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

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.

Disclosures
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