Processing Medical Devices in Settings With Limited Resources

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Processing medical devices in settings with limited resources

- a neglected priority for infection prevention.

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WHO Patient Safety Challenge
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Outline

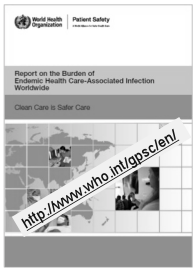
- Setting the scene
- Discuss challenges faced by limited resource countries
- Outline the basic concepts and practical points to achieve effective decontamination
- Key references

Term **DECONTAMINATION** includes *cleaning*, *disinfection* and *sterilization*

WHO Report on the Burden of Endemic Health Care-associated Infections (HCAI)

(A systematic review of the literature)

- 5% to 15% of hospitalized patients in general wards and as many as 50% or more of patients in intensive care units (ICUs) in resource rich countries acquire HCAIs
- Magnitude of the problem in low/ middle income countries is unknown and/or underestimated due to lack of surveillance data



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- Reprocessing of medical devices is common worldwide due to :
  - *cost constraints*
  - *availability of adequate no. of devices*
- Full scale of adverse events (including HCAIs) due to inadequate decontamination and re-processing of medical devices is unknown

Adverse events: Re-processing medical devices

- 1996-1999: 245 adverse events are examined by FDA associated with the reuse of single medical devices
  - 7 deaths
  - 72 injuries
  - 147 device malfunctions
  - 19 others

Source: Food and Drug Administration, 2011 www.fda.gov

Risk of cross infection due to inadequate decontamination of medical devices

Spread of **BLOOD BORNE VIRAL** infections e.g. Hepatitis B&C, HIV	• Re-use of needles & syringes • Inadequate cleaning and decontamination of items in dentistry and other setting
Risk of **SURGICAL SITE INFECTIONS**	• Inadequate sterilization of surgical instruments • Use of non-sterile gloves, wound dressings and other items
Risk of Catheter associated UTI Central Line infections Ventilator Associated Pneumonia	• Re-use of single use sterile devices
Spread of **MULTI-DRUG RESISTANT MICROORGANISMS**	• Inadequate cleaning and decontamination of items/equipment and environment between patients

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Risks of inadequate decontamination & re-processing of medical devices

RISK	
Biological	• **Health care associated infections** • Debris that remain fixed to surface
Chemical	• Absorption of cleaning agents and chemical disinfectants • Poor rinsing of cleaning agents may lead to toxic or pyrogenic reactions
Physical	• Alteration of device´s dimensions, material stiffness and torsional strength • Embrittlement or cracking • Malfunction or poor performance that delays the procedure • Softening of adhesives • Weakening of components

Current status of decontamination of medical devices in resource limited countries

Reuse syringes and needles

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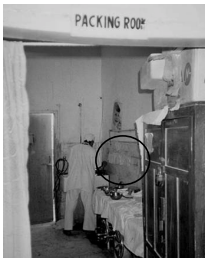
Proctoscopes reused without cleaning and disinfection

Reuse of surgical gloves in Operating Theatre



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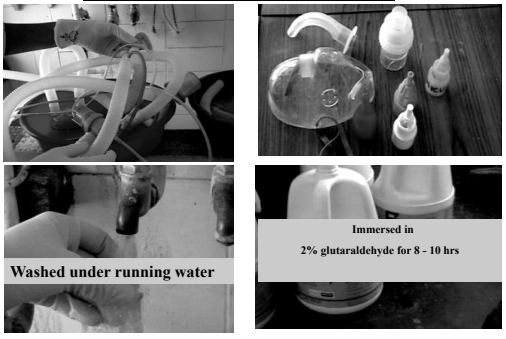
Ventilator circuits, urinary catheters etc



Challenges faced by limited resource countries..1

- Lack of awareness on the risks associated with inadequate decontamination of medical devices and items
- Items are rarely cleaned before decontamination
- Education and training
  - Issue with the availability of qualified and trained personnel due to lack of career path
  - Lack of formal training with no regular update
  - Lack of Standard Operating Procedures (SOP)
- Inadequate design of an area/building of Sterile Service Dept. and endoscopy units

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Challenges faced by limited resource countries..2

- Items/equipment are often donated by charities without
  - Adequate training on how to use them correctly
  - No back-up support for maintenance & repair
  - No service contract for maintenance of equipment
  - Lack of availability of spare parts
- Issues with the availability of
  - Running water and electricity on 24 hr. basis
  - Suitable quality of water (microbial and chemical)
  - Quality control indicators for sterilization process e.g. biological and chemical indicators

Challenges faced by limited resource countries..3

- Inadequate no. of items in the system with tendency to locally decontaminate instruments to avoid loss in the 'system'
- More reliance on the use of chemical disinfectants
- Common methods of decontamination are:
  - Use of chemical disinfectants esp. 2% glutaraldehyde, hypochlorite solution and Quaternary Ammonium Compounds
  - Boiling of items to 'sterilize' in a hot water boiler
  - Use of heat sterilization using either hot air oven or benchtop steriliser

BASIC CONCEPTS

How inadequately decontaminated devices spread infections

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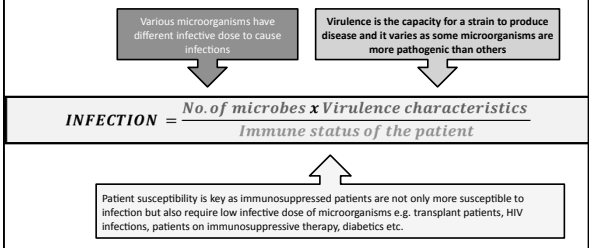

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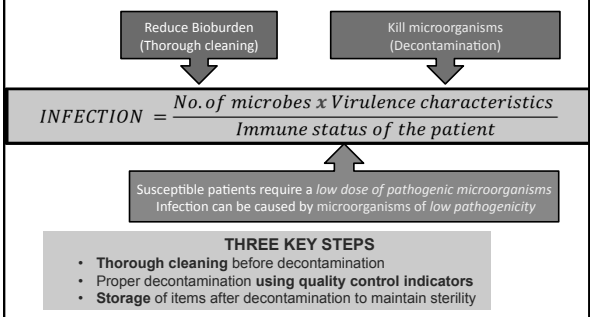
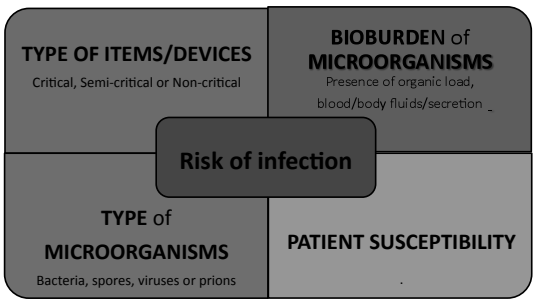


Risk of infection due to inadequate decontamination of devices/items/equipment



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1. Types of devices and level of disinfection & sterilization required

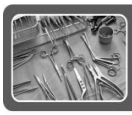
Spaulding classification of medical devices

Non-critical : Contact with intact skin

- **Germicidal action**: Kill vegetative bacteria, fungi and lipid viruses Can be expected to be contaminated with some microorganisms
- **Low-level disinfection** (chemical)
- **Examples** : OT theatre table, ECG leads, bedside tables, furniture, baths, basins etc.

Semi-critical: Contact with mucous membranes *or* non-intact skin

- **Germicidal action**: Kills all microorganisms except high numbers of bacterial spores
- **High-level disinfection** (Heat or chemical)
- **Examples** : Respiratory therapy and anesthesia equipment, endoscopes, vaginal specula, re-usable bedpans and urinals, etc.



Critical: Contact with sterile tissue, vascular system etc

- **Germicidal action**: Kill all microorganisms, including bacterial spores
- **Sterilization** (Steam, Ethylene oxide, gas hydrogen peroxide plasma) Most are single-use devices
- **Examples:** Surgical instruments/devices, cardiac catheters, implants, needles & syringes etc.

Symbol for single use items

Critical items: In contact with a break in the skin or mucous membrane

***Class 1* : Very high risk**

- Intravascular, intraventricular, intraoptic devices, needles & syringes etc
- Cause serious infections e.g. endocarditis, meningitis, endophthalmitis, transmission of blood borne viral infections
- Difficult to clean, heat labile; sterilization is necessary

Class 2

- Usually cleanable, heat tolerant, sterilization is necessary e.g. surgical instruments

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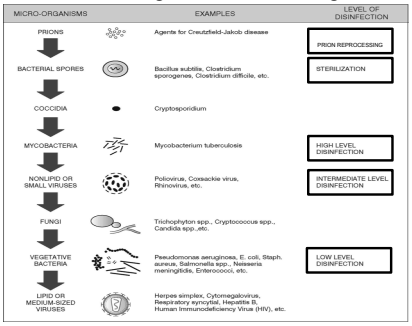
Descending order of resistance to germicidal activity of chemical disinfectants against various microorganisms



What is Prion ?

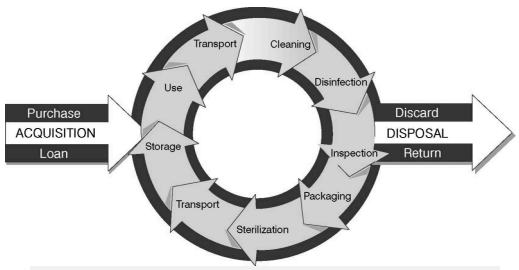
- Prions are infectious agents (abnormal proteins), smaller than viruses and unlike other pathogens, contain no DNA or RNA
- They accumulate in the central nervous system where they can trigger neurological symptoms
- They are associated with Transmissible spongiform encephalopathy e.g. vCJD (Creutzfeldt-Jakob Disease)
- ***Very resistant to all conventional methods*** of decontamination as most chemical and physical means of cleaning, disinfection and sterilization of medical devices are only partially effective at inactivating prion proteins

•UK Dept. of Health. *Transmissible spongiform encephalopathy agents: safe working and the prevention of infection.*
http://www.dh.gov.uk/ab/ACDP/TSEguidance/index.htm
•SHEA Guideline. Guideline for Disinfection and Sterilization of *Prion-Contaminated Medical Instruments. Infection Control and Hospital Epidemiology* 2010; 31(2):107-115.

Processing medical items/devices in settings with limited resources

- Is it safe for the patient?
- Is it safe for the staff?
- Is it cost effective?
- Is it practical i.e. do you have the facility to do it?
- Will the item/device be safe to use?
- Have you validated the decontamination process?
- Have you carried out risk assessment?
- Any legal consequences?

Life cycle of a reusable medical device



For effective decontamination, every step in the process must be satisfied and subject to monitoring and proper Quality Control

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BASIC CONCEPTS

(Decontamination i.e. cleaning, disinfection & sterilization)

Why cleaning is important

- Cleaning is a process that aims to remove contamination from reusable medical devices and environmental surfaces
- It does not necessarily destroy all microorganisms but it does ***reduce*** their numbers (bioburden by 2-3 $\log_{10}$ reduction) and as a result it is more likely that decontamination processes will succeed
  - Organic matter and microorganisms can cause inactivation of the chemical disinfectant
  - Cleaning also allows complete surface contact with chemical disinfectant during decontamination procedures
- Cleaning removes extraneous matter that may result in adverse patient reactions e.g.
  - soil and dust
  - chemical residues
  - degradation products, pyrogens (substances that cause fever)
- These substances could all affect the performance of a medical device and produce a harmful effect when the device is next used

- Cleaning is the *most important* step as the effectiveness of decontamination depends upon the efficiency of the cleaning process
- ***Cleaning…Cleaning…Cleaning…!***
- You can clean without disinfection but you can *never* disinfect *without cleaning !*

Definition: Disinfection

- Disinfection is a process that reduces the number of microorganisms on a reusable medical device or surface, but it does not necessarily destroy certain viruses and bacterial spores
- Disinfection is not generally as effective as sterilization in reducing microbial contamination
- **Medium-risk** (semi-critical) medical devices and environmental surfaces

Disinfection methods

WASHER DISINFECTORS

•Washer-disinfectors provide cleaning and disinfection of medical devices.

•**Thermal disinfectors are the preferred method**, but chemical disinfectors are necessary for heat-sensitive items.

•Typical cycles include a warm power wash, disinfection phase, rinse and drying.

Washer Disinfector Temp.
•71 °C for 3 min
•80 °C for 1 min
•90 °C for 1 sec

LOW TEMPERATURE STEAM

•Low-temperature steam disinfection is an automated physical process used to disinfect reusable medical devices that are not damaged by the process conditions.

•The process works by removing air and exposing every surface of the device to saturated steam, below atmospheric pressure, at 73°C for 10 minutes.

•Sealed, oily or greasy items and those that retain air are not suitable for low-temperature steam disinfection.

•Only trained staff should operate the machines.

LIQUID DISINFECTANT

•Liquid disinfectant immersion is used only for disinfecting devices when alternative methods are not available or appropriate.
•The process is only effective if you clean the device thoroughly, choose the correct disinfectant, use it at the specified concentration, and achieve good contact between the disinfectant and the device for the specified minimum time.
•Only trained staff should carry out chemical disinfection.

Chemical disinfection

- The efficacy of chemical disinfection is often uncertain and, whenever possible, *disinfection by heat is preferred* to chemical methods
- For high-risk items if no practical means of sterilization is available e.g. flexible endoscopes
- They should be freshly prepared and must be clearly labelled and used before the expiry date
- They must be used at the correct concentration/contact time and stored in an appropriate container
- Solutions must be prepared and stored in a manner to avoid contamination with microorganisms
- Manufacturers' instructions must be consulted on the compatibility of materials
- Chemical disinfectants are hazardous substances and may cause damage on contact with skin, eyes, or mucous membranes, by inhalation of vapours, or by absorption through the skin. Therefore, relevant safety precautions (e.g. appropriate protective equipment) should be worn when using chemical disinfectants

Sterilization

- Sterilization is a process used to make reusable medical devices **free** from **viable microorganisms**, including **bacterial spores** and **viruses**
- However, normal sterilization methods will not destroy prions (causative agents for Transmissible spongiform encephalopathy e.g. CJD)
- **High-risk** (critical) medical items/devices, that penetrate skin or mucous membranes or enter a sterile body cavity
- Steam sterilization is achieved through direct contact of the device with pure dry saturated steam at a specified temperature for the required time, in the absence of air
- Whenever practicable, the Sterile Services Department should carry out sterilization
- Steam sterilization is the method of choice for sterilizing reusable medical devices
- However, in the absence of a central sterilizing service, a **vacuum benchtop steam sterilizer** may be used, provided it is validated, maintained and operated correctly as per manufacture's guidance.

Sterilization methods

STEAM

Steam sterilization is the method of choice for sterilizing reusable medical devices.
•However, it is not suitable for sterilizing devices (e.g. fibreoptic endoscopes) that cannot withstand exposure to temperatures of 121°C to 138°C at a pressure higher than atmospheric.
•Steam sterilization is achieved through direct contact of the device with pure dry saturated steam at a specified temperature for the required time, in the absence of air.
•Operators must be fully trained.
Whenever practicable, the Sterile Services Department should carry out sterilisation. However, in the absence of a central sterilising service, a benchtop steam sterilizer may be used, provided it is validated, maintained and operated correctly.
The simplest types are known as downward displacement sterilizers. Vacuum benchtop steam sterilizers are also available.

Steam
Autoclave/ Sterilizer
•115 °C for 30 min
•121-124°C for 10 min
•134-138°C for 3 min

Dry Heat
•160 °C for 2 hours

GAS PLASMA

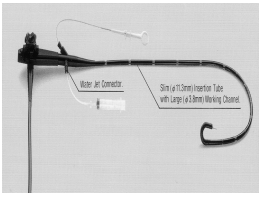
Gas plasma is a **highly active gas containing ions and molecules and free radicals** that are capable of inactivating micro-organisms at low temperature (below 50°C)

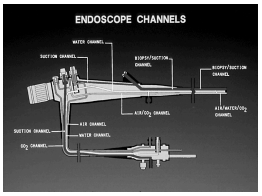
STERILANT GAS & LOW-TEMPERATURE STEAM

Sterilization is achieved by the **combination of a gas** (ethylene oxide or formaldehyde) **and low-temperature steam** at sub-atmospheric pressure

Ethylene oxide or formaldehyde and low-temperature steam

Decontamination of endoscopes





ASGE –SHEA Guidelines. Multisociety Guidelines on Reprocessing Flexible GI endoscopes: 2011. *Infection Control and Hospital Epidemiology* 2011; 32 (6):527-537.

Endoscope reprocessing

*Chemical disinfectants are used for fibreoptic endoscopes as they **cannot** withstand exposure to temperatures of 121°C to 138°C at a pressure higher than atmospheric*.

Endoscopes & Accessories
Diagnostic and therapeutic procedures

ENDOSCOPES

Rigid endoscopes
- Arthroscopes, Laparoscopes
- Some are not heat labile - steam sterilization possible

Flexible endoscopes
- GI: Gastroscopy, Colonoscopy, Sigmoidoscopy
- Bronchoscopy, Cystoscopy , Laparoscopy
- Laryngoscopy, Rhinoscopy, Pharyngoscopy
- Complex, more difficult to clean & disinfect/ sterilize
- Heat labile and are damaged when exposed > 60°C
- Use chemical ('sterilant') disinfectant

ACCESSORIES
BREAK MUCOSAL BARRIER
- Biopsy forceps
- Cytology brushes
- Cautery probes
- Needles for injecting
- Banding devices
- Laser fibers
- Snares for tissue removal

Reusable endoscopic accessories that *break the mucosal barrier* should be mechanically cleaned and sterilized between patients *or* single use

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Exogenous Infections

Sources: From patients *or* the environment

Infections traced to deficient practices

- Inadequate manual cleaning
- Inappropriate/ineffective disinfection e.g. time exposure, channel irrigation, test concentration, ineffective disinfectant, inappropriate disinfectant
- Inadequate rinsing and drying
- Failure to follow recommended disinfection practices e.g. rinsing with tap water
- Contaminated cleaning and/or disinfection agents
- Contaminated cleaning accessories - channel brushes
- Flaws in design of endoscopes or Automatic Endoscopic Reprocessors (AERs)
- Biofilms: both in the AERs & inside the endoscope itself
- Biofilm: resistant to disinfection and removal

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Transmission of infection

Transmission of both Hepatitis B & C are documented in the literature

Birnie GG. *Gut* 1983:24:171-174: Bronowicki JP. NEJM 1997;337: 237-240: Ouzan D. *Presse Med* 1999;28:1091-1094.

Gastrointestinal endoscopy

- >300 infections transmitted
- 70% agents *Salmonella sp.* and *P. aeruginosa (Klebsiella* spp., *Enterobacter* spp., *Serratia marcescens, Salmonella* spp., and *Helicobacter pylori)*
- Clinical spectrum ranged from colonization to death (~4%)

Bronchoscopy

- 90 infections transmitted
- *M. tuberculosis*, atypical *Mycobacteria* e.g. *M.chelonae, M. xenopi, M mesophilicum & M.abscessus*
- Misdiagnosis and Pseudo-infection; must use bacteria-free water for bronchoscope) . *M.chelonae* are resistant to glutaraldehyde
- *P. aeruginosa*

Spach DH et al Ann Intern Med 1993: 118:117-128 and Weber DJ, Rutala WA Gastroint Dis 2002

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Nosocomial Outbreaks via GI Endoscopes

Infections Associated with Accessories

- Infections associated with biopsy forceps
  - Contaminated biopsy forceps
    Dwyer DM. Gastroint Endosc 1987;33:84
  - Contaminated biopsy forceps (no cleaning between cases)
    Graham DY. Am J Gastroenterol 1988;83:974
  - Biopsy forceps not adequately sterilized
    Bronowicki JP. NEJM 1997;334:237
- Reusable endoscopic accessories that *break the mucosal barrier* should be mechanically cleaned and sterilized between patients *or* single use

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Endoscope reprocessing Glutaraldehyde: Advantages

- > 40 years on the market
- Numerous studies published
- Excellent compatibility with materials
- Non-corrosive to metals and other materials
- Lasts up to 14 days
- Relatively inexpensive

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Endoscope reprocessing Glutaraldehyde: Disadvantages

- Relatively slow mycobactericidal activity
- Poor sporicidal activity
- Coagulates blood and fixes tissue to surfaces
- Supplied as acidic solution (stable but less microbicidal), requires activation with alkaline buffer (less stable but more microbicidal)
- Limited life once activated

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Endoscope reprocessing Glutaraldehyde: Disadvantages

- Eye and nasal irritant and may cause respiratory illnesses e.g. asthma and allergic dermatitis
- Must only be used in a **well-*ventilated area***
- Stored in containers with ***close-fitting lids***
- **Personal protective equipment**:
  - Eye shields
  - Plastic apron
  - *Gloves:* Latex gloves if the duration of contact is short (1-15 minutes); nitrile gloves for longer duration
- *Monitor Environment*: Occupational Exposure Standards (OES: 0.2 ppm/0.7 mgm^{-3}, 10 minutes only)
- If you can smell it, the vapour concentration is too high

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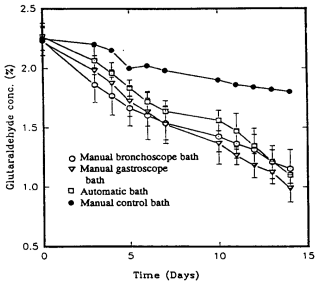
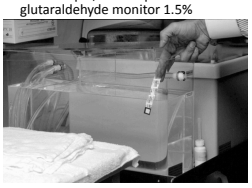
Endoscope reprocessing : Glutaraldehyde
Minimum Effective Concentration (MEC)



- Dilution of disinfectant occurs during use
- Test strips are available for monitoring Minimum Effective Concentration (MEC)
- For example, test strips for glutaraldehyde monitor 1.5%



Source: WA Rutala

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Endoscope reprocessing : Glutaraldehyde
Minimum Effective Concentration (MEC)

- Dilution of disinfectant occurs during use
- Test strips are available for monitoring Minimum Effective Concentration (MEC)
- For example, test strips for glutaraldehyde monitor 1.5%
- Test strip not used to extend the life beyond the expiration date (date test strips when opened)
- Testing frequency based on how frequently the solutions are used (test at least daily)
- Record results

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Endoscope reprocessing

Unacceptable Chemical Disinfectants

- Benzalkonium chloride
- Iodophor
- Hexachlorophene
- Alcohol
- Chlorhexidine gluconate
- Cetrimide
- Quaternary ammonium compounds
- Glutaraldehyde (0.13%) with phenol

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Endoscope reprocessing

Acceptable Chemical Disinfectants

- Glutaraldehyde
- Ortho-phthalaldehyde (OPA)
- Hydrogen Peroxide
- Peracetic acid
- Peracetic Acid/Hydrogen Peroxide
- Chlorine dioxide

Must follow manufacturer's instructions & get approval from endoscope manufacturer before use because of compatibility issues

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BOILER :THERMAL DISINFECTION

ADVANTAGES	DISADVANTAGES
• Effective • Inexpensive • No toxic residues	• Unsuitable for heat sensitive items • No process controls i.e. time/ temperature interlock • Scald risk • Items must be clean before immersion • Forceps required for instrument removal • May become contaminated when not in use

BOILER :THERMAL DISINFECTION

- Boiling Water: 100°C for 5-10 minutes
- Requirements:
  - Temperature Control (Thermometer)
  - Time (Timer)
  - Basket (avoid use of cheatle forceps to prevent contamination)
  - Cover with lockable lid to avoid more items being added before the timed period has elapsed
  - Total immersion of instrument

Benchtop sterilizers

- Should only be used as an alternative if the items cannot be decontaminated in the SSD
- They must be properly used, adequately maintained, and monitored according to the manufacturer's instructions
- All persons who use the machine should be *properly trained* and deemed *competent* to use it
- Periodic testing and routine monitoring must be carried out and records must be kept according to the guidance provided by the manufacturer

Benchtop sterilizers

Gravity displacement benchtop sterilizers

•These sterilizers displace air *passively* from the chamber and load by steam generated within the sterilizer chamber or in a separate chamber within the sterilizer's casing

•*Only unwrapped ins*truments without crevices or lumens may be processed in these machines

Benchtop sterilizers

Vacuum benchtop sterilizers

•These sterilizers have a pump or some other *active* method of removing air from the chamber and load

•'Porous loads', i.e. instruments which are hollow, tubular, have crevices or are wrapped, can only be processed in these machines

•More complicated machines therefore require greater care in their use and maintenance to ensure that they function effectively and require regular and rigorous testing

- UK Medical Devices Agency. ***Benchtop steam sterilisers*** – *Guidance on purchase, operation and maintenance*. 2002. Device Bulletin DB2002(06). London: Department of Health.

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Thank you