistance to it.

One of the chief disadvantages of PAA is that it is less stable than GA. The shelf-life of products containing PAA is 12-18 months, depending on storage conditions. Solutions with a longer shelf-life can be prepared at the customer site by chemical reaction immediately before the first use; once prepared the solution requires replacement every 24 hours. Used solution requires replacement every 1-7 days. The PAA concentration should be checked using the appropriate test kits which detect the minimal effective concentration against the complete range of expected pathogens. If diluted solutions are used, large volumes have to be stored. This can be avoided by using concentrated products.
Further disadvantages of PAA are its vinegary odor and corrosive action, depending on the formulation. Both properties are strongly linked to the pH value, temperature, PAA concentration, and composition of the disinfectant (i.e. inclusion of anticorrosive agent, etc). Damage of flexible endoscopes has been reported after disinfection with some brands of PAA. The oxidizing ability of PAA may expose leaks in internal channels of the endoscope, especially if the endoscope was previously disinfected with GA. PAA also causes discoloration of endoscopes, but without any functional damage. There is concern about the effect of some PAA solutions on disinfection machines that contain polymer-based seals and brass components within the hydraulic circuit. Endoscope damage due to the use of PAA has also been reported in the US.

It should be noted that there are various brands of PAA available with variations in effectiveness and side-effects. There are also various labeling claims, depending on the brand of PAA.

5.3.5 Electrolyzed Acid Water

Electrolyzed acid water (EAW) is produced by subjecting water and salt to electrolysis with membrane separation. It contains HCLO, generating hydroxy-radicals that have a rapid and potent bactericidal effect. Additionally, the low pH (pH 2.7) and high oxidation-reduction potential (1100 mV) are toxic to microorganisms. Bacteria do not survive in an environment with a redox potential >900 mV and pH <3. EAW disrupts the bacterial cell wall and degenerates various inner components of the bacterium (including chromosomal DNA). At present two types of EAW are available: electrolyzed strong acid water (pH < 3) and electrolyzed weak acid water (pH 6-7)

There are a number of advantages of EAW, above all its rapid and pronounced bactericidal action (especially electrolyzed strong acid water). After manual cleaning, freshly generated EAW was found to be highly effective against mycobacteria (*M. tuberculosis, M. avium-intracellulare, M. chelonae*), *Escherichia coli*, *Enterococcus faecalis*, *Pseudomonas aeruginosa*, *Bacillus subtilis* var. *niger* spores, methicillin-resistant *Staphylococcus aureus*, *Candida albicans*, poliovirus type 2 and HIV type 1, producing a $\geq$5 log10 (99.99%) reduction in organism count within 2 minutes or less. The chlorine content is 10 ± 2 ppm, and should be monitored using test paper.

EAW is classified as non-irritant, and has minimal toxicity. It is considered safe for patients, staff and the environment, and does not harm human tissue. A further advantage of EAW is its low production costs since only salt, tap water and electricity are required.

One of the disadvantages of EAW is that the bactericidal effect is drastically decreased in the presence of organic matter or biofilm. To ensure maximal bactericidal action, it is essential that items are first cleaned thoroughly. It is also essential that all the manufacturer's production criteria are met - for example with respect to generating current, redox potential and pH. If EAW is not continuously supplied with H+, HCLO and Cl2 by electrolysis, the solution rapidly loses its oxidative and acidic properties.

There are many commercial products available and the user should be aware of variations in their properties that may result in either damage to the endoscope or inadequate disinfection. Only one EAW product has so far been approved by the FDA. However, its high 650-675 ppm free chlorine

level may not be compatible with manufacturers' requirements since damage to the material covering the insertion tube has been reported. Other non-FDA approved products with 30-50 ppm chlorine are available, but they may fail to achieve a high level of disinfection.

5.4 Manual disinfection

In manual disinfection the endoscope and endoscope components should be completely immersed in high-level disinfectant/sterilant, ensuring that all channels are perfused. (Any non-immersible gastrointestinal endoscopes should already have been removed from circulation.) At least once a day the water bottle and its connecting tube should be sterilized – these are used for cleaning the lens and irrigation during endoscopy. If possible, the water bottle should be filled with sterile water.

The value of simple soap and water should not be overlooked

5.5 Automatic reprocessing

In automatic endoscope reprocessing (AER) the endoscope and endoscope components are placed in the reprocessor, and all channel connectors attached according to AER and endoscope instructions. AER ensures exposure of all internal and external surfaces to a disinfectant or chemical sterilant. If an AER cycle is interrupted, disinfection or sterilization cannot be assured and the entire process should be repeated.

The advantages of automatic reprocessing compared to manual reprocessing are as follows:

- important reprocessing steps are automated and standardized
- the likelihood of an essential step being omitted is reduced
- all external and internal components of the endoscope are reliably and evenly subjected to thorough disinfection and rinsing
- all channels (biopsy, suction, air, water, auxiliary water, CO_2 channels) are properly irrigated
- cross-contamination with for example prions (vCJD) by transfer to other reprocessing batches is prevented by the once only use of cleaning, disinfection and rinse solutions
- eye, skin and respiratory tract exposure to the disinfectant is reduced
- atmospheric pollution by the disinfectant is reduced

The disadvantages of automatic reprocessing are:

- outbreaks of infection or colonization which have been linked to AER
- possible failure the AER water filtration system to provide bacteria-free rinse water if not maintained properly
- outbreaks of infection implicating endoscopic accessories such as suction valves and biopsy forceps which emphasize the importance of cleaning to remove all foreign matter before high-level disinfection or sterilization
- the flushing pressure required to flush the narrow channel is not achieved by most AERs resulting in inadequate disinfection of the elevator wire channel used in duodenoscopy and ERCP – this step must be performed manually using a 2-5 ml syringe
- the machines and, if needed, exhaust ventilation and water treatment systems are expensive to purchase, install and maintain

Water used for rinsing in automatic endoscope reprocessors should be maintained free of microorganisms and other particles by means of bacterial filters, biocides or other methods. If the local supply delivers hard water, water softeners should be used. Samples of final rinse water from the automatic reprocessor should be subjected to microbiological testing at least weekly.

5.6 Importance of rinsing and drying

Endoscopes are generally not dried between consecutive examinations. The drying process is designed to prevent growth of microorganisms during storage. The final drying steps greatly reduce the possibility of recontamination of the endoscope with waterborne microorganisms. Alcohol drying can be hazardous. It should be noted that in many guidelines an alcohol flush for drying is considered unnecessary if the drying process is carried out properly.

The recommended steps are as follows:

- after disinfection, rinse the endoscope and flush the channels with water to remove the disinfectant/sterilant.
- discard the rinse water after each use/cycle
- flush the channels with 70-90% ethyl alcohol or isopropyl alcohol
- dry with compressed air

The disinfectant or chemical sterilant must be rinsed from the internal and external surfaces of the endoscope. If tap water is used, a flush with 70% alcohol should be performed. Caution is necessary using alcohol due to the risk of explosion.

6. Sterilization

Sterilization is used primarily for processing endoscope accessories and is accomplished by either physical or chemical methods. It is important to note that the term 'sterilization' should not be equated with 'disinfection', and that there is no such state as 'partially sterile'.

Steam under pressure, dry heat, ethylene oxide gas, hydrogen peroxide, gas plasma, and liquid chemicals are the principal sterilizing methods used in healthcare facilities. When chemicals are used for the purpose of destroying all forms of microbiological life, including fungal and bacterial spores, they are referred to as chemical sterilants. These same germicides may also be used for shorter exposure periods in the disinfection process (high-level disinfection).

Flexible endoscopes do not tolerate high processing temperatures (> 60 °C) and cannot be autoclaved or disinfected using hot water or subatmospheric steam. They may be sterilized, however, provided they have been thoroughly cleaned and the manufacturer's processing criteria are fulfilled. Although the value of sterilization would seem to be obvious, there is no evidence available indicating that sterilization of flexible endoscopes improves patient safety by reducing the risk of transmission of infection.

7 Accessories

Disposable accessories should not generally be used more than once. If they are to be used more than once due to limited resources, it is imperative that they are subjected to a complete cleaning, disinfection and sterilization cycle between each use. The steps involved are summarized as follows:

dismantle →brush →flush →dry

Good quality water (sterile, filtered or drinking-quality) and a disinfectant solution, or at least a soap detergent, should be used.

- **Consider whether legal implications allow re-use**
- **If local regulations allow reuse, arrange for reprocessing with optimal efficacy**
- **Consider the implications for manufacturer guarantees**

Endoscopic accessories that penetrate the mucosal barrier (e.g. biopsy forceps, guidewires, cytology brushes, other cutting instruments) should be either used once only or cleaned ultrasonically or mechanically and then sterilized or autoclaved between each patient use. Endoscope accessories that are not passed through the working channel of the endoscopes (such as water bottles and bougies) are normally reusable and should be autoclaved for 20 minutes at 134^{o}C. Rubber valves should be changed after the passage of biopsy forceps, guidewires and/or other accessories.

8 Endoscope Storage

Colonized water or residual moisture can be a source of microorganisms, and proper drying will remove any moisture from internal and external surfaces of the endoscope. Drying of endoscopes especially prior to prolonged storage decreases the rate of bacterial colonization. Forced air drying adds to the effectiveness of the disinfection process.

The following are recommendations for storage:

- ensure proper drying prior to storage
- hang preferably in a vertical position to facilitate drying
- remove caps, valves and other detachable components according to the manufacturer's instructions
- uncoil insertion tubes
- protect endoscopes from contamination by placing a disposable cover over them
- use a well ventilated room or cabinet for reprocessed endoscopes only
- clearly mark which endoscopes have been reprocessed

It is important to avoid contamination of disinfected endoscopes by contact with the environment or by prolonged storage in an area that may promote pathogen growth. Special storage cabinets are available that decrease the risk of post-disinfection contamination.

9 Quality Assurance

9.1 Quality control

It is important to monitor the efficacy of the disinfection procedure at regular intervals. All endoscope channels should be checked for contamination. The manufacturer's instructions should be followed with regard to the intervals, media and culture conditions for quality controls.

9.2 Personnel training

All healthcare personnel in an endoscopy unit should receive training in standard infection control measures, including those designed to protect both patients and healthcare workers.

Personnel assigned to reprocess endoscopes should receive device-specific reprocessing instructions to ensure they are qualified to carry out cleaning and high-level disinfection or sterilization procedures correctly. The competency of personnel reprocessing endoscopes should be tested on a regular basis. All personnel handling chemicals should receive information on the biological and chemical hazards associated with procedures using disinfectants.

Protective equipment (e.g. gloves, gowns, goggles, facemasks, respiratory protection devices) should be readily available to healthcare workers, and should be used as appropriate to protect them from exposure to chemicals, blood or other potentially infectious material.

Facilities where endoscopes are used and disinfected should be designed to provide a safe environment for healthcare workers and patients. Air-exchange equipment (e.g. ventilation system, exhaust hoods) should be used to minimize the exposure of all persons to potentially toxic vapors from substances such as glutaraldehyde. The vapor concentration of the chemical sterilant used should not exceed the allowed limits; tests should be conducted regularly to ensure that this is the case.

9.3 Reprocessing errors

Very few cases of pathogen transmission during gastrointestinal endoscopy have been reported in the literature over the last ten years. Reported causes include failure to sterilize biopsy forceps between patients, a breach of accepted endoscope reprocessing protocols, and failure to observe general infection control practices (inappropriate use of multi-dose vials/bottles and/or reuse of syringes).

Frequent organizational problems leading to reprocessing errors include administrative failures, an insufficient number of endoscopes, understaffing and failure of the disinfection process.

The risk of transmitting infection via endoscopic procedures is related to the following factors:

- exposure of equipment to microorganisms
- instrument design
- insufficient exposure time
- sub-standard materials
- contaminated water bottles or irrigation solutions
- contamination of the automatic reprocessor
- improper use of the automatic reprocessor
- design of the automatic reprocessor
- inadequate drying before storage

There are also several very specific problems which contribute to reprocessing errors. When the operating channel becomes damaged, a pocket of persistent colonization may form within the endoscope. The damage may not be recognizable until it is advanced and fluid invasion causes malfunction. Another problem is a small air-water channel which in many endoscopes cannot be brushed manually. Such endoscopes must be disinfected with air under pressure and liquid or gas disinfectants. Contamination of water bottles with *Pseudomonas* species is a major problem. Bottles should therefore be routinely tested, and infected bottles discarded. Yet another problem relates to the limited number of endoscopes in most endoscopy units. This requires a reasonable turnaround time for endoscope reprocessing, which may conflict with highly effective but time-consuming disinfection or sterilization procedures. For example, while enzymatic detergents are highly effective, they need a minimum of 15 minutes contact time – this may conflict with scheduling times.

10 Guidelines and References

Guidelines

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These WGO-OMGE/OMED guidelines have made extensive use of information published in the existing guidelines No. 1-4 listed above. A special thanks is due also to their authors.

12 Queries and Feedback

The Practice Guidelines Committee welcomes any comments and queries you may have. Do you feel we have neglected some aspects? Do you feel some procedures carry extra risks? You are invited to tell us of your experiences. Click the button below and let us know your views.