MSOS Member Briefing
July 2020

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July 2020

Moderated by: E. Robert Feroli, PharmD, FASHP

MSOS
MEDICATION SAFETY OFFICERS SOCIETY

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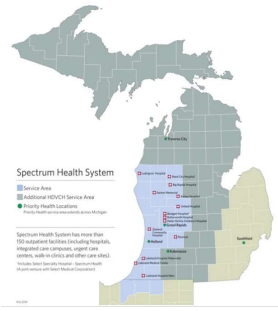
Spectrum Health System

- 31,000 compassionate professionals
- 4,600 medical staff experts
- 14 hospitals, including Helen DeVos Children's Hospital
- 150 ambulatory sites and telehealth offerings



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Eliminating Inadvertent Exposure with Patient Specific Scanning of Multi-Use Medications

Steve Mogridge PA-C
Medication Safety Manager, Spectrum Health
Megan Fletcher, PharmD
Director of Pharmacy, Spectrum Health

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Learning Objectives

- Identify gaps that can lead to inadvertent patient to patient exposure.
- Discuss risk mitigation strategies to reduce and eliminate patient harm from wrong patient exposures.

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Outline

- Situation
- Gaps and Interventions
- Outcome
- Lessons Learned

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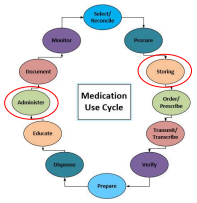
Situation

- 36 known patient-to-patient exposures over a 24 month period from insulin pens
  - Self reported through event reporting system
- Situational Awareness didn't make an impact
- Gap Analysis revealed multifactorial Issue
  - Storage
  - Technological Complacency
    - BCMA dependence
  - Culture



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Risk Mitigation Gap/Solution

Storage

- Medications previously kept in wooden locked drawer in room
- Patient discharged and medications left in the drawer if not removed
- Multiple Pens with different patients in one drawer
- No visual management

Solution

- Medication storage removed from non-visible wooden drawer
- Transparent locking orange box mounted on wall
- Standard work changed for Nursing and Environmental Services to stop the line and suspend the room for cleaning affecting throughput.

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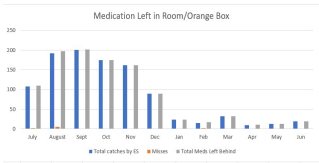
Risk Mitigation Solution/Result



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Risk Mitigation Gap/Solution

Five Rights of Medication Administration

- 53% able to recall all 5 rights (right patient, right drug, right dose, right route and right time)
- When asked, many stated they relied on barcode scanning to alert them if something wasn't correct.

Solution

- Reinforcement of the 5 Rights of Medication Administration
- Visual management

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Risk Mitigation Solution/Result

- Add a visual reminder of the 5 rights of medication administration
- Each unit will place the "talk to the hand" card on each workstation in the patient room

- Post visual management roll out, knowledge of 5 Rights of Medication Administration **increased to 78%.**
- **Behavior did not change with utilization and reliance on BCMA being strong**
- Reflects both and educational and cultural opportunity.
- Medication administration needs to be a BCMA **and** the 5 rights, not BCMA **or** the 5 rights

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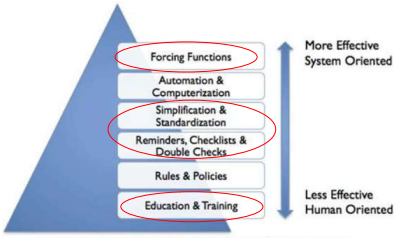
Hierarchy of Effectiveness



Ref: www.cassiemcdaniel.com/blog/hierarchy-of-effectiveness-process

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Risk Mitigation Gap/Solution

Forcing Function with BCMA Scanning

- Installed patient specific label printers in each medication room.
- Common short acting and long acting insulin moved to ADC with appropriate dating
- New worksheet build within Epic that prints bar code label at new printer in medication room
- Medication removed from ADC is labeled with patient specific label

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Multi-Use Labeling for Insulin

EPICPOC, SHANE
MRN: 30007833
DOB: 9/24/1992 (27 yrs)

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Administration Process

- Unique forcing function build within Epic
- Scan Patient wrist band, scan new bar code on product, scan manufacturer bar code (triple scan)
- Ensures correct patient, correct patient's product and correct product

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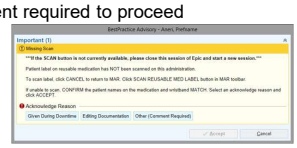
Patient Specific Scanning Best Practice Alerts (BPA's)

- Correct: Green Banner **Correct patient scanned. Close this form by clicking 'Accept' and scan product barcode**
- Incorrect: Red Banner **Incorrect Patient. Do not use this device for this patient. Obtain a new device and apply the patient label.**
  - Additional comment required to proceed and additional stop alert
- Wrong Order: Orange Banner **The barcode scanned was not the expected patient label. Please clear the field above and scan the patient barcode.**
  - Additional comment required to proceed
- Missing Scan BPA



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Outcome

- Over 214,000 administrations, recorded 274 near misses
- Tableau Report
  - Ability to drill down to unit, patient and nurse level
- ZERO recorded exposures since go-live
- Trifecta win for pharmacy, nursing, and patients

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Lessons Learned

- Previous exposures were under reported
- Opportunity still exists utilizing the 5 Rights during administration
- Expanded to inhalers and seeking additional functionality
- Multidisciplinary collaboration was essential to success

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Questions

Contact Info –
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Prescriber – Information Overload

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Microlearning...

'short, easily digestible, bite-sized units of learning activated by the learner at the point when they are most receptive to receiving it'

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Your mission, should you choose to accept it...

Deliver medication safety learning in ≤ 60 seconds

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Features of the Medication Safety Minute

A Brand

Prescribe Safely... Every Patient, Every Time

stealth medication

noun [stelθ medɪˈkeɪʃ(ə)n]

Def. potent pharmacological agent operating covertly

Graphics

Can you identify one?

A Question

Disclaimer: St. James's Hospital cannot accept legal responsibility for any errors or omissions. Minutes are compiled for an acute-teaching hospital setting & may not be applicable in other settings/jurisdictions. Refer to the SPC & other appropriate references for complete safety information.

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Answer: Transdermal (TD) Opiates, i.e. fentanyl or buprenorphine patches

Pathway of a Stealth Medication

Single learning objective

Opiate patch is hidden under clothing

On admission, staff may be unaware pt is receiving a potent opiate at that point in time

Potential Risks

1. Admitting dr is *unaware* a TD opiate is one of the pre-admission meds (e.g. when it is not possible to determine med hx, or med hx incomplete)
   - TD opiate is not charted
   - Additional opiate analgesia is rx'd as team does not realise pt already has a patch applied

2. Admitting dr is *aware* a TD opiate is a pre-admission med
   - TD opiate is prescribed for application later that day
   - A duplicate patch is applied

Opiate Toxicity

Based on local risks

Boo!

Uncover the Stealth Medication

- When taking a med hx enquire about meds taken by routes other than oral, e.g. TD patches
- If a TD opiate is a pre-admission med always ask the pt if they currently have a patch applied

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A Serious Message

...but a Light Delivery!

Visual Language

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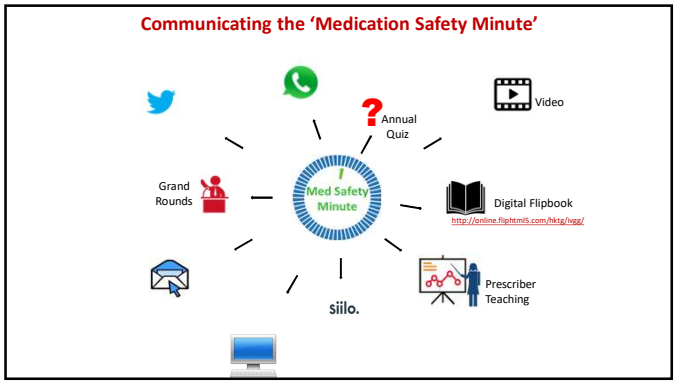

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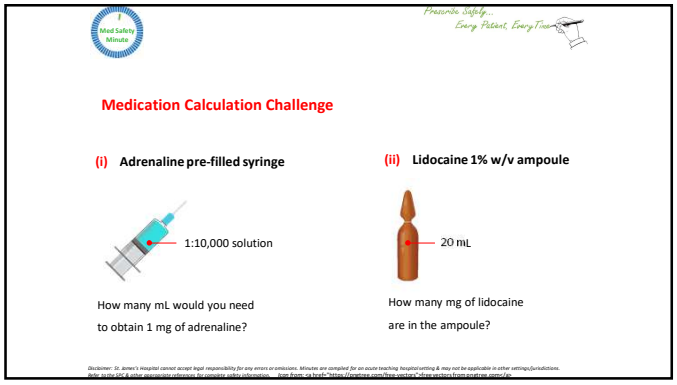

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Answer:

(i) 10 mL

Working it out:

1:10,000 = 1 g in 10,000 mL

i.e. 1000 mg in 10,000 mL

i.e. 1000 mg in 10,000 mL

∴ 1 mg is in 10 mL

(ii) 200 mg

Working it out:

1% w/v = 1 g in 100 mL

i.e. 1000 mg in 100 mL

i.e. 1000 mg in 100 mL

∴ 20 mL contains 200 mg

30 Seconds of Statistics!

Normal distribution

Paranormal distribution

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Med Safety Minute

Proactive Safety... Every Patient, Every Time

A Scary Story

You are a doctor performing an endoscopic procedure. You need to administer flumazenil (Anexate®) IV injection to reverse the effects of midazolam as the patient's oxygen saturation has dropped substantially.

A nurse draws up the medication from a vial and then hands you a tray containing the syringe of medication and the empty vial.

You pick up the syringe and inject the patient and just as you do the label on the vial catches your attention – 'Anectine® (suxamethonium)'.

Shocked, you realise you have administered a neuromuscular blocker instead of the reversal agent.

You shout for help, begin to ventilate the patient and start preparing for an emergency intubation...

THE END

What action could you have taken so this story would have a different ending?

Disclaimer: St [illegible] Hospital cannot accept legal responsibility for any errors or omissions. Minutes are compiled for an acute teaching hospital setting & may not be applicable in other settings/jurisdictions. Refer to the HSE & other appropriate reference for complete safety information.

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Answer: A second person check

Why is it needed?

- If the person preparing a medication has made an error then only the intervention of a second individual can prevent that error reaching the pt.
- IV medications are high risk & a second-person check is always warranted & is mandatory in SJH.

Choose a different ending to the story!

A Success Story

You are a doctor performing an endoscopic procedure. You need to administer flumazenil (Anexate®) IV injection to reverse the effects of midazolam as the patient's oxygen saturation has dropped substantially.

A nurse draws up the medication from a vial and then hands you a tray containing the syringe of medication and the empty vial.

You pick up the empty vial to check it is the correct medication. Immediately you spot the error – it is a vial of Anectine® instead of Anexate®.

Error detected; harm averted.

You highlight this near miss to the medication safety office.

As a result, organisational-wide safety measures are taken to reduce the risk of future similar events.

THE END

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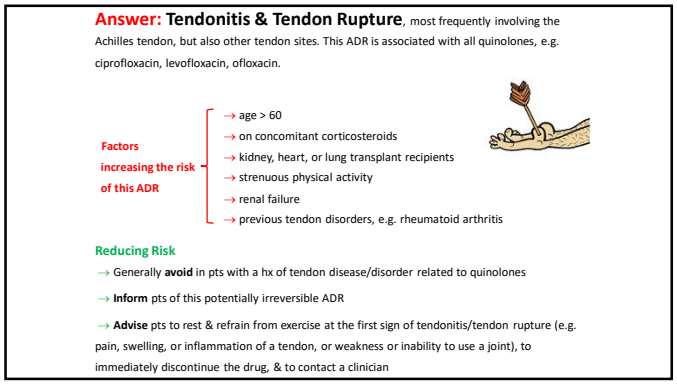

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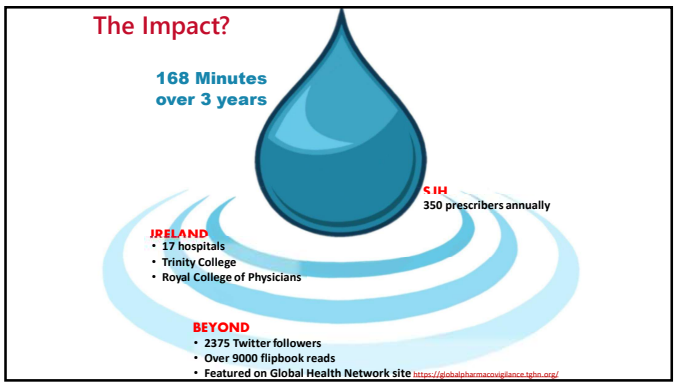

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The Medication Safety Minute –
Microlearning in Medicine

Questions?

Eileen Relihan
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Pharmacy and Anesthesia:
A Match Made in Medication Standardization and Safety Heaven

Jameika Stuckey, PharmD, BCACP
Medication Safety Manager

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The Journey

- How this relationship journey began
- Some things we've accomplished
- Where are we going from here

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Initial introductions…

- Initially brought onto a project that had already begun
  - Included nursing, providers, and pharmacy
  - Representation from ICUs, Emergency department, and Anesthesia
  - Project's aim was to increase medication standardization amongst the services
  - Invited from a medication safety perspective

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Beautiful beginnings….

- Established official committee and goals
  - Identify Champions (Pharmacy and Anesthesia co-chairs)
  - Included colleagues previously involved (nursing, providers, pharmacy)
  - Increased involvement to include additional key stakeholders
    - EPIC IT team
    - Smartpump library administrators
    - Clinical engineering and patient equipment
  - Identify medications that had historically been problematic and required standardization
  - Identify and overcome barriers
  - Establish education

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Gaining momentum…

- Medication list established
- Concentrations agreed upon
  - Reviewed literature and ASHP/ISMP publications
  - Required some changes in EMR and pharmacy workflow
- Smartpump limits selected
  - Reviewed limits and alert reports
  - In-depth discussions and debates
- Set go-live date
  - COVID-19 postponement
  - Now mid-August

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Building trust…

- Identified some workflow opportunities in pediatric cardiac perioperative workflow
- During standardization project, discussions with anesthesia champion regarding error event reporting
- Began to co-investigate anesthesia errors and work closely with risk management
- Identified some contributing factors in several errors
  - Smartpumps not addressing all anesthesia needs
    - Some medications missing
    - Units in pump didn't match dosing units
  - Providers/trainees not as comfortable with pumps as perceived
  - Not enough pumps available

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Fruits of relationship labor…

- Growing **partnership** amongst Pharmacy and Anesthesia
  - Safety
  - Controlled substance stewardship
- Transitioned pediatric ORs to Alaris™ smartpumps
- Pharmacy participation in Anesthesia grand rounds on various topics
- Hosted first grand rounds discussing errors and lessons learned
  - Anesthesia, Pharmacy and Risk Management involvement
  - Led to ISMP discussion with manufacturer for possible medication package change

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Where do we go from here…

- Improved use and auditing of smartpumps and guardrails use
- Labeling and dating of bags and syringes
- Multi-dose vial usage
- Perioperative glucose management
- Controlled/non-controlled medication security
- Developing pharmacy/medication boot camp for anesthesia residents

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Thank You!

Questions?

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Contact information

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An ECRI Affiliate

ISMP Update
MSOS Briefing July 23, 2020

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

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ISMP Medication Safety Fellows 2020-2021

- **Merissa Anderson, PharmD, MPH**
  ISMP International Medication Safety Management Fellow
- **Jill Paslier, PharmD, CSP**
  ISMP International Medication Safety Management Fellow
- **Bennet Ninan, PharmD**
  ISMP Medication Safety Management Fellow

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U.S. FOOD & DRUG ADMINISTRATION

NDA 209376

NDA APPROVAL

American Regent, Inc.
Attention: Elizabeth Ernst
Global Executive Director of Regulatory Affairs
5 Ramsey Road
Shirley, NY 11967

Dear Ms. Ernst,

Please refer to your new drug application (NDA) received on September 5, 2019, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TRALEMENT™ (trace elements injection 4*).

This new drug application provides for the use of trace elements injection indicated in adult and pediatric patients weighing at least 10 kilograms as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We note that your June 29, 2020, submission includes final printed labeling (FPL) for your Prescribing Information. We have not reviewed this FPL. You are responsible for assuring that the wording in this proved labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov [1]. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information)as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidance periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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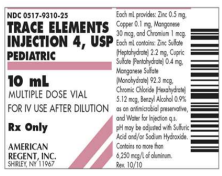
American Regent Trace Element Products

Unapproved trace lement-4 injection



TRALEMENT

Trace Elements Injection-4, USP
1 mL Single Dose Vial

Trace Elements	Strength
Copper Sulfate	300 mcg/mL
Manganese Sulfate	55 mcg/mL
Selenious Acid	60 mcg/mL
Zinc Sulfate	3000 mcg/mL

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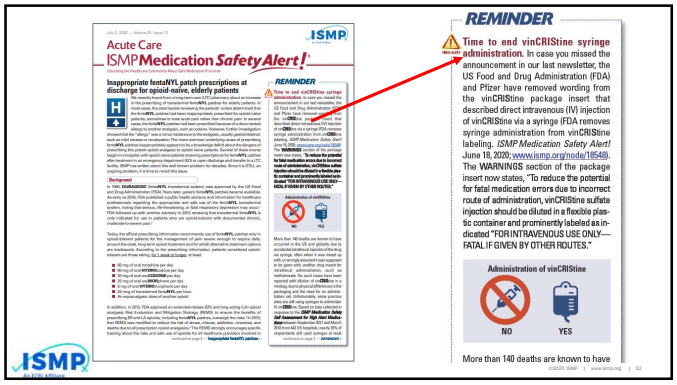

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Methotrexate tablets label change

- 2.1 Important Dosage and Safety Information
  - Instruct patients and caregivers to take the recommended dosage as directed, because medication errors have led to deaths (see Warning and Precautions, 5.9)
- 2.3 Recommended Dosage for Rheumatoid Arthritis
  - The recommended starting dosage of Methotrexate Tablets is 7.5 mg orally once weekly with escalation to achieve optimal response.
- 5.9 Risk of Serious Adverse Reactions with Medication Error
  - Deaths occurred in patients as a result of medication errors. Most commonly, these errors occurred in patients who were taking methotrexate daily when a weekly dosing regimen was prescribed.
  - For patients prescribed a once weekly dosing regimen, instruct patients and caregivers to take recommended dosage as directed, because medication errors have led to death.

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NRFit (ISO 80369 standard neuraxial connector)

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ISMP Self Assessment for Perioperative Settings

FDA Broad Agency Announcement (BAA)

- Advisory Group calls continue to review/refine items (~215 items)
- Planning for pilot testing in August and still on target for Fall tool release
- Marketing and endorsement plan in process of being updates
- Analysis plan with AHA statistician also being developed

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ISMP Survey on the Two New 2020-2021 TMSBPs

- Data collected March 20 through July 17, 2020
  - Extended timeframe due to COVID-19
- Covered new Best Practice #15 (opioids) and #16 (automated dispensing cabinets)
- Received 245 responses
  - 27% from hospitals with less than 100 beds
  - 45% from hospitals with 100 to 499 beds
  - 28% from hospitals with 500+ beds
  - Only about half (58%) of respondents employed one or more full- or part-time Medication Safety Officer

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Best Practice 15

Practice	None	Partial	Full
Verify and document a patient's opioid status (naïve versus tolerant) and type of pain (acute versus chronic) before prescribing and dispensing extended-release and long acting opioids	41%	44%	15%
Default order entry systems to the lowest initial starting dose and frequency when initiating orders for extended-release and long-acting opioids	47%	30%	23%
Alert practitioners when extended-release and long-acting opioid dose adjustments are required due to age, renal or liver impairment, or when patients are prescribed other sedating medications	36%	40%	24%
Eliminate the prescribing of fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain	22%	37%	41%
Eliminate the storage of fentaNYL patches in automated dispensing cabinets or as unit stock in clinical locations where acute pain is primarily treated (e.g., in the emergency department, operating room, post-anesthesia care unit, procedural areas)	14%	15%	71%

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Best Practice 16

Practice	None	Partial	Full
Limit the variety of medications that can be removed from an automated dispensing cabinet (ADC) using the override function	9%	32%	59%
Require a medication order (e.g., electronic, written, telephone, verbal) prior to removing any medication from an ADC, including those removed using the override function	18%	32%	50%
Monitor ADC overrides to verify appropriateness, transcription of orders, and documentation of administration	3%	44%	53%
Periodically review for appropriateness the list of medications available using the override function	8%	25%	67%
Restrict medications available using override to those that would be needed emergently (organization-defined) such as antidotes, rescue/reversal agents, life-sustaining drugs, and comfort measure medications (e.g., for acute pain, intractable nausea/vomiting)	7%	37%	56%

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Questions?

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Questions?

- A copy of today's slides will be posted on our website
- Next MSOS Briefing date – September 24, 2020.

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