Processing Medical Devices in Settings With Limited Resources
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Processing 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

Processing medical devices in settings with limited resources

• 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 reprocessing 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, HCV

• 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

• 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

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| 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

Processing medical devices in settings with limited resources
- Proctoscopes reused without cleaning and disinfection
- Reuse of surgical gloves in Operating Theatre

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 sterilizer

BASIC CONCEPTS

How inadequately decontaminated devices spread infections

INFECTION = \( \text{No. of microbes} \times \text{Virulence characteristics} \times \text{Immune status of the patient} \)

Susceptible patients require a low dose of pathogenic microorganisms. Infection can be caused by microorganisms of low pathogenicity

THREE KEY STEPS
- Thorough cleaning before decontamination
- Proper decontamination using quality control indicators
- Storage of items after decontamination to maintain sterility

Processing medical devices in settings with limited resources

Reduce Bioburden (Thorough cleaning)

Kill microorganisms (Decontamination)

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

TYPE OF ITEMS/DEVICES
- Critical, Semi-critical or Non-critical

BIOBURDEN of MICROORGANISMS
- Presence of organic load, blood/body fluid/secretion

TYPE of MICROORGANISMS
- Bacteria, spores, viruses or prions

PATIENT SUSCEPTIBILITY

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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: IR, vegetative bacteria, fungi and lipid viruses
- Can be expected to be contaminated with some microorganisms
- Examples: O’Theatre trolley, EOS trolley, bedside tables, furniture, stools, boards 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 anesthesiology equipment, endoscopes, vaginal specula, reusable needles and syringes

**Critical**: Contact with sterile tissue, vascular system etc.
- Germicidal action: Kills all microorganisms, including bacterial spores
- Sterilization: Steam, Ethylene oxide, gas hydrogen peroxide alone
- Most are single-use devices
- Examples: Surgical instruments, arterial catheters, implants, needles & syringes

== Symbols 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

== 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

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**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


== 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)

- 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!**

**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 Disinfecter Temp.:
    - 71°C for 3 min
    - 60°C for 5 min
    - 50°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 71°C for 10 minutes.
  - Soiled, 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 the disinfectant is 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.

**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 log₁₀ 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.

**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.

**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.

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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 mucus 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 manufacturer’s guidance.

Decontamination of endoscopes

Endoscope reprocessing

Chemical disinfectants are used for fiberoptic 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 > 80°C
- Use chemical ‘sterilant’ disinfectant

**ACCESSORIES**

- Break mucosal barrier
- Snare for tissue removal

Reusable endoscopic accessories and brush the mucosal barrier should be mechanically cleaned and sterilized between patients or single use.

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. flexible endoscopes) that cannot withstand exposure to temperatures of at least 121°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.

**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.

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

Nosocomial Outbreaks via GI Endoscopes
Infections Associated with Accessories
- Infections associated with biopsy forceps
  - Contaminated biopsy forceps
    - Bronowicki JP. Gastroint Endosc. 1997;334:237
  - Contaminated biopsy forceps (no cleaning between cases)
    - Bronowicki JP. Gastroint Endosc. 1997;334:237
  - 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

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

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

Transmission of infection
Transmission of both Hepatitis B & C are documented in the literature
Gastrointestinal endoscopy
- >300 infections transmitted
  - 70% agents Salmonella sp. and P. aeruginosa
  - Enterobacter sp., Serratia marcescens, Salmonella sp., 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. abscessus
  - Misdiagnosis and Pseudo-infection; must use bacteria-free water for bronchoscope. M. chelonae are resistant to glutaraldehyde
  - P. aeruginosa

Sources:
From parents
Infecions traced to deficient practices
Exogenous Infections
Transmission of both Hepatitis B & C are documented in the literature
Gastrointestinal endoscopy
M. tuberculosis, atypical Mycobacteria e.g. M. chelonae, M. xenopi, M. abscessus
Misdiagnosis and Pseudo-infection; must use bacteria-free water for bronchoscope. M. chelonae are resistant to glutaraldehyde
P. aeruginosa

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 mgm3, 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%
- 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

Endoscope reprocessing

Unacceptable Chemical Disinfectants

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

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

BOILER: THERMAL DISINFECTION

Advantages
- Effective
- Inexpensive
- No toxic residues

Disadvantages
- 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

Boiling Water: 100°C for 5-10 minutes

Requirements:
- Temperature Control (Thermometer)
- Time (Timer)
- Basket (avoid use of cheater 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 instruments 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

KEY REFERENCES


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