How to Assess Risk of Disease Transmission When There is a Failure to Follow Recommended Disinfection & Sterilization Principles

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How To Assess Disease Transmission When There Is A Failure to Follow Recommended Disinfection and Sterilization Principles

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Failure to Follow Disinfection and Sterilization Principles

- Overview of disinfection and sterilization principles
- Failure Scenarios
- Recommended Protocol for Exposure Evaluation

Failure to Follow Disinfection and Sterilization Principles

- Overview
  - Achieving disinfection and sterilization through the use of disinfection and sterilization practices is essential for ensuring that medical and surgical instruments do not transmit pathogens to patients
  - Deficiencies leading to infection have occurred when there has been failure to follow disinfection and sterilization principles
  - These failures resulted from human error, equipment failures or system problems
  - Discuss a 14 step method for managing a failure incident

Disinfection and Sterilization Principles

Disinfection and Sterilization

EH Spaulding believed that how an object will be disinfected depended on the object's intended use.

CRITICAL - objects which enter normally sterile tissue or the vascular system or through which blood flows should be **sterile.**

SEMICRITICAL - objects that touch mucous membranes or skin that is not intact require a disinfection process (**high-level disinfection[HLD]**) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL -objects that touch only intact skin require **low-level disinfection**.

Efficacy of Disinfection/Sterilization Influencing Factors

Cleaning of the object

Organic and inorganic load present

Type and level of microbial contamination

Concentration of and exposure time to disinfectant/sterilant

Nature of the object

Temperature and relative humidity

Critical Patient Care Objects

Processing "Critical" Patient Care Objects

Classification:	Critical objects enter normally sterile tissue or vascular system, or through which blood flows.
Object:	Sterility.
Level germicidal action:	Kill all microorganisms, including bacterial spores.
Examples:	Surgical instruments and devices; cardiac catheters; implants; etc.
Method:	Steam, gas, hydrogen peroxide plasma or chemical sterilization.

Critical Objects

- Surgical instruments
- Cardiac catheters
- Implants

Recommendations
Methods of Sterilization

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Use immediately critical items that have been sterilized by peracetic acid immersion process (no long term storage)

Chemical Sterilization of "Critical Objects"

Glutaraldehyde (≥ 2.0%)
Hydrogen peroxide-HP (7.5%)
Peracetic acid-PA (0.2%)
HP (1.0%) and PA (0.08%)
HP (7.5%) and PA (0.23%)
Glut (1.12%) and Phenol/phenate (1.93%)

Exposure time per manufacturers' recommendations

Semicritical Patient Care Objects

Processing "Semicritical" Patient Care Objects

Classification:	Semicritical objects come in contact with mucous membranes or skin that is not intact.
Object:	Free of all microorganisms except high numbers of bacterial spores.
Level germicidal action:	Kills all microorganisms except high numbers of bacterial spores.
Examples:	Respiratory therapy and anesthesia equipment, GI endoscopes, thermometer, etc.
Method:	High-level disinfection

Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Diaphragm fitting rings

High Level Disinfection of "Semicritical Objects"

Exposure Time ≥ 12 m-30m, 20°C

Germicide	Concentration
Glutaraldehyde	≥ 2.0%
Ortho-phthalaldehyde (12 m)	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	7.5%/0.23%
Hypochlorite (free chlorine)*	650-675 ppm
Glut and phenol/phenate**	1.21%/1.93%

*May cause cosmetic and functional damage; **efficacy not verified

Noncritical Patient Care Objects

Processing "Noncritical" Patient Care Objects

Classification:	Noncritical objects will not come in contact with mucous membranes or skin that is not intact.
Object:	Can be expected to be contaminated with some microorganisms.
Level germicidal action:	Kill vegetative bacteria, fungi and lipid viruses.
Examples:	Bedpans; crutches; bed rails; EKG leads; bedside tables; walls, floors and furniture.
Method:	Low-level disinfection

Low-Level Disinfection for "Noncritical" Objects

Exposure time ≥ 1 min

Germicide	Use Concentration
Ethyl or isopropyl alcohol	70-90%
Chlorine	100ppm (1:500 dilution)
Phenolic	UD
Iodophor	UD
Quaternary ammonium	UD

UD=Manufacturer's recommended use dilution
- Point-of-use system, no long-term storage

- material used to wrap the item/tray. Once the expiration date is exceeded the pack should be reprocessed.

Disinfection and Sterilization of Emerging Pathogens

Disinfection and Sterilization of Emerging Pathogens

- Hepatitis C virus
- *Clostridium difficile*
- *Cryptosporidium*
- *Helicobacter pylori*
- *E.coli* 0157:H7
- Antibiotic-resistant microbes (MDR-TB, VRE, MRSA)
- SARS Coronavirus, avian influenza, norovirus
- Bioterrorism agents (anthrax, plague, smallpox)

Disinfection and Sterilization of Emerging Pathogens

Standard disinfection and sterilization procedures for patient care equipment are adequate to sterilize or disinfect instruments or devices contaminated with blood and other body fluids from persons infected with emerging pathogens

Creutzfeldt Jakob Disease (CJD): Disinfection and Sterilization

Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

Prions
Spores
Mycobacteria
Non-Enveloped Viruses
Fungi
Bacteria
Enveloped Viruses

Epidemiology of CJD in the US

- Degenerative neurologic disorder
- CJD (a prion) incidence
  - One death/million population
  - No seasonal distribution, no geographic aggregation
  - Both genders equally affected
  - Age range 50-80+ years, average 67
- Long incubation, rapid disease progression after onset
- Prions resistant to conventional disinfection/sterilization

CJD and Medical Devices

- Six cases of CJD associated with medical devices
  - 2 confirmed cases-depth electrodes; reprocessed by benzene, alcohol and formaldehyde vapor
  - 4 cases-CJD following brain surgery, index CJD identified-1, suspect neurosurgical instruments
- Cases occurred before 1980 in Europe
- No cases since 1980 and no known failure of steam sterilization

CJD: Disinfection and Sterilization
Conclusions

- Critical/SC-cleaning with special prion reprocessing
  - NaOH and steam sterilization (e.g., 1N NaOH 1h, 121°C 30 m)
  - 134°C for 18m (prevacuum)
  - 132°C for 60m (gravity)
- No low temperature sterilization technology effective*
- Noncritical-four disinfectants (e.g., chlorine, Environ LpH) effective (4 log decrease in LD_{50} within 1h)

*VHP reduced infectivity by 4.5 logs (Lancet 2004;364:521)

CJD: Disinfection and Sterilization

- Epidemiologic evidence suggest nosocomial CJD transmission via medical devices is very rare
- Guidelines based on epidemiologic evidence, tissue infectivity, risk of disease via medical devices, and inactivation data
- Risk assessment based on patient, tissue and device
- Only critical/semicritical devices contaminated with high-risk tissue (brain, eye, spinal cord) from high risk patients (suspected CJD) requires special treatment

Endoscopes/AERS

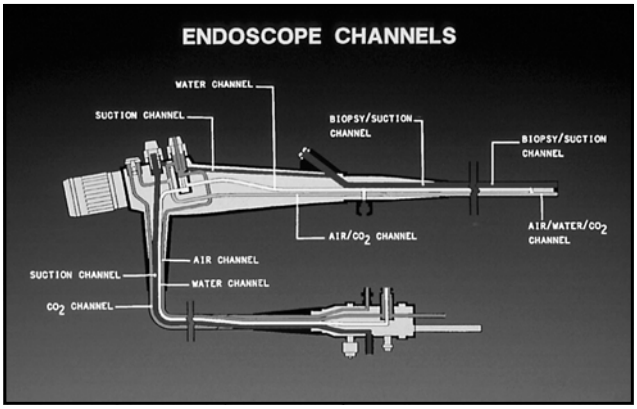
Murphy Was an ICP!

Murphy's Law

"Whatever can go wrong will go wrong"

Corollary

"…in the worst possible way at the worst possible time"



GI ENDOSCOPES AND BRONCHOSCOPES

- Widely used diagnostic and therapeutic procedure
- Endoscope contamination during use (GI 10^9 in/10^5 out)
- Semicritical items require high-level disinfection minimally
- Inappropriate cleaning and disinfection has lead to cross-transmission
- In the inanimate environment, although the incidence remains very low, endoscopes represent a risk of disease transmission

TRANSMISSION OF INFECTION

- Gastrointestinal endoscopy
  - >300 infections transmitted
  - 70% agents *Salmonella sp.* and *P. aeruginosa*
  - Clinical spectrum ranged from colonization to death (~4%)
- Bronchoscopy
  - 90 infections transmitted
  - *M. tuberculosis*, atypical *Mycobacteria*, *P. aeruginosa*

Spach DH et al Ann Intern Med 1993: 118:117-128 and Weber DJ, Rutala WA Gastroint Dis 2002;87

ENDOSCOPE INFECTIONS

- Infections traced to deficient practices
  - Inadequate cleaning (clean all channels)
  - Inappropriate/ineffective disinfection (time exposure, perfuse channels, test concentration)
  - Failure to follow recommended disinfection practices (tapwater rinse)
  - Flaws is design of endoscopes or AERs

ENDOSCOPE DISINFECTION

- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immerse scope and perfuse HLD/sterilant through all channels for at least 12 min
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water followed by alcohol
- DRY-use forced air to dry insertion tube and channels
- STORE-prevent recontamination

Disinfection and Sterilization
Conclusions

- When properly used, disinfection and sterilization can ensure the safe use of invasive and non-invasive medical devices.
- Method of disinfection and sterilization depends on the intended use of the medical device
- Cleaning should always precede high-level disinfection and sterilization
- Current disinfection and sterilization guidelines must be strictly followed.

Failure to Follow Disinfection and Sterilization Principles

Failure to Follow Disinfection and Sterilization Principles

- These events are relatively frequent; however, not commonly appreciated
- Human errors
  - Time setting of 132°C steam sterilizer at 0 min rather than 4 min
  - Failure to sterilize items after cleaning
  - Exposure time on AER set at 5 min rather than 20 min
- Equipment failures-biopsy port caps not secure
- System problems-unwrapped specula

Failure to Follow Disinfection and Sterilization Principles

- Method for assessing patient risk for adverse events
- Although exposure events are often unique, can approach the evaluation of potential failure using a standardized approach
- Propose a sequence of 14 steps that form a general approach to a possible failure of disinfection/sterilization (D/S)
- D/S failure could result in patient exposure to an infectious agent

Failure to Follow Disinfection and Sterilization Principles

Scenario:

Hospital A has been purchased an AER for GI endoscope reprocessing. The AER has been in use for 9 months. The hospital was using >2% glutaraldehyde with an intended exposure time of 20 minutes. It was discovered that the exposure time was incorrectly set at 10 minutes. Endoscopes for 9 months were processed at 10 minutes rather than the recommended 20 minutes.

What Do You Do?

Failure to Follow Disinfection and Sterilization Principles

Scenario:

Hospital B discovered that for the past 3 days all surgical instruments were exposed to steam sterilization at 132°C for 0 minutes rather than the intended 4 minutes. A central processing technician turned the timer to 0 minutes in error.

What Do You Do?

Failure to Follow Disinfection and Sterilization Principles

- Step 1-confirm failure
  - Confirm that the suspected failure did, in fact, occur.
  - ICP must review the circumstances of the reported failure including: the time and date of the possible failure; type of D/S method; and evidence of process parameters (printout) and results of physical, chemical and/or biological indicators

Failure to Follow Disinfection and Sterilization Principles

- Step 1-confirm failure
  - If the initial evaluation reveals that no medical items that were potentially inadequately processed were used in patient care, there is no patient safety issue involved
  - Then one can limit the evaluation to determining if the disinfection/sterilization process failed and correcting the processing error
  - All potentially inadequately processed items must, of course, be reprocessed
  - If a disinfection/sterilization failure is not confirmed, the investigation may be concluded

Failure to Follow Disinfection and Sterilization Principles

- Step 2-embargo improperly D/S items
  - If a D/S failure has occurred, one should immediately embargo any medical items that may not have been appropriately D/S
  - All items since the last successful processing (as demonstrated by process measures and/or physical, chemical, or biological indicators) should be embargoed.
  - Retrieving all items may require visiting all areas where the medical/surgical items may be stored or used including CP, ORs, community-based practices, storerooms, etc

Failure to Follow Disinfection and Sterilization Principles

- Step 3-do not use questionable D/S item
  - The incriminated D/S item should be immediately placed off line and not used for D/S of medical or surgical devices until its proper functioned can be assured
  - This may involve several runs with assessment of process parameters and physical, chemical and/or biological indicators
  - Medical engineering or the manufacturer's representative usually performs repairs and evaluation of the unit

Failure to Follow Disinfection and Sterilization Principles

- Step 4-inform key stakeholders
  - All key stakeholders should be informed of the problem
    - Risk management
    - Medical/nursing director of the involved units (e.g., OB, GI)
    - Personnel involved in disinfection/sterilization
  - If is often easier to arrange a face-to-face conference to assure complete transmission of the facts with feedback than to use email or telephone consultation

Failure to Follow Disinfection and Sterilization Principles

- Step 5-investigate the cause of the D/S problem
  - A complete and thorough evaluation of the possible D/S failure should be rapidly completed.
  - ICP should review the exact circumstances of the possible D/S failure including dates and results of all process measures (e.g., temperature, time, sterilant/HLD concentration) and physical, chemical and biological indicators obtained in the recent past going back far enough to assess the time/date of the first possible malfunction

Failure to Follow Disinfection and Sterilization Principles

- Step 6-line listing of exposed patients
  - Once a failure of D/S has been documented, it is important to initiate the evaluation of potential patient exposures
  - First step is to create a line listing of all possible patients who may have been exposed to possibly contaminated medical/surgical devices
    - Patient name, identification number, date(s) of exposure, contaminated device used, underlying risk factors for infection, development of HAIs (pathogen, body site), and other potentially adverse events

Failure to Follow Disinfection and Sterilization Principles

- Step 7-does D/S failure increase patient risk for infection
  - Once a failure of D/S process has been documented with possible exposure to a contaminated item, it is crucial to determine whether in fact the failure could result in an adverse patient event.
  - For example, 3 min for flash sterilization rather than 4 min. Would not consider 3 min flash sterilization cycle as representing a patient hazard.
  - Assessing risk should always include on a review of the scientific literature and national guidelines

Failure to Follow Disinfection and Sterilization Principles

- Step 8-inform expanded list of stakeholders
  - All stakeholders should be informed of the progress of the investigation, especially if an increased risk to patients is possible or documented
    - Risk management
    - Medical/nursing director of the involved units (e.g., OB, GI)
    - Personnel involved in disinfection/sterilization
    - Public relations, healthcare administration, and legal
  - A press release should be prepared in case of need and a spokesperson appointed

Failure to Follow Disinfection and Sterilization Principles

- Step 9-develop hypothesis for D/S failure and initiate corrective action
  - Corrective actions (e.g., reset timer, monitor concentration of HLD) should be initiated to correct the deficiencies in reprocessing
  - Reprocessing of any item that may not have been appropriately disinfected/sterilized must be done

Failure to Follow Disinfection and Sterilization Principles

- Step 10-assess adverse patient events
  - Initiate a more detailed study, if necessary, of possible adverse outcomes in patients
  - This may entail designing a prospective cohort study
  - This may require reviewing medical records and/or examining patients for infections, chemical reactions, or other adverse events
  - Specific laboratory tests may be necessary such as testing source patients and exposed persons for bloodborne pathogens such as HIV, HBV, and HCV

Failure to Follow Disinfection and Sterilization Principles

- Step 11
  - In conjunction with the legal department, notify state and federal authorities if required by regulation or law

Failure to Follow Disinfection and Sterilization Principles

- Step 12-consider patient notification
  - Consider whether patients should be notified of the disinfection/sterilization failure
  - If it is determined the failure could result in adverse patient events, then patients should be notified
  - Determine who will notify the patients
    - Patient's local medical provider, risk management, attending physician at the time of failure, ICP
  - One should develop a script to be used in notification to ensure all patients receive the same information

Failure to Follow Disinfection and Sterilization Principles

- Step 12 (continued)
  - Notification may be accomplished by a face-to-face meeting, phone or registered mail
  - More than one method may be used to ensure complete notification
  - Notification should include: an assessment of risk, possible adverse events that may occur, symptoms and signs of the adverse event, time period for the adverse event, risk to other contacts, possible prophylactic therapy (risks and benefits) and recommended medical follow-up

Failure to Follow Disinfection and Sterilization Principles

- Step 12 (continued)
  - The healthcare facility must decide who will provide these services and whether the facility will cover the cost of care.
  - In general, we believe that if the facility was responsible for the failure then it should provide these services at no patient charge
  - However, it the exposure resulted from failures outside the institution (receipt by the facility of inadequately sterilized devices), then the facility may want to offer the services but at patient expense or causative party's expense (e.g., manufacturer)

Failure to Follow Disinfection and Sterilization Principles

- How about if you were able to conduct a risk assessment and the risk for infection was 2 in 100 trillion
  - There is no fixed or accepted frequency that necessitates risk disclosure.
    - Hospital could conclude that the risk frequency of 2 in 100 trillion is so small that they are effectively, legally, of no weight or less than the risk of many other daily life exposures we all endure
    - Hospital could conclude that all exposures should be communicated to the patient regardless of the 2 in 100 trillion risk for an adverse event
  - Decision to inform patients is made by the hospital stakeholders

Failure to Follow Disinfection and Sterilization Principles

- Step 13-develop long term follow-up plan
  - Once the problem leading to the D/S failure has been identified and corrective action initiated, it is essential to assess whether these interventions have eliminated the problem over the long-term
  - This may require long-term surveillance, changes in current policies or procedures, development of new policies or procedures, evaluation of current equipment, etc

Failure to Follow Disinfection and Sterilization Principles

- Step 14-perform after-action report
  - A report of the event should be prepared for presentation to the appropriate healthcare system committees
  - Consideration should be given to publishing the evaluation it it provides a contribution to the scientific literature

Failure to Follow Disinfection and Sterilization Principles

Summary

- Follow the 14 steps-they provide a general outline, but each event is unique and you must be flexible and adaptable
- Steps are delineated in a linear fashion but the evaluation is often done simultaneously
- Communication among key stakeholders is very important
- Ethical to notify patients if there is a risk-should be upfront and factual
- Train staff and access processes/practices to minimize recurrence
- These are stressful events (patients and staff) but the goal is to assess failure and protect patients rather than assessing blame

Failure to Follow Disinfection and Sterilization Principles

- Overview of disinfection and sterilization principles
- Failure Scenarios
- Recommended Protocol for Exposure Evaluation

Thank you

References

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The Next Few Teleclasses

August 24 — ***How to Assess Risk of Disease Transmission When There is a Failure to Follow Recommended Disinfection and Sterilization Principles***
… with Dr. William Rutala, UNC
Teleclass sponsored by Virox Technologies Inc www.virox.com

September 14 — ***Disinfecting Soft Goods***
… with Dr. Curt White, Aegis

September 20 (South Pacific Teleclass) — ***The SARS Experience in Singapore – What Can We Learn***
… with Dr. Chris Wynne, CBHB, New Zealand
Teleclass sponsored by Deb Australia www.deb.co.au

September 21 — ***Preventing Central Line Associated Bacteraemia***
… with Robert Garcia, Brookdale University Medical Center

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