MSOS Member Briefing
March 2023

MSOS Member Briefing
March 2023

Moderated by: E. Robert Feroli, PharmD, FASHP

MSOS
MEDICATION SAFETY OFFICERS SOCIETY

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HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

The Power of Speaking Up

Shannon Manzi, PharmD, BCPPS, FPPA

Director, Safety & Quality, Department of Pharmacy
Boston Children's Hospital

Faculty, Applied Informatics, Computational Health Informatics Program
Assistant Professor of Pediatrics, Harvard Medical School

"When the systems depend on human vigilance, they will fail." Carter Mecher

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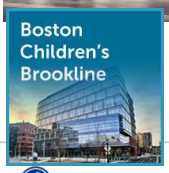

Boston Children's Hospital

- 150+ years old! Founded in 1869
- 450 bed* free-standing, academic pediatric quaternary care medical center
- More than 750 affiliated Boston Children's physician practices across Massachusetts, Connecticut, New Hampshire, New Jersey, and New York
- Eight satellite and physician office complexes
- Seven community hospitals
- One community health center
- Boston Children's Hospital is home to the world's largest research enterprise at a pediatric medical center

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The Event

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The Event

- During an OR case, an anesthesiologist discovered an ePHEDrine 5 mg/mL, 5 mL prefilled syringe that had been previously opened
- A review of the syringes revealed that it is impossible to tell when a syringe has been opened and recapped due to defective tamper evident seals
- A total of 10 syringes were recovered from Pyxis machines that had been previously opened
  - **RISK**: Bloodborne pathogen transmission and lack of sterility

In the picture please note that the top syringe is unopened and the bottom syringe is opened and used.

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Root Cause Analysis – The Ws and an H

WHO: Anesthesia staff, Anesthesia technicians, Pharmacy technicians, Pharmacists

WHAT: Anesthesia practice is to recap partial syringes while the case is in progress so that the drug does not become contaminated.

WHEN: After the case, anesthesia technicians clean the room, returning any unused medications (vials, bags, syringes, etc) to the pharmacy for redispensing.

WHERE: Anesthesia workroom → OR Pharmacy → Pyxis

WHY:
- 503B prediluted, ready to use syringes are preferred for safety over vials requiring dilution
- Minimization of waste, backorders and shortages

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Root Cause Analysis – The Ws and an H

HOW: In this case, it was nearly impossible for the anesthesia technician, the pharmacy technician or the pharmacist to detect that these syringes had been previously opened.

- Noticing if the volume is significantly lower than expected (which is difficult because there is a large air bubble in the unopened syringes)
- Running a finger over the seal to feel a rupture

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The Resolution

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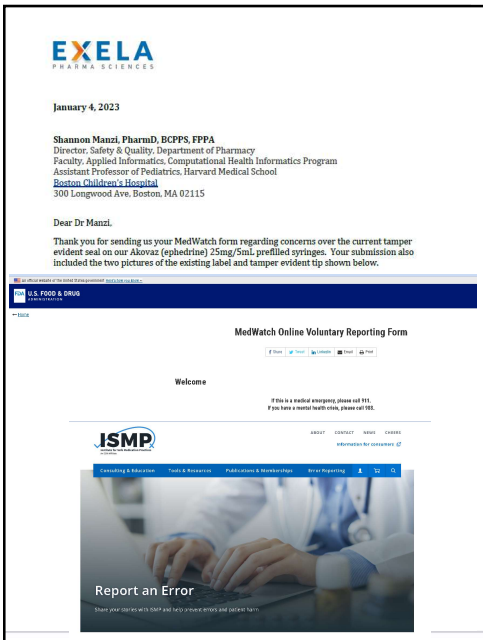

EXELA PHARMA SCIENCES

January 4, 2023

Shannon Manzi, PharmD, BCPPS, FPPA
Director, Safety & Quality, Department of Pharmacy
Faculty, Applied Informatics, Computational Health Informatics Program
Assistant Professor of Pediatrics, Harvard Medical School
Boston Children's Hospital
300 Longwood Ave, Boston, MA 02115

Dear Dr Manzi,

Thank you for sending us your MedWatch form regarding concerns over the current tamper evident seal on our Akovaz (ephedrine) 25mg/5mL prefilled syringes. Your submission also included the two pictures of the existing label and tamper evident tip shown below.

U.S. FOOD & DRUG ADMINISTRATION

MedWatch Online Voluntary Reporting Form

Welcome

If this is a medical emergency, please call 911.
If you have a mental health crisis, please call 988.

ISMP

Report an Error

Actions Taken

- Discarded all ePHEDrine syringes after cases, regardless if used or not
  - Of note, Exela is the only commercial supplier of these syringes. Very soon the other 503B manufacturers will not be able to supply these syringes, leaving the only option from Exela
- Ordered interim supply from alternate 503B (of note they use the wrong TALLman lettering!)
- Compounded syringes in house
  - Increases technician workload, already at capacity and attempting to minimize dilutions to mitigate repetitive motion injuries
- Added physical test of tamper evident seals for all medications during new product review process
- Reported to MedWatch, ISMP and the company
- Met with Exela, discussed concerns

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Response from the Company

This new design will provide a much tighter seal of the tamper evident portion of the label and the effort required to twist the tip off will be greater, enhancing the knowledge for any caregiver to know that the syringe seal remains intact prior to use. Should the tip twist off easily, (as would be the case if someone removed and tried to replace the tip), the provider would know it was tampered with based on the ease of which the tip was removed. There is also no way to physically pull the tip off without breaking the label/seal in the new labels. We are in the process of validating the new equipment that will place these new syringe labels on our prefilled syringes and look to introduce this second-generation label/tamper evident seal in the first quarter of 2023.

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Next Steps

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High Reliability in practice

- Review product defect reports at the ADE Committee in addition to unit level investigations
  - Go beyond the band-aid fix in the moment (First Order problem solving)
  - **Encourage reporting of anything that does not seem right**
  - Complete ACA/RCA of events and address system level issues (Second Order problem solving)
  - **Elimination and forcing functions are the ultimate goal**
  - Avoid human based interventions if possible (e.g. attaching stickers)
  - Minimize the impact of education
  - Review processes for returning medications to pharmacy and subsequently to Pyxis
- The importance of reporting and sharing beyond your organization!!

High Reliability In Action

AT BOSTON CHILDREN'S HOSPITAL
EVERY MOMENT MATTERS

Daily Operations Brief	Error Prevention Training	Senior Leadership Rounding to Influence	Apparent Cause Analysis

All employees are required to complete high reliability safety training

Goal

- Teach key principles of high reliability
- Empower staff to use high reliability principles to prevent and identify opportunities to drive system change
- Foster a non-punitive safety culture where speaking up for safety is encouraged and reinforced

Training

- Training is for all employees
  - Active medical staff
  - Associate scientific clinical staff
  - BCH-based house staff
  - Administrative and support staff
- High reliability safety training began in 2015. Since then, all staff complete training at new hire orientation or through computer-based learning modules via NetLearning.

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Questions?

Thank You

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MAKING SMARTER ALERTS FOR "SMART" INFUSION PUMPS

STEPHEN R. ANDREWS, PHARMD, BCPS, CPPS
DRUG INFORMATION SPECIALIST

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UNIVERSITY OF UTAH HEALTH

- 5 hospitals
  - University Hospital: 546 beds
  - Huntsman Cancer Hospital: 100 beds
  - 5 infusion clinics across the valley
- > 1,000,000 infusions annually

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CONTEXT OF OUR INFUSION SYSTEM

- 2 main pump vendors
  - 1 integrates with our electronic health record and is our primary infusion pump
  - 1 does not integrate and is used for epidurals and in ambulating inpatients for continuous infusions
- Focus for today's presentation is on our primary pump
  - 3 libraries: Adult, Pediatric ICU, and Newborn
- All infusion setups have been reviewed by Pharmacy Informatics and Medication Safety Committee
- Standard Concentrations Policy for Parenteral Drug Infusions

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THE RESURGENCE OF ALERT REVIEW

- In February 2019:
  - 6.1% of infusions had an alert
  - 38.2% of infusions were completed without a drug entry
  - 72.9% had a patient ID entered
- In July 2019, approximately 68% of pump limit overrides occurred in less than 2 seconds

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STAFF WERE FRUSTRATED WITH MEANINGLESS ALERTS

- Why were there 4,100 alerts?
- Why were there so many basic infusions?
  - 16,713 infusions had no limits out of 43,775 total
- What drugs were missing alerts because they did not infuse through a drug entry with limits?
- Wasn't pump integration supposed to fix this?

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Digging into the pump data

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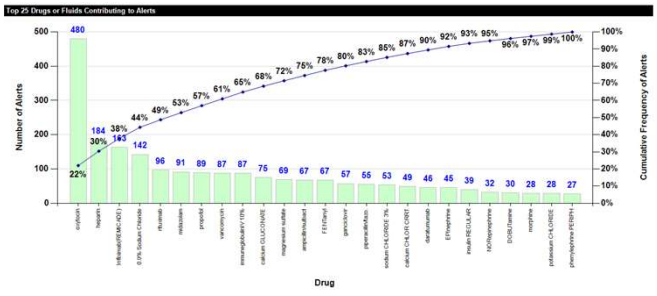
FOCUSING ON ALERTS FIRST

- Our infusion analytics portal has a prebuilt pareto chart
- If the alerts were poorly set, then the easiest way to infuse the drug without interruption is an infusion with no limits, jeopardizing safety



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FIRST OBSERVATIONS

- Oxytocin infusions are a problem*
- We lacked a strategy on when to use a soft alert and a hard alert
- Intermittent infusions that are titrated caused pump limit conundrums
- Most of these drugs pump integrate…so why are they still causing alerts to fire?
- Nursing staff are annoyed by the alerts and don't see much utility

*More on oxytocin infusions later

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FIRST DIRECTIONS TO A SOLUTION

- First goal was to improve trust in the alerts that the pump was firing. Distrust in alerts = distrust in the pump
- The intermittent infusions in the top 10 drugs accounted for 508 alerts: **these were top priority**.
- Implementation of scheduled reports for easy access to data and routine Med Safety review
- Oxytocin was reviewed, and determine to need to remain the same setup:
  - 2 therapies and 2 limits: antepartum and postpartum. To reprogram, the channel had to be turned off and new dose programmed (~5 minutes interrupted infusion) – this is never done.

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A LENGTHY, INTERRUPTED, JOURNEY: 2019 TO NOW

- Monthly library updates were standard, but now included more medication updates
- Many infusion room medications had high alert volumes: total infusion duration limit must be equal or greater than the amount of time the infusion would run over at the lowest infusion rate to prevent an alert
- Every 3 months, new alert data was reviewed at the committee meeting

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Continuous Improvement Mentality

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EXAMPLE: EPINEPHRINE CONCENTRATION LIMITS

- Increases in volume of alert changes improves reliability of alerts, as long as they are correctly entered into software for the pump
- Standard concentration: 16 mcg/mL
- Pump programming needs a double-check, just like some medications: 16 mg/250 mL instead of 16 mg/1,000 mL

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UPDATES TO CONFIGURATION PROCESS

- The Drug Information Service already provided Pharmacy Informatics with limit recommendations based on evidence
- Once sent from Drug Info to Pharmacy IT, the only other safety check was with the Med Safety Committee
- Current state: 2 more double-checks implemented
  1. The recommendation of limits double-checked internally at Drug Info
  2. The programmed alert checked after input into the software

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So where are we now?

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FEBRUARY 2019 VS FEBRUARY 2023

- In February 2019:
  - 6.1% of infusions had an alert
  - 38.2% of infusions were completed without a drug entry
  - 72.9% had a patient ID entered
- In July 2019, approximately 68% of pump limit overrides occurred in less than 2 seconds
- Total infusions: 43,775

- In February 2023: Stable metrics for >6 months
  - 1.2% of infusions had an alert
  - 20.6% of infusions were completed without a drug entry
  - 86.9% did not have a patient ID entered
  - 60.6% of pump limit overrides occurred in less than 2 seconds
- Total infusions: 90,618

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SO WHAT NEXT IF ALERTS ARE STABLE?

- With alerts less of a nuisance, we could turn our focus to other topics
- Review of alerts based on safety event reports
- Harmonizing our electronic medical record, standard concentrations policy, and pump library (resident project!)
- Focus on continuous infusions and decimal place errors (eg, epinephrine)
- Implementing pump integration for Investigational Drug Service medications

Christensen SM, Andrews SR, Fox ER. Development of a proactive process to harmonize policy, infusion pump library, and electronic health record entries for continuous infusions at an academic medical center, https://doi.org/10.1093/ajhp/zxac384

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RESOURCES ARE AVAILABLE!

- ISMP Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps
- Sentinel Event Alert #63: Optimizing smart infusion pump safety with DERS

https://www.ismp.org/guidelines/safe-implementation-and-use-smart-pumps
https://www.jointcommission.org/resources/sentinel-event/sentinel-event-alert-newsletters/sentinel-event-alert-63-optimizing-smart-infusion-pump-safety-with-ders/

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FINAL THOUGHTS

- Acknowledge the gap first, then review and determine possible explanations
- Set up multi-layer reviews of settings to improve reliability and safety
- Change takes time and engagement from multiple groups, but is possible!
- Once engaged, these groups are invaluable in reviewing safety events to provide real-world feedback
- Use the resources available to you!

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QUESTIONS?

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Gene Therapy: Medication Safety

Winnie Stockton, PharmD, BCPPS
Investigational Drug Services Pharmacy Supervisor
CHOC Children's

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What is Gene Therapy?

Gene therapy modifies or manipulates the expression of a gene to treat or cure a disease

- Replace a disease-causing gene
- Inactivate a disease-causing gene
- Introduce a new or modified gene into the body

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https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products

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Center for Biologics Evaluation and Research

- Center for Biologics Evaluation and Research (CBER) regulates cellular therapy products and human gene therapy products
- CBER currently lists 27 approved products
  - 22 cell therapies
  - 5 viral vector gene therapies
- Investigational products

FDA
Center for Biologics Evaluation and Research

CHOC https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products 35

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Types of Gene Therapy

Type of Gene Therapy	Description
Viral vectors	Viruses can be modified to remove their ability to cause infectious disease. The modified viruses can be used as vectors to carry therapeutic genes into human cells
Bacterial vectors	Bacteria can be modified to prevent them from causing infectious disease and then used as vectors to carry therapeutic genes into human tissues
Plasmid DNA	Circular DNA molecules can be genetically engineered to carry therapeutic genes into human cells
Human gene editing technology	The goals of gene editing are to disrupt harmful genes or to repair mutated genes
Patient-derived cellular gene therapy products	Cells are removed from the patient genetically modified (often using a viral vector) and then returned to the patient

CHOC https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products 36

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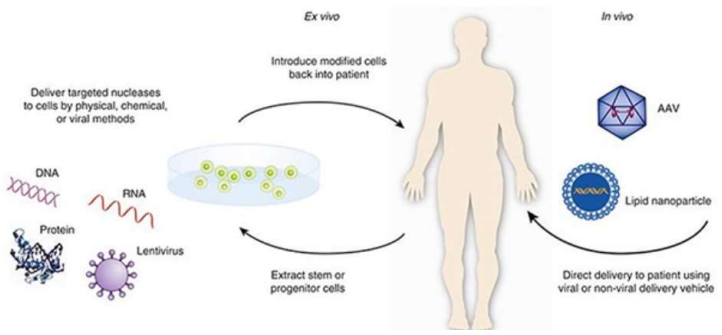
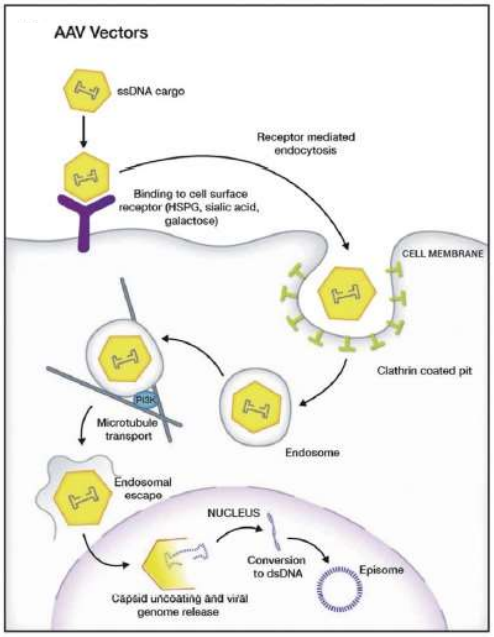
Types of Gene Therapy





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https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products
Choudhury SR, et al. Viral vectors for therapy of neurologic diseases. Neuropharmacology. 2017 Jul 1;120:63-80.

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Gene Therapy Preparation Guidelines

- USP 797
- USP 800
- Manufacturer Recommendations
- **NIH Guidelines** — NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- **BMBL Guidelines** — Biosafety in Microbiological and Biomedical Laboratories
- **EAHP Guidance** — European Association of Hospital Pharmacists

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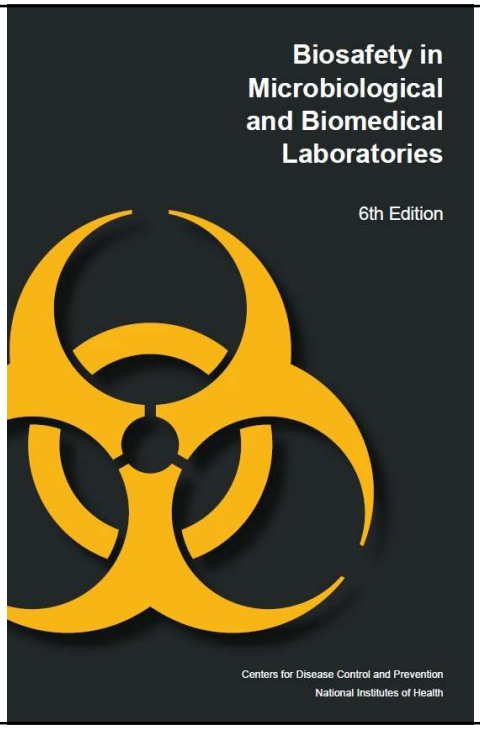
NIH and CDC Resources

NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (NIH GUIDELINES)

APRIL 2019



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NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2019)
Biosafety in Microbiological and Biomedical Laboratories (2020)

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Risk Groups

Risk Group	Characteristics	Example
RG1	Not associated with disease in healthy humans	Adeno-associated viruses
RG2	Associated with human disease which is rarely serious and for which preventative or therapeutic interventions are often available	Adenoviruses
RG3	Associated with serious or lethal human disease for which preventative or therapeutic interventions may be available	Retroviruses
RG4	Likely to cause serious or lethal human disease for which preventative or therapeutic intervention are not usually available	Ebola virus

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NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2019)
Biosafety in Microbiological and Biomedical Laboratories (2020)

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Risk Assessment

- Make initial risk assessment based on the Risk Group (RG) of an agent (RG1-RG4)
- Consider how the agent will be manipulated
  - Strains more hazardous than the parent (wild-type) strain may need handling at a higher containment level
  - Strains that have been demonstrated to have irreversibly lost known virulence factors may qualify for reduction of containment level
  - Multiple sources: What is the highest risk group? What percentage does each contribute? What is the function or purpose of each contributing sequence?
- Set containment level: Biosafety Level (BL1-BL4)
- Consult Institutional Biosafety Committee

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NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2019)
Biosafety in Microbiological and Biomedical Laboratories (2020)

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Biosafety Level: Containment

- Confine organisms containing recombinant or synthetic nucleic acid molecules
- Reduce exposure to staff
- Reduce exposure to the environment

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NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2019)
Biosafety in Microbiological and Biomedical Laboratories (2020)

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Biosafety Level 1

NIH Guideline

- Access is restricted
- Work surface is decontaminated once a day and after spill
- Wash hands after handling materials and upon exit
- Minimize aerosols
- Waste is sealed in a durable leak-proof container

BMBL Guideline

- A hazard warning sign is posted at room entry
- Needles are not recapped or removed. Sharps container as close to point of use as possible.

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NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2019)
Biosafety in Microbiological and Biomedical Laboratories (2020)

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Biosafety Level 2

NIH and BMBL Guideline

- Biological Safety Cabinet (BSC)
  - Pharmacy preparation in BSC at BSL I

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NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2019)
Biosafety in Microbiological and Biomedical Laboratories (2020)

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European Association of Hospital Pharmacists (EAHP) Guidance

Guidance on the Pharmacy Handling of Gene Medicines

European Association of Hospital Pharmacists (EAHP) Guidance on the Pharmacy Handling of Gene Medicines

Authors
Arnold G Vulto, PharmD, PhD[1]; Nicola Stoner, BSc (Hons), MRPharmS, Dip Clin Pharm, PhD[2]; Hana Balásová, PharmD[3]; Ana-Cristina Cercos, PharmD, PhD[4]; Torsten Hoppe-Tichy, PhD[5]; Juan L Vinent Genestar, PharmD[6]; Kirsi Kontra, PharmLic[7]; Per Nydert, MScPharm[8]; András Vermes, PharmD, PhD[9]; Andrea Wolfsberger, PharmD[10]

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Vulto AG, et al. European Association of Hospital Pharmacists (EAHP) Guidance on the Pharmacy Handline of Gene Medicines. EJHPPPractice. 2007;13:29-39.

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European Association of Hospital Pharmacists (EAHP) Guidance

- Receipt: Open inner shipping container in the BSC
- Storage area: Restricted access
- Transport: Sealed leak-proof bag
- Transport: Labeled biohazardous
- Spill kit available
- Incorporate manufacturer recommendations (decontamination, deactivation, disinfection agents)

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Vulto AG, et al. European Association of Hospital Pharmacists (EAHP) Guidance on the Pharmacy Handline of Gene Medicines. EJHPPPractice. 2007;13:29-39.

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European Association of Hospital Pharmacists (EAHP) Guidance

- Prepare doses in class II BSC
- Wipe materials placed in BSC with IPA
- Disinfectant available during preparation
- Decontaminate the BSC before and after gene therapy preparation
- Allow BSC to eradicate aerosols after gene therapy preparation

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Vulto AG, et al. European Association of Hospital Pharmacists (EAHP) Guidance on the Pharmacy Handline of Gene Medicines. EJHPPPractice. 2007;13:29-39.

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Prescribing and Dose Preparation

- Closed System Drug-Transfer Device (CSTD): “A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of the hazardous drug or vapor concentrations outside the system”
- Sponsor may not allow CSTD or may require testing with specific products prior to use

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https://www.bd.com
https://bbraunusa.com

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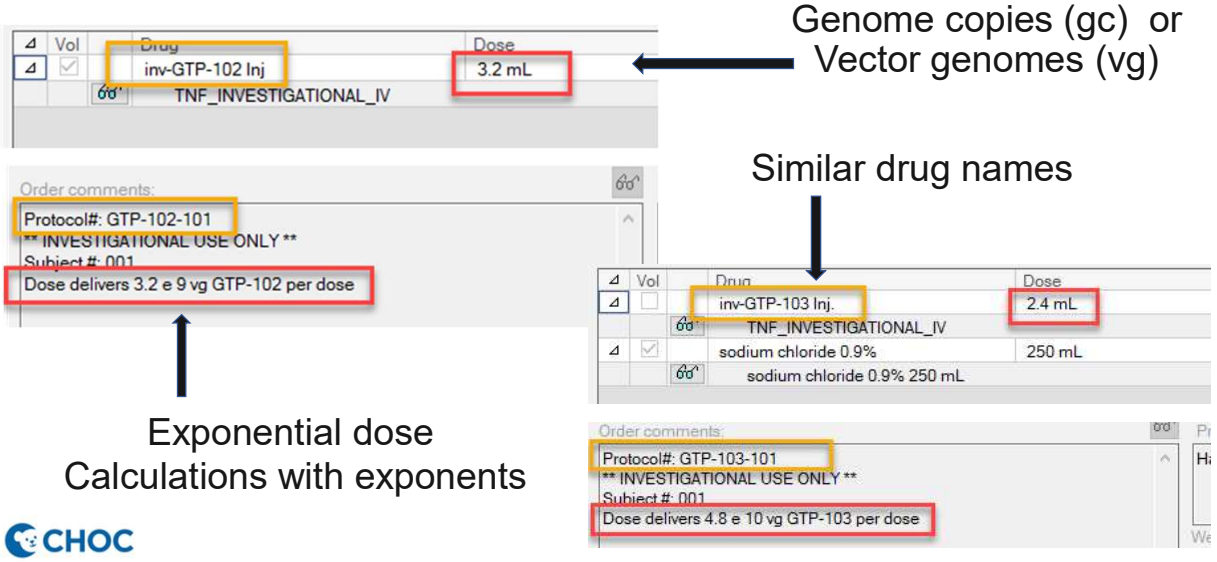
Prescribing and Dose Preparation



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Prescribing and Dose Preparation

Investigational Drug Product Label

Protocol Number: [redacted]
[redacted]
Lot Number: AAV10[redacted]
Date of Manufacture: 10/13/20
Store at ≤-65°C
Refer to Certificate of Analysis for Concentration
Total Number of Vials:
Vol: 0.6ml
Sponsor: [redacted]
Principal Investigator:
Caution: New Drug – Limited by Federal Law to Investigational Use

Variable concentrations

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Prescribing and Dose Preparation

Certificate of Analysis

Material Name		Manufacturing Site	
[redacted] Material Number		Date of Manufacture	
Lot Number		Retest Date	
Specification Reference		Revision Reference	
Extractable Volume			

Test	Test Method	Specification	Result	Pass/Fail
Sterility				
Sub-visible particles				
Vector Genome Titer (ddPCR)				

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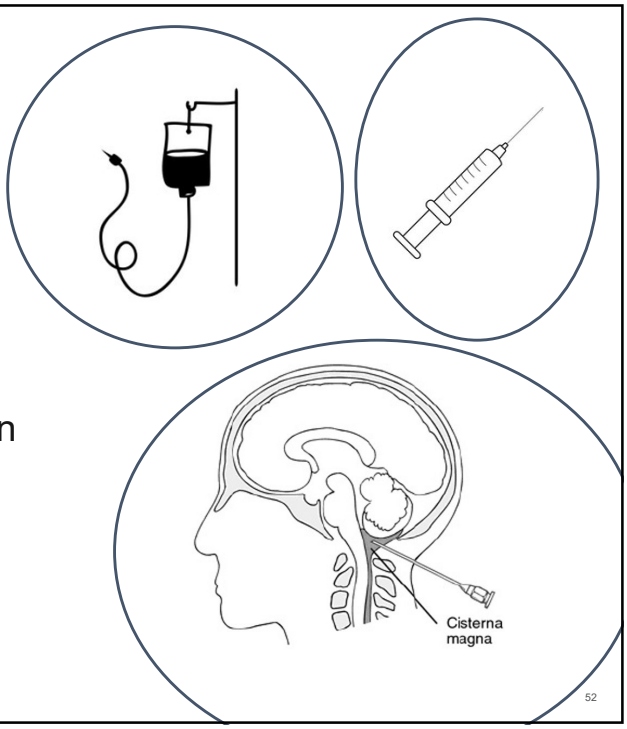
Administration Routes

IV infusion

Subcutaneous injection

Intra-cisternal (IC) infusion

Intracerebroventricular (ICV) infusion



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Conclusion

- Gene therapies offer new opportunities for treating or curing disease
- It is important to set an appropriate biosafety level for handling
- Be cautious with unusual parameters (e.g., exponential dose and concentration, vector genome dosing units).

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Questions?

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ISMP Update
MSOS Briefing March 2023

Rita K. Jew, PharmD, MBA, BCPPS, FASHP
President
Institute for Safe Medication Practices

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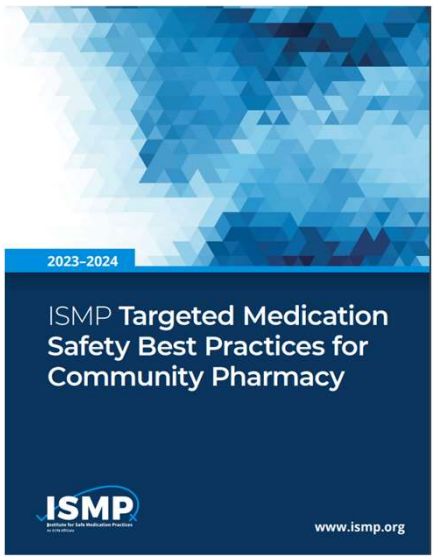
ISMP Targeted Medication Safety Best Practices for Community Pharmacy 2023-2024



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Top 10 Patient Safety Concerns 2023

- Overreliance on Holding Practitioners Accountable for the Five Rights
- Medication Errors Resulting from Inaccurate Patient Medication Lists
- Accidental Administration of Neuromuscular Blocking Agents

Top 10 Patient Safety Concerns 2023 (ecri.org)

ISMP An ECRI Affiliate

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BD Alaris Pump Shut Off Unexpectedly

SAFETY briefs

BD Alaris Pump shut off and did not infuse vasopressors. ISMP and ECRI have updated an alert warning about damaged BD Alaris Inter-Unit Interface (IUI) connectors on the Alaris Pump modules that can result in medication infusions suddenly stopping (www.ismp.org/ext/1133). As we previously published in a 2017 ***Safety* brief** (www.ismp.org/node/165), damage to the IUI connectors, which attach the modules of the Alaris System together, may result in an interrupted electrical communication between a module and the PC unit (PCU) or the pump "brain." As a result, the pump modules may display a "communication error" and/or shut down with a channel disconnect alarm on the PCU. When this occurs, the infusion may stop without warning until the module(s) are restarted or replaced. Over the past few years, ECRI and ISMP have continued to receive reports involving IUI connector problems, some of which have resulted in patient harm.

ISMP An ECRI Affiliate

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ISMP Updates Tall Man List

— Seven new name pairs have been added to ISMP's list of look-alike drug names with recommended tall man (mixed case) letters, to help prevent mix-ups.

- cyclo**PHOS**phamide (can be confused with cyclo**SPORINE** and cyclo**SERINE**, already on FDA list)
- dro**PER**idol and dro**NAB**inol
- dex**AMETH**asone and dexmede**TOMID**ine
- py**RID**ostigmine and **PHYS**ostigmine
- **AL**fentanil (can be confused with **SUF**entanil and fenta**NYL**, already on the ISMP list)
- **BUP**ivacaine and **ROP**ivacaine
- oxy**BUTY**nin (can be confused with oxy**CODONE**, Oxy**CONTIN**, and oxy**MOR**phone, already on the ISMP list)

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Educational Programs – On Demand Webinars

— International Medication Safety Update

- **This webinar discussed how organizations around the world interact with and complement one another with a focus on The International Medication Safety Network (IMSN), an international network of established safe medication practice centers, who monitor for adverse drug reactions and medication errors and produce guidance to minimize preventable harms from medication use in practice.**
- **https://www.ismp.org/events/international-medication-safety-update**

— ISMP's New Targeted Medication Safety Best Practices for Community Pharmacy: 2023-2024

- **Learn about ISMP's new Targeted Medication Safety Best Practices for Community Pharmacy and why they were selected for national action.**
- **https://www.ismp.org/events/introducing-ismps-new-targeted-medication-safety-best-practices-community-pharmacy-2023-2024**

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https://www.ismp.org/events/international-medication-safety-update

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Educational Programs – Drug Diversion Webinars

- Part I: The Pursuit of Prevention – Confronting Drug Diversion
  - How to confront drug diversion through the lens of a drug diversion program manager.
  - https://www.ismp.org/events/part-i-pursuit-prevention-confronting-drug-diversion
- Part II: Reducing the Risk and Infection Outbreaks from Drug Diversion
  - A look at drug diversion through the lens of a risk manager and their role to reduce risk in hospitals and healthcare facilities, as well as the impact of diversion on infection outbreaks from the lens of an infection control preventionist.
  - https://www.ismp.org/events/introducing-ismps-new-targeted-medication-safety-best-practices-community-pharmacy-2023-2024

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https://www.ismp.org/events/international-medication-safety-update

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Questions?

- A copy of today's slides will be posted on our website
- Next MSOS Briefing date – May 25, 2023.

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