MSOS Member Briefing
September 2020

Moderated by: E. Robert Feroli, PharmD, FASHP

MSOS
MEDICATION SAFETY OFFICERS SOCIETY

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Nonsterile Compounding Medication Event

CASEY MOORE, PHARMD
MEDICATION SAFETY PHARMACIST- PEDIATRICS
CLEVELAND CLINIC

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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 2021)*

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Event Timeline

Day 0	• Prescription dispensed to index patient using tacrolimus 0.5 mg/mL compounded suspension
+ 2 weeks	• Index patient tacrolimus level < 2.0 (trough goal 5-7 ng/mL) • Index patient/caregiver returned tacrolimus 0.5 mg/mL suspension dispensed for testing
+ 5 weeks	• Index patient specific tacrolimus 0.5 mg/mL bottle resulted in 32% (0.16 mg/mL) potency
+ 6 weeks	• Medication Safety Director notified and reported in safety event reporting system

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Immediate Actions

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Event Timeline

- Compiled a list of patients dispensed tacrolimus 0.5 mg/mL suspension from outpatient pharmacy batch in question
- 24 patients identified

- Meetings conducted with legal, pharmacy, clinical risk, quality, corporate communications, and providers
- Previous tacrolimus 0.5 mg/mL batches in stock and new compounded batches from inpatient and outpatient pharmacy were sent for testing

- Patients contacted by providers
- New medication was sent via carrier from outpatient pharmacy to all patients
- Patients were instructed to have tacrolimus trough levels drawn within week

All compounded batches sent for testing during this time period had a potency between 101%-103%

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Root Cause Analysis

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Root Causes and Contributing Factors

Root Cause	Contributing Factor
Medication Preparing /Distributing	The process used to compound the tacrolimus oral suspension was considered sufficient but a better process exists per Professional Compounding Centers of America (PCCA)
Medication Labeling	**A "shake well" sticker was not applied to the large stock bottle after it was compounded, so was likely not shaken upon dispensing patient specific doses**
Providing Patient Education	Patient education not sufficiently specified for the medication in the outpatient pharmacy setting
Inadequate Policies and Procedures	Lack of quality assurance (QA) process for nonsterile compounded product(s) so pharmacy was unaware that compounded product had low potency prior to dispensing
Human Factors: Staffing Skill Mix	Lack of knowledge by staff present on how to send out medication for testing
Communication Amongst Caregivers	Escalation of the issue did not occur, preventing quicker intervention by providers through additional lab tests
Communication Amongst Caregivers	No process for providers to check with pharmacy about product when patient's levels come back sub or supratherapeutic
Medication Formulary	Compounded tacrolimus oral suspension has been known to have varying potencies even when prepared appropriately

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Corrective Action Plan

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Corrective Action Plan

Overview
Update compounding processes to align with best practices per USP 795 and standardize to all areas where nonsterile compounding occurs
Apply "shake well" auxiliary labelling on stock bottles and compounding worksheets as well as signage in storage areas; Consider using agitators or other equipment to standardize shaking bulk bottles prior to filling patient-specific doses
Implement prompts at point-of-sale with each fill to counsel patient on the need to shake product very well prior to every dose administration
Create and implement QA processes to align with best practices per USP 795
Expand training and implement competency assessment on nonsterile QA compounding processes
Reinforce the importance of escalating medication safety issues and using error reporting system so that the medication safety team, providers, and clinical risk can be aware and involved as needed
Develop a process for improving communication among providers and pharmacy staff regarding suspected issues with a medication dispensed from the outpatient pharmacy
Encourage transition from compounded suspension to capsules

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Promoting a Reporting and Learning Culture

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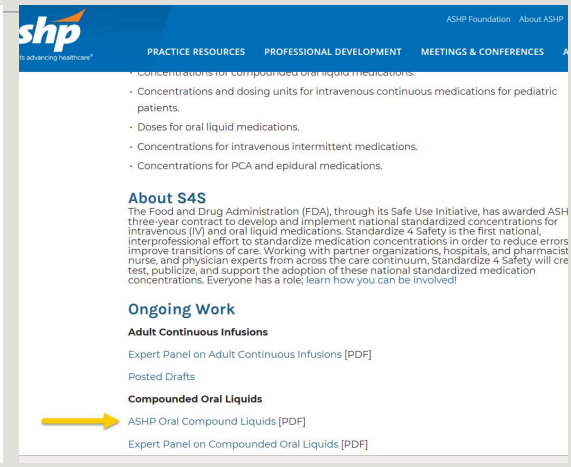
ASHP Recommendations



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Concentration Change

0.5 mg/mL to 1 mg/mL

- ✓ 1 mg/mL concentration provides a straight forward dose to volume ratio for patient and caregivers when drawing up medications
- ✓ Patient education will be simpler with the 1 mg/mL concentration and communication with patients and caregivers over the phone regarding dose changes will be safer
- ✓ Regionally and nationally inpatient and outpatient pharmacies are being urged to standardize to one concentration, 1 mg/mL, for safety as patients frequently transfer care between institutions and/or pharmacies
- ✓ Beyond Use dating is longer with 1 mg/mL recipe (132 days verses 56 days)

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Failure Mode Lessons Learned

- ✓ Use signage and labeling to reinforce shaking compounded suspensions prior to dispensing
- ✓ Prescribe manufactured liquids or tablets/capsules when possible

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Secondary Lessons Learned

- ✓ Standardization of non-sterile compounding and quality assurance processes is vital
- ✓ When a medication event is suspected or occurred, immediately report through internal system and escalate as needed
- ✓ Increase awareness of second victims throughout process while also focusing on patient needs

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Questions?

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System Change Reports

Eileen Kasda, DrPH, MHS
Assistant Director, Patient Safety Analytics

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Redonda Miller
President of The Johns Hopkins Hospital

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"Throughout my career at Johns Hopkins, I have served in many roles, including Vice Chair for Clinical Operations, Vice President for Medical Affairs, and since July 2016, as President of The Johns Hopkins Hospital. In each of these roles, one of my areas of responsibility has been patient safety. Consequently, I have had the opportunity over many years to work closely with our Medication Safety Officers (MSOs). With this collaboration, **I have always been impressed by their specialized understanding of the medication-use system and the many medication-related error mechanisms encountered in our complex hospital environment. Their ability to use this knowledge to implement system changes across many disciplines has led to improved patient safety throughout our institution.** While it is not possible to calculate the savings associated with their efforts, I have no doubt that our MSOs are a cost effective and valuable asset, and without them, our ongoing patient safety efforts would be at a disadvantage."

(ISMP White Paper: Case for Medication Safety Officers)

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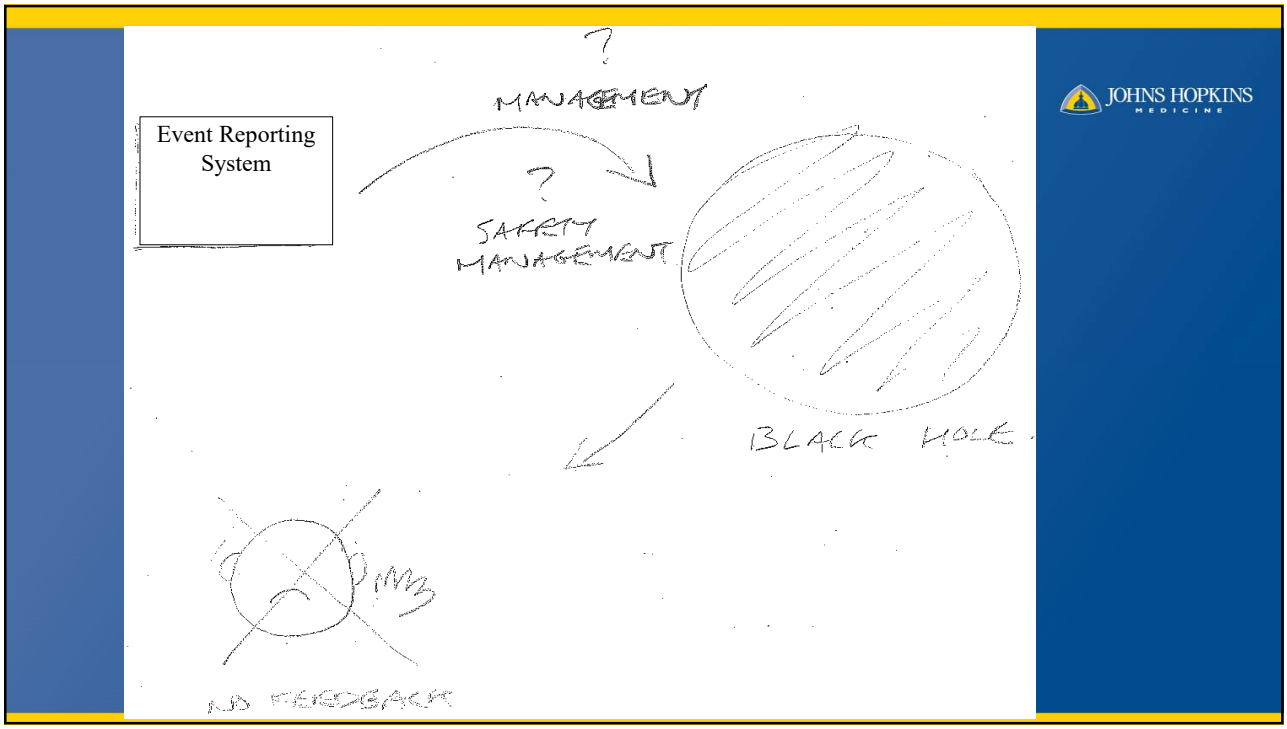

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Why Have a System Change Report

- Debunk the black hole myth with frontline staff
- Learning from HROs, provide transparency into improvement efforts is part of an important enabling infrastructure
- Systems are flawed and constantly changing
- Identifying and correcting system flaws is an ongoing effort
- Tool to educate senior leadership about your efforts

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The Signal

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Bi-monthly "newsletter" designed to:

- Dispel the event reporting "black hole" myth by sharing deep dives and quality improvement project successes
- Support a learning environment across the health system by sharing systems changes and lessons learned that historically only lived in local infrastructures

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Collection and Dissemination

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- Sent to CUSP facilitators and HERO reporting leads across the health system via e-mail
- Posted on event reporting website, accessible to all HERO reviewing managers

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Editorial Board

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- Eileen Kasda
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- Cathy Keech *(Suburban)*
- Julie Lewis *(JHCP)*
- Marcy Post *(HCGH)*
- Susan Shermock *(HCGH)*
- Kathleen Pressimone *(JH Bayview)*

Responsibilities:
- Facilitate request, collection, and review submission of system changes
- Develop content and dissemination guidelines
- Share and disseminate within our distribution guidelines

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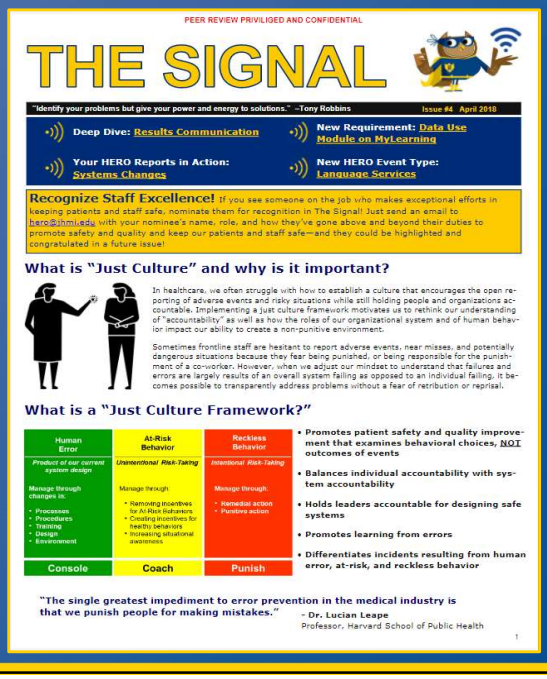
Issue #1: March 2017
- Deep dive on workplace violence
- Top HERO indicators
- Intro to the non-rate based preventable harm council

Issue #2: August 2017
- Deep dive on equipment and devices
- NRBPH retreat summary
- Systems change reports

Issue #3: January 2018
- Deep dive on Ambulatory Lab Specimens
- Recap of Patient Safety Summit and acknowledgement of Safety Stars
- RISE Team information
- Systems change reports


PEER REVIEW PRIVILIGED AND CONFIDENTIAL

THE SIGNAL

"Identify your problems but give your power and energy to solutions." –Tony Robbins — Issue #4 April 2018

Deep Dive: Results Communication

New Requirement: Data Use Module on MyLearning

Your HERO Reports in Action: Systems Changes

New HERO Event Type: Language Services

Recognize Staff Excellence! If you see someone on the job who makes exceptional efforts in keeping patients and staff safe, nominate them for recognition in The Signal! Just send an email to hero@jhmi.edu with your nominee's name, role, and how they've gone above and beyond their duties to promote safety and quality and keep our patients and staff safe—and they could be highlighted and congratulated in a future issue!

What is "Just Culture" and why is it important?

In healthcare, we often struggle with how to establish a culture that encourages the open reporting of adverse events and risky situations while still holding people and organizations accountable. Implementing a just culture framework motivates us to rethink our understanding of "accountability" as well as how the roles of our organizational system and of human behavior impact our ability to create a non-punitive environment.

Sometimes frontline staff are hesitant to report adverse events, near misses, and potentially dangerous situations because they fear being punished, or being responsible for the punishment of a co-worker. However, when we adjust our mindset to understand that failures and errors are largely results of an overall system failing as opposed to an individual failing, it becomes possible to transparently address problems without a fear of retribution or reprisal.

What is a "Just Culture Framework?"

Human Error	At-Risk Behavior	Reckless Behavior
Product of our current system design	Unintentional Risk-Taking	Intentional Risk-Taking
Manage through changes in: • Processes • Procedures • Training • Design • Environment	Manage through: • Removing incentives for At-Risk Behaviors • Creating incentives for healthy behaviors • Increasing situational awareness	Manage through: • Remedial action • Punitive action
Console	Coach	Punish

- Promotes patient safety and quality improvement that examines behavioral choices, NOT outcomes of events
- Balances individual accountability with system accountability
- Holds leaders accountable for designing safe systems
- Promotes learning from errors
- Differentiates incidents resulting from human error, at-risk, and reckless behavior

"The single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes." – Dr. Lucian Leape, Professor, Harvard School of Public Health

Issue #4: April 2018
- Overview of Just Culture
- Deep dive on Results Communication
- New HERO event type
- Patient Safety Week video contest winners
- Systems change reports

Issue #5: June 2018
- Just Culture: Part 2
- Deep dive on Transport Events
- How To: Use the Learning from Defects tool
- Systems change reports

Issue #6: August 2018
- What's a Sentinel Event?
- Deep dive on Handoff Events
- Leadership Academy scholars
- IPFCC 8th International Conference
- Systems change reports

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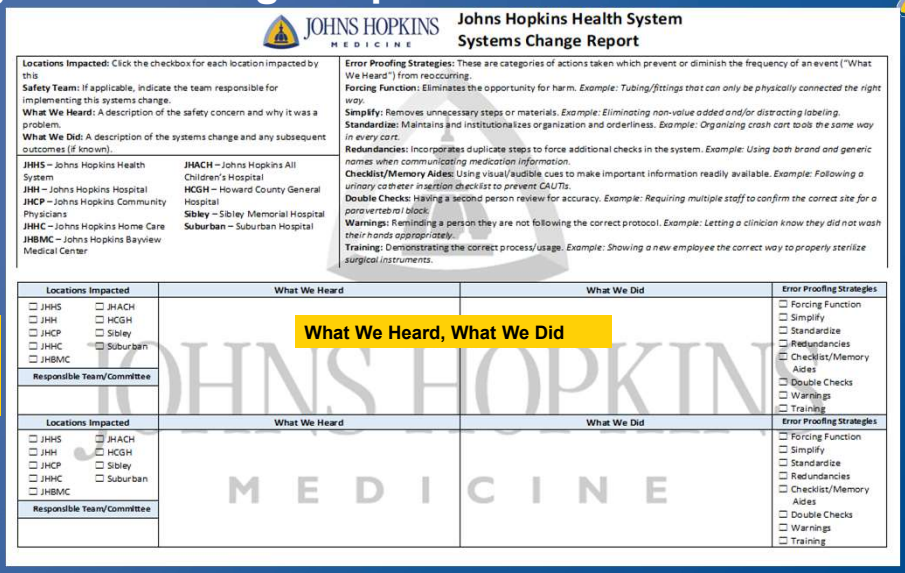
Systems Change Reports



Johns Hopkins Health System
Systems Change Report

Locations Impacted: Click the checkbox for each location impacted by this
Safety Team: If applicable, indicate the team responsible for implementing this systems change.
What We Heard: A description of the safety concern and why it was a problem.
What We Did: A description of the systems change and any subsequent outcomes (if known).

JHHS – Johns Hopkins Health System
JHH – Johns Hopkins Hospital
JHCP – Johns Hopkins Community Physicians
JHHC – Johns Hopkins Home Care
JHBMC – Johns Hopkins Bayview Medical Center
JHACH – Johns Hopkins All Children's Hospital
HCGH – Howard County General Hospital
Sibley – Sibley Memorial Hospital
Suburban – Suburban Hospital

Error Proofing Strategies: These are categories of actions taken which prevent or diminish the frequency of an event ("What We Heard") from reoccurring.
Forcing Function: Eliminates the opportunity for harm. *Example: Tubing/fittings that can only be physically connected the right way.*
Simplify: Removes unnecessary steps or materials. *Example: Eliminating non-value added and/or distracting labeling.*
Standardize: Maintains and institutionalizes organization and orderliness. *Example: Organizing crash cart tools the same way in every cart.*
Redundancies: Incorporates duplicate steps to force additional checks in the system. *Example: Using both brand and generic names when communicating medication information.*
Checklist/Memory Aides: Using visual/audible cues to make important information readily available. *Example: Following a urinary catheter insertion checklist to prevent CAUTIs.*
Double Checks: Having a second person review for accuracy. *Example: Requiring multiple staff to confirm the correct site for a paravertebral block.*
Warnings: Reminding a person they are not following the correct protocol. *Example: Letting a clinician know they did not wash their hands appropriately.*
Training: Demonstrating the correct process/usage. *Example: Showing a new employee the correct way to properly sterilize surgical instruments.*

Locations Impacted	What We Heard	What We Did	Error Proofing Strategies
☐ JHHS ☐ JHACH ☐ JHH ☐ HCGH ☐ JHCP ☐ Sibley ☐ JHHC ☐ Suburban ☐ JHBMC			☐ Forcing Function ☐ Simplify ☐ Standardize ☐ Redundancies ☐ Checklist/Memory Aides ☐ Double Checks ☐ Warnings ☐ Training
Responsible Team/Committee			
Locations Impacted	**What We Heard**	**What We Did**	**Error Proofing Strategies**
☐ JHHS ☐ JHACH ☐ JHH ☐ HCGH ☐ JHCP ☐ Sibley ☐ JHHC ☐ Suburban ☐ JHBMC			☐ Forcing Function ☐ Simplify ☐ Standardize ☐ Redundancies ☐ Checklist/Memory Aides ☐ Double Checks ☐ Warnings ☐ Training
Responsible Team/Committee			

Location(s) Impacted and Responsible Teams

What We Heard, What We Did

Error Proofing Strategies
- Forcing Function
- Simplify
- Standardization
- Redundancies
- Checklist/memory aids
- Double checks
- Warnings
- Training

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Sample System Change

What We Heard

A patient unintentionally received two doses of insulin glargine 25 units in a 3 hour time period. Insulin glargine nightly was ordered at 1800 and an Include Now dose was selected. This occurred because the "Duplicate Dose Interval" time setting on the "Nightly" frequency was 120 minutes, and as the standard administration time for nightly is 2100, the EMR scheduled the first dose for 1800 and the subsequent dose for 2100 on the same day.

What We Did

The "Duplicate Dose Interval" time setting for the "Nightly" frequency was changed from 120 minutes to 720 minutes. This matches the settings for the "Daily" frequency.

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Lessons Learned

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- Keep it simple and clear through the use of standardized template
- Consider the audience for your system change reports
- Don't include changes that haven't been implemented as they may never be implemented and will decrease credibility
- More changes isn't necessarily better, be careful what you incentivize and make substantive changes
- Avoid using jargon that may make sense at the sharp end but not to a senior leader and vice versa
- To support peer review privileged protections, partner with legal on plan for report design and dissemination
- Collect feedback about the usefulness of the report and iterate

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Challenges

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- Different interpretations on what meets criteria for a system change
- Different perceptions on the error proofing strategies used
- Striving for higher-level system changes is hard work
- Dissemination due to peer review privileged information
- Quantifying the value and impact of changes implemented

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"Safety Lives In System Changes"
~E. Robert Feroli

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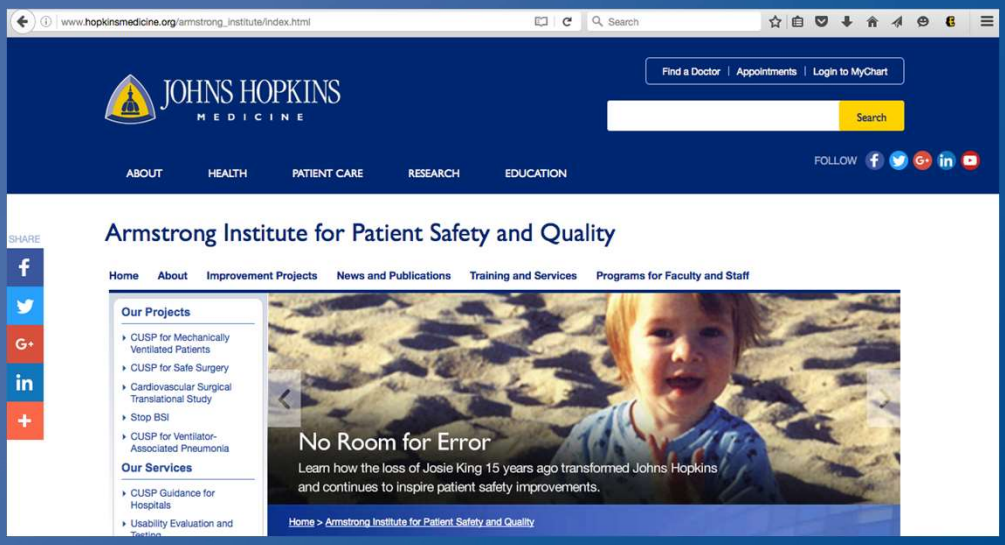

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QUESTIONS?

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Medication Safety Strategic Planning Process

Christopher Walsh, PharmD, FISMP
Medication Safety Pharmacist
St. Joseph Medical Center
Reading, Pennsylvania

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Learning Objectives

- Discuss benefits of strategic planning for medication safety
- Review process for designing a medication safety strategic plan
- Review an example of a medication safety strategic plan

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Strategic Planning Benefits

- Balance between short-term needs and long-term goals of the organization
- Formally identify specific medication safety strategic initiatives
- Establishes a framework for tracking progress toward the medication safety goal

"Pathways for Medication Safety - Leading a Strategic Planning Effort" (available at https://www.ismp.org/resources/strategic-planning)

Vaida A, Kurcher L. Practical tools for medication safety in acute care. J Am Pharm Assoc. 2003 Sep-Oct;43(5 Suppl 1):S48-9.

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Steps to Strategic Planning

- Involve key people
- Assess your current position
- Map a strategy for the future
- Select change projects
- Implement strategic plan
- Monitor performance

"Pathways for Medication Safety - Leading a Strategic Planning Effort" (available at https://www.ismp.org/resources/strategic-planning)

Vaida A, Kurcher L. Practical tools for medication safety in acute care. J Am Pharm Assoc. 2003 Sep-Oct;43(5 Suppl 1):S48-9.

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Involve Key People

- Establish a core team
  - Informal leaders from the front line
  - Senior administrative leaders
  - Physicians and high-level managers
  - Medication safety team or similar
- Review a sample plan

Vaida A, Kurcher L. Practical tools for medication safety in acute care. J Am Pharm Assoc. 2003 Sep-Oct;43(5 Suppl 1):S48-9.

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Assess your current position

- Medication error reporting systems
- Interventions by pharmacists, nurses, or physicians
- ISMP Self Assessment surveys
- Failure Mode and Effects Analysis
- Root Cause Analysis
- Staff or patient focus groups

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Assess your current position

- Do not spend too much time
- Prioritize time and energy
  - Reviewing the model plan;
  - Mapping an organization-specific strategy;
  - Implementing it; and
  - Monitoring the progress.
- Avoid data paralysis
- Can determine medication safety opportunities in a relatively short period of time.

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Map a strategy for the future

- Core team selection of medication safety long term goals
  - Can be different from model plan
- Documentation of enduring advantages, barriers and boundaries
- Each goal is manageable and achievable
  - Important to select what not to do vs what to do

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Select change projects

- For each long term goal, select change projects
  - Challenge the organization
  - Facilitate achievement of the long-term goal
  - Be measurable and realistic (i.e. "SMART")
  - Identify responsible party

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Prioritizing Projects

- Puts emphasis where needed, even if changes are difficult
- Proactively handles high impact issues
- Takes external influences into account without losing focus
- Takes considered risks

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Implement Strategic Plan

- Communication plan
- Leadership discussions with staff
  - Review new roles and responsibilities with affected staff.
  - Invest in training staff in new skills that may be needed to achieve the goals.
  - Establish a feedback mechanism and
  - Encourage comments and suggestions from staff and patients.

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Monitor Performance

- Timetable to periodically review
- Realistic assessments and flexibility
- Feedback from staff
  - how the change project is affecting jobs and patients

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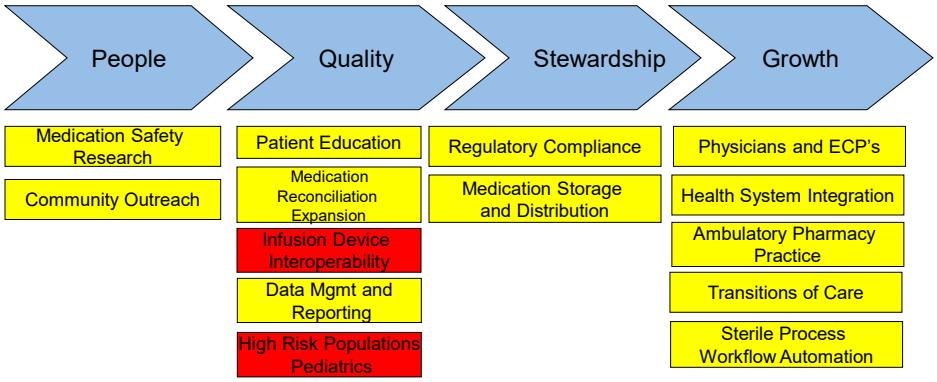
Medication Safety Strategic Pan 2020-2024



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People

AREA	Current State	Idealized State	Actions	Lead	Third Qtr 2020 Update
Community Relations	Medication safety information and education for community members Working with community groups	Community constituents at all ages and ethnic groups look to SJMC for medication safety information and education	Explore opportunities with colleges/ nursing schools for education and medication safety programs Embed clinical pharmacists in primary care practice sites **(Structure Measure #clinical pharmacists/#primary practices)**		Completed – Integrated into TUSP certificate program faculty; In Process – Pharmacy residency clinic at downtown residency practices 1 afternoon per week
Research	Publishable research on medication use at SJMC is limited to mainly pharmacy residents with descriptive statistics due to lack of statistical support.	Expanded professional research opportunities at SJMC for properly powered, publishable material in peer-reviewed journals.	Identify broad areas needed for medication use research throughout Penn State Health and share resources as needed to expand development of publishable material. (Measure:#medication safety related research protocols completed)		In Progress – Joint research training completed and biostatistician resource acquired and resourced

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Quality

AREA	Current State	Idealized State	Actions	Lead	Third Qtr 2020 Update
Patient Education	Room for improvement in patient satisfaction scores Basic information given, but not always explained, patients with multiple meds report confusion with information No tool available to identify patients at risk of adverse drug events. Non-specific ADE tool (LACE) utilized to guide use of limited pharmacy patient discharge counseling resources.	Utilizing a tool to specifically identify patients at high risk for ADE, identify patients who will be educated by pharmacy staff on all new and discharge medications via teachback methodology. Education session to be recorded for future reference utilizing Good To Go program	•Develop and implement a tool that specifically identifies patients at high risk for ADE's. •Implement pharmacy based discharge counseling and education on 1 unit piloting ADE risk assessment tool and expand as warranted. *•Readmission rates due to preventable adverse drug events* ***(Outcome Measure)*** *•Patient satisfaction scores for medications* ***(Outcome Measure)*** *•Rate of "Good to Go" recordings per unit of discharges* ***(Process Measure)***		In progress – ADE risk tool developed but not tested; In progress – Meds to beds program limited due to restriction against mobile devices at bedside
Medication reconciliation	Formalized process identified that includes 3 FTE's dedicated to admission medication reconciliation. Discharge reconciliation process completed that includes patient-friendly medication list and instructions. No formal transitions of care (TOC) process to compare discharge medication list with discharge note from hospital provider and discharge prescriptions.	Full medication reconciliation at all patient transitions with complete reconciliation of medication instructions and prescriptions upon discharge.	*Number of admission medication histories performed by medication history technician* ***(Outcome Measure).*** *Policies and procedures updated to include MHT position****(Structure Measure)*** *Completed discharge medication lists that are properly updated (****Process Measure)*** *Compliance with TJC NPSG for medication reconciliation* ***(Process Measure)***		Completed – 2.5 MHT FTE's in ED and 1 FTE added to SPU; In progress – Comparison of lists vs prescriptions – Pilot 9/2020

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QUESTIONS?

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ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

ISMP Update
MSOS Briefing September 2020

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

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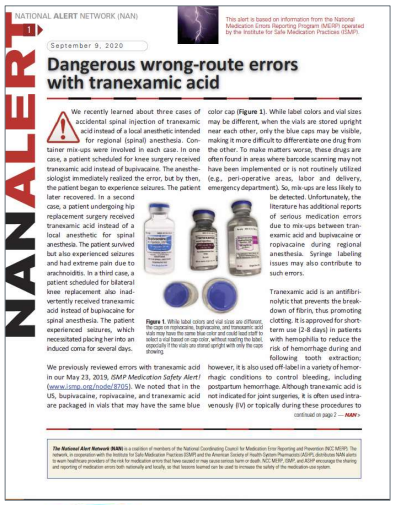
NAN (National Alert Network) Alert on tranexamic acid errors


NATIONAL ALERT NETWORK (NAN)

NANALERT 1

September 9, 2020

Dangerous wrong-route errors with tranexamic acid

We recently learned about three cases of accidental spinal injection of tranexamic acid instead of a local anesthetic intended for regional (spinal) anesthesia. Container mix-ups were involved in each case. In one case, a patient scheduled for knee surgery received tranexamic acid instead of bupivacaine. The anesthesiologist immediately realized the error, but by then, the patient began to experience seizures. The patient later recovered. In a second case, a patient undergoing hip replacement surgery received tranexamic acid instead of a local anesthetic for spinal anesthesia. The patient survived but also experienced seizures and had extreme pain due to arachnoiditis. In a third case, a patient scheduled for bilateral knee replacement also inadvertently received tranexamic acid instead of bupivacaine for spinal anesthesia. The patient experienced seizures, which necessitated placing her into an induced coma for several days.

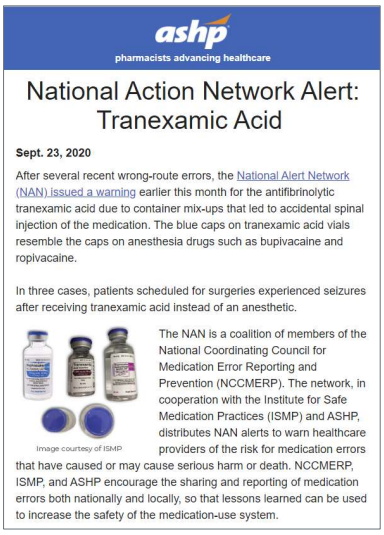
We previously reviewed errors with tranexamic acid in our May 23, 2019, *ISMP Medication Safety Alert!* (www.ismp.org/node/8255). We noted that in the US, bupivacaine, ropivacaine, and tranexamic acid are packaged in vials that may have the same blue color cap (**Figure 1**). While label colors and vial sizes may be different, when the vials are stored upright near each other, only the blue caps may be visible, making it more difficult to differentiate one drug from the other. To make matters worse, these drugs are often found in areas where barcode scanning may not have been implemented or is not routinely utilized (e.g., peri-operative areas, labor and delivery, emergency department). So, mix-ups are less likely to be detected. Unfortunately, the literature has additional reports of serious medication errors due to mix-ups between tranexamic acid and bupivacaine or ropivacaine during regional anesthesia. Syringe labeling issues may also contribute to such errors.

Tranexamic acid is an antifibrinolytic that prevents the breakdown of fibrin, thus promoting clotting. It is approved for short-term use (2-8 days) in patients with hemophilia to reduce the risk of hemorrhage during and following tooth extraction; however, it is also used off-label in a variety of hemorrhagic conditions to control bleeding, including postpartum hemorrhage. Although tranexamic acid is not indicated for joint surgeries, it is often used intravenously (IV) or topically during these procedures to

continued on page 2 — NANA>

Figure 1. While label colors and vial sizes are different, the caps on ropivacaine, bupivacaine, and tranexamic acid vials may have the same blue color and could lead staff to select a vial based on cap color, without reading the label, especially if the vials are stored upright with only the caps showing.

The National Alert Network (NAN) is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The network, in cooperation with the Institute for Safe Medication Practices (ISMP) and the American Society of Health-System Pharmacists (ASHP), distributes NAN alerts to warn healthcare providers of the risk for medication errors that have caused or may cause serious harm or death. NCC MERP, ISMP, and ASHP encourage the sharing and reporting of medication errors both nationally and locally, so that lessons learned can be used to increase the safety of the medication-use system.


ashp
pharmacists advancing healthcare

National Action Network Alert: Tranexamic Acid

Sept. 23, 2020

After several recent wrong-route errors, the National Alert Network (NAN) issued a warning earlier this month for the antifibrinolytic tranexamic acid due to container mix-ups that led to accidental spinal injection of the medication. The blue caps on tranexamic acid vials resemble the caps on anesthesia drugs such as bupivacaine and ropivacaine.

In three cases, patients scheduled for surgeries experienced seizures after receiving tranexamic acid instead of an anesthetic.

Image courtesy of ISMP

The NAN is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP). The network, in cooperation with the Institute for Safe Medication Practices (ISMP) and ASHP, distributes NAN alerts to warn healthcare providers of the risk for medication errors that have caused or may cause serious harm or death. NCCMERP, ISMP, and ASHP encourage the sharing and reporting of medication errors both nationally and locally, so that lessons learned can be used to increase the safety of the medication-use system.

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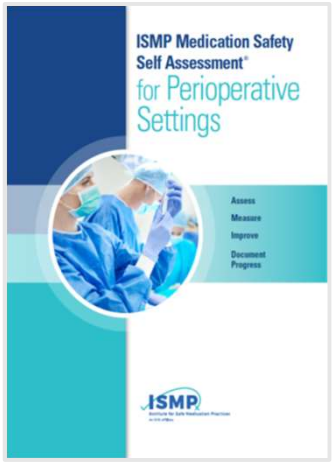
ISMP Self Assessment for Perioperative Settings

FDA Broad Agency Announcement (BAA)

- Meeting to be held with FDA to show the document and receive any input
- Pilot testing near completing and on target for October tool release



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MSOS Member Briefing
September 2020

Media

- Uppsala Reports article on tragedy after 2-component vaccine error in Samoa
- Written by ISMP Fellows with staff oversight


UPPSALA REPORTS

SERIOUS ERRORS WITH TWO-COMPONENT VACCINES RISK HARM AND DAMAGE TRUST

Medication errors can harm individual patients. But when errors also undermine trust in public health programmes, serious problems can ripple across entire communities.

RELATED ARTICLES

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Enoxaparin prefilled syringe failures


February 28, 2019 • Volume 24 Issue 4

ISMP 25 ADVANCING MEDICATION SAFETY

Acute Care
ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Your attention please… Designing effective warnings

Medication-related warning systems are often used to inform both practitioners and consumers about new risks, or remind them about known risks associated with the use of medications. The warning system may ask the recipient to choose between two or more courses of action, present only one safe option, or provide information only.[1]

The warning system may also include several components that complement each other and various forms of technology. For example, the warning system for a neuromuscular blocking agent, which is intended to alert practitioners to the drug's effect of respiratory arrest and the need for ventilation, may include: a statement about the risk in the package insert; a warning statement on the carton, immediate container label, and ferrule of the vial; an auxiliary warning label on product storage locations and vials/infusions; an interactive electronic warning that requires verification that the patient will be ventilated before removing the drug from an automated dispensing cabinet (ADC); and a visual/audible warning when the product's barcode is scanned and the drug has not been prescribed for that patient. The different components of the warning system may be intended for different audiences and may be embedded in different phases of the medication use process to ensure all who are involved with the neuromuscular blocking agent are aware of this critical information.

How the components of the warning system interact and complement each other is one significant aspect of an effective medication-related warning system.[2] Another is whether the warnings truly inform practitioners about crucial medication safety issues and influence their behavior in ways intended to improve safety. While warning systems are considered mid-level strategies because they mostly involve efforts to inform and influence behavior, they can be an extremely valuable tool to help reduce the risk of potentially serious errors when they are well designed and accompanied by high-leverage, system-level risk-reduction strategies. Recommendations to improve the design, delivery, and effectiveness of medication-related warnings are discussed in further detail below.

Effectiveness of Warnings

To be effective, warnings must: 1) reach their target audience; 2) capture the attention of recipients at the right time; 3) cause recipients to understand the risk, believe that the warning relates to them, and understand the actions they need to take; and 4) lead

SAFETY briefs

Enoxaparin syringe failures. In the past few months, the US Food and Drug Administration (FDA) and ISMP have received multiple reports from practitioners and manufacturers about enoxaparin prefilled syringe failures (Figure 1) and inadvertent activation of the needle safety mechanism. The syringe manufacturers mentioned in the reports include Sanofi, which provides the brand, LOVENOX, and various generic product manufacturers (e.g., Fresenius Kabi, Winthrop, Amphastar Pharmaceuticals [IMS Limited], Sandoz, Teva [not manufacturing enoxaparin at this time]). Sanofi manufactures generic enoxaparin syringes for Fresenius Kabi and Winthrop, and is responsible for investigating associated complaints.

Figure 1. When attempting to engage the safety mechanism on an enoxaparin syringe (Fresenius Kabi), the two pieces completely separated from each other.

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MSOS Member Briefing
September 2020

ISMP Nurse AdviseERR

June 2020 | Volume 18 Issue 6

ISMP

Nurse AdviseERR

Educating the Healthcare Community About Safe Medication Practices

COVID-19-related medication errors

In our April 2020 newsletter (www.ismp.org/node/163831), we shared an idea to add a question, "Is this event related to COVID-19 (coronavirus)?" to reporting systems to categorize COVID-19-related events, allow rapid analysis of quickly emerging risks, and reduce leadership's reaction time in knowing about and addressing some of these issues. Since then, we have received several COVID-19-related medication errors each week and wanted to update you on a few important issues.

Remdesivir investigational drug labeling confusion

ISMP received a report about a hospital compounding issue due in part to label confusion with the investigational drug remdesivir. Some facilities have received this drug, manufactured by Gilead Sciences, under a compassionate use program during a period of expanded access and through an emergency use authorization (EUA) program issued by the US Food and Drug Administration (FDA). The hospital had implemented an investigational study using intravenous (IV) doses of remdesivir to treat patients with severe COVID-19. The adult protocol called for an initial loading dose of 200 mg, followed by subsequent 100 mg doses. Each vial of remdesivir contains a total of 100 mg. Instead of using 1 vial to prepare each 100 mg subsequent dose, 2 vials were used, thus providing 200 mg for each subsequent dose instead of the intended 100 mg.

Remdesivir is available for use in clinical trials in at least two different dosage forms: a lyophilized powder for injection and a solution for injection. Like many investigational drug container labels, the vials are not clearly labeled, and the information presented is crowded and in a small font (see our 2-part article about problems with investigational drug labeling: www.ismp.org/node/1048; www.ismp.org/node/1049). The vials of lyophilized powder have a label listing the total amount (100 mg) of drug in the vial (**Figure 1**). The vials of remdesivir injectable solution have a label that lists the per mL strength, "Remdesivir (GS-5734) Injection, 5 mg/mL" (**Figure 2**). Below the 5 mg/mL listing, the vial label notes the total volume in the vial, "Contents: 21.2 mL," which may

continued on page 2 — COVID-19 errors >

Figure 1. Label on vial of remdesivir lyophilized powder notes that it contains 100 mg.

Figure 2. Label on vial of remdesivir injectable solution does not indicate the total amount (100 mg) of drug in each vial; instead, it lists a per mL amount (5 mg/mL) and below that, the total contents of the vial, 21.2 mL, which can be easily missed.

Figure 3. Another label from remdesivir injectable solution, which prominently lists the total amount of drug in each vial (100 mg/20 mL), with the per mL amount (5 mg/mL) in parenthesis below it.

SAFETY wires

Should the PillCrusher syringe be used for crushing tablets? To reduce the risk of handling hazardous drugs, pharmacy staff evaluated self-contained devices used for pill crushing. One that stood out was the 60 mL PillCrusher syringe, which is an enteral syringe that can be used to crush and dissolve tablets while contained in the syringe. According to the manufacturer, the syringe can then be used to administer medication directly to the patient (www.ismp.org/sec/963). The syringe can also be used for enteral irrigation. A YouTube video demonstrates how the syringe is used (www.ismp.org/sec/1346).

The Welcon brand PillCrusher syringe by Nurse Assist is available through several medical equipment distributors. The pharmacy staff decided to try it out with a tablet that nurses found hard to crush—sodium chloride 1 g tablets (Westminster Pharmaceuticals). When they tried to crush the tablet per the manufacturer's instructions, the tablet "shredded" the plunger's plastic grinding teeth and some other plastic components, while the tablet was barely scathed (Figure 1). Incidentally, the syringe has a tapered tip used to connect with feeding tubes but is not ENFit compatible. It also has an orange cap that could be a choking hazard if the capped device is used for

Figure 1. Plunger's teeth broke when used with a hard-to-crush tablet.

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ISMP

Nurse AdviseERR

Educating the Healthcare Community About Safe Medication Practices

Education is "predictably disappointing" and should never be relied upon alone to improve safety

An editorial in the May 2020 issue of *BMJ Quality & Safety* provides a noteworthy description of why education alone is a weak, low-value improvement intervention.[1] The editorial examines the impact of a national education program in Australia aimed at reducing outpatient proton-pump inhibitor (PPI) prescriptions, which found no significant changes in discontinuation or dose reductions, the primary outcomes of the intervention. The authors acknowledge that educational initiatives alone are unlikely to make the inroads required to curb the prescribing of PPIs. They offer several salient reasons why educational initiatives alone fail to produce results. They first reviewed numerous studies that have found negligible or no improvements when examining the impact of education on practitioners' behavior and clinical outcomes. Despite healthcare's over-reliance on this low-value intervention, the authors conclude that education is "predictably disappointing among improvement efforts," earning it a "necessary but insufficient" status among improvement interventions.[1]

ISMP agrees and has stated for years that education alone is a weak improvement strategy. Education has its place as a basic prerequisite—it provides healthcare practitioners with the required knowledge (what they know) needed to develop the skills (applying that knowledge) to do their job well. For example, education about new medications, devices, automation, processes, and known risks is fundamental to forming a well-qualified complement of practitioners to manage medication safety. But while knowledge and skills are a necessary first step, education ranks among the least effective interventions in ISMP's hierarchy of effectiveness of risk-reduction strategies (**Figure 1**), right

below rules and policies, continuing p 2 — Education >

Figure 1. ISMP's hierarchy of effectiveness of risk-reduction strategies. High-leverage strategies are most effective because they can eliminate the risk of errors and associated harm by "designing out" hazards; however, they often require complex implementation plans. Medium-leverage strategies, which are easier to implement, reduce the likelihood of errors or minimize harm. Solutions in this category need periodic updating and reinforcement. Low-leverage strategies, which aim to improve human performance, are easy and quick to implement; however, they are the least effective strategies for error prevention although frequently relied upon.

SAFETY wires

FDA approves syringe administration from vinCRIStine labeling. At the request of the US Food and Drug Administration (FDA), Pfizer has revised the prescribing information and product packaging for vinCRIStine sulfate injection. FDA recommended the revision at the request of ISMP, the National Comprehensive Cancer Network, and The Joint Commission. The labeling of vinCRIStine now states: To reduce the potential for fatal medication errors due to incorrect route of administration, vinCRIStine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated "FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES." Furthermore, administration of the drug via syringe has been totally removed from the package insert.

ISMP specifically called on FDA to eliminate syringe administration of vinCRIStine in official product labeling in our April 2019 issue of the *ISMP Medication Safety Alert!* (www.ismp.org/node/1514). More than 130 deaths are known to have occurred from accidental intrathecal injection of the drug via syringe. Whereas no cases of accidental intrathecal administration have been reported with dilution of the drug in a flexible plastic container or minibag.

The KIDs List. To create a standard of care for the safe use of medications in pediatric patients, the Pediatric Pharmacy Association (PPA) commissioned a group of pediatric pharmacists to evaluate the literature and compile a list of potentially inappropriate drugs for pediatric patients. This "KIDs List" is the first list of drugs that should be "avoided" or "used with caution" in all or a subset of pediatric patients. It is

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https://www.ismp.org/newsletters/nursing

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ECRI and the ISMP PSO

- Over a decade of experience as a PSO accredited by AHRQ
  - **More than 3.7 million events in database, including >13,000 COVID-related events**
- Experienced staff with backgrounds in medicine, pharmacy, nursing, risk management, patient safety and quality improvement (many with CPPS, CPHQ or CPHRM certifications)
  - **Access to additional expertise, such as engineers, human factors specialists, librarians, supply chain specialists, etc.**

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ECRI and the ISMP PSO

- Joint PSO between ECRI and ISMP provides
  - **Unique expertise in medication safety**
  - **Access to long-term leaders in the field**
- ECRI ISMP PSO has extensive experience in different healthcare markets (acute care, aging services, federally qualified health centers, specialty groups)

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ECRI and the ISMP PSO

- Medication safety issues are typically one of the top three patient safety issues reported to PSOs
- ISMP multidisciplinary staff plus ECRI experts available to help PSO members
- The two combined PSOs increase medication safety expertise and resources
- To learn more about ECRI and the Institute for Safe Medication Practices PSO, or to request a demo, visit https://www.ecri.org/pso, call (610) 825-6000, or e-mail clientservices@ecri.org. Or contact us at ismpinfo@ismp.org.

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MSOS Member Briefing
September 2020

Questions?

- A copy of today's slides will be posted on our website
- Next MSOS Briefing date – November 19, 2020.
  Register:
  https://ecri.zoom.us/webinar/register/WN_loWq1CLwQ46GCmie6oYWUA

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