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
- Failure Scenarios
- Recommended Protocol for Exposure Evaluation

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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

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- 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

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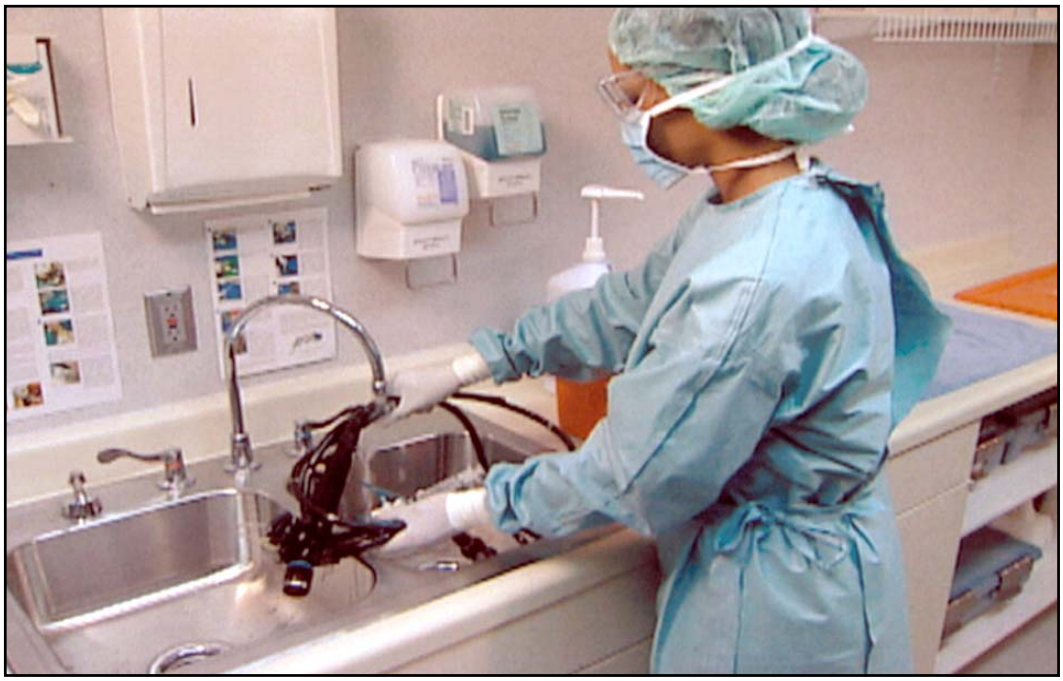
- Method for assessing patient risk for adverse events
- Although exposure events are often unique, can approach the evaluation of potential failure using a standardized approach
- Propose a sequence of 14 steps that form a general approach to a possible failure of disinfection/sterilization (D/S)
-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



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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?

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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?

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- 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

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- 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

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- 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

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- 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
  - Biomedical engineering or the manufacturer's representative usually performs repairs and evaluation of the unit

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- 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

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- 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

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- 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

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- 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 a review of the scientific literature and national guidelines

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- 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

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- 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

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- 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

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

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- 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

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- 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), how the problem will be corrected and recommended medical follow-up

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- 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's expense or causative party's expense (e.g., manufacturer)

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- 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

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- 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

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- 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 if it provides a contribution to the scientific literature

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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 prevent recurrence
- These are stressful events (patients and staff) but the goal is to assess failure and protect patients rather than assessing blame

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Thank you