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Crash Course in United States Pharmacopeia Standard 797 (USP 797): Investigation of Positive Sterility Cultures from a Hospital Pharmacy Preparation

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Crash Course in United States Pharmacopeia Standard 797 (USP 797): Investigation of Positive Sterility Cultures from a Hospital Pharmacy Preparation Terry Burger, MBA, BSN, RN, NE-BC, CIC; Deborah Fry, MT(ASCP), MBA, CIC; Gary Tallarita, MT(ASCP), CIC; Cindy Mitman, Pharm D Lehigh Valley Health Network, Allentown, PA

Issue

Due to a national shortage, a batch of 30 – 10 ml syringes of sodium bicarbonate was prepared in the pharmacy clean room for use by the perfusion department. Sterility testing was performed on the batch although the USP 797 guideline does not recommend testing if the beyond use date (BUD) limits are not to be exceeded as was the case with this batch. The tests came back positive after the syringes were released. A look back of prior test results revealed additional positive sterility tests over the previous 5 months however no products had reached any patients.



Project

- - batch (5)
 - Retrieved unused syringes and returned to pharmacy
 - Notified physicians
 - Disclosed event to patients
 - Contacted Risk Management
 - Diseases
 - Screened patients
 - Blood cultures (all were negative)
- Created Action Plan
 - Reviewed USP 797 Testing Guidelines
 - Reviewed current pharmacy and laboratory testing practices
 - Investigated potential sources of contamination
 - Reviewed infection prevention practices
 - Aseptic technique
 - Protective attire
 - Traffic control
 - Hand hygiene
 - Excessive talking
 - Educated pharmacy staff and improved competencies
- Amplified environmental air & surface sampling
 - Volumetric air sampling
- Enhanced environmental sanitation
- Verified communication protocol for positive sterility tests

Response following identification of positive sterility test results – Identified patients that received sodium bicarbonate syringes from affected

– Risk Management engaged Infection Control, Lab, Pharmacy and Infectious

Results

- patients

Lessons Learned



Sterile Room with Staff in PPE



Volumetric Air Sampler

Increased compliance with Standard Operating Procedures for compounded sterile preparations

 Created written notification standard for compounding staff to report positive sterility tests when product has been released to

Infection Preventionists must understand requirements of USP 797 if pharmacy makes compounded sterile preparations.

 Communication of positive results in a timely and effective manner is a critical component of patient safety.

 Routine monitoring of infection prevention practices and environmental parameters are key to safe preparation of compounded sterile products.











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