

Diving for Medication Safety Pearls in an Ocean of Opportunities

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Objectives

- Describe three examples of interventions that have improved safety or quality of patient care in health-systems
- List steps for implementation of at least one safety improvement program
- Explain how to apply three strategies for preventing patient harm



Outline

Session 1

- Refrigerator Medication Management
- <USP 800>
- Interdisciplinary PI Collaboration
- Management Promotion of Safety
- High Reliability Concepts

Session 2

- Auditing Smart Infusion Pumps
- Immediate Use CSPs
- Acetaminophen Overdose
- Novel Oral Anticoagulants
- Septic Shock

Brrr! It's Cold!
Network Barrier Analysis Impact on Refrigerator Medication Management

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Objectives

- Discuss how a barrier analysis can be utilized as an improvement method for the refrigerated medication management at a network level.
- Describe implemented best practices to enhance refrigerated medication management.
- Discuss lessons learned when utilizing a barrier analysis to improve a process from a network perspective to ensuring reduction in process variation.



Overview

Background

- Refrigerated temperature monitoring, and ensuring the cold chain process is not broken, is a complex process.
- This process, observed in both the ambulatory and acute care settings, was reviewed by conducting a network barrier analysis.

Presentation

- Gaps discovered within refrigerator medication management
- Implemented best practice solutions
- Lessons learned when conducting a network focused barrier analysis



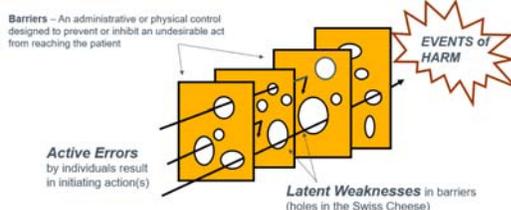
Problem Discovery

- Routine safety audit (conducted Fall 2017), discovered a concern at an ambulatory care site
- Medications and vaccines may have been exposed to temperatures outside the manufacturers' recommended range
- Findings led other sites to investigate discovering similar events may have occurred
- Determined that the extent of the situation potentially crossed the network, including both acute and ambulatory sites, which lead to a network-wide Barrier Analysis to be commissioned



Barrier Analysis

Barriers – An administrative or physical control designed to prevent or inhibit an undesirable act from reaching the patient



1. Examines threats/hazards to people who require protection related to missing or inadequate barriers.
2. Accidents or events can be traced to the failure of barriers and safeguards.
3. Analyses works well for cluster events or when there is difficulty building an accurate timeline.
4. The goal of a Barrier Analysis is identification of a Root Cause and Root Solutions.



Team Members

- Executive Sponsors
 - Representing Ambulatory and Acute Care
- RCA Analysts
 - Network Medication Safety Director
 - Network Patient Safety Director
- Stakeholder group

Facilities	Acute Care
MedCheck	Cancer Centers
Information Technology	Worksite Care Clinic
Community Physician Practices	Community Care Clinic



Identified Process Variations

Root Cause Statement: Temperature monitoring process variation led to lack of understanding of scope of responsibilities and accountability

- Equipment
 - Cooling units: Medical grade vs Consumer grade
 - Temperature monitoring: Manual vs Digital Data Logger
 - Standardized process, including responsibilities, regarding ordering, preparation, and set up
- Profiles
 - Temperature profiles: Nearly 100 different identified
 - Alert profiles: Person/Role alerted, escalation process
 - Defined responsibilities and standardized monitoring workflows
- Preventative maintenance
 - Monthly reports: appropriate personal receiving, understanding importance, deploying corrective action
 - Equipment (Cooling unit and temperature monitoring) routine maintenance
- Excursion response
 - Standardize response to excursions
- Education
 - Ability to understand monthly reports and system program



Work Groups

After stakeholder group identified barriers (i.e. safe guards), these were bundled to become the following work groups

Preparation Response
Alert Profiles
Inventory/Asset Management
Policy/Procedure
Excursion Response



Identified Process Variations

	Identified Process Variations	Workgroup Assigned
Equipment	Cooling units	Inventory/Asset Management
	Temperature monitoring	Inventory/Asset Management
	Standardize process	Inventory/Asset Management
Profiles	Temperature	Alert Profiles
	Alerts	Alert Profiles
	Standardized monitoring workflow	Inventory/Asset Management
Preventative Maintenance	Monthly reports	Inventory/Asset Management
	Routine maintenance	Inventory/Asset Management
Excursion Response	Standardize excursions response	Excursion Response
Education	Process understanding	Policy/Procedure



Lessons Learned	
Challenges	Resolution
Front line staff serving as first time leaders	<ul style="list-style-type: none"> • Know the skills of team members when selecting workgroup facilitators • Ensuring all tools provided <ul style="list-style-type: none"> • Creating WebEx meetings • Guidance to shift thinking towards strategic instead of task oriented • Providing groups checklist of tasks • Periodic workgroup facilitator meetings
Duplicative work	<ul style="list-style-type: none"> • Facilitator was assigned to each group • Providing groups checklist of tasks
Information required from other groups to proceed	<ul style="list-style-type: none"> • Facilitator was assigned to each group • Periodic workgroup facilitator meetings
Representation from all health care settings	<ul style="list-style-type: none"> • Workgroups included staff outside of the original stakeholder group as content experts were identified from Acute and Ambulatory care settings • Executive Sponsors established from both settings
Quickly implement approved solutions	<ul style="list-style-type: none"> • Don't let perfect get in the way of good! • Prioritize tasks and deploy once approved; Waiting may result in becoming stagnant • Define progress/completed work

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**The Hazards with <USP 800>:
 Updates on Implementation**

Monica Macik, PharmD, BCPS, BCOP



Learning Objectives

- 1) Discuss the structure of an effective institution specific USP <800> implementation team
- 2) Discuss tactics to justify the cost of IV room updates, additional personal protective equipment (PPE), etc.
- 3) Review approaches to updating, creating, or writing policies for USP <800>
- 4) List effective education methods for nursing, pharmacy, physician staff on implementation of USP <800>
- 5) List effective education methods for patient notification and education regarding changes related to USP <800>



Background

- Created to identify requirements of hazardous drug (HD) handling to protect:
 - Patient
 - Healthcare workers
 - Environment
- USP <800> affects each step of Medication Use Process



EVS = Environmental Services



United States Pharmacopoeia, USP General Chapter <800> Hazardous Drugs—Handling in the Healthcare Settings, 2017.

Implementation Team



Cost Justification

- Ensure Senior Leadership is on board with implementation plan
 - USP <800> regulations are mandatory
- Obtain budget approvals for any necessary capital (i.e. IV room remodeling) well in advance
- Consolidate PPE vendors to potentially obtain discounted rates with increased volume



Policy Approaches

USP <800> Master Policy

- Once source of truth with all pertinent attachments

USP <800> Policy Index

- Table of contents with sub-policies & standard operating procedures (SOPs)
- Example: Pharmacy Preparation & Dispensing Policy
- Example: Spill Response Policy



Staff Education

Physicians

- High level overview handout
- Education at monthly meetings

Pharmacy

- Education at monthly staff meetings
- Detailed overview policy changes
- SOP reviews

Nursing

- Education at monthly staff meetings
- Detailed overview policy changes
- PPE overview with drug administration



Patient Education

- Provide education handout to patients at USP <800> go-live
- Handout components
 - Explanation why nurses wearing various PPE
 - Describe how medication is "hazardous" to the nurse, but it safe for the patient to take
 - Explain how patient or caregivers should handle hazardous medications



The Hazards with <USP 800>: Updates on Implementation

Monica Macik, PharmD, BCPS, BCOP



Collaborative Model for Process Improvements

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Objectives

- Describe various health care collaborative models that can be used for process improvement
- Understand different team member roles within patient care and how they may be utilized during process improvement initiatives
- Describe a method to utilize when deciding which members/health care disciplines should be key stakeholders in a workgroup

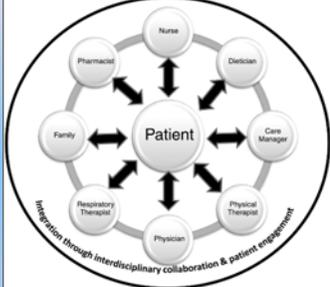


Collaborative Models

- Numerous collaborative models exist
- Many are specific to only one discipline
- Many models are created for non-healthcare settings yet lend themselves to be utilized fully in improvements
- Goal is to utilize a model that is adaptable to your setting, facility



**The Menefee Model:
Patient-Centered, Interdisciplinary
Team-Based Health Care**



Menefee Model(MM)

- Belief that evidence based plans of care without interdisciplinary team collaboration & patient engagement, are ineffective tools for patient care.
- Model relies on the presence of plans of care that are used to coordinate interventions that are based on goals & needs of patient



The Value of Creating a Culture of Interdisciplinary Collaboration between Nursing & Pharmacy

- Pharmacy on every unit creates visibility & creates an awareness of the value of each team member
- Improved communication
- Enhanced communication allows greater understanding of care and interventions to enhance quality of care delivered
- Reduction of harm
- Improves care as a process rather than individuals
- Collaboration creates a sense of team work & engagement
- Assist in the improvements in provider orders



Specific Examples

We have found interdisciplinary collaboration to be crucial in initiatives related to:

- Adverse drug events-hypoglycemia; naloxone utilization; VTE prevention(Coumadin)
- Falls
- Medication Safety-Reviewing practice with potassium; heparin; oxytocin & high alert meds; Independent double check education
- Pump Library development & interoperability



Naloxone Improvement

- Reduction as a network with naloxone utilization
- Deep dive into medications intraoperatively & in PACU that can impact post operative sedation. Collaborative education(Pharmacy & CNS)
- Reviewed handoff communication between intra-op and PACU and PACU to Acute care
- Better understanding of non-opioid medications being used that can potentiate sedation
- Reduction in hypoglycemic events
- Reduction in INR elevations
- Insight into med



Hypoglycemia Improvements

- Work with Certified Diabetic Educators & pharmacy & unit staff to look at events from each building
- Order set improvements related to DKA
- Review of events related to insulin utilization for Hyperkalemia—order set developed & education



Medication Safety

- Nursing engagement at the network medication safety level, including bedside, operations, & CNS's
- Medication Safety Committee's in each building allowing interaction & dialogue between pharmacy and bedside nursing staff- has assisted in improved methods to reduce diversion; waste of controlled substances; port less tubing's; and lock boxes



Independent Double Checks— Network Improvement

- Assessed as a need after several events with high dose opioids and insulin infusions
- Process already hardwired for Chemotherapy
- Different than dual signature and a dependent double check
- ISMP recommendations followed
- Selected high risk agents will include oxytocin, high dose opioids, insulin, heparin, OB magnesium, etc.
- Collaborating with network nursing education to develop interactive learning to allow this process and cultural change to occur



Strategies to Enhance Interdisciplinary Collaboration

- Review each project as a process
- Determine key stakeholders that could impact the information needed to improve
- Determine key stakeholders in the process— who is direct in the process & who is an indirect influence to the process
- When in doubt just ask, dialogue & communicate----



Lessons Learned with Nursing Pharmacy Collaboration

- Collegial relationships exist on units
- Engagement with shared governance at the unit & building levels
- Engagement with shared governance has resulted in spread in improvements across the network



"The ability for a group of people to do remarkable things hinges on how well those people can pull together as a team."
Simon Sinek

Collaborative Model for Process Improvements
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Management promotion of patient safety, communication openness, and event reporting in hospital pharmacy

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* At the time of this study, Maryam Noureldin was a PGY2 Ambulatory Care Pharmacist at IU Health.

Introduction

- The Hospital Survey on Patient Safety Culture (H-SOPS)
 - used by institutions to evaluate current patient safety culture¹
- Contains 12 domains, including communication openness, management support, and teamwork.¹



Ahrq.gov

Previous literature/gap

- Pharmacists who report high levels of communication openness at their institution were more likely to report medical errors that occur.²
- There is limited research evaluating other patient safety culture domains and what factors might influence frequency of error reporting.



Objectives

Examine the relationship between:

1. hospital pharmacists' perception of management's promotion of patient safety and their perception of communication openness
2. hospital pharmacists' perception of management's promotion of patient safety and frequency of event reporting



Methods

- Hospital pharmacist data from the 2016 AHRQ H-SOPS
 - De-identified data obtained via a data-use agreement
- Study variables:
 - Management promotion of patient safety: 4 item composite score
 - Communication Openness: 3 item composite score
 - Frequency of Events Reporting: errors that could harm the patient but did not



Data analysis

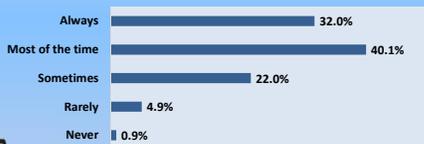
- Composite scores were calculated based on item percent positive responses. **Higher score represent more positive perceptions.**¹
- Descriptive statistics and mixed linear and logistic regression modeling
 - accounted for presence of multiple pharmacists within the same hospital
- Control variables
 - hospital and pharmacist characteristics.
- STATA 15.0 (College Station, TX)



Results

- A total 7,671 pharmacists responded to the 2016 H-SOPS, representing 1.9% of all respondents.

When a mistake is made that could harm the patient, but does not, how often is this reported? (N=7,419)



Results

Supervisor/Manager Expectations & Actions to Promote Patient Safety My supervisor/manager...	% positive responses
Says a good word when a job is done according to established patient safety procedures	74.2%
Seriously considers staff suggestions for improving patient safety	79.1%
Wants us to work faster even if we take shortcuts (negatively worded)	78.5%
Overlooks patient safety problems that happen over and over (negatively worded)	78.5%
Mean composite score (N=7,238)	77.6 ± 31.3
Communication Openness In our hospital work unit, staff	% positive responses
Freely speak up if they see something that may negatively affect patient care	74.3%
Feel free to question the decisions or actions of those with more authority	52.3%
Are afraid to ask questions when something does not seem right (negatively worded)	70.4%
Mean composite score (N=7,315)	65.7 ± 37.0

Multivariate Regression

Multivariate Linear Regression-Communication openness		
Variable	Coefficient (Std Error)	95% CI
Management promotion of patient safety	0.62 (0.01)	0.60, 0.65

Multivariate Logistic Regression-Error Reporting Frequency		
Variable	Crude OR (95% CI)	Adjusted OR (95% CI)
Management promotion of patient safety	1.51 (1.43, 1.58)	1.49 (1.41, 1.57)

Control variables include pharmacist characteristics (patient interaction, average weekly hours worked, number of years worked), and hospital characteristics (bed size, type of hospital, and geographic region)
Std Error= Standard Error, OR= Odd's Ratio, CI= Confidence Interval

Discussion

- Hospital pharmacists nationwide
 - favorable view of their managers' actions to promote patient safety
 - felt comfortable communicating issues impacting patient care
- **Positive perceptions of managers' actions toward patient safety were associated with**
 - higher communication openness scores
 - increased likelihood of error reporting frequency



Conclusion/Implications

- Only 1/3 indicated that errors that could harm the patient are always reported
- Management plays essential role in facilitating a work culture focused on open communication and patient safety



References

1. Sorra J, Gray L, Stregale S, et al. AHRQ Hospital Survey on Patient Safety Culture: User's Guide. (Prepared by Westat, under Contract No. HHS290201300003C). AHRQ Publication No. 15-0049-EF (Replaces 04-0041). Rockville, MD: Agency for Healthcare Research and Quality. January 2016. <http://www.ahrq.gov/professionals/quality-patientsafety/patientsafetyculture/hospital/index.html>
2. Patterson ME, Pace HA, Finchman JE. Associated Between Communication Climate and the Frequency of Medical Error Reporting Among Pharmacists Within an Inpatient Setting. J Patient Saf 2013; 9: 129-133.



Thank you!

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Management promotion of patient safety, communication openness, and event reporting in hospital pharmacy

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Using High Reliability Concepts to Develop Actions that Promote Consistency & Reliability

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Christian Hospital 2017 Statistics

Employees: 1864
Registered Nurses: 444
Physicians: 541
Allied Health: 102

Staffed Beds: 220
Admissions: 12,142
ED Visits: 106,301

Surgical Procedures: 6379
Cath Lab Procedures: 2225



Metrics Measured for HRO

SEMS reporting volume
(Safety Event Management System)

- % Near Miss reporting*
- % Harm Event reporting*
- SEMS reporting: % close in 30 days

* Using National Coordinating Council for Medication Error and Prevention Index



Investigation looks like -----

- Talk to staff involved (delegate to Supervisor)
- Chart Review
 - Consider a Timeline
- Equipment involved
 - If yes, was it sequestered?
 - Were all parts saved.. ie tubing, bag and IV pump?
 - Check for Serial Numbers etc in SEMS report
- Process / Equipment / Person issue
 - Just Culture algorithm. What happened? What should happen? What normally happens? Why did it happen?
- Timely: Investigation occurs close to time of event
- Involved people: ie physician/employee concern: please enter the name so Medical Staff Office can track

Follow-up looks like.....

- Results of Investigation: Answers to Just Culture:
 - What should happen?
 - Why did it happen?
- Action Plan: What strategies should you put into place to prevent reoccurrence?
 - Strength of intervention
- Status of patient
 - Final actual Harm Score Recommendations

Closing Loop:

- Follow-up with employee who reported concern in your area
- Recognize Great Catches
- Share in weekly huddles (good and possible negative outcomes from near misses)

SEAT: Serious Event Action Team

- Monthly
 - Physicians, Leadership, Risk, & Executives
 - Prepped in advance
 - Strength of Intervention focus
 - Action items brought back for Follow-up

Remember the goal!

The SEAT process offers us the opportunity for collaboration to increase situational awareness, better assess risk, and promote a safer environment for our patients, visitors, and co-workers.

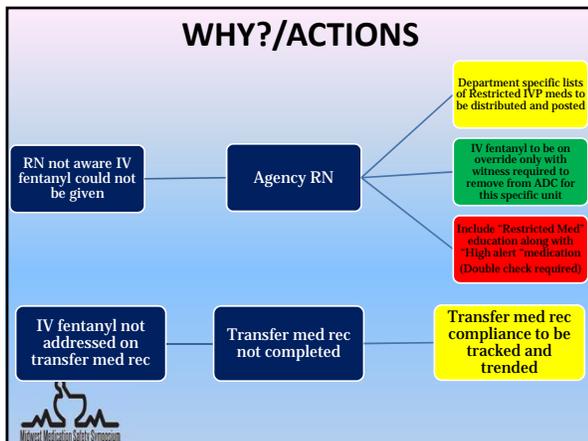


Strength of Intervention		
Description	Example	NCPs Hierarchy of Actions <small>National Center for Patient Safety</small>
Forcing Functions	Create a "hard stop" in a process	Strong <ul style="list-style-type: none"> Not dependent on staff to remember to do the right thing Strong controls
Automation and computerization	Use processes and tasks to limit reliance on memory	
Standardization	Create a uniform model to adhere to	Intermediate <ul style="list-style-type: none"> Somewhat dependent on staff remembering to do the right thing Provide tools to remember or promote clear communication
Redundancies	Incorporate duplicate steps or force additional checks in	
Reminders and Checklists	Make important information readily available	
Rules and Policies	Provide guidance toward an intended outcome	Weak <ul style="list-style-type: none"> Dependent on staff remembering training or what is written in the policy
Education and Information	Providing training	

What Happened?

- Patient had order for Fentanyl IV 50 mcg from a transfer med rec
- Medication was administered to patient
- Specific Unit cannot push IV Fentanyl
- No double check performed

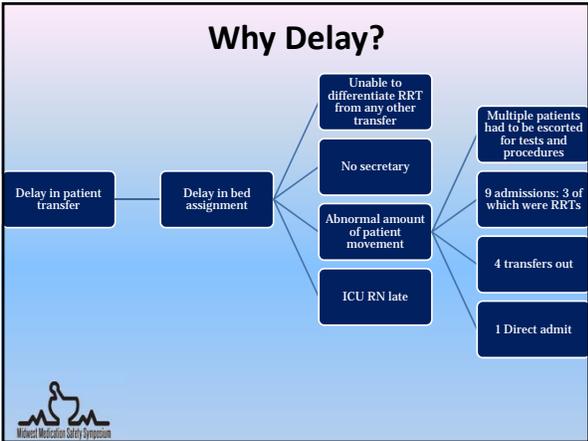


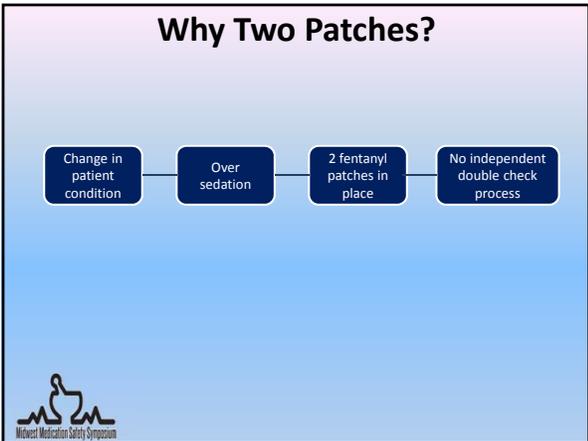


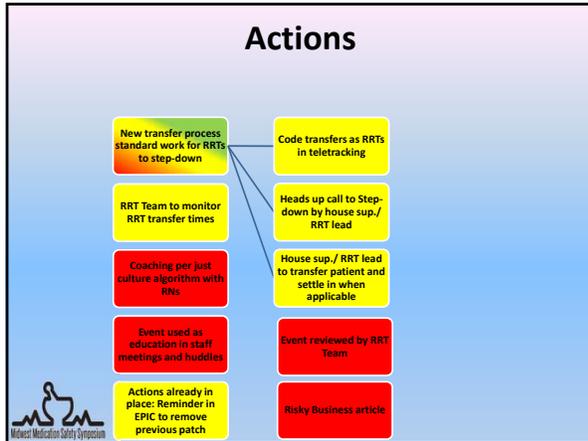
What Happened?

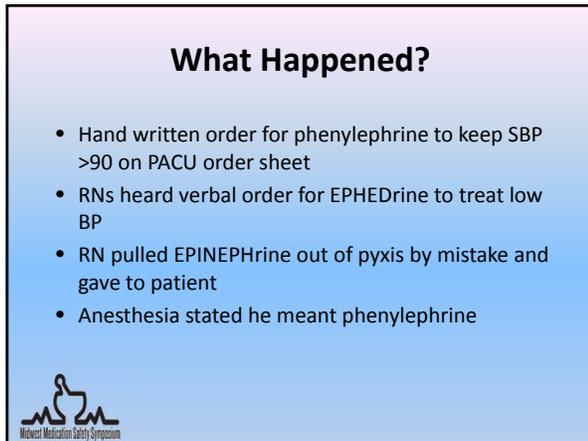
- Rapid Response Team was called for patient
- Upon assessment 2 fentanyl patches were in place
- Patient was ordered to be moved to Stepdown for closer monitoring at 1150.
- The bed was assigned at 1410.
- The patient needing a higher level of care remained on floor for 2 hours and 20 minutes.
- Patient improved and stayed on floor.

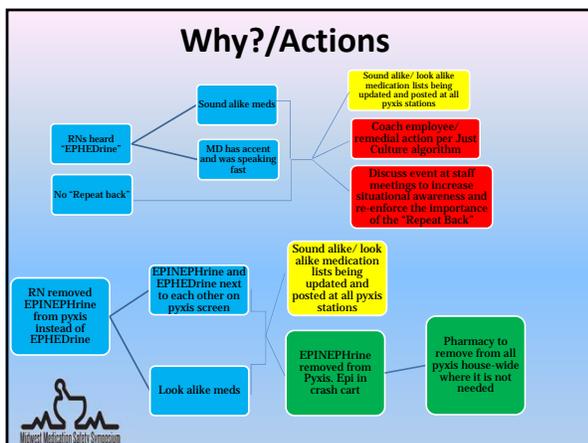


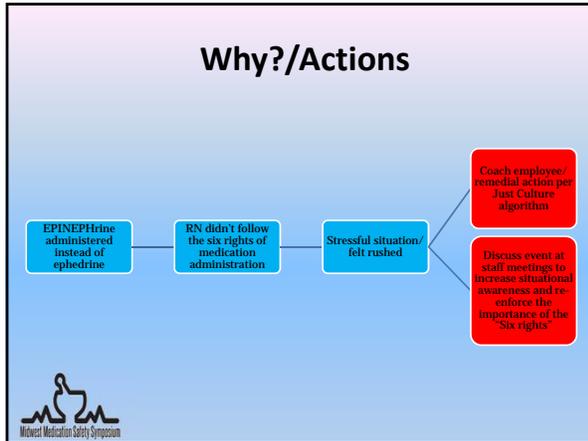












Accountability Tracker

SEAT Date	Action Item	Strength of Intervention	Owner	Goal Date	Status/ Findings	Completed Prior To Seat	Date Completed
1/18/18	Random daily audits on radiology rounding	Yellow	Crystal	1/18/18	x	Yes	1/18/18
1/18/18	Coaching	Red	Crystal	x	x		1/18/18
1/18/18	Transporters to assist with checking on patients in holding rooms	Red	Drew/Kelly Walter	1/18/18	x	Yes	1/18/18
2/15/18	Patient profile fixed to reflect correct medications	Green	Karen Scott	2/15/18	x	yes	2/15/18
2/15/18	Medication fixed in Epic to not offer incorrect substitution	Green	Karen Scott	2/15/18	x	yes	2/15/18
2/15/18	Bulk Med no longer available as an option in Epic	Green	Willow Team	2/15/18	x	yes	2/15/18

Midwest Medication Safety Symposium

Risk Management/ Patient Safety Newsletter Volume 1

Risky Business

What's trending in SEMS?

...

- There were 5551 SEMS reports submitted last year.
- Highest reported general event type was treatment and care.
- Highest reported specific event type was hypoglycemia followed by hyperglycemia.
- The glycemic control team has been working diligently to help us improve and keep our patients safe.

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Safety is....

- A culture and a lifestyle
- A leadership quality
- A priority
- Accountability
- Developing situational awareness
- Patient/employee/leadership responsibility
- The platform that supports all necessary efforts to become a highly reliable organization.



Safety is NOT....

- Telling someone to be more careful
- Telling someone to try harder
- Placing blame on others
- Assigning a new project
- Explaining that our patients are “sicker”
- Just a clinical or hospital problem.



**Responding to a Near Miss today
can prevent tomorrow’s
Serious Event.....**

Thank You/Questions?

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**Using High Reliability Concepts
to Develop Actions that
Promote Consistency &
Reliability**

Karen Scott RPh, MBA
Christian Hospital
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Q & A

Refrigerator Medication Management
<USP 800>
Interdisciplinary PI Collaboration
Management Promotion of Safety
High Reliability Concepts



Break



**Information Overload:
Auditing the Clinical Utility of Smart
Pump Reporting Tools**

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Midwest Medication Safety Symposium

Purpose

- Assessment of smart pump reporting tools available at Froedtert Hospital
- Development of a CQI process for optimal utilization of smart pump reporting tools



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Interoperability Scope

- Interoperability does not capture:
 - Medications administered in procedural areas
 - Operating room
 - Emergency department
 - Interventional radiology
 - Out-of-scope medications
 - Blood products
 - Penicillin G
 - Selected chemotherapeutic agents



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Definitions

- **Interoperability:** two-way interface between smart pumps and electronic health record (EHR)



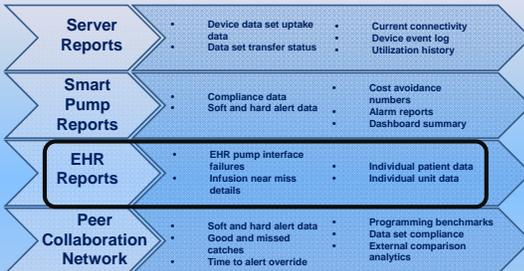
- **“Near miss”** related to interoperability: differences in medication, dose, rate, concentration, or patient weight



Carefusion. Alaris™ System with Guardrails™ Suite MX User Manual. Cardinal Health, Dec. 2016.

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Figure 1. Comparison of Select Features from Smart Pump Analytics Reporting Tools Available at Froedtert Hospital



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Study Primary Outcomes

- Identify top 10 medications implicated in smart pump near miss events
- Reduce number of near miss events related to smart pump programming



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Figure 2. Continuous Quality Improvement Process for Smart Pump Reporting Tools

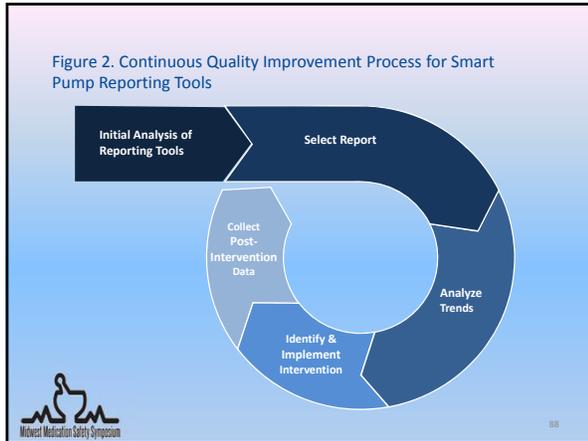
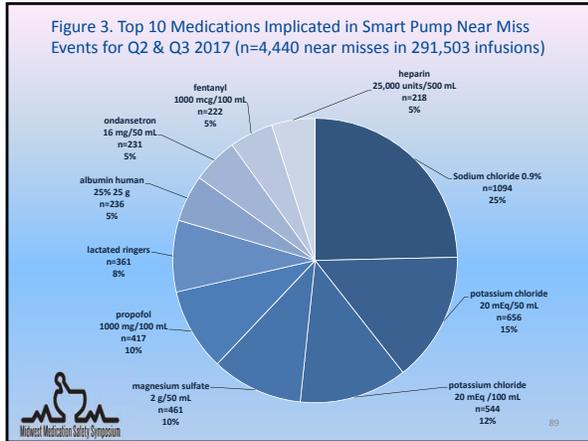


Figure 3. Top 10 Medications Implicated in Smart Pump Near Miss Events for Q2 & Q3 2017 (n=4,440 near misses in 291,503 infusions)



Example Near Misses

Pump [ID]	Order [ID]	Admin Date/Time	Overdose?	Pump	Near Misses
HH14560404 LVP FH [14560404]	propofol (DIPROFAN) 1000 mg/100mL, 1000 mg/100 mL infusion [210833483]	01/04/2018 2202	No	Med No value from pump	MAR PROPOFOL 1000 MG/100ML IV EMUL
HH13916823 LVP FH [13916823]	lactated ringers bag [213063331]	01/30/2018 1519	No	Med No value from pump	MAR LACTATED RINGERS 1000 ML BAG
HH14879274 LVP FH [14879274]	magnesium sulfate in water prefilled bag 2 g 50 mL [211622013]	01/14/2018 0640	Yes	Rate 45 mL/hr	MAR 50 mL/hr
HH13924660 LVP FH [13924660]	ondansetron (ZOFTRAN) 16 mg in dextrose 5 % 50 mL bag [212246687]	01/21/2018 1218	Yes	Rate 240 mL/hr	MAR 200 mL/hr

Determining Intervention

- Risk matrix
- Modified Delphi approach



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Risk Matrix



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Intervention

- Adjusted propofol order sets to promote ordering of bolus from the bag
- Paired propofol order panel with nursing order for sedation vacation to increase ordering from panel



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Future Directions

- Collect and evaluate post-intervention results
- Repeat CQI process using smart pump-specific reports
- Biannual reporting to Medication Safety and Pharmacy Quality Committees



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Conclusions

- Evaluation of interoperability reports demonstrates technology is working well
- Interoperability reports are useful for workflow and patient-specific information
- Out-of-scope medications and areas not on interoperability were not captured



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Acknowledgements

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- Kristin Hanson, BSPHarm, MS
- Philip Brummond, PharmD, MS



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**Immediate-Use Compounded Sterile
Preparations: Ensuring Institutional
Compliance with USP <797>**

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Clinical Pharmacy Specialist – Adult Critical Care



USP <797>: Sterile Compounding

Purpose: Ensure preparation of quality products free from contaminants and are consistent in intended identity, strength and potency for patient use

- Outlines responsibilities of personnel, training, facilities, environmental monitoring, and storage and testing of finished compounded preparations
- All Compounded Sterile Preparation (CSPs) must comply with the standards of practice defined by The United States Pharmacopeia (USP) Chapter 797
- Noncompliance risks patient safety, regulatory repercussion, and reimbursement



CMS State Operations Manual – Appendix A
Sterile Compounding <797>. Available at www.cms.gov

Compounding vs. Immediate-Use CSP

Compounding

Reconstitution or manipulation of a commercial product that may or may not require addition of one or more ingredient

- Irrigation solutions
- IV admixtures
- Removal of a dose from a multi-dose vial
- Transfer of a product from a vial to a syringe

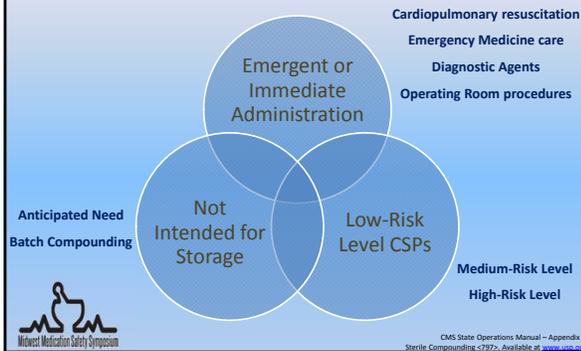
Immediate-Use CSP

Compounded medications needed for immediate or emergency use for a particular patient and are not to be stored for anticipated needs



CMS State Operations Manual – Appendix A
Sterile Compounding (C97) Available at www.cms.gov

Immediate-Use CSPs



CMS State Operations Manual – Appendix A
Sterile Compounding (C97) Available at www.cms.gov

Requirements for Immediate-Use CSP

Products must meet *all* criteria to be considered safe:

- #1 • Contain 3 or less ingredients
- #2 • Administration begins within 1 hour of preparation
- #3 • Under continuous supervision by the person who prepared it, until it is administered
- #4 • If not continuously supervised, then it is appropriately labeled



APPROPRIATE FOR USE

CMS State Operations Manual – Appendix A
Sterile Compounding (C97) Available at www.cms.gov

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NOT APPROPRIATE FOR USE



CMS State Operations Manual – Appendix A
Sterile Compounding (C72) – Available at: www.cms.gov

Labeling Requirements

All Medications	Immediate-Use CSPs
<input type="checkbox"/> Medication name, strength, and amount/quantity	<input type="checkbox"/> Patient identification information
<input type="checkbox"/> Diluent name and volume	<input type="checkbox"/> Names and amounts of all ingredients
<input type="checkbox"/> Expiration date/time* <small>*Except for short procedures</small>	<input type="checkbox"/> Initials of person who prepared it
	<input type="checkbox"/> Exact 1-hour expiration date/time



CMS State Operations Manual – Appendix A

Evaluation of Current Practices

Review Practices for All Care Areas

- Emergency Department
- Operating Room
- Interventional Radiology
- Specialty Clinics
- Radiology
- Cardiac Diagnostics

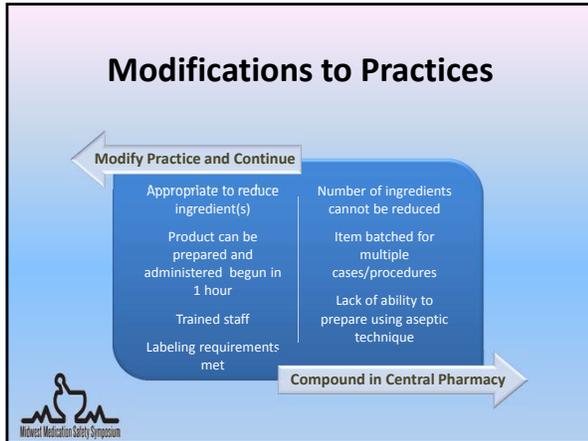
Competency and Training

- Aseptic technique
- Safe handling and proper labeling

Workflow

- Evaluate timing of product administration related to procedure
- Consider urgency of product administration





- ### Key Takeaways
- Consider if workflow will allow for preparation under sterile procedures by Central Pharmacy
 - Limit compounding practices to situations that are emergent or require immediate administration
 - Label all prepared medications appropriately
 - Use aseptic technique
 - Ensure yearly competencies of compounding practices where Immediate-Use CSPs are administered
 - Evaluate new preparations as they are introduced to practice, procedures, and care areas
- 

Immediate-Use Compounded Sterile Preparations: Ensuring Institutional Compliance with USP <797>

Andrew C. Fritschle, PharmD, BCPS, BCCCP
Clinical Pharmacy Specialist – Adult Critical Care



3+3+2= Danger!
Simplifying treatment of acetaminophen overdose

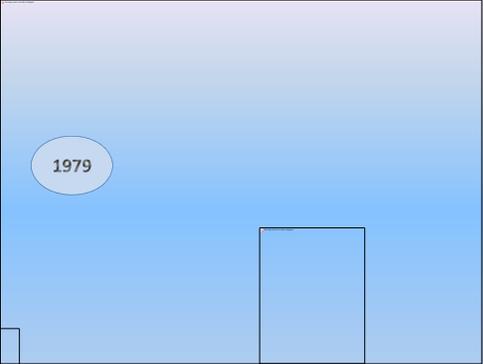
Paul E. Milligan, Pharm D
System Medication Safety
Pharmacist
BJC HealthCare- St. Louis, MO



Acetaminophen OD Is Prevalent



Dated Protocol?



1979

Complex to Prepare and Administer

Amplified Risk Points

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

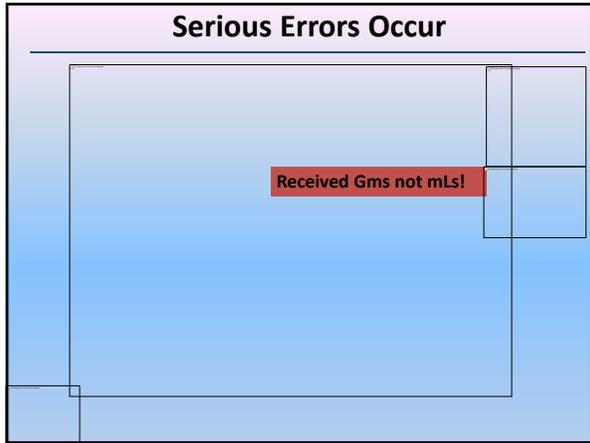
Midwest Medication Safety Symposium

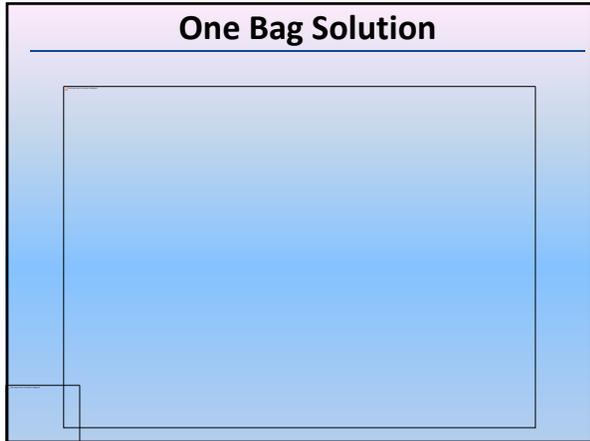
NAC is Dangerous

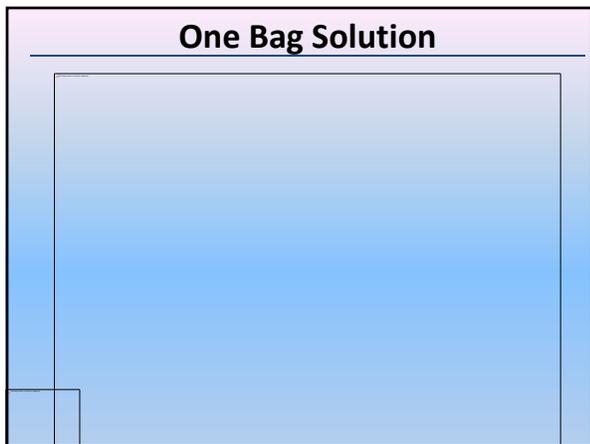
Midwest Medication Safety Symposium

Errors Occur

Midwest Medication Safety Symposium







BJC One Bag Protocol: Used Since 2008

- 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

Prescott Protocol- 3 Bags

Prescott LF, et al. Br Med J 1979 Nov 3;2(158):1097-100.

BJC Protocol: One Bag Solution

Summary



References

<p>Acknowledgement: Slides were adapted from presentation by Michael E. Mullins MD FACEP FAACT Medical Toxicologist Associate Professor</p>	<p>Division of Emergency Medicine Washington University School of Medicine St. Louis, Missouri mullinsm@wustl.edu</p>
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3+3+2= Danger!
*Simplifying treatment of
acetaminophen overdose*

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BJC HealthCare- St. Louis, MO



Small Interventions with an Epic Impact

Karishma Deodhar, PharmD, BCPS
Eskenazi Health
September 13, 2018





- Use only oral unit-dose products, prefilled syringes, or premixed infusion bags
- Use approved protocols for the initiation and maintenance of anticoagulant therapy.
- Assess the patient's baseline coagulation status
- Use authoritative resources to manage potential food and drug interactions.
- Use programmable pumps in order to provide consistent and accurate dosing.
- A written policy addresses baseline and ongoing laboratory tests that are required for anticoagulants.
- Provide education regarding anticoagulant therapy to prescribers, staff, patients, and families
- Evaluate anticoagulation safety practices, take action to improve practices, and measure the effectiveness of those actions



Identify Problem Areas

- Gather information from prescribers, nurses, students, or patients
- Review Institute for Safe Medication Practices (ISMP) Quarterly Agenda Items
- How is institution addressing NPSGs?
- Look for patterns in medication errors



Medication Error Categorization

<u>Type of Error</u>	<u>Follow Up</u>
<ul style="list-style-type: none">• Prescribing• Dosing or Monitoring• Dispensing• Administration	<ul style="list-style-type: none">• Individual education• Group education• Protocol or process change• CPOE safety check

Dosing and Monitoring of Direct Oral Anticoagulants

- Specific to indication
- Affected by renal function
- Dependent on when therapy started
- BPAs are subject to alert fatigue or warnings being overridden



TEST



TEST



A slide with a light blue gradient background. The word "TEST" is centered at the top in a white box. A red rectangular box highlights a small area on the right side of the slide. The logo for the Medwest Medication Safety Symposium is in the bottom left corner.

TEST

- Test
- Test
- Test



A slide with a light blue gradient background. The word "TEST" is centered at the top in a white box. A red rectangular box highlights a small area at the top left. Below the title is a bulleted list of three "Test" items. A red rectangular box highlights a small area at the bottom. The logo for the Medwest Medication Safety Symposium is in the bottom left corner.

Future Directions

- Dosing guidance during order entry phase
- Minimize daily checkoffs
- Using reports to identify issues
- Communication of warfarin regimens between inpatient and outpatient providers



A slide with a light blue gradient background. The title "Future Directions" is centered at the top. Below it is a bulleted list of four items. The logo for the Medwest Medication Safety Symposium is in the bottom left corner.

Barriers

- Alert fatigue
- Too much information on screen
- Learning curve for Epic users and analysts



Small Interventions with an Epic Impact

Karishma Deodhar, PharmD, BCPS
Eskenazi Health
September 13, 2018



The SHOCKing Truth About Novel Therapies for Treatment of Sepsis

Allison N. Boyd, PharmD
Clinical Pharmacy Specialist – Trauma/Burn
Rhode Island Hospital



Finding the Right Balance

MANAGING SHOCK

Midwest Medication Safety Symposium

Finding the Right Balance

ANG II

MANAGING SHOCK

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Finding the Right Balance

Vit C
Hydrocortisone
Thiamine

ANG II

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Finding the Right Balance

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Finding the Right Balance

MANAGING SHOCK

Pop Quiz!

1. Which vasopressor is more expensive?
 Norepinephrine
 Vasopressin
2. Who has added angiotensin II to formulary?
3. Who has adopted the vitamin C protocol?
4. Do you know the dosing units for angiotensin II?

MANAGING SHOCK

Cost Information: Vitamin C

- Dose: 1500 mg IVPB Q6hrs x 4 days (or until ICU discharge if sooner)
- Preparation: 1.5 gm/100 mL
- Cost per vial: \$82.89/vial (25 gm/50 mL)
 - Expiration: 4 hours once opened; 24 hours in IVPB
 - One vial could provide 16 doses, but due to stability restrictions is limited to 4 doses
- Cost per treatment course: **\$331.56***

*Does not include cost of thiamine/hydrocortisone



Cost Information: Vasopressors

Drug	Normal Concentration	Average Cost	Maximum Concentration	Average Cost
Norepinephrine	8 mg/250 mL	\$27.48	16 mg/500 mL	\$54.96
Vasopressin	40 units/100 mL	\$17.86	--	--
Angiotensin II	2.5 mg/500 mL	\$1500	5 mg/500 mL	\$3000



Storage Issues

Issue	Vitamin C	Angiotensin II
Refrigeration required?	Yes	Yes
Stability/Expiration	4 hours room temp 24 hours once compounded	24 hours once compounded at room temp or refrigerated
Vial sizes	25 gm/50 mL	2.5 mg/mL
Vials needed to compound	1 vial per day (up to 4 days)	1-2 vials per infusion bag (duration varies)



Vitamin C Protocol Order Set

High dose ascorbic acid (for treatment of sepsis)
Panel for high dose
<input checked="" type="checkbox"/> ascorbic acid (VITAMIN C) 1,500 mg in sodium chloride 100 mL IVPB 1,500 mg, intravenous, at 206 mL/hr, Administer over 30 minutes, every 6 hours standard Protect from light
<input checked="" type="checkbox"/> thiamine (B-1) 200 mg in dextrose 5% (D5W) 100 mL IVPB 200 mg, intravenous, at 200 mL/hr, Administer over 30 minutes, every 12 hours standard
<input checked="" type="checkbox"/> hydrocortisone sodium succinate (Solu-CORTEF) infection recon soln 50 mg 50 mg, intravenous, every 6 hours standard Reconstitute the diluent included in the product by pushing the cap down. Concentration of mixed product equals 50 mg/mL



Angiotensin II Dosing



<http://giapreza.com/Resources.pdf>

Angiotensin II Product Label



<http://giapreza.com/Resources.pdf>

Angiotensin II Concentrations



Criteria for use?



<http://giapreza.com/Resources.pdf>

Angiotensin II Alaris® Guardrails Behind the Scenes

	Wildcard: mg/mL
Dosing units	ng/kg/min
Soft min	1.25
Soft max	40
Hard max	80
Additional information	No initial value No bolus Central line advisory

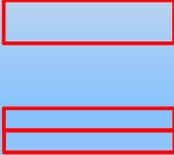


Adverse Effects of Vitamin C

- Osmotic diuresis**
 - Can lead to acute kidney injury and/or hypovolemia
- Oxalate nephropathy**
 - Due to calcium oxalate accumulation (metabolite)
 - Can worsen kidney injury or delay kidney recovery
- False elevation in POC glucose testing**
 - Lab draws required for all glucose measurements while on vitamin C therapy



Adverse Effects of Angiotensin II



<http://gianreza.com/Resources.pdf>

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Q & A

Auditing Smart Infusion Pumps
Immediate Use CSPs
Acetaminophen Overdose
Novel Oral Anticoagulants
Septic Shock



**Diving for Medication Safety Pearls
in an Ocean of Opportunities**

Thank you to all of our presenters!