Closing the Gap: Revising Sterility Testing Policies and Procedures Based on the United States Pharmacopeia (USP) 797 Guidelines and a Near Miss

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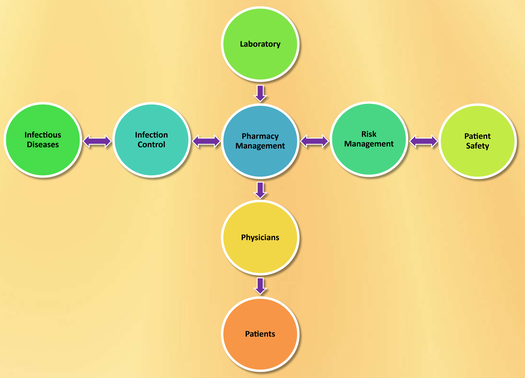
Purpose

- Due to a national shortage, a batch of sodium bicarbonate syringes was compounded from vials into unit-dosed syringes
  - Prepared in the pharmacy clean room
  - Given a 9 day beyond use date (BUD)
  - Sterility tested
  - Released to stock
  - Sterility tests came back positive within 24 hours
- Previous procedure for recalling products from positive sterility tests was not documented in policy and procedure manual

Methods

- Response following positive sterility test results
  - Notified providers
    - Disclosed event to patients (5)
    - Contacted Risk Management
  - Retrieved unused syringes
  - Sterility tested more syringes from batch
  - Screened patients (blood cultures negative)
  - Risk Management engaged:
    - Infection Control
    - Microbiology Lab
    - Pharmacy
    - Infectious Diseases

Notification



Results

- Identified gaps in the existing policies and procedures at initial meeting between departments
- Created Action Plan (Pharmacy portion listed below)
  - Reviewed USP 797 and USP 71 Guidelines with all stakeholders
  - Re-educated pharmacy staff with infection prevention strategies
    - Aseptic technique
    - Personal Protective Equipment
    - Traffic control
    - Hand hygiene
    - Excessive talking
  - Improved environmental air sampling procedure:
    - Monthly settling plate sampling → monthly volumetric sampling
  - Documented communication protocol for positive sterility tests in policies and procedures

Policy Amendments

- Products that get sterility tested, but do not surpass the USP 797 BUD recommendations for sterility testing
  - Released without quarantining
  - Notification to Pharmacy Management, Infection Control and Risk Management if any products that tested positive reached patients
  - Further dissemination of information to additional stakeholders
- Products that get sterility tested based on USP 797 guidelines
  - Quarantine period
  - Notification to Pharmacy Management and Infection Control, but not Risk Management if no products dispensed to patients
  - Pharmacy will then consult with Infection Control to investigate possible causes

Conclusions

- Hospital Pharmacy Departments should collaborate with their Infection Preventionist colleagues to identify activity that fall under the purview of USP 797.
- On site observations of personnel practices are imperative to insure proficiency and competency of the individuals responsible for sterile preparations.
- Definition of formal policies and procedures is needed to safely prepare and recall sterile products for patient use.
- Clear communication and swift response to positive sterility test results is critically important to mitigate patient harm.

Volumetric Air Sampler

Aseptic Technique and Proper Garb

Disclosures

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation.

- Cindy Mitman: Nothing to disclose
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Medication Safety Collaborative

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