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November 2019

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November 2019

Moderated by: E. Robert Feroli, PharmD, FASHP

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Take a Walk for Safety

L. Hayley Burgess, Pharm.D., MBA, BCPP, CPPS
AVP, Clinical Pharmacy Services and Medication Safety
HCA Healthcare Clinical Services Group
Nashville, Tennessee

CSG Pharmacy Services

HCA Healthcare

HCA Healthcare

HCA Healthcare is comprised of locally managed facilities that include 184 hospitals and approximately 1,800 sites of care in 21 states and the United Kingdom.*
*As of May 2019

Other sites of care:

HCA Healthcare Ambulatory Surgery Division

HCA Healthcare | Physician Services Group

SARAH CANNON

CareNow

Patient Care Statistics:
Each year approximately five percent of all U.S. hospital services happen at a HCA Healthcare facility, including:

31.2 million
patient encounters

8.9 million
emergency room visits

224,000
babies delivered

*Figures represent the year 2018

3 | About HCA Healthcare

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The goal of the tool is to focus on the sharp end of harm and create actionable change.

-Bob Feroli

Agenda

- Goals of a medication safety walkarounds
- How to take a walk for safety
- Example of findings and solutions
- Share targeted tools for unit based pharmacist and pharmacy operations

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Medication Safety
Across the Continuum

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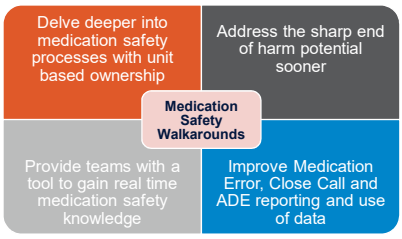
Goals of Medication Safety Walkarounds



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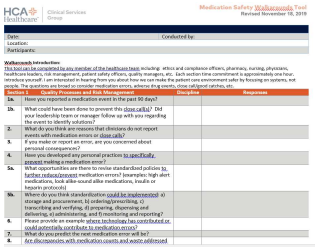
Medication Safety Walkarounds Tool



Questions designed for healthcare team to gauge hospital-wide med safety processes unit by unit and in pharmacy

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Walkarounds Steps Example

Opening Statement
- Begin with the same statement each time so that it becomes a value statement for the facility
- Introduce yourself. "I am interested in hearing from you about how we can make the patient care environment safer by focusing on systems, not people. The questions are broad so consider medication errors, adverse drug events, close call/good catches, etc."

Discussion
- Ask the group questions: "What aspects of your environment are likely to lead to medication errors?"
- Write down responses to questions: "As the nurse, when I complete computerized charting, the system keeps crashing. This may affect patient flow and the transfer of information between shifts."
- Read issues back to the group: "The computer system crashes multiple times per shift, which negatively affects workflow and information accessibility."
- Ask the group to prioritize the responses

Closing Statement
- Elicit help from participants in changing the culture: "Reports will not lead to disciplinary action."
- Articulate leaders' commitment: "Leadership supports walkarounds and is committed to changing culture and promoting patient safety."
- Communicate next steps to participants: "Next steps will be to research why computers are crashing, and we will provide an update at the department meeting next month."

Providing Feedback
- Establish process for timely feedback, multiple times, to all areas of the organization
- Write thank you cards for participating in walkarounds
- Communicate from leadership to frontline staff about what is being done with the information gathered: "As a result of the walkarounds, the computers that crashed were updated to fully support the needs of the charting software."

http://www.wsha.org/wp-content/uploads/ExecLeadershipRounding.pdf
https://www.ahrq.gov/downloads/pub/advances/vol4/Graham.pdf

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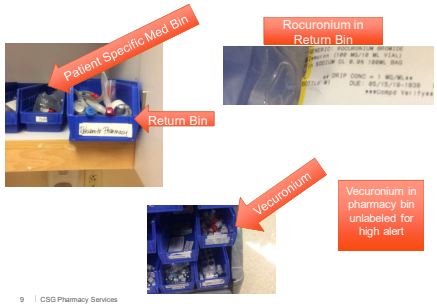
Walkarounds findings: Safety of Neuromuscular Blockers (NMB)



- Unit Finding: rocuronium placed in pharmacy return bin in close proximity to medications for administration
- No identification for high-alert medication or NMB
- Pharmacy storage: vecuronium unlabeled as high alert, no paralytic warning visible

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Enterprise Action Plan: Take Action Now to Help Keep Our Patients Safe

- **ISMP 2018-2019 Targeted Medication Safety Best Practice #7:** Segregate, sequester, and differentiate all neuromuscular blocking agents (NMBs) from other medications, wherever they are stored in the organization.
- Actions for facility:
  - Segregate NMBs from all other medications in the pharmacy by placing them in separate lidded containers in the refrigerator or other secure isolated storage area
  - Eliminate storage of NMBs in areas of the hospital where they are not routinely needed
  - In patient care areas where used (e.g., ICU), place NMBs in a sealed box or preferably in a rapid sequence intubation kit
    - If NMBs must be stored in ADCs, standardize storage practices throughout the organization by keeping them in lock-lidded pockets
  - Place auxiliary labels on all storage bins and/or ADC pockets and drawers that contain NMBs, and all final medication containers of NMBs (e.g., syringes, IV bags) that state: **"WARNING: PARALYZING AGENT – CAUSES RESPIRATORY ARREST – PATIENT MUST BE VENTILATED"**
  - Automated dispensing cabinet: standard clinical decision support; Is this patient ventilated or in the process of being ventilated? (Yes or No?)

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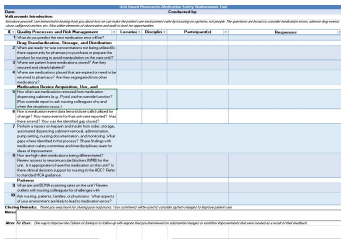
Medication Safety Walkarounds: Tool for Unit-Based Pharmacists



Questions designed for Unit Based Pharmacists with focus on:
- Basic safety processes to detect drift
- Medication management opportunities for high-alert medications

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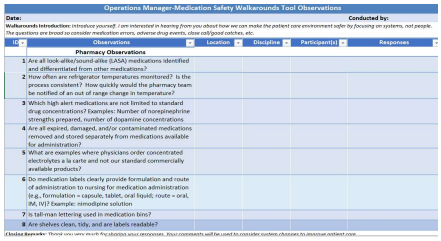
Medication Safety Walkarounds: Tool for Pharmacy Operations Managers



Questions designed for Pharmacy Operations Managers with focus on:
Basic pharmacy-centric operational processes

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Next Steps

- Use the Medication Safety Walkarounds Tool to train unit based and operational pharmacists
  - Particularly in the Pharmacy and Pharmacy Satellites
- Perform medication safety walkarounds to meet safety needs of physicians and nurses
- Provide feedback routinely
- Monitor for changes in evaluation measures
- Take action to implement best practices identified on other hospital units and across health-systems
- Review safety issues with the medication /patient safety committees and executive leadership huddles as appropriate

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Questions?

Thank you!

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Identifying Patients at Highest Risk for Opioid Induced Respiratory Depression (OIRD)
Medication Safety Officer Society, Nov 2019

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System Medication Safety Pharmacist
BJC HealthCare
St. Louis, Missouri

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Respiratory Compromise and OIRD

- Post-operative respiratory failure is the largest single-source of **avoidable in-patient days** and is the third most common patient safety event.[1]
- Respiratory compromise **increases patient mortality rates** by over 30% and hospital and ICU stays by almost 50%.[2]
- A recent study found **41% of patients on general care floors** experienced respiratory depression.[5]
- **Inadequate monitoring** of patients is a major cause for adverse events associated with opioid use. Advanced respiratory monitoring reduces high cost events.[3,4]

1. "HealthGrades Sixth Annual Patient Safety in American Hospitals Study," Healthgrades, 2011. https://www.hospitals.healthgrades.com/CPM/assets/File/PatientSafetyInAmericanHospitalsStudy2009.pdf
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3. Quach JL, Downey AW, Hasse M, Hasse-Fwilitz A, Jones D, Bellomo R. Characteristics and outcomes of patients receiving a medical emergency team review for respiratory distress or hypotension. J Crit Care.
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5. Khanna AK, et al. Derivation and validation of a novel opioid induced respiratory depression risk prediction tool. Presented at: Society of Critical Care Medicine's 48th Critical Care Congress; Feb. 17-20, 2019; San Diego

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Regulatory: TJC Standards on Pain Management Jan. 2018

- **Who?:** Standard PC.01.02.07: 6. The hospital **monitors patients identified as being high risk** for adverse outcomes related to opioid treatment.
- **How?:** Standard LD.04.03.13: 7. Hospital leadership works with its clinical staff to identify and acquire the **equipment needed to monitor patients who are at high risk** for adverse outcomes from opioid treatment.
- **Measure?:** Standard PI.02.01.01: 19. The hospital **monitors the use of opioids** to determine if they are being used safely
  - (for example, **the tracking of adverse events** such as respiratory depression, naloxone use, and the duration and dose of opioid prescriptions).

https://www.jointcommission.org/

The Joint Commission

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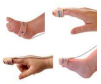
Monitoring Options

Pulse Ox
- Measures saturation of oxygen carried in RBCs
- Lagging indicator



Minute ventilation
- Minute Ventilation (MV) is the amount of air someone breathes in a minute
- From chest wall movement, device calculates
  - Tidal Volume X Resp Rate= MV.

Capnography (EtCO2)
- Measures exhaled carbon dioxide known as end **tidal** CO_2 ($EtCO_2$)
- Direct measure of Ventilation
- Allows for early identification of Respiratory Compromise
- Not affected by supplemental Oxygen

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Respiratory Monitoring Technology

Method of monitoring	Advantages	Disadvantages
Pulse Ox	Cheap Well tolerated	Poor with supplemental O2 Thresholds alarm: False Positives
Capnography	Direct measure of ventilation Useful with Supp O2 Detects apnea Can display wave forms	Sampling line can be obtrusive More expensive the Pulse Ox
Minute ventilation	Indirect measure of ventilation Can detect apnea Non-invasive	Not studied well Prone to motion artifacts Imputed value, may not detect obstruction
Continuous Monitoring	Early and regular detection	Emerging data on risk assessing patients Possible alarm fatigue
Spot checks	Low labor	Will miss many events

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Minutes Are Brain Cells, Aren't They?

Who do we use this technology on?

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Who Is At Risk?

NO standardized tool exists for predicting risk of OIRD, yet…

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MOSS: Michigan Opioid Safety Score

- **Incorporates** patient risk, respiratory rate, and sedation into one bedside score
- Developed for **post-surgical patients receiving IV opioids**
- **Not validated**

1Pt: Snoring/obesity/sleep apnea history.
1Pt: Site of surgery (abdominal/thoracic) and anesthesia time (if 0.3 hours within 24 hours of MOSS assessment).
1Pt: Concomitant sedative use (if within 2 hours of MOSS assessment).
1Pt: Advanced age as well as current smoking history
Above: Max of 2 pts
0Pts: >10 breaths/minute yields
2Pts: < 10 breaths/minute

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MOSS Interpretation

- **(0-1 Pt) Safe:** Patients may receive continued opioid therapy.
- **(2 Pts) Concern**: Patients should be identified during nursing handovers as at-risk patients that may need to be monitored more closely on the clinical unit than those deemed safe.
- **(3-4 Pts) Caution:** Opioids should be decreased and levels of monitoring increased. This may necessitate transfer to an intensive care or step-down unit, or the need for continuous pulse oximetry, respiratory rate, or capnographic monitoring on the clinical unit.
- **STOP**: If patient drifts off to sleep, difficult to arouse or unarousable: Opioids should be discontinued immediately, primary care providers should be notified, and patients should be monitored/treated aggressively to prevent hypoventilation, hypercapnea, hypoxemia, apnea, and death.

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PRODIGY Study

(Prediction of Opioid-Induced respiratory Depression In patients monitored by capnoGraphY)

Only abstract published and presented in February 2019. (Publication in process)

- 1384 inpatients on general hospital floors receiving opioids, 16 states, Europe and Asia.
- Blinded continuous capnography and pulse-ox with alarms silenced (spot checking okay)
- Respiratory depression defined as having at least 1 of following:
  - etCO2 <15 or >60 for > 3mins
  - Resp rate <5 for > 3 mins
  - SpO2 <85% for > 3 mins
  - Apnea >30 sec
  - Respiratory opioid-related adverse event

Khanna AK, et al. Derivation and validation of a novel opioid induced respiratory depression risk prediction tool. Presented at: Society of Critical Care Medicine's 48th Critical Care Congress; Feb. 17-20, 2019; San Diego.

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PRODIGY Study Results

Positive predictors of Opioid Induced Respiratory Depression (OIRD)

- >70 years old
- Male
- Major organ failure
- CHF or cardiac disease
- CAD
- COPD or pulmonary disease
- Pneumonia
- Type 2 diabetes
- HTN
- Kidney failure
- Opioid naivety

Independent Predictors Used in Model

- Age >60 or >70
- Male sex
- CHF
- Sleep disorders
- Opioid Naivety

Khanna AK, et al. Derivation and validation of a novel opioid induced respiratory depression risk prediction tool. Presented at: Society of Critical Care Medicine's 48th Critical Care Congress; Feb. 17-20, 2019; San Diego.

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PRODIGY Score and Results

- Score ranges from 0-39
  - High >15
  - Intermediate 8-15
  - Low 0-7
- Identified 76% of the patients with confirmed respiratory depression
- Good separation: High risk group was 6 times higher risk for OIRD than the lowest risk group
- Scoring is not published yet

It's Not Carelessness→
It's Complexity!!

Khanna AK, et al. Derivation and validation of a novel opioid induced respiratory depression risk prediction tool. Presented at: Society of Critical Care Medicine's 48th Critical Care Congress; Feb. 17-20, 2019; San Diego.

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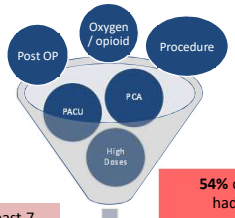
BJC Risk Assessment Model

We tested several hypothesis based on risks found in the literature to identify our highest risk population- balancing sensitivity and specificity.



Community Standard: At least 7 other local hospitals are utilizing capnography at the bedside only on patients receiving a PCA.

54% of our patients with OIRD had a concurrent order for **parenteral narcotic and were receiving supplemental oxygen** prior to the oversedation event. (vs. **18%** on PCA)

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Take Home Points

- OIRD is bad
- Continuous monitoring of ventilation is good
- Numerous risk factors with no well accepted method to identify highest risk patients
- PCA identifies 18% patients with events
- Supplemental O2 + order for IV opioid identifies 54% patients with events
- PRODIGY trial may be better: 76%

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ASSESSMENT QUESTION

- What are 3 methods that can help identify a population at high-risk of Opioid Induced Respiratory Depression(OIRD)?

a) The Prodigy Trial (soon)
b) The BJC method of Opioid and O2
c) The MOSS scale
d) Patients receiving a PCA

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Questions?

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Improving Medication Safety from the Source:
Leveraging Vendor Partnerships to Improve Patient Care

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Network Medication Safety Director
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Objective/Overview

Describe the various benefits which may be seen when collaborating with vendors during new product development

- Product Development Overview
- Collaboration Approaches and Benefits
- Vendor Interaction Questions

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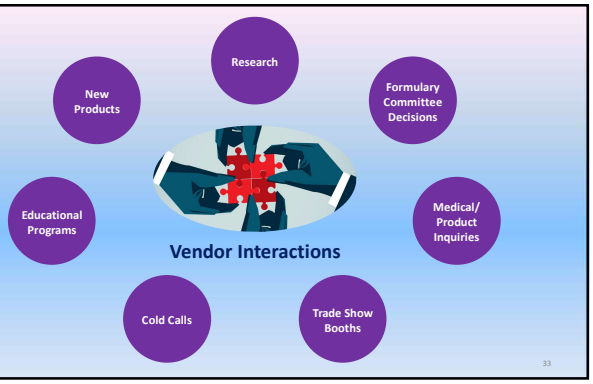

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Background
Case Study

Regardless of how interaction began, we may find ourselves in this common experience…

After several meetings with a vendor, you decide to purchase their product/upgrade. You are excited for this new opportunity to enhance patient safety, but after product implementation you start to recognize the following …

- Numerous system design "flaws" in the product
- UNEXPECTANTLY needing to redesign current workflow
- Ultimately not fixing the original problem

What if a product…

- Did not create unexpected, new workarounds?
- Was designed around all of your patient and caregiver safety needs?

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Several factors may contribute to inadequate product design…

….One of these reasons include **lack of consumer influence**

So…
let's pull back the green curtain!

But in order for us (i.e., users/consumers) to influence product design…

….We need to first understand the development process

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Product Design
Non-Medication

Non-medication items do not involve the same protection and rigorous review required for medications

Only items considered as devices with the FDA require completion of a 510(k) form
- For example, refrigerators to be purchased for medication storage do not need FDA approval to be considered medical grade

Class	Key Features	Examples
I	• No premarketing requirements • Majority are exempted from GMP regulations (as long as not labeled or marketed as sterile)	• Gloves with chemo labeling
II	• No premarketing requirements	• Infusion Pump • Remote Medication Management System • Syringes (insulin, midazolam, EPINEPHrine)
III	• Only class requiring premarket approval (i.e., data from studies must be provided to FDA when submitting for approval)	• Any device that supports or sustains human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury

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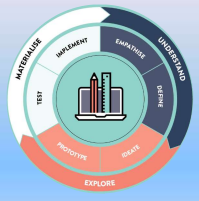
Product Design



Transforming ideas to create an item that will

- Perform its intended functionality in an *efficient, safe, and reliable* manner
- Meet a need or fill a gap in the consumer market

UNDERSTAND

Interviews, Shadowing, Field Research, Attitude Research/Focus, Confirm Challenges and Pain Points

Conduct research to discover user needs and their current processes

- Understand user challenges to evolve problem space
- Identify correct problem to ensure appropriate corresponding solutions are generated

EXPLORE

Brainstorming, Advisory Boards, Mockups, Sketches, Trade Booth Exhibits

Potential solutions generated and preliminary model created

- Cross-disciplinary team utilized to develop solutions
- Hands-on exploration allowed with low-resolution idea version

MATERIALISE

Beta Testing, Help Center Information, Direct Consumer Feedback, Surveys

Put vision into effect after user testing/feedback

- Continue monitoring/discovery for improvement

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Collaboration Benefits

Sustainable solutions require key stakeholder input during process improvements

- Important to recognize the value end user expertise/knowledge can provide
- Including stakeholders when formulating solution(s) ensures design will serve those utilizing the process

Mutual Benefits

Designer/Vendor	User/Consumer
Provide Real World Experiences	Different Lens/Perspective Reviewing Process
Key Stakeholder Inclusion	Connection/Build Relationships
Sustainable Product Design	Expand Process Design Knowledge
	Influence Product Design

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Vendor Questions

Application

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Vendor Questions

Example 1

- Why was a product designed in a certain manner?
  - Especially when best practices (i.e., ISMP, USP, FDA, etc.) are not incorporated?

Situation: Interaction during vendor trade show booth

Product: Small-bore Connectors Intended for Enteral Applications

- Class II medical devices
- Approved through 510(k) process and only require evidence of substantial equivalence to an originator medical device

- **User Question:** Why do some of your syringes have two measurement scales?
- **Vendor Response:** During research, they discovered a need from the user that required both measurement scales (mL and ounces).

Why did they not incorporate ISMP recommendations of utilizing metric scale only?

- **Vendor Interaction:** After a conversation with the vendor, discovered they did not know about this best practice. They requested where they could find this information for future use and noted them writing down as a reminder to follow up with their product development team to discover how they could incorporate this best practice in future product designs.

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Vendor Questions

Example 2

- Was the study design appropriate for the metrics/claims of the product?

Situation: Interaction during vendor trade show booth

Product: Closed System Drug Transfer Device (CSTDs)

- Class II medical devices
- Approved through 510(k) process and only require evidence of substantial equivalence to an originator medical device
- **FDA states only the manufacturer has data to support their product's ability to reduce hazardous expose by being "closed"; No statement on providing data regarding how well the device works**

- **User Question:** How often has your product been known to fail and how does your company utilize this information?
- **Vendor Response:** Their product was able to demonstrate a fail rate of zero.

How did they acquire this data?
How many times did they test the product?
How do they make improvements to their product?

- **Vendor Interaction:** Representative provided a published paper showing a fail rate of zero. When reviewing paper with the representative, discovered the claim for their failure rate was formulated after only testing the product 20 times. Discovered company did not have a method to gather failures from customers to make product improvements.

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Key Takeaways/Application

Encourage audience to interact with vendors

Variety of roles/perspectives ensures full understanding of the process, which is important when creating a product/solution

Allows exchange of knowledge/expertise between vendors and product users

Ensures usability testing is completed to identify and resolve potential problems of new product

Determine if product is best for your organization by providing focus questions to investigate their product development process

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Questions?

ISMP Update

Institute for Safe Medication Practices

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
- Next MSOS Briefing date coming soon….
  - Check the MSOS website for updates

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