Management Case Study: Rapid Response- How a Large, Nonprofit Teaching Hospital Managed the Compounding Crisis

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Learning Objectives

1. Describe the impact of the compounding crisis on a large academic medical center.
2. Recognize the importance of a multidisciplinary approach in managing a large scale crisis.
3. List several challenges faced during the crisis.

Self Assessment Questions

1. In a large academic medical center confronted with the compounding crisis, what strategic methodologies were considered to sustain sufficient quantities of safe compounded sterile preparations (CSPs) to meet the patient needs?
2. What functional requirements and system enhancements were employed to maintain self-sufficient compounding operations?
3. What are the major components of USP <797> compliance?

Massachusetts General Hospital (MGH): Multi-center Academic Medical Center

- 950+ bed Acute Care Services
  - Admits 47,000 patients/yearly
- Emergency Department
  - Records 88,000 emergency room visits
- Operating Room Services
  - Performs 38,000 operations
- 120 + Ambulatory Care Practices
  - Handles nearly 1.4 million outpatient visits
- Seven Satellite Health Centers

Department of Pharmacy

MASSACHUSETTS GENERAL HOSPITAL 1811 - 2011

Overview

- FDA announces closure of New England Compounding Center (NECC) for contaminated sterile products (Oct 2012)
- 64 Deaths and over 750 reported cases in 20 states
- Subsequent closure of Ameridose (voluntary closure of affiliate)
- At that time, MGH procured 68,000 doses/month from Ameridose

Compounding Crisis Impact

- MGH Tiger Team Response:

• Anesthesia	15,500
• Commercial preparations	12,000
• Nursing	11,000
• Pharmacy	27,000
• Practice Change	2,500
Total:	68,000

- FY 2012 Inpatient Drug Budget:
  - Total budget 42 million
  - 3.35 million with Ameridose (8% of total budget)

Case-based Scenario

- With widespread skepticism of the reliability–e.g. sterility and potency–of outsourced compounds leading to the elimination of outsourcing…
  - Hospital was forced to become self-sufficient
  - Standard parenteral product line of medications compatible with four SMART infusion pump drug libraries was needed

Goal: To ensure that the Pharmacies' (CSPs) final products were safe and effective for patient administration in accordance with USP <797>, Department of Public Health, MA BOP requirements

Sequential Steps & Key Decisions

- Tiger Team
- Risk assessment to identify areas of vulnerability
- Strategies to mitigate impact on patient care
- Communication Methods
- Batch production
  - Streamlined product line
  - Restricted Use guidelines
  - Self-Reliance: 3rd Party laboratory sterility and stability data
- Ready to use preparations
  - Commercially available products
  - Reconstitution devices

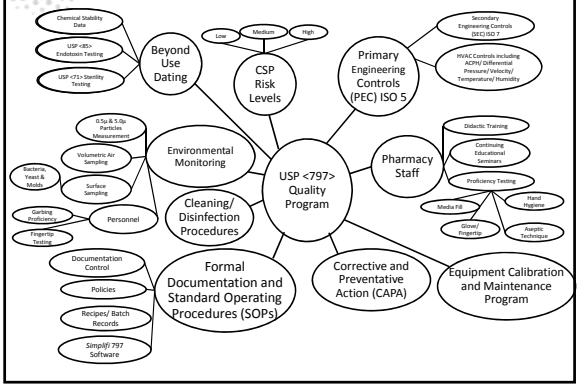
Challenges

- Supply and Demand
  - Ongoing assessment of utilization data
  - Large quantity of products needed
- Employee health and well-being
- Staffing
  - Internal issues with availability (absence of staff)
  - External temporary employees
  - Competency and Proficiency
- Quality Unit oversight

Challenges (continued)

- Space limitations
  - Equipment (Limited number of hoods to prepare compounded sterile preparation (CSPs)
  - Supplies (cassettes, IV bags, solutions, etc.)
  - Finished preparations
- Outside vendor assessment
  - Liability and formal assessment

USP <797> OVERVIEW



USP <797>

- Compliance assessment included:
  - Gap Analysis performed
  - Facility design and engineering controls review
  - Documentation (Simplifi 797, policy and recipe review)
  - Focus discussions with Pharmacy Leadership and area managers
  - Quality control review, inspection testing and environmental monitoring data
  - Employee training and competency file inspection
  - Cleaning/disinfection verification

Requirements for Improvement

- Space
- Facility Changes
- Resources
  - Staff (minimize overtime)
  - Systems (new hoods/robotics)
  - Ongoing funding (FTEs and Environmental, Personnel & Product Testing)

Overall Recommendations for Improvement

- Establish independent pharmacy quality assurance review
- Tighten document controls for recipes and documents
- Formalize **B**eyond-**U**se **D**ating (BUD) for all products
- Establish "secondary engineering controls" for production areas
- Perform cleaning verification study to demonstrate efficacy of procedures
- Update sterility testing to meet USP <71> requirements
- Invest in robotics and sterilization equipment

Options explored but not implemented…

- Creation of a Partners Compounding Pharmacy
  - Separate facility with appropriate primary and secondary engineering controls for high, medium and low risk CSP's
  - Multiple robotic automation for sterile IV's and hazardous CSP's
  - Independent quality control (QC) and quality assurance functions
  - Ensures dedicated supply and quality
- HazMeds Preparation and Storage requirements (Challenge: negative pressure environment)

Results

There's a better way to do it – find it." –Thomas Edison

Coming soon…

▪March 2014: State of the art in-house MGH Pharmacy Compounding Center with robotic automation for batch compounding of sterile preparations to ensure:

- Capacity, larger batch sizes, cost efficiency and possible BUD stability extension

In a large academic medical center confronted with the compounding crisis, what strategic methodologies were considered to sustain sufficient quantities of safe compounded sterile preparations (CSPs) to meet the patient needs?

A Keeping employees healthy

B Purchase commercial products when available

C Limit concentrations of PCA and Epidural Medications

D All of the above

What functional requirements and system enhancements were employed to maintain self-sufficient compounding operations?

A Facility redesign considerations

B Introduction to Automation (Robotics)

C Staffing pattern adjustments

D All of the above

What are the major components of USP <797> compliance?

A Personnel competency and assessment

B Environmental sampling and testing

C End product testing for sterility and potency testing with strict conformance to the beyond use dating

D All of the above