

# MSOS Member Briefing

## January 2019

MSOS Member Briefings  
January 2019  
*Moderated by: E. Robert Feroli, PharmD, FASHP*

**Medication Safety**



Supported by educational grants from Novartis.



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**Protecting Medications from Light in Automated Dispensing Cabinets (ADCs)**

Stacy L. Carson, PharmD, BCPS, FISM  
Medication Safety Coordinator  
AdventHealth Orlando  
Orlando, FL  
January 24, 2019



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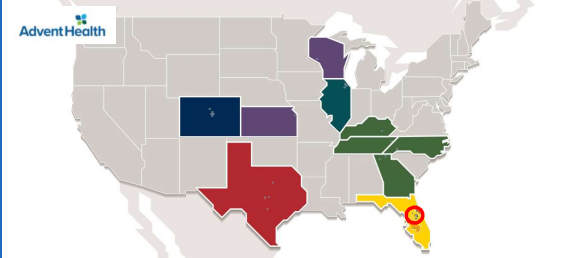
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- 8 Hospitals
- 2 Free Standing Emergency Departments
- 592 Automated Dispensing Cabinets



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### Situation

- At my institution, we found inconsistent methods of storing “protect from light” medications in Automated Dispensing Cabinets (ADCs)
  - Started with labetalol syringes
  - Decided to take a broader look for all medications stored in ADCs

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### Background

- Light may affect drug stability
- Many drugs contain wording in their Package Inserts stating to “protect from light during storage”
- Articles published by Hospital Pharmacy include comprehensive lists of medications that need protection from light
  - No mention about storage in Automated Dispensing Cabinets (ADCs)

<sup>1</sup> Hosp Pharm. 2014;49(2):136-163.  
<sup>52</sup> Hosp Pharm. 2009;44(12):1112-1114.

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### Background

- **Literature:** No studies were found using a PubMed search on ADCs protecting medications from light
- **Drug Manufacturer:** Limited information by the manufacturer on medication light protection
  - How do they want us to protect from light?
  - When do they want us to protect light (storage, dispense)?
  - Do ADCs provide protection?
- **BD/Pyxis (manufacturer):** Confirmed there is no data on this but believe the lidded drawers do not provide UV protection

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### Background: How **other institutions** handle protect from light medications

- Light protect everything that has the recommendations in the package insert → Use brown overwrap bags
- Contact the manufacturer regarding the frequency of light and length of light exposure
- Evaluate based on UV light intensity reaching the drug (direct or fluorescent light, etc.)
- Apply tinting material on tower doors of ADCs
- No brown bags needed in lidded pockets b/c are protected by ADC
- Nothing. Do not consider ADC as a "storage" location of medications and therefore the light protection recs do not apply

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ASHP Connect List Serve; Searched 7/20/18.

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### Summary of the Issue

- No standard universal way to handle protect from light medications while stored in ADCs
- Some institutions are conservative and place everything in brown overwrap bags, while others are more liberal and feel the ADC is adequate and/or not considered storage and do nothing extra

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### Recommendations for our Facilities

For drugs where the manufactures explicitly states to protect from light and the drug is not already in light protection packaging:

- If stored in ADC lidded drawers, do not require additional light protection (i.e., brown bags).
  - The drawers are shut the majority of time and light exposure is limited
- If stored in ADC towers with transparent doors, require additional light protection due to extended light exposure
- Policy change approved in Dec 2018 and in the process of implementation

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### Future Considerations?

Why does every facility need to take steps for light protecting medications? Why can't the manufacturer place medications in packaging sufficient to light protect during storage??

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### Questions?? Thank you!

Stacy L. Carson, PharmD, BCPS, FISMP  
Medication Safety Coordinator  
AdventHealth Orlando

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**3+3+2= Danger!**

***Simplifying treatment of acetaminophen overdose***



Paul E. Milligan, Pharm D  
System Medication Safety Pharmacist  
BJC HealthCare- St. Louis, MO

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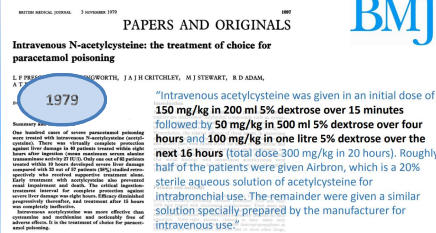
### Acetaminophen Overdose Is Prevalent



- >2 Million human exposure calls in 2015
- >100,000 regarding acetaminophen
  - > 20,000 received IV acetylcysteine

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### Prescott Protocol: Effective, But Dated and Complex



NO Internet  
Average Pharmacist  
Salary: ~\$20,000/year  
Tuition: ~\$15,000 (Total!)  
Average Monthly Rent  
\$280.00  
Cost of a gallon of Gas 86  
cents

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### Prescott Protocol: Complex to Prepare and Administer

Specifies a bag size that does NOT exist.

Uses NON-UNIT intervals for 2<sup>nd</sup> & 3<sup>rd</sup> bags.

Uses VOLUME instead of MASS units in preparation.

Two different concentrations which are unique to each patient.

Table 1. Three-Bag Method Dosage Guide by Weight, patients > 40 kg

Body Weight	LOADING Dose 150 mg/kg in 200 mL diluent over 60 min	SECOND Dose 50 mg/kg in 500mL diluent over 4 hours	THIRD Dose 100 mg/kg in 1000mL diluent over 16 hours
(kg) (lb)	Acetadot (mL)	Acetadot (mL)	Acetadot (mL)
100 220	25	25	50
90 198	67.5	22.5	45
80 176	60		40
70 154	52.5		35
60 132	45		30
50 110	37.5		25
40 88	30		20


**Amplified Risk Points**

- Dose Determination
- Preparation
- Administration
  - Programming
  - Bag Changes
- Transfers of Care!


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# Even Acetylcysteine is Dangerous



BRITISH MEDICAL JOURNAL VOLUME 203 28 JULY 1981

## PAPERS AND SHORT REPORTS

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### Adverse reactions to acetylcysteine and effects of overdose

T G K MANT, J H TEMPOWICK, G N VOLANS, J C C TALBOT

**Abstract**

Since the introduction in 1979 of intravenous acetylcysteine (Parvolex) as an antidote for paracetamol poisoning the National Poisons Information Service and the manufacturers have been advised of 19 cases of paracetamol that were complicated in major and/or accidental overdoses. The present authors review the clinical features reported including anaphylaxis, hypotension, and hepatotoxicity, all the patients recovered. The features associated with an overdose of acetylcysteine are similar but severe adverse reactions died, but the extent to which the occurrence of anaphylaxis may have been implicated was not clear in either case.

**1979 to 1983**


UK NPIS sent follow-up questionnaires to physicians who treated APAP ODs. Among these were 19 NAC overdoses. Three were 10X overdoses, of which 2 died. They learned of 3 more NAC ODs. 2 were 10X and 1 was 3X. All survived after hypotension (3), DIC (3), ARF (2).

**Introduction**

Intravenous acetylcysteine (Parvolex) is an effective antidote for the treatment of overdosage of paracetamol.<sup>1</sup> In the course of a survey of the use of acetylcysteine in the treatment of overdoses in adults the National Poisons Information Service encountered patients associated with the use of acetylcysteine—severe adverse reactions and accidental overdosage.

[illegible]

# Prescott Protocol: Serious Errors Occur



Clinical Toxicology, 2011, 48, 759-760  
Copyright © 2011 Informa Healthcare USA, Inc.  
DOI: 10.3109/15458879.2011.628622  
DOI: 10.3109/15458879.2011.628622

## BRIEF COMMUNICATION


### Hemolysis and Hemolytic Uremic Syndrome following Five-fold N-Acetylcysteine Overdose

MICHAEL E. MULLINS and BRINA V. VITKOVSKY


Washington University, Emergency Medicine, 660 S. Euclid Avenue, Campus Box 8072, St. Louis, 63110 United States

**Context:** Intravenous acetylcysteine (Acetadote<sup>®</sup> in the US) is the treatment of choice for acute acetaminophen poisoning in most of the world. However, the complicated clinical regimen is prone to errors in preparation and administration. Case report: A 21-year-old woman (70 kg) took acetylcysteine of acetaminophen and ethanol. Her serum acetaminophen concentration was >200 mg/L. Acetylcysteine infusion was initiated. Due to a misreading of the volume in the table in the Acetadote<sup>®</sup> package insert, she received 4.6x-fold overdose of 25.2 g of acetylcysteine in 500 mL over 10 hours then 17.5 g of acetylcysteine in 500 mL in run over 2 h. The dose error was detected 20 min into the second infusion. Her acetaminophen concentration fell quickly, and her higher transferrin saturation and higher total bilirubin, hemoglobin and hematocrit quickly dropped from 14.8 g/dL and 44.9% on admission to 6.2 g/dL and 17.3% on day 7. Subsequently the developed hemolysis and a steadily rising serum creatinine. She was transferred to a tertiary care hospital, received 20 mg/kg of intravenous hematology every two days for two weeks, transfusion of packed red blood cells, and plasmapheresis until hematology testing ruled out thrombotic thrombocytopenic syndrome. Discussion: A five-fold overdose of acetylcysteine was followed by unexpected hypotension and acute renal failure. The mechanism of hemolysis after acetylcysteine overdose is unclear. A simpler infusion regimen with standard concentrations would prevent a similar error.

**Keywords:** Acetylcysteine; Hemolysis; Renal failure; Medication error; Overdose



**Received Gms not mLs!**



	(g)	(mL)	Acetadote <sup>®</sup> (mL)
100	25.2	100	100
80	19.6	87.5	87.5
60	14.7	65.6	65.6
50	12.4	54.5	54.5
40	9.9	43.6	43.6

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### RCA<sup>2</sup> Action Hierarchy

"Teams should identify at least one stronger or intermediate strength action.."

- One bag
- Simplified Process
- Standardize Process

Action Category	Example
<b>Stronger Actions</b>	<ul style="list-style-type: none"> <li>Administrative/physical plant changes: Reduce running time of the main patient entrance into the building with personnel entry to emergency areas to reduce potential.</li> <li>New device with stability testing: Purchase device with stability testing to ensure device will not stop and allow the most appropriate to the patient population when needed.</li> <li>Engineering control (Biosafety Cabinet): Eliminate the use of manual pipettes and implement device for manual pipette work and use of pipettes that can only be connected to the correct tubing by making one connection that cannot physically be connected to incorrect connection device or tubing.</li> <li>Simplify process: Review emergency steps in systems.</li> <li>Standardize or implement on process: Standardize the order and use of medication pumps used throughout the institution. Use bar coding for medication administration.</li> <li>Targeted intervention to the building: Audit space and patient safety medication environment and staff support for RCPA process purchase needed equipment ensure staffing and workload are balanced.</li> </ul>
<b>Intermediate Actions</b>	<ul style="list-style-type: none"> <li>Redundancy: Use two WTs to independently calculate high risk medication dosages.</li> <li>Increase in staffing/decrease in workload: Make that staff available to assist when workload peak during the day.</li> <li>Software enhancements, modifications: Use computer alerts for drug dosing thresholds.</li> <li>Eliminate reduncancies: Provide quiet zones for programming PCA pumps, remove distractions for nurses when programming medication orders.</li> <li>Education using simulations: Conduct patient rounds, a simulation demonstration, with other action strategies and debriefing.</li> <li>Checklist together with: Use pre-induction and pre-induction checklist in operating rooms. Use a checklist when separating fluids from other containers.</li> <li>Eliminate task and workload: Do not store look alike look alike in the unit medication room.</li> <li>Standardized communication: Use readback for all critical lab values. Use readback on repeat back for all unit look.</li> <li>Enhanced documentation, communication: Highlight medication name and dose on all flags.</li> </ul>
<b>Weaker Actions</b>	<ul style="list-style-type: none"> <li>Double checks: One person calculates dosage, another person reviews their calculations.</li> <li>Warnings: Add audible alarm on audible alerts.</li> <li>New procedure/communication policy: Reminders to check IV rates every 2 hours.</li> <li>Training: Demonstrate the need to use medication with hidden dose during in service training.</li> </ul>

Action Hierarchy levels and categories are based on Root Cause Analysis Tools, 9th National Center for Patient Safety, 2016. Hierarchy levels are provided for reference only. A 10-point scale is provided for reference only.

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### BJC ONE Bag Protocol: Preparation

IV Acetylcysteine at BJH and SLCH

**30 grams of Acetylcysteine in 1 L of D5W.**

Standard concentration: **30 mg/mL.**

If Pt Wt <= 40 kg, then 15 grams in 500 mL of D5W. (30 mg/mL)

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### BJC ONE Bag Protocol: Administration

IV Acetylcysteine at BJH and SLCH

- Loading dose: **150 mg/kg/h for 1 hour**
- Maintenance infusion: **12.5 mg/kg/h** (equal to rate in middle bag of three bag method)
- Recheck APAP, AST, ALT at 20-24 h from ingestion (if known) to decide whether to stop or continue.

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### BJC One Bag Protocol: Used Since 2008



#### Evaluation of a Simplified N-Acetylcysteine Dosing Regimen for the Treatment of Acetaminophen Toxicity

Michael T Johnson, Craig A McCannnon, Michael E Mullins, and S Eliza Holcomb

**BACKGROUND:** Acetaminophen poisoning is the US. The lab intravenous N-Acetylcysteine (NAC) Administration (FDA) for treatment process that produces frequent label, uncomplimented dosing regimens. NAC 30 g in 1 L of 5% dextrose infused over 1 hour followed by an objective: To evaluate the hepatotoxicity, and tolerability of acetaminophen toxicity.

**METHODS:** This single-center, retrospective study evaluating the regimen across 70 patients. Charts were reviewed for prescribing practices, dosing errors, and clinical outcomes.

- 70 Patients
- 22 administration errors
  - 19 Related to Loading Dose
  - Did not allow bolus programming from smart pumps
- 3 interruptions longer than 60 minutes
- No ADE associated with admin errors
- All patients successfully discharged

**RESULTS:** In criteria, 35 medication errors (153 protocol infusion errors). The errors per 100 administration errors with 11 rate-related and 8 errors occurred in only 3 patients, education errors. The mean (SD) (17.8), range 1-76.5, and mean 7). All patients with hepatotoxicity to acute acetaminophen toxicity discharged. NAC is effective and well tolerated, the overall rate of administration was; thus, our protocol may be an

**KEY WORDS:** acetaminophen, antidote, infusion, intravenous, medication errors, N-Acetylcysteine, toxicity.

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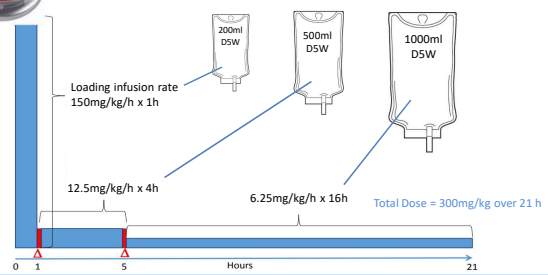
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### Recap: Prescott Protocol- 3 Bags, 3 Rates, 2 Patient Specific Concentrations (Converted to mg/kg/hr)



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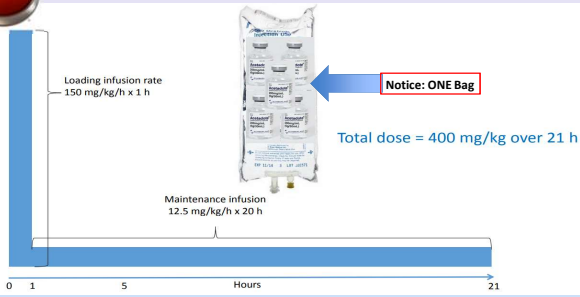
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### Recap: BJC Protocol- One Bag & Concentration



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### Summary

Standard concentration, easier to prepare, easier to administer, fewer errors, well tolerated

**30 grams** of Acetylcysteine in 1 L D5W.

Standard concentration is **30 mg/mL**.

Loading dose: **150 mg/kg/h for 1 hour**

Maintenance infusion: **12.5 mg/kg/h** until patient meets stopping criteria.



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### KEY TAKEAWAYS

1) The current treatment protocol for acetaminophen OD is:

- 1) Dangerous
- 2) Complex
- 3) Fraught with opportunities for error

2) THE BJC ONE Bag Protocol is

- 1) Easier to prepare
- 2) Easier to administer
- 3) Results in fewer errors
- 4) Is well tolerated



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### References

Acknowledgement:  
Slides were adapted from presentation by  
Michael E. Mullins MD FACEP FAAC  
Medical Toxicologist  
Associate Professor  
Division of Emergency Medicine  
Washington University School of  
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St. Louis, Missouri  
mullinsm@wustl.edu

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### Questions??

Paul E. Milligan, Pharm D  
System Medication Safety Pharmacist  
BJC HealthCare- St. Louis, MO

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### ISMP Survey on IV Push Medication Practices in Adults

Judy Smetzer, BSN, RN, FISMP  
Vice President  
Institute for Safe Medication Practices  
January 24, 2019



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### Timeline

2010

- Survey: Impact of the economic crisis/shortages on medication safety**
- Increase in nurses preparing or manipulating parenteral medications on the clinical unit

2012

- Survey: Practices when using CARPUJECT prefilled medication syringes**
- Withdrawing medication from prefilled syringe cartridges

2014

- Survey: IV push practices**
- Unnecessary dilution of dispensed ready-to-administer medications
  - Inappropriate use of prefilled saline flush syringes for dilution
- Summit: ISMP Safe Practice Guidelines for Adults IV Push Medications [2015]**  
[www.ismp.org/node/97](http://www.ismp.org/node/97)

2018

- Survey: IV push practices**
- Follow up to understand current practices associated with IV push medications
  - Determine if ongoing drug shortages and teaching strategies around this critical skill have impacted current practices

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# MSOS Member Briefing

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2018 IV Push Practice Survey Results

### HIGHLIGHTS OF SURVEY RESULTS

#### FOUR UNSAFE PRACTICES

- 1 Using prefilled syringes or cartridges as vials
- 2 Diluting adult IV push medications unnecessarily despite their availability in a ready-to-administer form
- 3 Diluting or reconstituting an IV push medication in a prefilled 0.9% sodium chloride flush syringe that is rarely relabeled
- 4 Failing to properly label syringes of IV push medications prepared away from the patient's bedside

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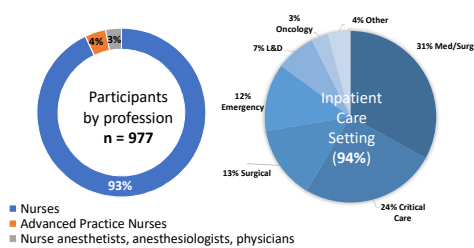
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2018 IV Push Practice Survey Results

### PARTICIPANT PROFILE



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2018 IV Push Practice Survey Results

### FINDINGS: UNSAFE PRACTICE 1

#### WITHDRAWING MEDICATIONS FROM PREFILLED SYRINGES

##### 2018

- 66% of participants report withdrawing medications from prefilled syringes/cartridges and transferring to another
- 16% report doing this more than half of the time they encounter a prefilled syringe

##### 2012

- 12% reported concern about this unsafe practice in the comments section

Reason	Percent of Participants (%)
Dilution	64
No designated syringe (cartridge) holder	22
Taught to do this	15
Hard to read syringe dose increments	14
Syringe without a needleless connector or removable needle	14
Other (e.g., shortages; filtering medications; erroneous belief that a 10 mL syringe must be used to administer medications via port/PICC)	22

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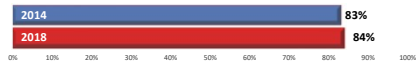
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2018 IV Push Practice Survey Results

### FINDINGS: UNSAFE PRACTICE 2

#### DILUTION OF IV PUSH MEDICATIONS

Participants who further dilute certain adult IV push medications prior to administration



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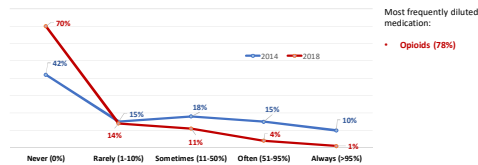
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2018 IV Push Practice Survey Results

### FINDINGS: UNSAFE PRACTICE 2

#### DILUTION OF IV PUSH MEDICATIONS

Frequency of diluting IV push medications  
\*from manufacturer's prefilled syringe\*



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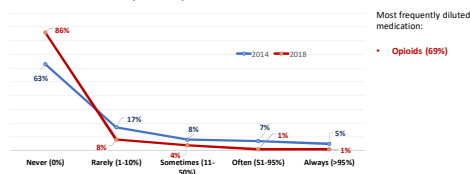
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2018 IV Push Practice Survey Results

### FINDINGS: UNSAFE PRACTICE 2

#### DILUTION OF IV PUSH MEDICATIONS

Frequency of diluting IV push medications  
\*from pharmacy-prepared syringe  
with patient-specific dose\*



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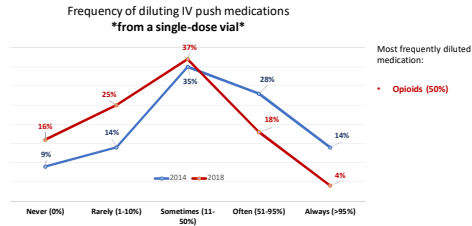
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2018 IV Push Practice Survey Results

### FINDINGS: UNSAFE PRACTICE 2

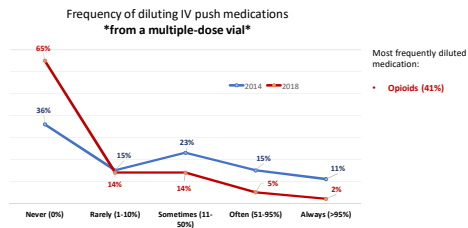
#### DILUTION OF IV PUSH MEDICATIONS



2018 IV Push Practice Survey Results

### FINDINGS: UNSAFE PRACTICE 2

#### DILUTION OF IV PUSH MEDICATIONS



2018 IV Push Practice Survey Results

### FINDINGS: UNSAFE PRACTICE 2

#### DILUTION OF IV PUSH MEDICATIONS

Reasons for further dilution	
Reason	Percent of Participants (%)
Desire to administer the drug slowly	94
Avoid patient discomfort	70
Reduce the risk of extravasation	33
Measure small volume doses accurately	25
Other (e.g., drug-specific requirements, facility policies, drug reference recommendations, prior education)	13

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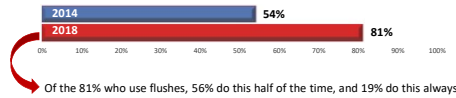
## January 2019

2018 IV Push Practice Survey Results

### FINDINGS: UNSAFE PRACTICE 3

#### DILUTION OF IV PUSH MEDICATIONS IN FLUSH SYRINGE

Use of saline (0.9% sodium chloride) flush syringe\* to dilute medications  
\*commercially or pharmacy prepared



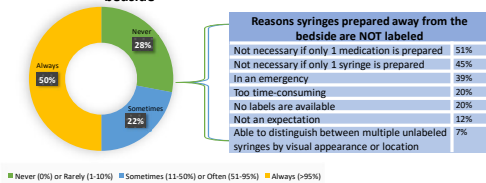
When describing this practice, most participants did **NOT** include relabeling of the flush syringe

2018 IV Push Practice Survey Results

### FINDINGS: UNSAFE PRACTICE 4

#### UNLABELED SYRINGES

Frequency of labeling syringes that are self-prepared away from the patient's bedside



2018 IV Push Practice Survey Results

### FINDINGS: UNSAFE PRACTICE 4

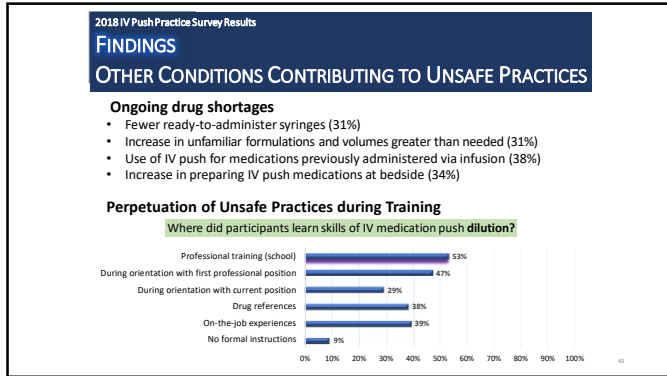
#### LABELING OF SYRINGES

Those who do **NOT** always label syringes self-prepared away from the bedside reported ways to distinguish between multiple syringes:

- 76% - different volumes in the syringes
- 40% - different sizes of syringes
- 36% - differences in needles, caps, or medication colors
- 16% - orientation on a tray or sterile field
- 12% - carrying syringes in different hands
- 12% - carrying syringes in different pockets

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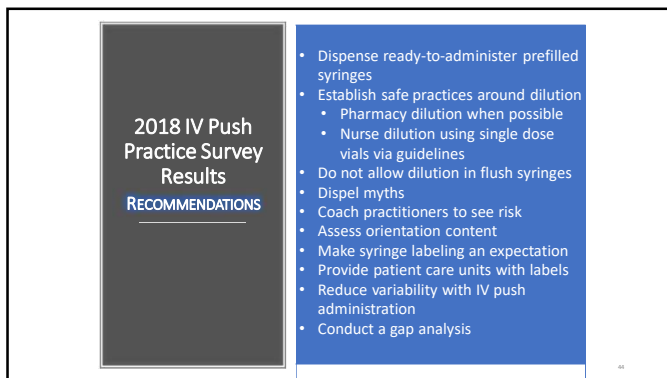
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### Gap Analysis Tool

New				
ACQUISITION AND DISTRIBUTION OF ADULT IV PUSH MEDICATIONS				
	A	B	C	D
1. The facility purchases <b>READY-TO-ADMINISTER</b> injectable medications for <b>IV PUSH</b> use when they are available.				
2. Adult <b>IV PUSH</b> medications are dispensed in a <b>READY-TO-ADMINISTER</b> form to minimize the need for manipulation and protect the integrity of the <b>PHARMACY STERILE COMPOUNDING AREA</b> .				
3. Only commercially-available or pharmacy-prepared, prefilled syringes of an appropriate IV solution are used to <b>FLUSH</b> and <b>LOCK VASCULAR ACCESS DEVICES (VADs)</b> .				

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### Questions??

Judy Smetzer, BSN, RN, FISM  
Vice President  
Institute for Safe Medication Practices  
January 24, 2019



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Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon), FASHP  
President, ISMP




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# MSOS Member Briefing

## January 2019

### Questions?



- A copy of today's slides will be posted on our website
- Don't forget to mark you calendar:
  - Our next MSOS Briefings webinar will be held on March 28, 2019.

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from Novartis.



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