Explain the nature of microorganisms and their relationship to sterilization and disinfection

Describe the different types of sterilization and high-level disinfection processes used in health care facilities for medical instrument reprocessing

Discuss the responsibilities of the medical device, sterilizer and disinfectant manufacturers for testing and documentation of their products

Discuss the role of monitoring in sterilization assurance and why biological indicators are considered the most effective type of sterilization monitoring

The Nature of Microorganisms

- Science of small living organisms
- Pathogen is any microorganism capable of causing disease
- Primary agents of infection:
  - Bacteria (vegetative & spore form)
  - Fungi (yeasts & molds)
  - Viruses
  - Prions
  - Single-celled parasites
Bacteria

- Most common microorganisms
- Small single-celled
- Spheres, rods and spirals
- Ubiquitous in virtually every habitat on earth
- Essential to life in recycling nutrients
- Can cause disease in humans
- Some produce highly resistant spores
- Gram stain used for identification & classification
  - Based on properties of cell wall
  - Purple/blue = Gram positive
  - Pink/red = Gram negative


Bacterial Growth

You CAN'T see one
You CAN see millions

Bacterial Growth

- Bacteria divide and multiply based on their environment:
  - Temperature
  - Nutrients
  - pH
  - O₂ level
  - Inhibitory substances
  - Process of growth may result in:
    - Tissue damage
    - Release of toxins

Time

Bacteria

- Gram positive cocci in clusters
- Found in the nose and on skin of about 20% of the population
- Causes skin infections, sepsis, toxic shock syndrome
- Methicillin-resistant Staphylococcus aureus (MRSA)


Escherichia coli

- Gram-negative rod
- Non pathogenic strains commonly found in lower intestinal tract (enteric)
- Pathogenic strains can cause severe diarrhea
- Indicator of fecal contamination

Escherichia coli courtesy of http://en.wikipedia.org/wiki/Escherichia_coli
**Bacteria**
- Gram positive spore forming rod
- Strict anaerobe
- Causes severe diarrhea and other intestinal disease when the normal bacteria in the gut have been destroyed by antibiotics

**Clostridium difficile**
- Causative agent of most cases of tuberculosis
- Waxy coating on the cell surface provides resistance to chemical agents
- Requires high levels of oxygen (strict aerobe)

**Mycobacterium tuberculosis**
- Yeast
- Commonly found in GI tract and mouth
- Forms biofilms on the surface of implantable medical devices
- Causal agent of opportunistic oral and genital infections

**Fungus**
- Molds – grow as multicellular filaments (hyphae); produce spores
- Yeasts – grow as single cell
- Different structure than bacteria

**Candida albicans**
- Common human diseases include:
  - Influenza
  - Common cold
  - Cold sores
  - Chickenpox
  - Polio
  - AIDS
  - Avian Flu (bird flu)
  - SARS
  - Swine Flu (H1N1)

**Viruses**
- Very small intracellular parasites
- Replicate only inside the living cells of host
- Cannot see directly with light microscope
- Common human diseases include:
  - Type 1 produces cold sores
  - Type 2 produces most genital herpes
  - Ubiquitous in nature
  - Contagious by contact with an infected person

**Hepatitis A**
- Can cause an acute infection of the liver (infectious hepatitis)
- Usually transmitted by ingestion of contaminated food or water or through direct contact with an infected person
Infection Prevention and Control

- Infection prevention and control is the discipline concerned with preventing health care-associated infection (HAI) caused by various microorganisms.
- The purpose of sterilization and disinfection is to inactivate microorganisms, an integral component of an Infection Prevention and Control Program.

Disease Transmission Cycle

- Infectious Agent
- Susceptible Host
- Reservoir
- Portal of Entry
- Portal of Exit
- Mode of Transmission

Sterilization

A process that eliminates all forms of microbial life (including bacterial endospores). Common forms are:

- Steam (moist heat)
- Ethylene oxide, H₂O₂ vapor gas plasma, H₂O₂ vapor, O₃
- Dry heat
- Radiation (industry only)
Steam Sterilization

Approximately 85% of medical item sterilization in healthcare facilities is achieved with saturated steam under pressure

- Fast
- Highly effective
- Reliable
- Relatively low cost
- Easy to use
- Readily available
- Technology well understood
- No toxicity or hazardous residues

Low Temperature Sterilization

- Steam should always be the first choice for sterilization, but...many instruments are heat and/or moisture sensitive
- As minimally invasive surgery procedures increase, the need for low temperature sterilization is also increasing
- Penetration of sterilant gas and compatibility with device and packaging are primary limitations

Low Temperature Sterilization

- Ethylene oxide
  - Oldest LTS technology
  - Highly penetrating
  - Highly compatible
  - H₂O₂ vapor and gas plasma
  - H₂O₂ vapor
  - Ozone
  - All are strong oxidizers
  - All have penetration and compatibility issues

Sterilization Assurance

- As sterilization involves microorganisms, how do you determine its effectiveness??
- You can’t see sterility
  - You can’t inspect for sterility
  - You can’t test for sterility in a practical manner
Sterilization Assurance

- Industry and some health care facilities in Europe validate the sterilization process and implement a Quality System for ongoing control
- Health care facilities in the U.S. assure sterility by a combination of:
  - Recommended practices for reprocessing
  - Following device manufacturers instructions for reprocessing
  - Overkill sterilization cycles
  - Routine monitoring

Manufacturers’ Responsibilities

Manufacturers’ Responsibility for Reprocessing of Reusable Medical Devices

- Devices
- Sterilizers
- Disinfectants

Device Manufacturer Requirements

- 21 CFR Part 801 requires reusable device labeling to include reprocessing instructions
  - Manufacturer responsible for developing AND VALIDATING cleaning, and disinfection or sterilization methods
  - Clear reprocessing instructions
- Draft Guidance for Industry and FDA Staff - Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - May 2, 2011
  - Will replace FDA 1996 document for labeling reusable medical devices
  - Applicable to reusable medical devices AND single-use devices that are non-sterile but must be sterilized prior to use

FDA requirements include:

- Instructions for assembly and reassembly
- Validation of Reprocessing per FDA Quality System Regulation
  - Cleaning process (use of artificial soils and development of test methods)
  - Sterilization or disinfection

AAMI TIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

- Device design considerations
  - Physical
  - Materials
  - Total system
  - Misuse-related
- Decontamination/cleaning
  - Pre-cleaning at point of use
  - Disassembly/reassembly
  - Cleaning agents
- Disinfection
  - Type of disinfectant
  - Compatibility
  - Basin and/or AER
- Sterilization
  - Lethality to SAL of $10^{-6}$
  - Compatibility
  - Process type & parameters

Sterilizer and Device Manufacturer Testing

Additional 6 log reduction (theoretical) and a $10^{-6}$ SAL

The Role of Sterilization Monitoring
Routine Monitoring of the Sterilization Process

• AAMI, AORN and CDC recommend routine monitoring of the sterilization cycle with:
  • Physical monitors
  • Chemical indicators
  • Biological indicators

• All of these monitoring methods have both advantages and limitations

Biological Indicators (BIs)

• BIs are recognized by most authorities as being closest to the ideal monitors of the sterilization process – CDC*
• BIs provide the only direct measure of lethality of a sterilization cycle – AAMI**
• BIs are affected by the same kinds of changes in cycle conditions that would affect the microorganisms commonly found on items being sterilized

* 2008 CDC Guideline for D&S, p. 76

Use of BIs

Bioburden population & resistance
Unknown (cannot see or quantify)

BI population & resistance
Known (can see & quantify)

Sterilant Exposure Time

Disinfection

A process that eliminates many or all pathogenic microorganisms (but not bacterial endospores)

• Glutaraldehyde
• OPA
• H₂O₂ liquid
• Peroxid acid
• H₂O₂/peracetic acid
• Chlorine compounds
• Phenolic compounds
• Quaternary ammonium cmpds.
• Iodine compounds
• Chlorine dioxide
• Alcohols
• Heat (Pasteurization)
• Other chemicals
• Because it is not necessary to sterilize all patient items, health care facility policies must identify whether disinfection or sterilization is indicated based on each item’s intended use.

• Dr. Earl Spaulding proposed a scheme for classification and treatment of medical items based on how they were used and the subsequent risk of infection to the patient.

Spaulding Classification of Medical Equipment and Surfaces

• Critical - objects which enter normally sterile tissue, the vascular system or blood flows should be sterile.

• Semicritical - objects that touch mucous membranes or skin that is not intact require a high-level disinfection.

• Noncritical - objects that touch only intact skin require intermediate or low-level disinfection.

Critical Items and Sterility


• “Only sterile items should come in contact with the sterile field.”

• “Using sterile items during invasive procedures minimizes the risk of infection and provides the highest level of assurance that procedural items are free of microorganisms.”
Resistance of Microorganisms to Disinfection and Sterilization

<table>
<thead>
<tr>
<th>Resistant</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prions (Creutzfeld-Jacob Disease)</td>
<td>Prion Reprocessing</td>
</tr>
<tr>
<td>Bacterial Spores (Bacillus atrophaeus)</td>
<td>Sterilization</td>
</tr>
<tr>
<td>Cocidio (Cryptosporidium)</td>
<td></td>
</tr>
<tr>
<td>Mycobacteria (M. tuberculosis, M. terrae)</td>
<td>High</td>
</tr>
<tr>
<td>Nonlipid or small viruses (polio, coxsackie)</td>
<td>Intermediate</td>
</tr>
<tr>
<td>Fungi (Aspergillus, Candida)</td>
<td></td>
</tr>
<tr>
<td>Vegetative bacteria (S. aureus, P. aeruginosa)</td>
<td>Low</td>
</tr>
<tr>
<td>Lipid or medium-sized viruses (HIV, herpes, hepatitis B)</td>
<td></td>
</tr>
</tbody>
</table>

Susceptible

Disinfectant Manufacturer Testing

- All disinfectants used in U.S. health care facilities are tested against various microorganisms (depending on claims) per FDA (high level) or the EPA (intermediate & low level) requirements
- The primary testing for documentation of disinfectants used in the hospital environment is the AOAC* Use Dilution Test
- This testing involves immersing inoculated carriers into specified dilutions of disinfectant at various exposure times

Microorganisms can cause disease and must be aggressively controlled in the health care facility environment
Sterilization and disinfection of patient items are a means to aid in preventing the transmission of potential pathogens
Manufacturers of reusable medical devices, sterilizers and disinfectants must document the efficacy of their products
BIs are the most sensitive method of sterilization monitoring and provide the most information regarding the efficacy of the sterilization process
Disinfection of a patient item may be an alternative to sterilization depending on the intended use of the item

Questions?
References

Microbiology
- http://en.wikipedia.org/wiki/Microbiology

Sterilizer testing

Disinfectant testing

Sterilization monitoring

Recommended practice

Device reprocessing

Thank you