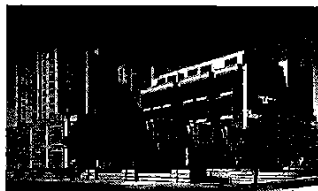


Use of IV Robotic Technology and Workflow Software for the Sterile Products Service



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Disclosure

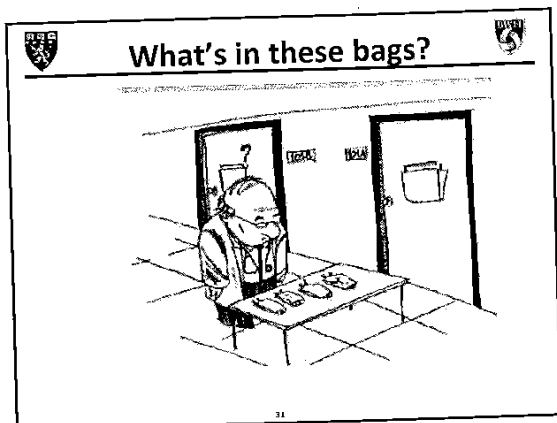
Caryn Belisle declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings and honoraria.

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IMAGINE.....



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Evidence Demonstrating Concerns about Compounded Sterile Products Prepared by Healthcare Workers

Occurrence and Impact of Unanticipated Variation in Intravenous Methotrexate Dosing

Medication Errors Detected in Infusions

Discrepancies between ordered and delivered concentrations of opiate infusions in critical care

Frequency of Medication Errors with Intravenous Acetylcysteine for Acetaminophen Overdose

Parshuram CS, et al. Occurrence and impact of unanticipated variation in intravenous methotrexate dosing. *The Annals of Pharmacotherapy*. 2006;40(5):305.

Anken C, et al. Medication errors detected in infusions. *Arch Intern Med*. 2003;163(10):992.

Parshuram CS, et al. Discrepancies between ordered and delivered concentrations of opiate infusions in critical care. *Critical care medicine*. 2003;31(10):2488.

Hayes RD, et al. Frequency of medication errors with intravenous acetylcysteine for acetaminophen overdose. *The Annals of Pharmacotherapy*. 2006;40(6):766.

Why do We Need to Know What's in Our Compounded Sterile Products?

Homepage > Local News > Latest Local News >

Ex-Cleveland pharmacist gets 6 mos. in fatal chemo dose

By Associated Press

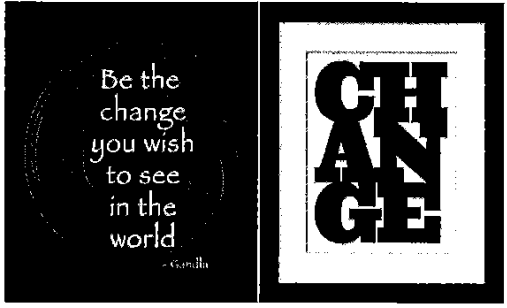
POSTED: 12:11 p.m. EDT, Aug 14, 2009

CLEVELAND: A former Ohio pharmacist has been sentenced to six months in jail and six months of house arrest in the death of a toddler given an incorrect tumor treatment.

At Friday's sentencing in Cleveland, 41-year-old Eric Cropp also was ordered to tell professional groups about his case as part of 400 hours of community service when he leaves jail.

Cropp pleaded no contest in May to involuntary manslaughter in the 2006 death of 2-year-old Emily Jany. Prosecutors said Cropp was responsible because he oversaw the mixing of the girl's chemotherapy at Rainbow Babies and

WE HAVE TO CHANGE!



Be the change you wish to see in the world
-Gandhi

CHANGE

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Gravimetrics vs. Volumetrics

Definitions

- **Gravimetric analysis** describes a set of methods in analytical chemistry for the quantitative determination of an analyte based on the mass of a solid
- **Volumetric** relates to measurement by volume or to a unit that is used to measure volume

http://en.wikipedia.org/wiki/Main_Page

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Gravimetrics vs. Volumetrics

- Gravimetric process utilizes Specific Gravity to calculate dose of medication prepared
 - Uses a highly accurate scientific scale
 - Calculates anticipated weight of bag based on specific gravity of drug, diluents and carrier fluid
 - Compares anticipated weight of the bag versus the weight of the robotically prepared bag and compares against the established plus/minus range ($\pm 5\%$ at BWH)

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Gravimetrics vs. Volumetrics

- Volumetric process relies on accurate drawing up of fluid volumes by pharmacy technicians
 - USP allows plus/minus 10% for FDA approved drug products
 - IV fluid bags plus/minus 10% or minimal fill volume
 - Syringe accuracy $\pm 5\%$ at half scale and $\pm 4\%$ at full scale


Which process seems to be more accurate??

**Our Vision:
The Sterile Products Room of the Future!**

- Part of our strategic plan is to move toward a fully automated process using gravimetrics to compound all sterile products
- Process includes a combination of robotics and work flow software



Robots, Robots, Robots!



1 cyto
2 vvs
1 sterile

Robots Provide Us With:

- Bar code verification
- Specific gravity and gravimetrics
- Optical scanning
- Central data storage
- High degree of accuracy and precision
- Efficient work flow
- Workload tracking
- Interfaces

Robots today DO have Limitations!

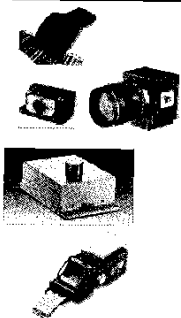
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What About Compounded Sterile Products that CANNOT be made in a Robot?

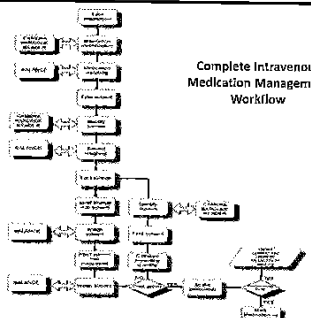
- Must provide a consistent process that uses same tools and functionality as robot
 - Bar code verification
 - Specific gravity and gravimetrics
 - Remote pharmacist verification
 - Optical scanning
 - Central data storage
 - High degree of accuracy and precision

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i.v.SOFT uses Robotic Logic & Accessories



Complete Intravenous Medication Management Workflow



Slide with Permission of Health Robotics

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Quality Improvement

- **Interfacing workflow software with hospital pharmacy software system is a CRITICAL STEP!**
 - Ideal situation would be with a full HL7 interface with the Pharmacy Information System
 - Eliminates potential transcription errors
 - Monitors productivity and reduce waste
 - Allows use of auto generated final container labels with the hospital's BCMA system
 - Triages sterile products room workload

Study Sample Results: i.v.SOFT Assist

- Study: 3 European hospitals
 - Study duration approximately 4 Months
 - Total doses studied approximately 25,000 Doses (both Chemo and Non-Chemo doses included)

Preparation Component	Passed Preparations (%)	Prevented Errors (N)	Prevented Errors (%)
Drug Quantity	99.7	8,250	33
Drug	100	193	0.8
Diluent	100	2,145	8.6
Label	100		
Spike (Camera Check)		439	1.8
Syringe Brand and Size		1,630	6.5


Data provided by Health Robotics

Training Your Staff: Some Challenges

- Full time staff of 20 technicians & 10 pharmacists that rotate through the Sterile Products Room
 - 10 part-time and per diem technicians
 - Training provided for 2 weeks during off peak hours and shift change
- Need to identify and designate "super users"
 - Super users get an enhanced overview of trouble shooting and maintenance
- Future training on new employees done by our staff (super users)
- **Use it, or lose it!**

Using Bar Code and Digital Imaging Technology to Reduce IV Compounding Errors

Potential Concerns with Changing to New Processes for Compounded Sterile Product Preparation



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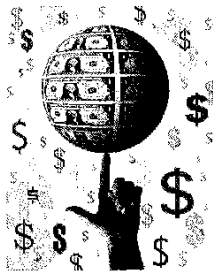
Potential Concerns with Changing to New Processes for Compounded Sterile Product Preparation

- Staff will need additional training to adapt to their new roles working with new technology
- Technology is relatively new and we are in the early adopter phase
- The technology is not proven as yet with evidenced based studies
- Potential exists for new kinds of errors to occur due to the introduction of the new technology, processes and roles for staff
- Staff may over-rely on the technology

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Financial Concerns

- Not a free lunch!
- Need to plan for the costs
 - Capital Leasing
 - Monthly Rental
 - Outright Purchase



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Can anyone say, Roadblocks?



- Obtaining Specific Gravity values
 - May need to contract with an outside lab for results
- Drug Shortages

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Lessons Learned

- Product shortages can greatly impact output volume using new workflow technologies
- New problems can arise unexpectedly and can be related to
 - vial sizes
 - drug product composition
 - Hardware
 - Software
 - Human Interface issues
- It takes time to add and validate new products to the workflow's database

Patience is key!

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Lessons Learned


- You must have clearly written implementation and validation protocols
- Ⓛ You must also have clear change management protocols for when hardware or software are upgraded
- Training of both the pharmacist and technical staff is a key success driver
- Establish a partnership with your vendor to keep in constant contact during implementation and expansion periods

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When trying anything new....

Don't forget your STAFF!



- Staff Input
- Suggestions
- They know daily work flow best!



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Experiences and Challenges with a Pharmacy Workflow Management System



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Disclosure

- The views and opinions presented are entirely my own. They do not necessarily reflect the views of Peninsula Regional Medical Center or the University of Maryland Eastern Shore School of Pharmacy.



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