State of Kuwait
Ministry of Health
Infection Control Directorate

Guidelines for Prevention of Endoscopy-Associated Nosocomial Infection

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Introduction:

There is an increase in number, complexity and invasiveness of endoscopic procedures. Diagnostic and therapeutic procedures are done without surgery and anesthesia as with these advances in technology complications have also arisen such as bleeding and perforation. However, infectious complications are more difficult to recognize, because infection may appear long time after the procedure.

Types:

Endoscopes can be categorized by their design as flexible or rigid:

I. ***Rigid endoscopes*** are relatively easy to clean, disinfect and sterilize. Most rigid endoscopes are compatible with steam, formaldehyde, ethylene oxide and certain liquid disinfectants.

II. ***Flexible endoscopes*** are more complex than rigid endoscopes, thus creating more problems with cleaning, disinfection and sterilization.

Flexible endoscopes are heat sensitive; therefore, chemical disinfection or sterilization must be performed at low temperature.

Accessories: Accessories used in endoscopic applications are either re-usable or single use. They consist of long flexible small diameter manipulators. There is a variety of types, each one made to fulfill a specific purpose, such as biopsy forceps, grasping forceps, diathermy snares, wire baskets, cannulae etc.

Infectious complications:

Pathogenesis and mechanism of transmission:

The vital process in the pathogenesis of endoscopy-induced-related infections is the tendency of bacteria to form bilofilms which consist of colonies forming structure in order to increase its growth potential. These biofilms usually take pillar and mushroom like shapes which interfere with the decontamination process.

Infections following endoscopic procedures are caused by both endogenous and exogenous pathogens.

I. ***Endogenous infections*** are cause by patient's own flora colonizing the mucosal surfaces of the gastrointestinal or respiratory tract that gain access to the blood stream or other normally sterile body sites as a result of the procedure.

These infections include cholangitis following manipulation of an obstructed biliary tract, pneumonia due to aspiration of oral secretions in a sedated patient. Transient bacteremia

may result from both upper and lower gastrointestinal endoscopy, such transient bacteremia may lead to endocarditis.

Uncommon infections such as brain abscess, subdural empyema may occur after variceal sclerotherapy.

II. ***Exogenous infections*** are introduced to the patient by endoscope or its accessories from patient to patient or from inanimate environment to patient these infections may be caused by the following micro-organisms:

(a). Gram negative bacilli are the most common causative organisms which are likely to grow in moist areas of endoscopes stored overnight. Pseudomonas aeruginosa is the most frequent isolate, especially after endoscopic retrograde chlonansiopancreaticography (ERCP). Klebsiella spp., Enterobacter spp. , Serratioa spp., Salmonella Spp. , and Helicobacter pylori have also been reported following gastrointestinal endoscopy.

Pulmonary infections with Serratia Marcesons have also been reported following bronchoscopy.

(b). Mycobacterium: nosocomial infections of Mycobacterium tuberculosis has been reported following bronchoscopy.

Non-tuberculosis mycobacterium may contaminate tap water and cause nosocomial infections. Such mycobacterium tuberculosis and may require longer exposure times for irradiation.

(c). Viruses: Poor compliance with decontamination procedures with the increasing prevalence of HIV, HBV and HCV may lead to endoscopic transmission of serious viral infections.

(d). Parasites and Fungi: Transmission of some parasitic and fungal infections has been reported following endoscopic procedures.

Definitions:

1. ***Cleaning*** is a process which physically removes organic material and or soil from objects, usually using water with proper detergents.
2. ***Disinfection*** is a process which achieves the removal or destruction of vegetative micro-organisms but not necessary the spores.
3. ***Sterilization*** is a process which achieves the complete killing or removal of all types of micro-organisms including the resistant spores.
4. ***Levels of disinfection:***
   - ***High level disinfection*** is a process in which all micro-organisms including mycobacterium tuberculosis are destroyed except high numbers of bacterial spores.
   - ***Intermediate level disinfection*** is a process that destroys vegetative bacteria most viruses, most fungi, inactivates mycobacterium tuberculosis but does not kill bacterial spores.

- ***Low level disinfection*** is a process that destroys most vegetative bacteria, some viruses and some fungi but not resistant micro-organisms e.g.; tubercle bacilli and bacterial spores.

5. Instrument Categorization:

- ***Critical items:*** objects that enter sterile tissue or the vascular system, e.g. surgical instruments, cardiac and urinary catheters, biopsy forceps. Items in this category should be used as sterile.
- ***Semi-critical:*** objects which come in contact with mucous membranes or with non-intact skin, e.g., respiratory and anesthesia equipment and endoscopes. Items in this category require high to intermediate level disinfection.
- ***Non-critical items:*** objects that come in contact with intact skin but not with mucous membranes, e.g., bedpans and blood pressure cuffs. Items in this category require low level disinfection or just simple cleaning.

Processing of Endoscopes and Accessories:

Meticulous and reliable mechanical cleaning is the most important step in endoscopic reprocessing. Efficient cleaning, disinfection and sterilization is recommended, thus staff with specialized training and knowledge of the instrument are required.

I. Cleaning:

(1). Organic material (blood. Tissue, feces, and respiratory secretion, etc.) may interfere with the disinfection process by preventing the penetration of the disinfectant. Moreover, some disinfectants are inactivated by organic soil and may lead to tissue fixation which may cause blockage of the lumens and stiffening of the taps and moving parts of the endoscopes.

(2). Cleaning of endoscopes and accessories should be performed immediately after use to prevent drying of secretions using a non-abrasive manufacturer recommended enzymatic detergent for medical instruments.

(3). All channels should be irrigated with generous amount of detergent and tap water to soften and dilute the organic debris, and the air-water channel cleared with forced air according to the manufacturer recommendation. This process should be performed before the mechanical cleaning.

(4). All detachable parts (hoods, suction valves, etc.) should be removed and soaked in a detergent solution.

(5). The insertion tube should be cleaned with detergent solution and rinsed thoroughly.

(6). All accessible channels and ports should be brushed to remove organic material, and the detergent solution should be suctioned or pumped through all channels to wash out the dislodged material.
Special attention must be given to crevices which are likely to harbour soil material.

(7). The tip of endoscope should be wiped or brushed gently to remove organic material impacted in or around the air and water nozzle.
(8). The distal tip of ERCP endoscope, should be brushed with the elevator both up and down to ensure that no material is impacted in that movable part.
(9). Detachable parts of the endoscope should be thoroughly cleaned with suitable detergent, and the irregular surfaces must be brushed to ensure that all soil has been completely removed.
(10). All immersible parts should be thoroughly rinsed with clean water after mechanical cleaning. Non-immersible endoscope should not be in service. However, when total immersion of the endoscope is impossible, because of potential damage to the scope the non-immersible parts should be cleaned with water and detergent and then wiped with 70% isopropyl alcohol.
(11). Accessories that penetrate mucosal membranes such as biopsy forceps and cytology brushes are considered critical and therefore must be sterile before use. They should be mechanically cleaned with an ultrasonic cleaner after being cleaned manually with the proper detergent.
(12). Ultrasonic washers may be used for most rigid endoscope components and accessories, (with the exception of the telescope).
(13). Cleaners brushes should be thoroughly cleaned then receive high-level disinfection or sterilization after each use, or used once and discarded.

II. Automated Endoscope Re-processing:

Automated machines have been developed for endoscopic decontamination; however, meticulous manual cleaning must precede the use of Automated Endoscope Preprocessors (AERs). The available AERs differ in certain basic aspects including type of chemical agent, mechanisms of channel irrigation and exposure time and temperature.

AERs are useful as they may reduce exposure of personnel to toxic chemicals and standardize the contact time of the disinfectant. However, it is important to be sure that a given endoscope can be processed safely in AERs by consulting the endoscope manufacturers.

AERs vary in their efficiency and capability in cleaning channel blockage, thus manual cleaning must precede automated reprocessing.

Some machines have a dedicated pre-programmed disinfection cycle while others are capable to carry out self-disinfection using the normal operating cycle in the absence of the endoscope. Machines that are not fully automated, and do not have facility of self disinfection will require manual disinfection of the fluid pathways. Whichever disinfection programme is adopted is essential that all parts of the machines that come into contact with fluids are accessed including disinfection of water delivery system.

III. Disinfection and Sterilization:

Heat disinfection or sterilization is the most effective method, thus whenever possible it should be used rather than chemicals.

Endoscopes that come into contact with mucous membranes such as laryngoscopes and gastroscopes are considered semi-critical and should either be sterilized or at least receive high-level disinfection. Endoscopes that enter/penetrate sterile body cavities such as laparoscopes and arthroscopes are considered critical and should be sterilized.

Some endoscopic accessories (e.g., sclerotherapy needles, cutting forceps) are considered critical.

Chemicals recommended for high-level disinfection:

High-level disinfectant should destroy all micro-organisms but not necessary bacterial spores. It should work in pressure of organic matter, does not cause damage to the endoscope nor cause toxicity to personnel.

1. **Gluteraldehyde preparation**: 2% gluteraldehyde solution acts as high-level disinfectant as well as chemical sterilant. To achieve adequate high-level disinfection with gluteraldehyde all immersible internal and external surfaces and channels should be in contact with the disinfecting agent for at least 20minutes.
2. **Hydrogen peroxide:** 7.5% hydrogen peroxide 0.85% phosphoric acid solution is considered a high-level disinfectant. Some endoscopic equipment are incompatible with this agent.
3. **Peracetic acid:** 1% peracetic acid solution is a broad-spectrum disinfectant. It is a corrosive agent and may cause several health hazards.
4. **Orthophalaldehyde:** is a new product which contains 0.55% 1,2-benzenedicarboxaldehyde, it is stable over a wide PH range 3-9, not irritating to the eyes and nasal passages and does not require activation before use.

Among all the above mentioned chemicals, gluteraldehyde is recommended. However, endoscopes manufacturer's recommendations should be followed.

Chemicals not recommended for disinfection of endoscopes:

Some agents are not recommended for disinfection of endoscopes and endoscopic equipment, such as skin antiseptic (povidone iodine, chlorhexidine gluconate), hypochlorite (presept, chloros), quaternary ammonium compounds (Dettol ED, cetavlon) and phenolics (hycoline, Gardol).

IV. Dealing with Endoscopes after disinfection or sterilization:

1. **Rinsing:** In order to prevent toxic effects of residual chemicals, endoscopes and accessories should be thoroughly rinsed using sterile water. In situations where sterile water cannot be used tap water followed by 70% alcohol rinse is recommended. Only sterile water should be used for endoscopes that enter sterile tissues.
2. **Drying**: In order to prevent microbial growth or transmission in a moist environment all endoscopic equipment and accessories should be thoroughly dried. Rinsing channels with 70% alcohol and forced air through lumens will facilitate drying.
3. **Storage:** Endoscopes should be stored in a way to prevent recontamination or damage, they should not be stored coiled, should be hung in vertical position to facilitate drying and should be stored in a well-ventilated and dust-free area.

V. Processing Endoscopic Accessories:

All endoscopic accessories that pass through sterile tissue or penetrate mucosal membrane (e.g., biopsy forceps) must be disposable or sterilized between uses.

Sterile water should be used for endoscopic irrigation. Cleaning and disinfection of water bottle and connecting tubes is usually difficult, therefore they should be sterilized or receive high-level disinfection at least daily. Disposable sterile accessories that cannot be reprocessed must be used once and discarded.

VI. Endoscopy Personnel:

Endoscopes are delicate and complex equipment, therefore only well-trained personnel should be assigned for reprocessing of the endoscopes and their accessories. Temporary personnel are not allowed to work there. ***Personnel must be:***

1. Able to implement endoscope reprocessing protocols properly.
2. Involved in a continuous infection control educational program.

3. Educated about biological and chemical hazards while performing or assisting with endoscopy procedures and reprocessing.

4. Aware of the universal precautions (including gloves, mask, eye-protection, fluid-proof gowns or aprons). Personnel dealing with suspected or confirmed mycobacterium tuberculosis whether during performing endoscopic procedures of handling used endoscopic equipment should wear specific respirators.
5. Vaccinated against preventable infectious diseases such as Hepatitis B and tuberculosis.

VII. Quality control Measures:

Excessive use of the disinfectant solution for long period results in dilution or decreased activity. In-use disinfectant solution should be changed according to manufacturers recommendation or when visibly contaminated.

Endoscopes and accessories should be inspected before use, during procedure, immediately after cleaning, and before disinfection or sterilization. Leak-test for fibroptic endoscopes should be performed according to manufacturer's recommendation before starting the cleaning process.

All endoscopic procedures should be documented including but not limited to: date of procedure, patient identification data, endoscopist(s), assistant(s), endoscopic procedure, type of endoscopic instrument, endoscope identification number, duration of procedure, and findings.

Microbiological testing of the endoscopes and accessories is recommended when clinical or epidemiologic findings suggest endoscopy related infection.

VIII. Design of Endoscopic Procedure Area:

The area should be designed according to several factors such a: patient volume, traffic flow, types of endoscopic procedures (e.g., bronchoscopy or gastrointestinal endoscopy). Space for endoscopic cleaning, disinfection, sterilization and storage should all be taken into consideration.

Space used for performing the endoscopic procedures should be separated form space allocated for cleaning and disinfection or sterilization of equipment.

Endoscopy room should be equipped with hand-washing facilities and the necessary emergency equipment.

Endoscopy procedure room especially for bronchoscopes should meet the following requirements:

- Negative pressure
- Adequate air changes (12-15/ hour)
- Air should not be received and should be exhausted to outside where it is safe.

Cleaning and disinfection or sterilization area should be supplied with adequate ventilation system to exhaust toxic vapors and air-borne pathogens. The air exchanges should be (12-15/ hour).

The area should be provided with an adequate utility sink suitable for cleaning and rinsing od endoscopes and accessories.

The area should be large enough to accommodate the machines being used. There should be enough storage space for the chemicals and clean endoscopes and accessories.

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Cabinets used for drying and storage of the endoscopes should be made of materials that can be easily cleaned.

The cleaning and disinfection room should be provided with adequate basins with tight-fitting lids for the disinfectant.

The area should be designed in a way to ensure that the work flow can facilitate implementation of infection control practices (e.g., avoid mixing of contaminated with clean equipment).

Eating and drinking in procedures and utility rooms should be prohibited. Personal protective wears and equipment should be easily accessible.

Summary:

1. Meticulous cleaning of endoscopes and accessories should be performed immediately after use. All immersible parts should be thoroughly rinsed with clean water.
2. Leak-test is recommended for flexible fibroptic endoscopes before immersion.
3. Endoscopes that enter sterile tissue should be sterilized before each use, or receive at least high-level disinfection if sterilization is not feasible.
4. Endoscopes which come in contact with mucous membranes should receive at least high-level disinfection.
5. All immersible internal and external surfaces should be soaked in gluteraldehyde solution for not less than 20minutes to achieve high level disinfection.

6. Endoscopes and accessories should be thoroughly rinsed after chemical disinfection using sterile water or tap water followed by 70% alcohol rinse.

7. Endoscopic equipment and accessories should be thoroughly dried. Rinsing channels with 70% alcohol and forced air through lumens will facilitate drying.
8. Endoscopes should be stored in a way to prevent recontamination or damage and should be hung in vertical position to facilitate drying.
9. Accessories that penetrate mucous membranes (e.g., biopsy forceps, cystology brushes) should be disposable or sterilized between each patient.
10. Water bottle and connecting tubes should be sterilized or receive high-level disinfection at least daily.
11. Endoscopes which cannot withstand the recommended cleaning, disinfection and sterilization process due to age, design or damage should not be used.
12. Endoscopy for patients with known infectious disease such as tuberculosis, HIV hepatitis B & C should be scheduled at the end of the list.
13. Endoscopy personnel should be well-trained about the proper reprocessing of endoscopic equipment. Personnel should be vaccinated against preventable infectious diseases such as hepatitis B and tuberculosis. They should be provided with suitable protective equipment.

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