Compounding Conundrums

Outsourcing, Shortages, Clean Room Design, and Hazardous Drugs

Disclosures

Patricia Kienle reports the following relevant financial relationships
Employee of Cardinal Health

Luci Power reports the following relevant financial relationships
Consultant: Intelligent Hospital Systems, S.E.A. Medical
Stockholder: S.E.A. Medical, Speakers Bureau: ProCE, Inc.
Scientific Advisory Board member: Intelligent Hospital Systems

Eric Kastango reports the following relevant financial relationships
Principal and co-sponsor/co-author: 2011 & 2012 USP 797 Compliance Survey, CriticalPoint, LLC
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Objectives

- State the process to assess the appropriate use of an outsourced sterile compounding pharmacy
- List components of a process to assess appropriateness of a vendor new to the organization
- List common issues that cause a cleanroom to fail a certification test
- List the concerns of occupational exposure of healthcare workers to hazardous drugs
- Identify NIOSH, OSHA, and accreditation organization activities in reducing hazardous drug exposure in healthcare workers

Speakers

- Eric S. Kastango, MBA, RPh, FASHP
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- Luci Power, MS, RPh
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Noun: co·nun·drum

1. A confusing and difficult problem or question
2. A question asked for amusement, typically one with a pun in its answer; a riddle

- Synonyms: riddle, puzzle, enigma, mystery

Compounding Conundrums:
Outsourcing, Shortages, and Issues with Cleanroom Design

Eric Kastango, MBA, FASHP

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Disclaimer

*Although I am a member of the USP Compounding Expert Committee, I am speaking today in my individual capacity and not as a member of the Committee or as a USP representative.

The views and opinions presented are entirely my own. They do not necessarily reflect the views of USP, nor should they be construed as an official explanation or interpretation of <797>.*

Good Quality can Cost Less

- The focus must be on reducing waste, improving quality and not on cost-cutting initiatives.
- The focus must be on the patient quality and safety.
- If you focus on quality, the costs will take care of themselves.
- Improve the system, rather than working harder.
- In order to make major changes, you need to start by making small improvements.
- Requires leadership and persistence.

Current push to reduce costs... but not ANY costs conundrum

- Select low hanging fruit first but be careful of rotten fruit
- Are any cost reductions, valuable cost reductions?
- Example: Using nonsterile gloves in compounding to save ≈ 10K per year...that cost reduction does NOT improve quality and potentially increases risk of contamination?

Conundrums

- Identify organizational activities in reducing hazardous drug exposure in healthcare workers
  - Acknowledgement Form and findings for the CriticalPoint 2011 and 2012 study data
- List components of a process to assess appropriateness of a vendor new to the organization
  - Vendor qualification form and TJC Eps
- List common issues that cause a cleanroom to fail a certification test
  - Using the CETA Guidelines to verify work of contractor
- State the process to assess the appropriate use of an outsourced sterile compounding pharmacy
  - What to keep and what to outsource

Right To Know Conundrum

- USP Chapter <797> says: Compounding personnel of reproductive capability (male and female) shall confirm in writing that they understand the risks of handling hazardous drugs
- Results of CriticalPoint 2011 and 2012 Compliance Survey
  - 2011-23.9% of 801 locations* met this requirement
  - 2012- 31.2% of 250 locations* met this requirement

*Indicated that they handled hazardous drugs.
Right To Know Conundrum

- Pharmacy, Purchasing and Products Magazine published the 2011 survey article and offered the HD Risk Form for free!
  - 6,123 people read the article
  - Only 40 accessed the HD Risk Form
- This year NIOSH published a new hazardous drug list
  - [http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf](http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf)
- PEARL-Both are free downloads!

Conundrum: What Do You Know About Them?

- List components of a process to assess appropriateness of a vendor new to the organization
  - Vendor qualification form
- Who are you buying your non-sterile bulk APIs from?
  - Registered with the FDA
  - Provides of Certificate of Analysis that is specific to the lot # of drug received
- Are you buying drugs from the grey market/parallel market?
  - How do ensure that the drugs have their maintained their pedigree?
  - Is the drug a counterfeit/adulterated/misbranded item?
  - How do you know that they [drugs] were stored properly?

Conundrum: What Do You Know About Them?

- LD.03.03.09: Care, treatment, and services provided through contractual agreement are provided safety and effectively
  - Element of Performance 1- Clinical leaders and medical staff have an opportunity to provide advice about the sources of clinical services to be provided through contractual agreement.
  - EP 2 – The hospital describes, in writing, the nature and scope of services provided through contractual agreements.
  - EP 4 – Leaders monitor contracted services by establishing expectations for the performance of contracted services.
  - EP 5 – Leaders monitor contracted services by communicating the expectations in writing to the provider of the contracted services.
  - EP 6 – Leaders monitor contracted services by evaluating these services in relation to the hospital’s expectations.
  - EP 7 – Leaders take steps to improve contracted services that do not meet expectations.
  - EP 8 – When contractual agreements are negotiated or terminated, the hospital maintains the continuity of patient care.

Outsourcing Conundrum

- Know what you are paying for by conducting a purchase cost analysis
- Identify top 10 drugs in volume and in dollar
- Decide what you what to keep and what you want to outsource
- Review Vendor Qualification elements with company

Outsourcing Conundrum

- What are your and your hospital’s responsibilities?
  - Do know what is in your contract?
  - One contract detailed the following requirements:
    - Customer shall be responsible for determining whether any compounded solution provided under this Vendor Agreement is clinically correct, appropriate or accurate for prescribing to any particular patient and for any particular disease or condition, and for determining and recording the individual patients that receive the medications.
    - Are outsourced drugs inspected upon delivery for correctness against the original order and documented?

Vendor Qualification

- Conduct an onsite visit of operation at least annually
- Review the following information during audit:
  - Have they done a gap analysis of their operation against USP 797? Results?
  - Summary of any regulatory inspection reports from SBOP or FDA
  - CAPA (corrective and preventive action) program, employee training records, sterility and stability data
  - How does management ensure operational control and fitness?
  - Observe personnel work practices and compare against vendor policy and procedure
Resources

- The American Society of Health-System Pharmacists (ASHP) published an updated guidance document on outsourced compounding services in 2010.
- ASHP Foundation, with sponsorship from PharMEDium Services, LLC, published an electronic tool titled, Outsourcing Sterile Products Preparation: Contractor Assessment Tool
- CriticalPoint, LLC USP 797 Gap Analysis Tool
- LDT Health Solutions Automated USP <797> GAP Tool

Reflection Point

“Doveryai, no proveryai”
“Trust but verify”
Former President Ronald Reagan

Certifier Conundrum

Facility Requirements
- ISO Class 5 devices
  - Require every 6 month certification
  - BSC/CACI required for hazardous drug preparation
- ISO Class 7 & 8 environments (buffer and ante area)
  - Required every 6 months certification
  - Negative-pressure required for hazardous drugs
- Controlled Environment Testing Association (CETA) is an organization providing guidance for certifiers

Certifier Conundrum

certify (sûrt-f)v. certified, certifying, certifies
1. a. To confirm formally as true, accurate, or genuine
   b. To guarantee as meeting a standard: butter that was certified Grade A. See Synonyms at approve
2. To acknowledge in writing on the face of (a check) that the signature of the maker is genuine and that there are sufficient funds on deposit for its payment
3. To issue a license or certificate to
4. To declare to be in need of psychiatric treatment or confinement
5. Archaic To inform positively; assure
http://www.thefreedictionary.com/certify

Properly Tested and Certified Facility

Images courtesy ClinicalIQ™, LLC
Conundrum: What Does the Report Say?

- Do you know how to read your certification report? SO: Who read their last report?
- Common failure issues:
  - The pressure differentials are too high, low or are in the wrong direction!
  - The tests are done “at-rest” and not dynamic per the chapter.
- Ultimate responsibility for assuring engineering controls lies with institution:
  - More than just a sticker
  - Interaction with certifier, dynamic testing

Properly Tested and Certified Facility

- Certification reference material
- Controlled Environment Testing Association (CETA)
  - CETA has established an application guide (CAG-003-2006) detailing procedures for certification of sterile compounding facilities
- Ask for a Registered Cleanroom Certification Professional for Sterile Compounding Facilities
- Choosing a Certification Professional to Evaluate Your Cleanroom and Engineering Control, James T. Wagner. Published in Pharmacy, Purchasing and Products Magazine (www.pppmag.com)

"Each problem that I solved became a rule which served afterwards to solve other problems."

- Rene Descartes (1596-1650), "Discours de la Methode"

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Compounding Conundrums: Hazardous Drugs

Luci A Power, BS, MS

Handling Hazardous Drugs: What are We Worried About?

- Acute exposure
- Hazardous Drug (HD) uptake
- Reproductive risks
- Long term exposure: cancer?
Acute Exposure

- Anecdotal reports of drug contact with exposed skin, eyes, etc. due to spills or mishaps
- Exposure due to cuts or needle sticks

HD Uptake

- HD uptake into workers has been shown to occur when work areas have surface contamination with HD residue

HD Residue

- 1999 study
  - 3 drugs measured in 6 hospitals: 75% of the pharmacy wipes & 65% of the nursing wipes were contaminated
- 2010 study
  - 5 drugs measured in 3 hospitals: 75% of the pharmacy wipes & 43% of the nursing wipes were contaminated

Connor TH. AJHP 7/1999; Connor TH. JOEM 10/2010

HD Compounding: Surface Contamination

- Work area of BSC
- IV bags
- Counter tops
- Storage bins
- Waste containers

Photo courtesy of TH Connor

co·nun·drum

Despite promotion of awareness of HD exposure; new guidelines from 2004-2008; and extensive marketing of new devices for improved safety…

NO MEASURABLE IMPROVEMENT

HD Uptake

- 1996
  - 53 biomarker studies and 12 drug in urine studies since 1979 were reviewed
  - 45% of biomarkers were positive
  - 83% of urine samples were positive

Baker ES, Connor TH. AJHP 11/1996
Reproductive Risks of Working with HD

- 2005 meta-analysis of 1983-2004 studies found increased risk of spontaneous abortion
- 2012 study of nurses exposed from 1989 found 2-fold increased risk of spontaneous abortion

Dranitsaris G. J OPP 2005
Lawson CC. Am J ObGyn 4/2012

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Although HDs are known reproductive hazards, US nurses are still reporting exposures to these during pregnancy

Long Term Risks

2010

- Study describes evidence of drug uptake and chromosomal changes in oncology workers
- Chromosomes 5 and 7 were affected as in t-AML after alkylating agent treatment

McDiarmid MA. JOEM 10/2010

co·nun·drum
Why isn’t somebody doing something?

NIOSH Activities

- 2004 Alert on Preventing HD Occupational Exposures
- Research activity including 2010 studies of worker contamination; chromosomal abnormalities; and occupational exposures among nurses

In 2011, senior officials of NIOSH, OSHA, and TJC collaborated on a letter that was sent to all hospital employers in the United States stating that hazardous drugs can pose serious job-related health risks to workers if proper precautions are not used in handling the drugs
NIOSH Topics Pages

- Occupational Exposure To Antineoplastic Agents
  www.cdc.gov/niosh/topics/antineoplastic/
- Hazardous Drug Exposures In Health Care
  www.cdc.gov/niosh/topics/hazdrug/

NIOSH HD List

- Update of HD list based on new drug approvals by the FDA and new warnings on existing drugs posted by the FDA
- Initial review by internal committee and review by peer reviewers and stakeholders
- List submitted for public comment

OSHA

- OSHA has no standard for exposure to HD but has generated 3 guidelines 1986, 1995, 1999
- Controlling occupational exposure to hazardous drugs. In: OSHA Technical Manual, TED 1–0.15A, Sec VI, Chap II: 1999
  - www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html

OSHA

- The Occupational Safety and Health Act is administered by OSHA
- Employers subject to the OSH Act have a general duty to provide work and a workplace free from recognized, serious hazards

OSHA - HazCom

- Hazard Communication Standard
  29 C.F.R. part 1910-2000
- Revised 2012
- Safety Data Sheet (SDS)
- Requires training programs and worker protection
- Defines hazardous chemicals and health hazards

The Joint Commission

Standard EC.3.10

- The organization manages its hazardous materials and waste risks.

Rationale for EC.3.10

- Organizations must identify materials they use that need special handling and implement processes to minimize the risks of their unsafe use and improper disposal
**co-nun-drum**
Whose job is it to promote safety?

**co-nun-drum ?**

**PEARLS !!!**

**HD Pearls**
Start work practices with RECEIVING
- Cartons may arrive broken
- There is drug residue on outside of vials and on packaging

**Totes Should be Labeled + Vials Wrapped**

**HD Pearls**
- Receiving staff must be trained to handle broken packages and have access to spill kits
Good Work Practices
Use gloves and bags!
Place disposable liner on surfaces

Bag Vials for Transport

Wipe Down HD Vials
- Spray the wiper, not the vial
- Spraying the vial may move HD residue to other items or areas
- Use wet wipes

Poor HD Technique

HD Residue?
- Generated with compounding in BSC or CACI
- Need better work practices

Magic Boxes?
Neither BSC nor CACI provide complete containment of HD residue!

Photos courtesy of TH Connor
Photos courtesy of NuAire, Inc.
HD Residue?
- Reaching out of BSC drops drug residue
- Residue may come from isolator pass throughs

Transfer of HD Residue
- Gloves get contaminated
- Don and remove gloves carefully
- Don't touch anything!
- Sanitize HD gloves with wipes not spray

Transfer of HD Residue
- Gowns have been shown to be contaminated
- Saving and reusing gowns may result in drug transfer

Conclusion
“Change requires a focus on safety, not occupational safety or patient safety, but just safety.”

Gerald Goodman, Dr.P.H.
Texas Woman’s University

co·nun·drum
Patient safety or MY safety?

Questions?