One Hospital Pharmacy’s Response to the National Compounding Tragedy of 2012

In response to the tragedy resulting from unsafe compounding practices at New England Compounding Center and other compounding pharmacies, the pharmacy staff at CMH has highlighted the significance of having a process in place that will ensure that our patients receive safe compounded products. As of today, 17,676 doses prepared by NECC in the contaminated lots of compounded medication, and over 14,000 have received injections from these batches. Sixty-four people have died and over 750 people have gotten sick. Recalls have occurred from compounding pharmacies nationwide and patients are scared. We at CMH are committed to improving our processes and ensuring safe medication use and patient safety.

- Description and goals of program or project
  - To ensure that all sterile products provided to the patient’s at CMH are safe and free of contamination
  - To refine and improve our process for preparation and storage of compounded sterile products (CSPs) that follows the guidelines from U.S. Pharmacopeia (USP) 797 (Pharmaceutical Compounding: Sterile Preparations), as well as to ensure proper training and QA of the staff that will be responsible for this process
  - Minimize risk by continually identifying areas of concern in our institution and making changes that will lower these risks
  - Make any necessary environmental changes to meet all standards

- Process(es) implemented
  - Discontinuation of purchasing and receiving of all CSPs that were prepared by a third party immediately after the news of the New England Compounding contamination was released.
  - We had to identify how to internalize the preparation and storage of these medications within our current workflow.
  - We ensure that engineering controls are in place so that our compounding areas meet the strict USP 797 standards
  - Ensure that chemotherapy is prepared in the appropriate environment and that other products are prepared separately to remove the potential for contamination
  - Engage in continuing education on safe compounding practices to all staff
  - Shorten Beyond-Use dates (BUD) for CSPs to meet USP 797 standards
  - Evaluate preparation of sterile products in other areas of the hospital and determine if these processes can be moved to the pharmacy where engineering controls are in place and staff is trained and QA for proper technique.

- Solution identified
  - Transition compounding of the following medications to our pharmacy
    - Morphine, hydromorphone, and fentanyl PCAs
    - Oxytocin (Pitocin) Infusions
    - Bacitracin syringes for the OR
    - Irrigations for the OR
    - Antibiotics that are not available as ready to hang infusions (ancf 2 grams, vancomycin 1.5grams, etc.)
  - Have compounding area certified by approved vendor on a bi-annual basis
  - Re-creation of BUD guide for pharmacist/technicians
  - Multiple irrigation solutions were identified as being prepared and administered in the OR. These have been added to a pre-op order set and surgeons are now requested to
order the medications 48 hours prior to planned procedures so that they can be
prepared in pharmacy
  o Move separate IV hood to Chemotherapy/infusion pharmacy for preparation of non-
  chemotherapy products

- Measurable outcomes
  o Yearly competency for compounding staff (all pharmacists and technicians)
  o Implementation of yearly aseptic technique evaluation by media fill test
  o Monitoring for hospital acquired infections

- Sustainability
  o These processes will continue with a plan to add additional services as compounding can
    be centralized to the pharmacy
  o The visibility of the NECC tragedy has opened the eyes of the legislators and other
    politicians who are making better regulations a priority. We will continue to work with
    our associations and legislators to develop helpful regulations

- Role of collaboration and leadership
  o The hospital staff including our surgeons and nursing staff having been willing to work
    with us in each process change
    ▪ For physicians in the OR, this means ordering these products ahead of time and
      developing standard compounds
    ▪ Nursing staff is being asked to learn about storage of CSPs which may include
      additional medications being stored under refrigeration

- Innovative attributes
  o USP 797 has been around since 2004, unfortunately many pharmacists struggled with
    interpretation and implementation of these standards. In January of 2008, revisions
    were made to assist with implementation, yet many organizations have made little
    progress. CMH has embraced the implementation of these regulations and standards to
    improve the safety of our patients.

- Related tools and resources
  o USP <795>
  o USP <797>
  o NIOSH & OSHA regulation
  o USP <71>
  o General Chapter USP <797> - [www.usp.org](http://www.usp.org)
  o Controlled Environmental Testing Association (CETA) – [www.CETainternational.org](http://www.CETainternational.org)
  o Centers for Disease Control & Prevention [www.cdc.gov](http://www.cdc.gov)
  o Pharmacy Purchasing and Products Magazine- [www.pppmag.org](http://www.pppmag.org)
  o Blueprint for implementing USP <797> for compounding sterile preparations Am J of
    Health Syst Pharm 2005;61(18):1928-1938 (E. Kastango)
  o Pharmacy Practice News-Special Report (Oct 2008) Outsourcing Compounding Services
    to meet USP <797> Requirements: An Overview (M. Sanborn)
  o A Review of FDA’s Approach to Medical Product Shortages (10.31.11) -
  o Premix vs. Custom TPN- A history of nutritional best practices and an examination of the
    use of premixed solutions for parenteral nutrition – © 2007 the Baxa Corporation – L.
    Diorio, D. Thomas
  o ASHP / Baxter discussion guide on USP Chapter <797> for Compounding Sterile
    Preparations- (Buchanan et.al.)
  o FDA Website – [www.FDA.gov](http://www.FDA.gov)
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NECC FDA form 483 -