MSOS Member Briefings

December 2017

Moderated by: E. Robert Feroli, PharmD, FASHP

Supported by educational grants from Novartis and Fresenius Kabi

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U.S. FOOD & DRUG ADMINISTRATION

Drug Shortage Update

Captain Valerie Jensen, RPh

Associate Director of the Drug Shortage Staff

Center for Drug Evaluation and Research (CDER)

US Food and Drug Administration, Silver Springs, MD.

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Storage of High and Low Concentration Ketamine in the Emergency Department

Jimmy Hernandez, PharmD
Clinical Pharmacist – Emergency Medicine

Jennifer Matias, PharmD, BCPS, CPPS
Medication Safety Officer

Riverside University HEALTH SYSTEM

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Riverside University Health System

- Level II adult and pediatric trauma center
- 362 licensed beds
- 10 ambulatory clinics
- Academic teaching institution
  - RN, RT, PA, PharmD, MD/DO
- Post-graduate residency training programs in medicine and pharmacy
- ED Volume 250-275 patients per day with greater than 75% of patients receiving some sort of medication

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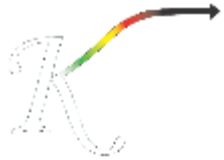

Ketamine Continuum

Dose Type & Use	Dose range	Characteristics
Analgesic dose	0.1 – 0.3 mg/kg	• Opioid sparing agent • Very minimal effect on emotion or mental perception
Recreational & Partial Dissociative Dose *(not used clinically)*	Greater than 0.3 mg/kg to less than 0.7 mg/kg	• Powerful analgesic • Euphoric "high" • Patient can go in and out of lucid consciousness; mixing the real with the unreal • "Bad trip"
Dissociative dose	Equal to or GREATER than 0.7 mg/kg	• Patient in trance-like state • Random and reflexive movements likely • Dissociated patients perceive no sights, sound or pain

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http://emupdates.com/2013/12/25/the-ketamine-brain-continuum/

Ketamine use in the ED

- Low concentration Ketamine **200 mg/20 mL** (conc: **10 mg/mL**)
  - Procedural sedation for painful procedures
  - Rapid sequence intubation for protection of airway
  - Analgesia as an opioid sparing agent
  - Refractory treatment of status asthmaticus
- HIGH concentration Ketamine **500 mg/5 mL** (conc: **100 mg/mL**)
  - Excited delirium syndrome
    - Lower volume required for IM administration

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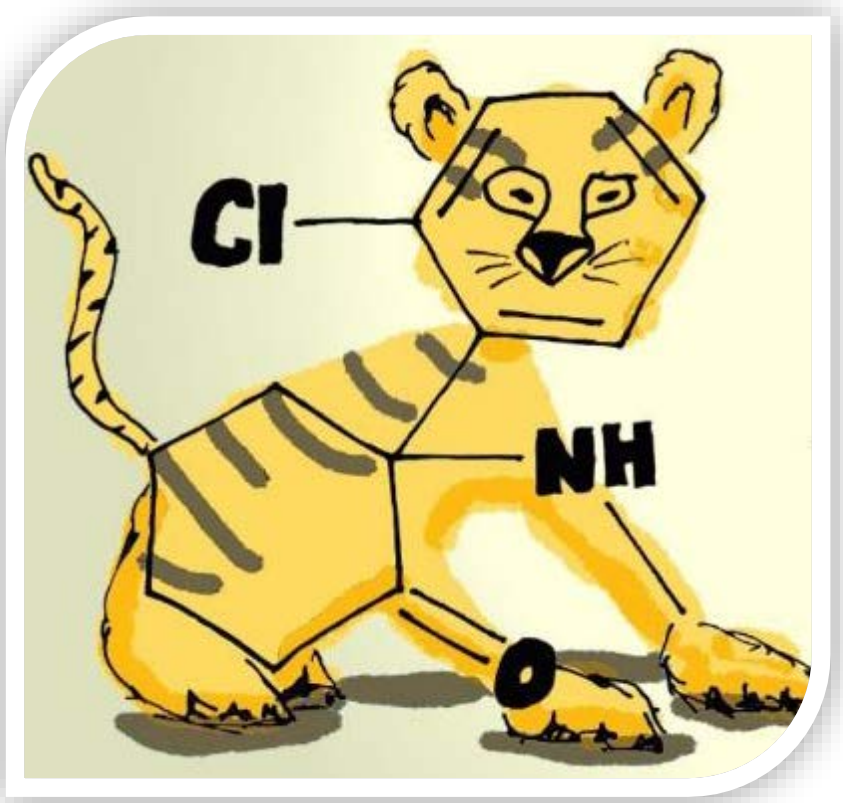
Ketamine Safety Concerns



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Confusion With Ketamine Concentration

- ISMP 2/8/2007 resulted in 10-fold error during GI procedure
- ISMP 7/11/2013 resulted in 10-fold error in ED
- Case in Vermont (2015) 5-fold error resulted in death

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Safe Use of Ketamine – A Layered Approach

- Prescribing
- Packaging
- Distribution
- Dispensing
- Administration
- Monitoring
- Education

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Safe Use of Ketamine – A Layered Approach

PRESCRIBING

- Pharmacy & Therapeutics (P&T) Approval
  - Multidisciplinary approach involving **Physician**, **Nursing**, **Pharmacy**, and **Risk Management** leadership
  - Clinical appropriateness and review of the literature conducted
  - Special emphasis placed on the **safety concerns** related to adding a different (higher) concentration of ketamine to the ADC
  - Prospective Pharmacist Review of medication orders ("Profiling") in the ED simultaneously approved

500 mg/ 5 mL
(conc: 100 mg/mL)

200 mg/20 mL
(conc: 10 mg/mL)

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Safe Use of Ketamine – A Layered Approach

PACKAGING

- Each HIGH concentration vial stored in its own **RED** 4 x 6 inch bag with a yellow sticker that reads:

"HIGH concentration ketamine
(100 mg/mL)
IM USE ONLY"

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DISTRIBUTION

- HIGH concentration (100 mg/mL) ketamine loaded in only **ONE** of the **FOUR** ADCs in the ED
- Par level = 3
- All medications are **scanned during refill** of the ADC

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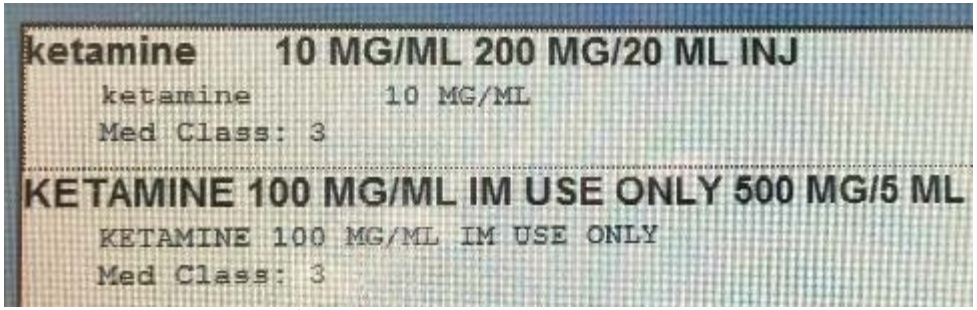
Safe Use of Ketamine – A Layered Approach

DISPENSING

- Made medication names appear **visually different** AND in a list order that makes sense

lower case

UPPER CASE



Number alignment

- Medications are **scanned upon removal**

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Safe Use of Ketamine – A Layered Approach

ADMINISTRATION

- Both patient and medications are scanned at bedside.
- Overall hospital BCMA scanning compliance GREATER than 95% for both medication AND patient wristband
  - BCMA Scanning Compliance in the ED 94%

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Safe Use of Ketamine – A Layered Approach

EDUCATION

- Once approved by P&T, Pharmacy Staff (technicians and pharmacists) educated on the outlined changes
- ED Physicians and ED Nurses informed through in-services that TWO concentrations of ketamine were going to be available in one ADC

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Safe Use of Ketamine – A Layered Approach

MONITORING

- Monitored workflow for 3 months to
  - …assess if nurses are pulling the wrong concentrations for a given patient
  - …assess if medication was being refilled properly
- Random spot checks

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Safe Use of Ketamine – VULNERABILITIES

- Drug return- If medication is not used, current workflow allows the nurse to return medication to ADC which opens up possibility of returning to wrong pocket.
- Process misunderstandings

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Safe Use of Ketamine – FUTURE OPPORTUNITIES

- ADC Alerts
- Use of Prefilled Ketamine Syringes

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Thank you for your time

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Elimination of Independent Double-Checks for Subcutaneous U-100 Insulin

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Stormont Vail Health, Topeka, KS

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Stormont Vail Health

- A 586-licensed bed acute care referral center in northeast Kansas
  - Trauma Center Level II
  - NICU Center level III
  - Part of the Mayo Clinic Care Network
  - American Nurses Credentialing Center Magnet Recognition
  - Stroke, MI and Total Joint Center Joint Commission accredited

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Is an Independent Double Check on Subcutaneous Insulin Justified?

- There is still insufficient scientific evidence to justify double checking medications.[1]
- Clinical trials are needed to evaluate whether double checking of the administration of medicines reduces medication errors.[1]
- With workload issues looming heavily over practitioners, independent double checks should only be used for very selective high-risk tasks or high-alert medications (not all) that most warrant their use.[2]
- Independent Double Checks are a poor substitute for system improvements that will actually help prevent errors.[2]

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Independent Double Checks

A procedure in which two individuals separately check (alone and apart from each other, then compare results) the accuracy of a process step.

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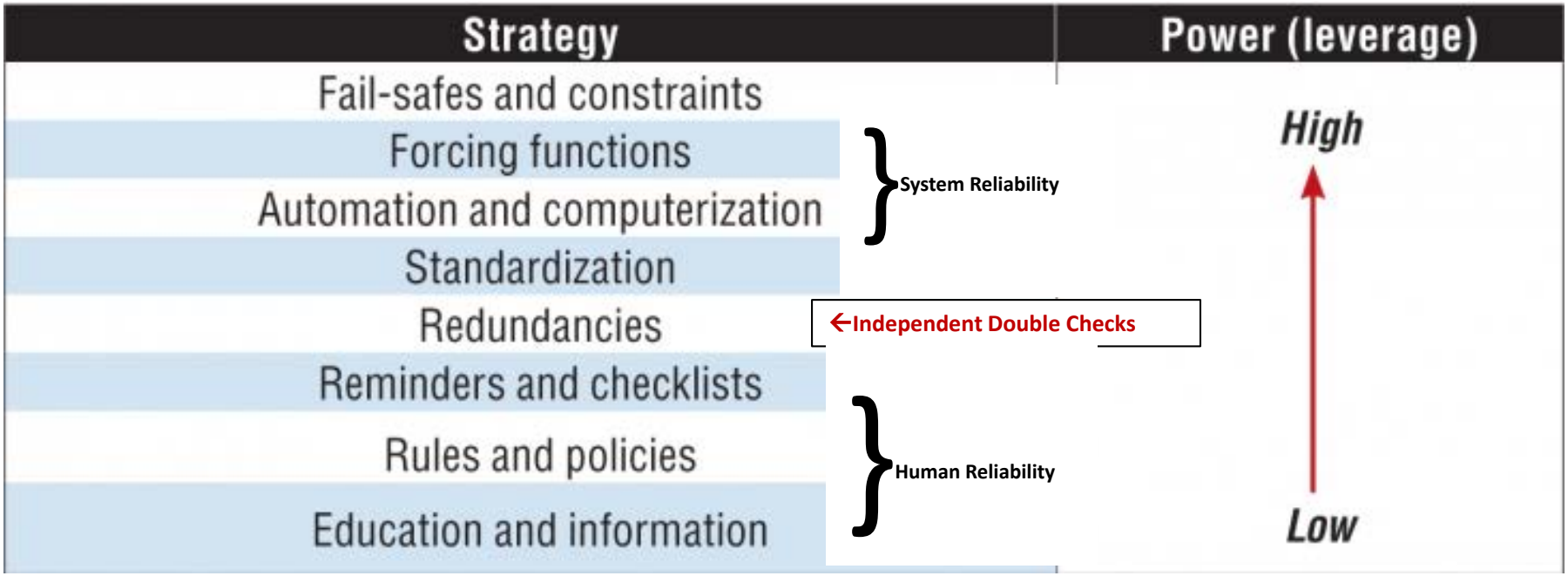
ISMP's Strategies to Prevent Medication Errors[3]



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Weaker Strategies to Prevent Medication Errors

Weaker Interventions	Example
Double Checks	One person calculates dosage and another person reviews their calculation.
Warnings	Add audible alarms or caution labels
New procedure/ Memorandum or Policy	Remember to check IV sites every 2 hours.
Training	Demonstrate the hard to use defibrillator with hidden door during in-service training.

RCA[2] Improving Root Cause Analyses and Actions to Prevent Harm[4]

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An Independent Double Check Should Typically be Reserved for[5]:

High Alert Medications (See ISMP for complete High Alert List)

- Chemotherapy
- Opioid infusions (including PCAs and epidurals)
- Anticoagulant Infusions
- Parenteral Nutrition
- Insulin Infusions

Complex Processes

- Compounded products (in particular products with multiple ingredients such as TPN).
- Tasks requiring calculations (titrated infusions dosed on patient weight (i.e. mcg/kg/min).

High risk populations

- Critical Care patients or patients on dialysis or with other poor organ function (heart failure, liver failure, etc.)
- Cancer patients (Chemotherapy)
- Neonatal/Pediatric patients
- Pregnant patients

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Consider Avoiding Independent Double Checks when[5]:

System improvements are more reliable and accurate than an IDC, and are used throughout the medication use process

- Barcode Scanning
- Technology to calculate dosage
  - Integrated smart pumps

The sheer volume of IDC's required will render the process ineffective

- SQ Insulin

The dose is manufactured/prepared in a ready to administer form

- Insulin pens vs. vials

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Study: Discontinuing Mandatory Double Verification of SQ Insulin to Improve Patient Safety and Nursing Satisfaction[6]

Patient Safety

- No change in glycemia profiles pre- and post- intervention.
- No increase in self-reported ADE pattern

Nursing Satisfaction

- Reduction in disruptions/interruptions
- More time with patients
- RN confidence in process (95% surveyed said no increased safety risk)

Cost Avoidance

- Waste reduction/workflow simplification

(incremental associated time for each IDC = 3 minutes)

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Stormont Vail Removal of Independent Double Checks (IDC's) for SQ Insulin (A3 Lean Project)

Cost Avoidance	Removal of IDC's for SQ insulin	Assumptions
Number of IDC's/year	97,530	
Minutes/per IDC	3 minutes	Incremental time associated with each independent double check[6]
Minutes saved/year	292,590	
Hours saved/year	4876.5 (2.7 FTE's*)	
Cost Avoidance	$137,900/year	Based on $28.00/hr average RN salary

*Includes Nonproductive Time

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References

1. Alsulami Z, Conroy S, Choonara I. Double checking the administration of medicines: what is the evidence? A systematic review Arch Dis Child 2012; 97: 833-837.
2. Independent double checks: undervalued and misused. ISMP NurseAdvise-ERR March 2014 Volume 12 Issue 3. Accessed at: http://www.ismp.org/newsletters/nursing/issues/NurseAdviseERR201403.pdf
3. Selecting the best error-prevention "Tools" for the Job, Community/Ambulatory Care ISMP Medication SafetyAlert! Newsletter, Published February 2006 and accessed at: https://www.ismp.org/newsletters/ambulatory/archives/200602_4.asp
4. RCA^2 Improving Root Cause Analyses and Actions to Prevent Harm. National Patient Safety Foundation. Accessed at: https://www.ashp.org/-/media/assets/policy-guidelines/docs/endorsed-documents-improving-root-cause-analyses-actions-prevent-harm.ashx?la=en
5. American Society of Health System Pharmacists: Medication Section Advisory Group: High Alert Medication Stratification Tool, Appendix A – Special Considerations for Independent Double Checks. See webinar attached PDF.
6. "Discontinuing Mandatory Double Verification of SQ Insulin to Improve Patient Safety and Nurse Satisfaction: An Evidence-Based Approach", Christopher Patty, DNP, RN, CPPS. Medication Safety Specialist at Kaweah Delta Medical Center in Visalia, California. Accessed at: https://www.northbay.org/upload/North-Bay-Insulin-Presentation-August-2015.pdf

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Questions?

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Changing Systems Based on Medication Error Reports

Rosemary Duncan, PharmD, BCPS
Medication Safety Officer, Adults
The Johns Hopkins Hospital
Baltimore, MD

MSOS Member Briefing Webinar: December 14, 2017

Root Cause Analysis

Should "…*result in the identification and implementation of sustainable systems-based improvement that make patient care safer…*"

RCA^2 Improving Root Cause Analyses and Actions to Prevent Harm.
National Patient Safety Foundation. Version 2. January 2016.

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… we cannot change the human condition, we can change the conditions under which humans work.

– James Reason

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Action	Action Category	Example
Stronger Actions	▪ Forcing functions	Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing/fittings that can only be connected the correct way
Intermediate Actions	▪ Software enhancements; modifications	Use computer alerts for drug-drug interactions
Weaker Actions	▪ New procedure/policy	Remember to check IV sites every 2 hours

RCA^2 Improving Root Cause Analyses and Actions to Prevent Harm. National Patient Safety Foundation. Version 2. January 2016.

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Hopkins Event Reporting Online (HERO)

- Voluntary event reporting system
- Events routed to “managers” for investigation
  - Med safety officers investigate med-related events
  - Focus on system, not on people

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Hopkins Event Reporting Online (HERO)

- "Significant" events reviewed at patient/med safety committees
  - **All** errors are significant
  - Event reports are often incomplete and/or inaccurate
  - Severity level may be used to prioritize review
  - Quality of review not quantity

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Medication Safety Meetings at Johns Hopkins Hospital

- Multidisciplinary
  - Weekly Hopkins Event Action Team
  - Weekly Significant Med Event Committee (SME)
  - Twice monthly Peds Med Safety Committee (PMSC)
  - Monthly Medication Event Reduction Improvement Team (MERIT)

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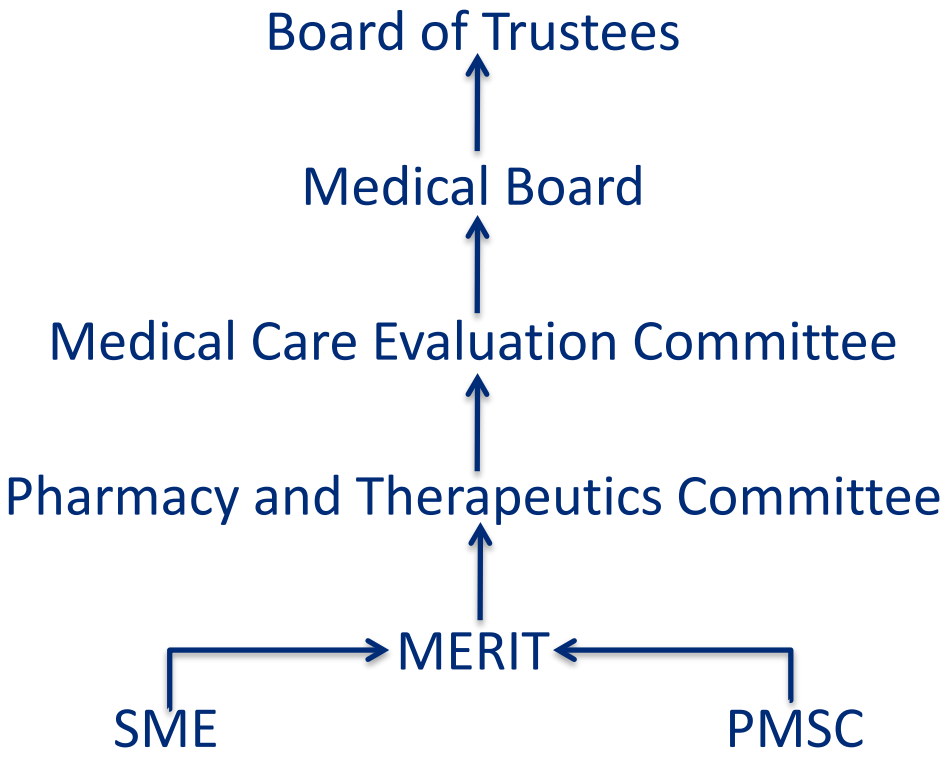
Medication Safety Meetings at Johns Hopkins Hospital



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Medication-Use System Change Report

- System Changes
  - Must be **implemented**
  - Does NOT depend on human memory
  - Can logically be argued to decrease the likelihood of patient harm
- Education (e.g., lectures, newsletters) important but **NOT** considered a system change

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System Change Report Principles

- Assume audience may not know the details of the medication-use system
  - Avoid jargon/editorials/subjectivity
  - Describe event clearly and succinctly
  - Describe system fix so that it is clear it will address the described problem

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THE JOHNS HOPKINS HOSPITAL MERIT COMMITTEE
MONTHLY REPORT OF SYSTEMS CHANGES

Date	Area	Event	System Change	Process Step	Strength of System Change
June-17	All Depts		Administration instructions stating "Can ONLY be administered by an authorized prescriber" were added to the botox medication record.	Administration	Weak
June-17	All Depts		Dispense-Prep scanning is now being used in the Ambulatory and Care Transitions (ACT), Adult Inpatient (AIP), Critical Care and Surgery (CCS), Pediatrics, and Weinberg Oncology Pharmacies for all products dispensed from these pharmacies.	Preparing/Dispensing	Intermediate
June-17	Pediatrics		An Exit Site Care section which includes gentamicin 0.1% cream and mupirocin 2% cream options was added to the pediatric PD order sets to facilitate appropriate ordering of exit site care.	Prescribing	Intermediate
June-17	Pediatrics		The pediatric pharmacy has historically repackaged ranitidine oral syrup into standardized prefilled doses, and it appears the initial build of these oral syringes in Epic was leading to barcoding issues for nurses thus new labels and custom barcodes were created and associated with the mg amount instead of volume of the dose. This update to the labels removed the inappropriate MAR dose warning.	Administration	Intermediate
June-17	All Depts		Upon investigating this error, discovered that tall man lettering is not reflected in the nomenclature in the outpatient medication browse. All outpatient medication records associated with clonazePAM and cloBAZam were updated to include tall man lettering as recommended by ISMP.	Prescribing	Weak
June-17	Pediatrics		The darbepoetin medication record was updated to allow for lower doses to be prescribed without standardizing i.e. any weight based dose less than 22 mcg will not standardize automatically to the nearest prefilled syringe.	Prescribing	Intermediate
July-17	Pediatrics		Update to Epic browse search to remove acetaminophen-containing medication records that had a synonym of that included the word "aspirin."	Prescribing	High
July-17	Pediatrics		Updates were made to the PICC placement order set requiring prescribers to select heparin flush orders.	Prescribing	High
July-17	Adults		A hard stop maximum dose limit of 3,001 mg was added to all adult vancomycin records. Doses greater than 3,000 mg cannot be ordered in adults. A similar hardstop exists in pediatrics for vancomycin. The maximum allowed dose for pediatrics is 2,000 mg.	Prescribing	High
July-17	All Depts		The dual-sign function was added to all IV push insulin records.	Administration	Weak

System Change Report

- Presented monthly to MERIT monthly and quarterly to Patient Safety Committee
  - Director of Patient Safety
  - Health IT Safety Officer for JHHS
  - VP Medical Affairs

System Change Report

- Promotes multidisciplinary collaboration
- Increases transparency / event sharing
- Strengthens support for dedicated medication safety resources
- *Safety lives in system changes*

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ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Update

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

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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 is on Thursday, February 22, 2018, 1-2pm EDT.

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