MSOS Member Briefing
March 2021

MSOS Member Briefing
March 2021

Moderated by: E. Robert Feroli, PharmD, FASHP

MSOS
MEDICATION SAFETY OFFICERS SOCIETY

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Increasing Pediatric Syringe Smart Pump Library Compliance

Casey Moore, PharmD
Medication Safety Pharmacist- Pediatrics

Sammy Burton, PharmD, FISMP
Medication Safety Pharmacist- Smart Pumps

Cleveland Clinic

2

Cleveland Clinic Enterprise

170-acre main campus, 11 regional hospitals and 19 full service family health centers throughout Northeast Ohio; locations also in Florida, Nevada, Toronto and Abu Dhabi *(London coming soon)*

3

Background

- Children's Hospital Institute syringe library compliance in 2018 = 58%
- Smart Pump Compliance Goal prior to 2019 = 90%
- New goal to align with ISMP/ECRI = 95%

Compliance (%) = Total guardrail infusions/ Total infusions

ISMP. Guidelines for optimizing safe implementation and use of smart infusion pumps. 2020.

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Reasons for Basic Mode Use

- Unable to find ordered medication in library (and/or specific care area)
- Unable to find ordered concentration in the library (and/or specific care area)
- Ordered concentration, rate, dose, duration outside of hard limits
- Alert fatigue
- Lack of awareness/importance

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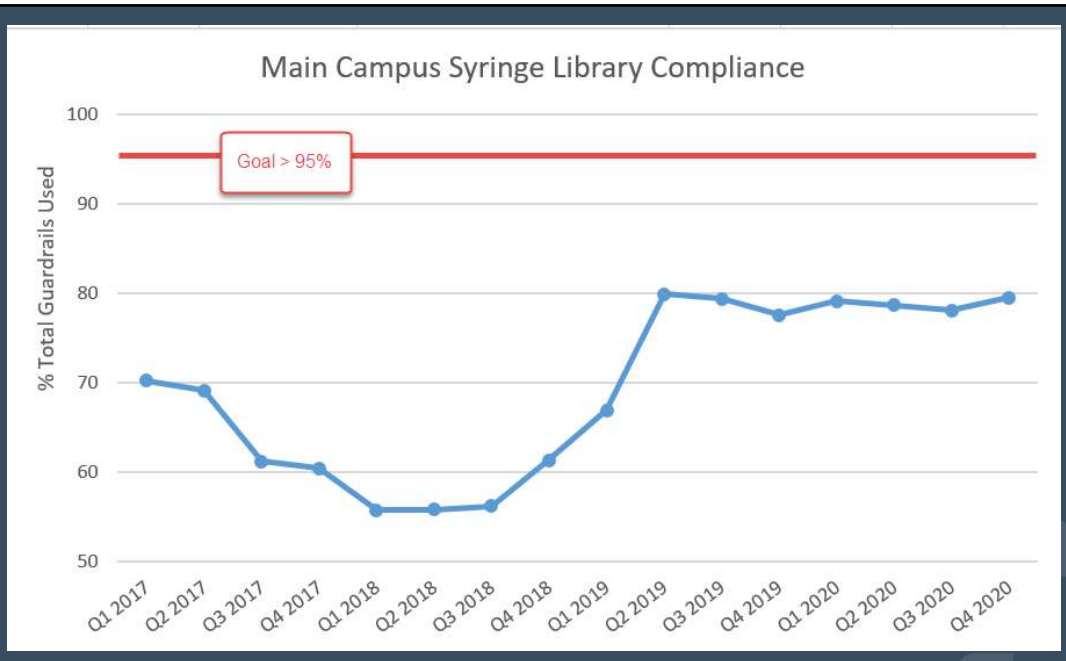

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Initiatives

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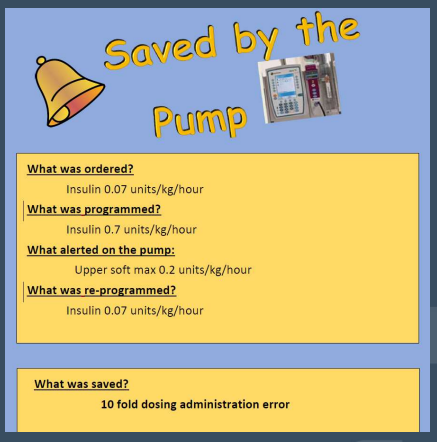
Cultural Campaigns



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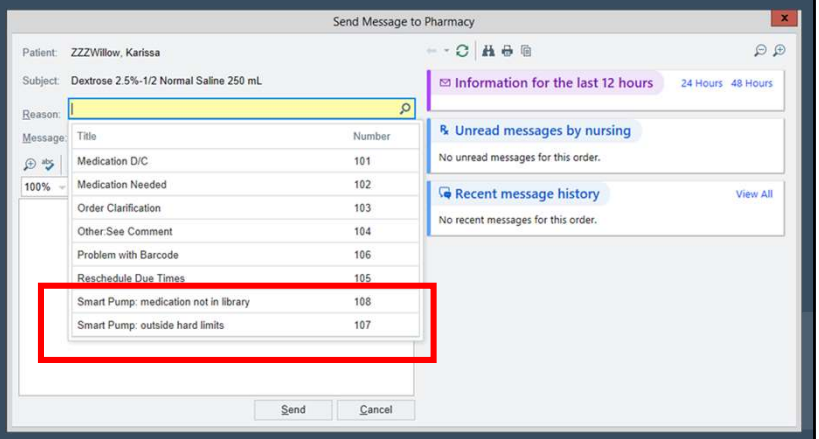
Feedback Submission and Review

- EPIC MAR In-Basket
  - ✓ RN submission of medications not in library or programming required is outside hard limits
- Quarterly Alert Data Review
  - ✓ Adjust guardrails if clinically appropriate to decrease alert fatigue



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Feedback Submission and Review

- EPIC MAR In-Basket Examples
  - ✓ Midazolam
    - Request submitted that ordered rate was above upper hard limit of 0.4 mg/kg/hr.
    - Upper hard limit increased to 2 mg/kg/hr with 11-17-2020 library update.
  - ✓ PHENobarbital
    - Request submitted to increase concentration limits to accommodate 130 mg/mL concentration.
    - Concentration limits updated with 01-26-2021 library update.

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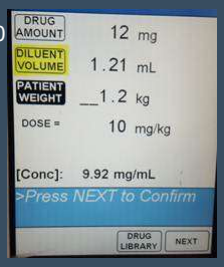
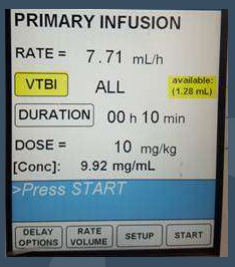
Feedback Submission and Review

- Quarterly Alert Data Review Example
  - ✓ Acetaminophen
    - Top medication contributing to hard limit alerts, with the majority due to duration value
    - It was discovered that a majority of these alerts were occurring because:
      - Diluent volume (manually entered by the user) ≠ the VTBI (auto-detected by the pump)
      - When this discrepancy occurs, the pump limits scale to accommodate the volume difference
    - Added a buffer to account for this scaling in August 2020
    - Total hard limit alerts for acetaminophen
      - Q3 2020: 258
      - Q4 2020: 58





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Next Steps

- Care area consolidation
  - ✓ PGY2 quality project
  - ✓ Current care areas:

Syringe:
Peds < 0.6 kg
Peds 0.6-1.199 kg
Peds 1.2-1.999 kg
Peds 2-4.999 kg
Peds 5-9.999 kg
Peds 10-40 kg
Peds > 40 kg

Large Volume Pump:
Peds CCM wt > 40 kg
Peds CCM 10-40 kg
Peds CCM 5-9.9 kg
Peds CCM 2-4.9 kg
Peds CCM 0-1.9 kg
Pediatric wt > 40 kg
Pediatric 10-40 kg
Pediatric 5-9.9 kg
Pediatric 2-4.9 kg
Pediatric 0-1.9 kg

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Next Steps

- Care area consolidation
  - ✓ PGY2 quality project
  - ✓ Future care areas:

Syringe:
NICU
Peds

Large Volume Pump:
NICU
Peds < 40 kg
Peds > 40 kg

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Next Steps

- Removal of upper hard dose limits (10% rounding is not currently factored in) for intermittent infusions
- Addition of upper hard dose limits to continuous infusions
- Regularly attend nursing and anesthesia meetings quarterly to share pump data and address concerns

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VANDERBILT UNIVERSITY
MEDICAL CENTER

Improving the Medication Use Process
3% Sodium Chloride

Jessica Anderson, PharmD, BCPPS
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Program Director, Quality, Safety, and Education

Monroe Carell Jr. Children's Hospital at Vanderbilt (VCH)

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3% Sodium Chloride-Situation

- 3% sodium chloride (NaCl) is commonly utilized at VCH for treatment of elevated intracranial pressure (ICP) after severe traumatic brain injury (TBI)

Recommendation	Hyperosmolar Therapy[1] 2012 (2nd Edition)	Hyperosmolar Therapy[1] 2019 (3rd Edition)
Evidence Level II	3% NaCl bolus should be considered Dose: 6.5 – 10 mL/kg	3% NaCl bolus is recommended Dose: 2 – 5 mL/kg
Evidence Level III	3% NaCl infusion should be considered Dose: 0.1 – 1 mL/kg/hour	3% NaCl infusion is suggested Dose: 0.1 – 1 mL/kg/hr 23.4% NaCl is suggested for refractory ICP and herniation Dose 0.5 mL/kg (max 30 mL)

[1]Mannitol-no studies meeting inclusion criteria were identified for use as evidence for this topic

Kochanek, P. et al. *Pediatric Critical Care Medicine*. March 2019; 20 (3S). S1-S82

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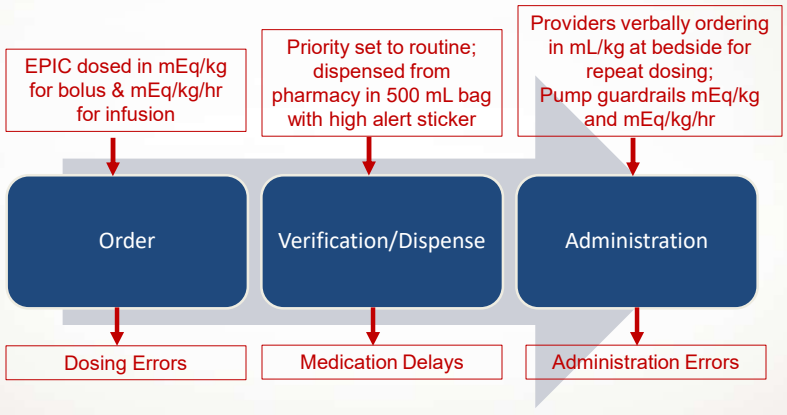
3% Sodium Chloride-Background

VCH Historical Medication Use Process



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3% Sodium Chloride-Assessment

Failure Modes and Effects Analysis (FMEA) Completed Enterprise Wide 8/26/2019

Highest Risk Areas Identified Based on Severity and Possibility	
Failure Mode	**Summary of Solutions and Plan**

Dosing in EPIC (mEq/kg only)	- Create indication-based panel
	  - Hyponatremia (mEq/kg and mEq/kg/hr)
	  - TBI/Cerebral Edema (mL/kg and mL/kg/hr)
	- Change nomenclature in eStar to 3% NaCl (HYPERTONIC)

Delays from Pharmacy	- Stock medication in ED trauma bays - Stock medication in PICU and PCICU Omnicell cabinets - Add to override list in Omnicell ED trauma bays and PICU
Dispensing Incorrect Fluid from Omnicell	- Change nomenclature in Omnicell - 3% NaCl ***HYPERTONIC*** - Provide high alert packaging and labeling

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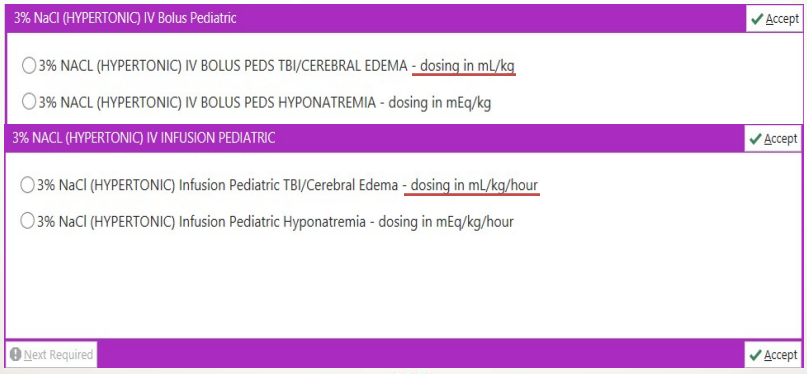
3% Sodium Chloride-Recommendations

Dosing Units

- ***Create indication-based panel to allow for different dosing units***
- ***Update nomenclature to include (HYPERTONIC)***
- ***Orders defaulted to STAT for faster pharmacy verification turn around***



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3% Sodium Chloride-Recommendations

Override Status

- ***Add 3% bolus to the pediatric code dosing sheet for guidance during an emergency when override function is utilized***

Traumatic Brain Injury/Cerebral Edema

Dosing Weight: **8.5 kg**

Medication	Dose	Volume	Dose/kg	Comments
Hypertonic 3% Sodium Chloride	21.25 mEq	**42.5 mL**	5 mL/kg (2.5 mEq/kg)	Concentration: 1 mL = 0.513 mEq Slow IV push via central line if possible Infuse over a minimum of 10 minutes Max 500 mL
Mannitol 25% (50 mL)	4.25 gm	**17 mL**	0.5 gm/kg	Use filter, Slow IV push via central line if possible over 20-30 minutes, do not administer with blood, inspect for crystals prior to administration (if crystals are present, redissolve by warming solution)
Mannitol 20% (500 mL)	4.25 gm	**21.25 mL**	0.5 gm/kg	Use filter, Slow IV push via central line if possible over 20-30 minutes, do not administer with blood, inspect for crystals prior to administration (if crystals are present, redissolve by warming solution)

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3% Sodium Chloride-Recommendations

Storage and Labelling

- ***Create a custom high alert label for nurse double check***

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3% Sodium Chloride-Recommendations

Storage and Labelling

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3% Sodium Chloride-Recommendations

MAR View – 3% Bolus TBI/Cerebral Edema

- ***Add indications to Alaris guardrails to correlate with EPIC ordering***
- ***Provide pump programming guidance for nurses***
- ***Add clinical advisory to Alaris to double check dosing units***

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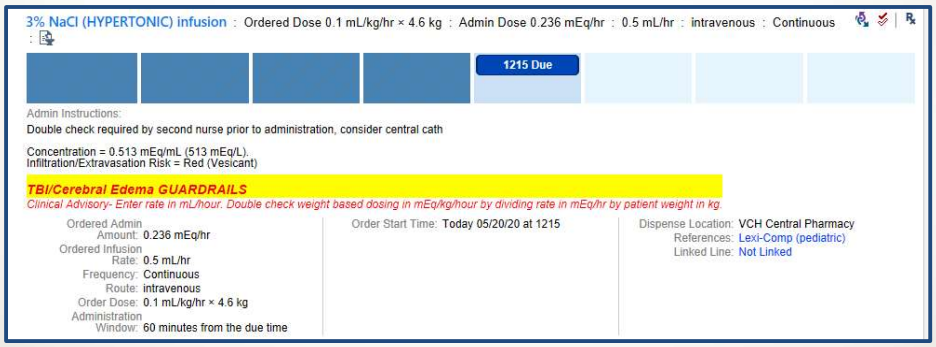
3% Sodium Chloride-Recommendations

MAR View – 3% Infusion TBI/Cerebral Edema

- ***Add indications to Alaris guardrails to correlate with EPIC ordering***
- ***Provide pump programming guidance for nurses***
- ***Add clinical advisory to Alaris to double check dosing units***



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23.4% Sodium Chloride Highlights

- Patient must reside in the PICU for use & requires PICU attending approval
- Restricted to patients with refractory intracranial hypertension & herniation
- Patients should have sodium levels monitored at a minimum every 6 hours
- Added to high alert medication list (dual signature by nursing on admin)
- BPA alerts were created in order to maximize medication safety
  - Sodium level $\geq$ 155
  - Maximum dose – critical warning
  - Location of patient outside of PICU
- Stocked in pharmacy and dispensed patient specific (not in Omnicell)
- Dual verification required with double check on dispense preparation
- Dispensed with high alert labeling
- Central line administration only
  - PICU attending must be at bedside for administration

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Questions?

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Rapid Access to Sodium Chloride 23.4% in Neurocritical Care

Callee Brooks, PharmD Candidate
University of Tennessee Health Sciences Center

G. Morgan Jones, PharmD, BCCCP, FCCM
Clinical Pharmacy Specialist – Neurocritical Care

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Intracranial Hypertension

- Components inside the cranium should be at a constant equilibrium

Blood 10%	Brain 80%	CSF 10%

- Compensatory mechanisms are able to maintain a normal ICP for small changes in intracranial volume
- Consensus definition of intracranial hypertension
  - 'Persistent' ICP ≥ 20 - 25 mm Hg
  - Diagnosis also based on clinical & CT scan findings

Wolfe TJ et al. *Curr Neurol Neurosci Rep.* 2009; 9:477-485.

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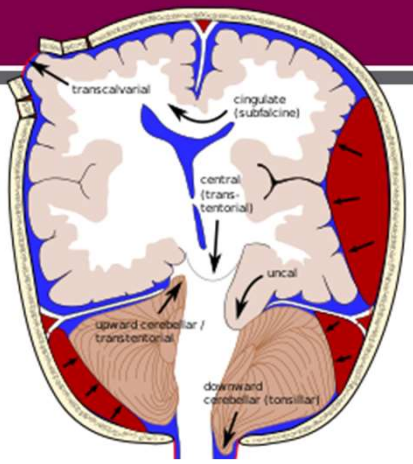
Herniation Syndrome

- Shifting of brain tissue from one space in the brain to another
- Caused by increased pressure inside cranial compartment
- Type of herniation determines extent of neurologic injury
  - Significant neurologic deficits
  - Brain death



Subfalcine	Transalar / Transphenoidal	Transtentorial Uncal	Central (upward / downward)	Cerebellar tonsillar	Transcalvarial

Wolfe TJ et al. *Curr Neurol Neurosci Rep.* 2009; 9:477-485.

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Intracranial Hypertension

Emergency Neurologic Life Support (ENLS)
Tier 1 Recommendations

Secure airway	Brief course (<2 hr) of hyperventilation	Hyper-osmolar Therapy	CSF Drainage	Consider surgical intervention

Cadena R et al. *Neurocrit Care*. 2017 Sep; 27(Suppl1):82-88.

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23.4% Sodium Chloride (NaCl)

Biphasic impact on ICP

- Early effects due to optimization of blood viscosity & cerebral blood flow
- Establishment of an osmotic gradient between extracellular & intracellular space

Theoretical advantages over mannitol

- Less blood brain barrier permeability
- Lack of diuretic effect
- Volume expansion
- Immunomodulation

Timing of ICP reduction
Onset: Minutes
Peak: 20 - 30 minutes
Duration: 6 – 24 hours

Torre-Healy A et al. *Neurocrit Care*. 2012; 17:117-130.

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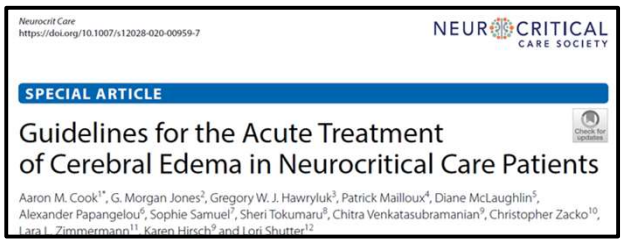
23.4% Sodium Chloride (NaCl)

- 23.4% NaCl is currently used to treat elevated ICP & cerebral edema in neurocritical care patients
  - Use is often during a life-threatening emergency where patient is exhibiting symptoms of herniation syndrome
  - Recent guidelines suggest use of 23.4% NaCl over mannitol in multiple neurologic injury subtypes


Neurocrit Care
https://doi.org/10.1007/s12028-020-00959-7

NEUROCRITICAL CARE SOCIETY

SPECIAL ARTICLE

Guidelines for the Acute Treatment of Cerebral Edema in Neurocritical Care Patients

Aaron M. Cook[1*], G. Morgan Jones[2], Gregory W. J. Hawryluk[3], Patrick Mailloux[4], Diane McLaughlin[5], Alexander Papangelou[6], Sophie Samuel[7], Sheri Tokumaru[8], Chitra Venkatasubramanian[9], Christopher Zacko[10], Lara L. Zimmermann[11], Karen Hirsch[9] and Lori Shutter[12]

Speed of administration may influence ability to reverse herniation syndrome!

Cook AM et al. *Neurocrit Care*. 2020.

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Safety Recommendations

- Recent ISMP guidelines suggest against stocking of concentrated electrolytes, including 23.4% NaCl, in automatic dispensing cabinets
  - Exception: In cardiac surgical areas, vials of concentrated potassium solutions are sequestered in sealed kits or locked storage areas and obtained immediately before use
- The Joint Commission recently updated their recommendations on storage to include the following:
  - Under limited circumstances where access is urgently needed, it may be necessary to store concentrated electrolytes in specific areas
  - Storage decision should be based on a robust risk assessment following implementation of appropriate safeguards

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23.4% Sodium Chloride

Methodist University Hospital (MUH) Approach

- In 2012, high risk / high alert policy was amended to allow stocking of 23.4% NaCl in select omnicells to facilitate rapid administration
- Risk assessment was completed & the following safety steps were put into place to reduce risk

MUH 23.4% NaCl Risk Reduction Strategies
1 - ONLY administered neurology, neurosurgery, or critical care licensed independent providers
2- ONLY stocked in omnicells in limited quantities in ED & neuro ICU
3 - Must be stored in a separate compartment from other medications
4 – Not able to be overridden
5 - Must be administered through central line

23.4% Sodium Chloride

Methodist University Hospital Approach

- Medication use evaluation (MUE) conducted 1 year after initial change showed no safety concerns
- Follow up MUE conducted in 2020 conducted to further evaluate

Objective = evaluate the storage, distribution, & safety outcomes following the addition of 23.4% NaCl to automated ADCs within ICU & the ED

Included random sample of patients treatment from August 2018 to September 2020

23.4% Sodium Chloride

Methodist University Hospital Approach

Overall Use (n = 125)	
Dose removed from omnicell, n (%)	103 (82.4%)
Dose dispensed from central pharmacy, n (%)	22 (17.6%)
Dose given in critical care unit, n (%)	93 (74.4%)
Charted that LIP-administered dose, n (%)	53 (42.4%)
Time to administration*, median minutes (IQR)	19 (10-37.5)
Time order entry to verification	2 (1-4)
Time verification to ADC removal	2.5 (1-11)
Time ADC removal to administration	8.5 (4- 16)

*Difference in the time the order placed until the time the administered dose was electronically documented

- No doses were overridden
- 121 of 125 doses **charted** on MAR as given through central line
- Less than half of doses were **charted** as given by provider

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23.4% Sodium Chloride

Methodist University Hospital Approach

- 89 patients treated due to clinical and/or radiographic symptoms without ICP monitor in place
- No patient with sodium increase that resulted in potential for harm
- One patient with hypotension (defined as SBP < 90 mm Hg) that rebounded with no intervention

Overall Use (n = 125)	
Pre-sodium, mean ± SD	141 ± 6
Post-sodium, mean ± SD	146 ± 6
Increase, mean ± SD	5 ± 4
Pre-SBP range°, median	128 - 136
Post-SBP range°, median	126 - 138
Maximum decrease in SBP, median (IQR)	8 (-1 - 30)

°Both the maximum & minimum value of SBP & ICP in the hour prior to & after administration were collected. Range is defined as the median minimum value to the median maximum value charted in the hour prior & post administration of 23.4% NaCl.

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23.4% Sodium Chloride

Methodist University Hospital Approach

- The medication-use process implemented at our institution is safe & increases ready access in areas of the hospital with neurocritical patients
- Institutions could utilize the same risk reduction strategies to allow for rapid administration in emergent cases
  - Stored separately in locked bin in limited quantities
  - Administered by an LIP through a central line
  - Must be verified by PharmD & cannot be overridden
  - Consideration of additional institution-specific safeguards based on risk assessment

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Rapid Access to Sodium Chloride 23.4% in Neurocritical Care

Callee Brooks, PharmD Candidate
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Clinical Pharmacy Specialist – Neurocritical Care

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ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

ISMP Update
MSOS Briefing March 2021

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP
President, Institute for Safe Medication Practices

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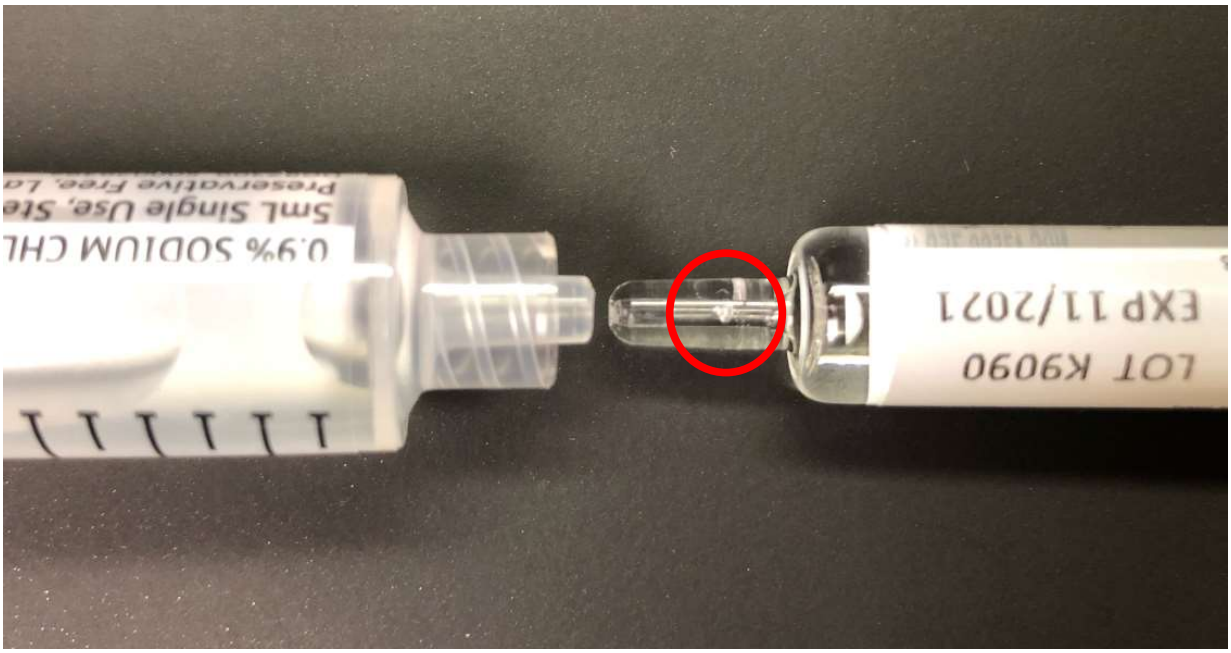
0.9% SODIUM CHL
5mL Single Use, Ste
Preservative Free, La
LOT K9090
EXP 11/2021

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Market-leading Infection Control Technology Proven to Minimize Bacterial Contamination3,4,5,6,7,8
MicroClave Clear can help your efforts to reduce infection risks by minimizing entry points for bacteria and maximizing the effectiveness of every flush.
Split-septum
a preferred design feature for connectors.9
Straight fluid path
for clearing blood and blood residual with low flush volumes.10
Minimal residual volume
(also referred to as priming volume) allows for lower flush volumes.
Clear housing
permits visual confirmation of flush after use with medications or blood.
Silicone Seal and Internal Cannula
Specifically designed to minimize contact between the connector's external surface and the internal fluid path upon luer activation, this proven Clave® technology minimizes entry points for bacteria. Several studies have attributed this feature to a significant reduction in bacterial contaminants passed through the connector. 6,7,8

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March 2021

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ISMP

Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Should FDA reconsider allowing the pooling of COVID-19 vaccine doses to obtain additional doses?

ISMP thanks Kevin N. Hansen, PharmD, MS, BCPS, BCSCP, from the Moses H. Cone Memorial Hospital in Greensboro, North Carolina, for contributing this article.

Vaccinators have observed remaining residual volume in the current coronavirus disease 2019 (COVID-19) vaccine vials (**Figure 1**) after obtaining the full labeled quantity of doses available from each vial (**Table 1**) and have expressed a desire to pool the leftover vaccine to obtain an additional full dose for administration. This practice would have the potential to increase the number of Americans who could be vaccinated with the existing supply and prevent unnecessary vaccine wastage. The US Food and Drug Administration (FDA) has advised that "... any further product remaining that does not constitute a full dose should not be pooled from multiple vials to create one."[1] This has created frustration as vaccinators continue to witness potential additional vaccine doses go to waste coupled with the existing challenges of limited vaccine supplies. This presents an opportunity to review the practice of drug pooling, drug preservatives, contamination risks, aseptic technique, and future directions to maximize the doses withdrawn from vaccine vials.

Figure 1. Pfizer-BioNTech COVID-19 vaccine vial after 6 doses removed, showing remaining volume in vial.

Drug Pooling Defined

Drug pooling is the act of combining the volume from multiple drug vials into a container or syringe to obtain a specified dose for administration. This is a routine practice for many drugs, both with and without preservatives, prepared in ISO (International Organization for Standardization) classified pharmacy cleanrooms within a primary engineering control, such as a laminar airflow workbench, that provides ISO class 5 unidirectional airflow in a controlled environment. These engineering controls are critical to prevent the contamination of the sterile drug when proper aseptic technique is used and to reduce the risk of potential harm to the patient.

ISMP joins the author and others who encourage FDA to reconsider the safe and responsible pooling of COVID-19 vaccines...

continued on page 2 — Pooling >

Table 1. Current FDA Emergency Use Authorization (EUA) COVID-19 Vaccines

COVID-19 Vaccine	Labeled Doses per Vial	Dilution Required?	# of Times Vial Accessed for Labeled # of Doses
Pfizer-BioNTech[2] multiple-dose vial, preservative-free	6*	Yes	7
Moderna[3] multiple-dose vial, preservative-free	10*	No	10
Janssen[4] multiple-dose vial, preservative-free	5*	No	5

* Reports have demonstrated that additional full doses may be present if using certain low dead-volume (LDV) syringes and needles; withdrawing these additional doses would require additional vial access.

SAFETY briefs

Vaccine card incorrect for single-dose COVID-19 vaccine. When a hospital received its first shipment of the single-dose Johnson & Johnson's Janssen coronavirus disease 2019 (COVID-19) vaccine, the accompanying supplies included COVID-19 Vaccination Record Cards that reference a two-dose vaccine series (**Figure 1**). The cards have the US Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) logos in the upper right corner. All vaccination sites receive these cards with the Moderna and Pfizer-BioNTech vaccines, which require two doses. The front of the card provides space to document the product name, manufacturer, and lot number of both the first and second vaccine doses.

Figure 1. COVID-19 Vaccination Record Cards accompanying the Janssen single-dose vaccine incorrectly call for two doses (front of card, top) and advises patients to return for a second dose (back of card, bottom).

continued on page 2 — SAFETY briefs >

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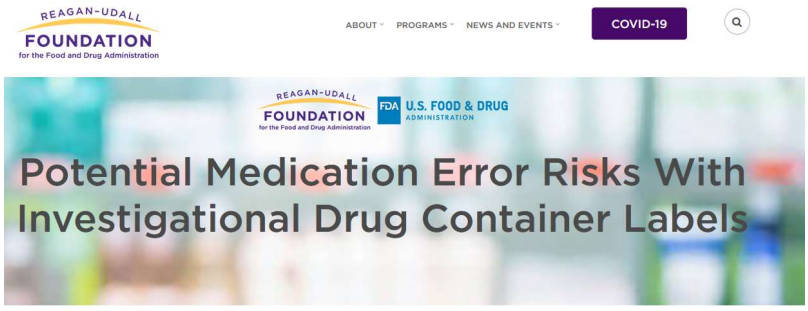
Advocacy – Public Meeting with FDA May 18 & 19

- https://www.fda.gov/drugs/news-events-human-drugs/potential-medication-error-risks-investigational-drug-container-labels-public-meeting-may-18-19-2021



NEWS AND EVENTS › EVENTS › POTENTIAL MEDICATION ERROR RISKS WITH INVESTIGATIONAL DRUG CONTAINER LABELS

Potential Medication Error Risks With Investigational Drug Container Labels

Public Meeting
May 18-19, 2021

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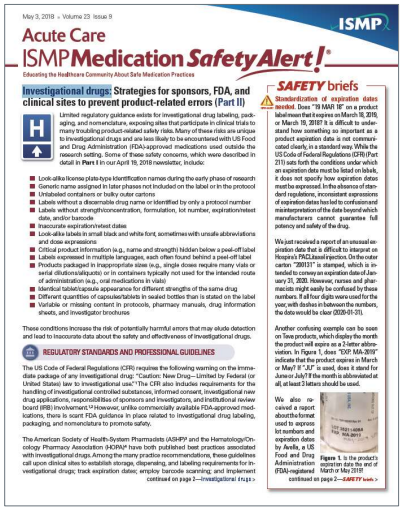
FDA

ISMP published a 2-part article in 2018 calling for action due to medication errors related to poor labeling of INDs. April 19 and May 3, 2018

Acute Care
ISMP Medication Safety Alert!

Investigational drugs: Product-related issues pose significant challenges (Part I)



Acute Care
ISMP Medication Safety Alert!

Investigational drugs: Strategies for sponsors, FDA, and clinical sites to prevent product-related errors (Part II)

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FDA BAA grant for Perioperative Self Assessment – Launch in April

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ISMP consumer website

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Questions?

- A copy of today's slides will be posted on our website
- Next MSOS Briefing date – May 27, 2021.
  Register:
  https://ecri.zoom.us/webinar/register/WN_yCZCG0OgQHORXJR_V3MsdA

MSOS
MEDICATION SAFETY OFFICERS SOCIETY

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