MSOS Member Briefing
May 2021

MSOS Member Briefing
May 2021

Moderated by: E. Robert Feroli, PharmD, FASHP

MSOS
MEDICATION SAFETY OFFICERS SOCIETY

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JOHNS HOPKINS
MEDICINE

Removing Bulk Bottles from Patient Care Units: Oral Methadone

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MSOS Member Briefing
May 2021

The Johns Hopkins Hospital

- 1,192 Beds
- Central Pharmacy + 6 Decentralized Pharmacy Divisions
  - Adult Inpatient
  - Critical Care & Surgery
  - Weinberg Oncology
  - Pediatric
  - Ambulatory & Care Transitions
  - Investigational Drug Service
- Automated Dispensing Cabinets: Pyxis™ MedStation™

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Current State of Oral Methadone

- Pyxis™ stocked with oral methadone solution
  - 2 mg/mL, 60 mL bulk bottles
- Repackaged in-house in Central Pharmacy

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Safety Concerns

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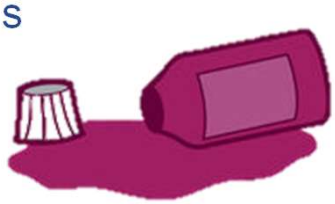
- Confusion about concentration, volume, or dose
- Incidents of under/over-dosing
- Incorrect stocking of Accu-Dose™ barcode labels
- Volume discrepancies
- Spills



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ISMP Targeted Medication Safety Best Practices for Hospitals 2020-2021

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BEST PRACTICE 4: (REVISED)

Ensure that all oral liquid medications that are not commercially available in unit dose packaging are dispensed by the pharmacy in an oral syringe or an enteral syringe that meets the International Organization for Standardization (ISO) 80369 standard, such as ENFit.

- Do not stock bulk oral solutions of medications on patient care units.
- Use only oral syringes that are distinctly marked "Oral Use Only."
- When ISO 80369 compliant syringes (e.g., ENFit) are used for administration of oral liquid medications, always highlight on the pharmacy label, or affix an auxiliary label, "For Oral Use Only" on the syringe.
- Ensure that the oral/enteral syringes used do not connect to any type of parenteral tubing used within the organization.

Exception: If the pharmacy is employing unit dose packaging automation that does not use oral syringes, unit dose cups/bottles may be provided in place of oral syringes. However, ensure that oral or ISO 80369 compliant syringes (e.g., ENFit) are available on nursing units in case patients cannot drink the medication from the cup or bottle.

5/27/2021 6

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Proposed Solution

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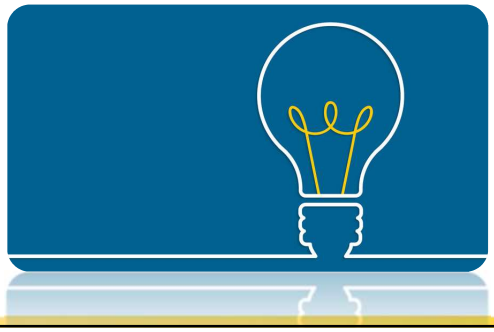
- Replace bulk bottles in Adult unit Pyxis™ with pre-filled oral methadone syringes
- Purchase pre-filled oral syringes from third party repackager



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Barriers to Implementation

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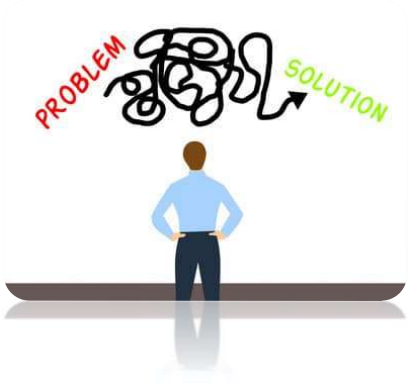
- Pyxis™ space
- DEA allocations
- New nursing workflows
- Informatics personnel to make changes
- Reliability of supply from repackager



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Developing a Plan

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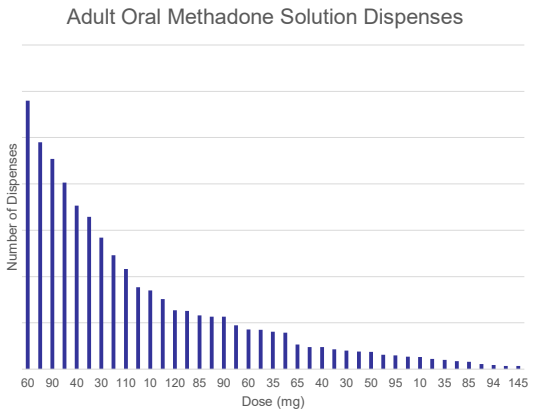
- Use analysis
- Product selection
  - Cups vs Oral Syringes
  - Associated Waste
- Cost analysis
- Multidisciplinary committee approval
- Contingency plans



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Replacement Products

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- New adult concentration
  - 2 mg/mL → 10 mg/mL
- Two amounts
  - 10 mg
  - 30 mg

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But What About Pediatrics?

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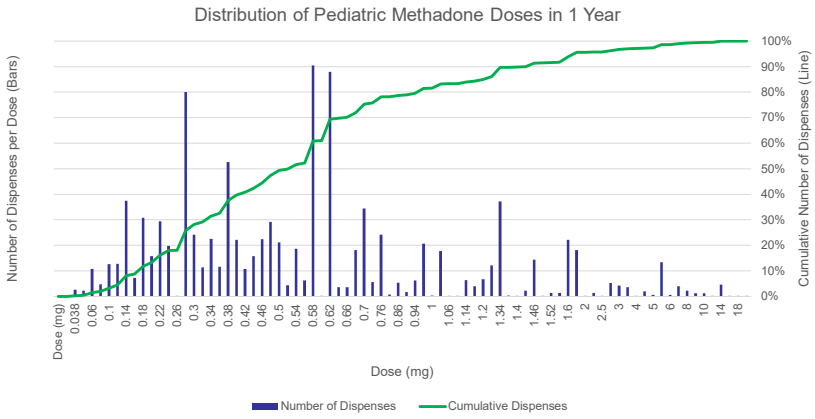
Full Analysis for Pediatrics

Dose	Percent of Total Dispenses
0.5 mg or less	47%
2 mg or less	96%
4 mg or less	97%
>4 mg	3%



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Ultimate Decision

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Adults

- Formulation: Oral Syringe
- Concentration: 10 mg/mL
- Amounts:
  - 10 mg
  - 30 mg

Pediatrics

- Formulation Oral Syringe
- Concentration: 1 mg/mL
- Amounts:
  - 0.5 mg
  - 4 mg

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Layers of Safety: Adult vs Pediatric Oral Syringes

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- Different syringe sizes
- Different labeling
- Barcode scanning
- Separate storage

- Low likelihood of need for in-house pediatric dose repackaging
  - Separate repackaging times

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Next Steps & Big-Picture Plans

- Distribute staff education
- Go-Live: June 2021
- Monitor changes
- Create checklist for remaining products in bulk bottles
- Determine sequence of remaining bulk bottle removal
- Develop timeline for removing remaining bulk bottles

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What Was Learned

- Involve relevant disciplines
- Use data
- Predict failure modes
- Have contingency plans
- Communicate changes
- Maintain vigilance for unintended consequences

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Questions?

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ONCOLOGY CLINICAL TRIALS PROTOCOL CLARIFICATIONS

Vivian Loo, PharmD, BCOP
Sarah Kim, PharmD, BCOP
Senior Protocol Content Administrators
City of Hope, Duarte, CA

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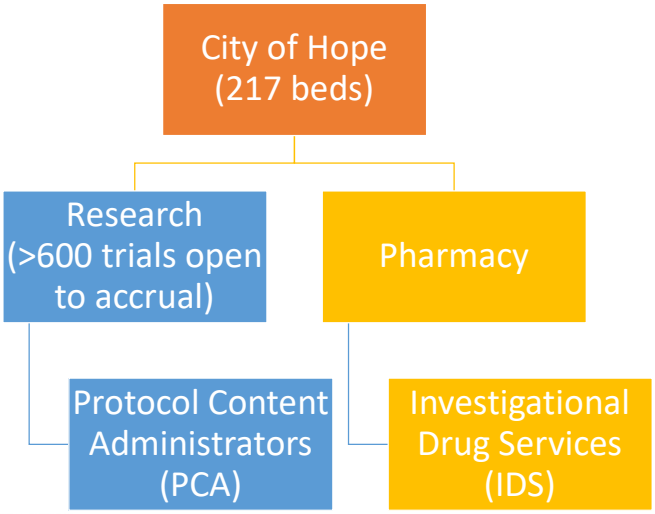
Protocol Content Administrators (PCA)



- Multidisciplinary team
  - Pharmacists and nurses
- Clinical and system certifications related to oncology
- Role and responsibilities
  - **Operationalize the protocol for execution** through creation of Beacon treatment plans within Epic electronic medical record (EMR) system
  - Review all research documents in entirety

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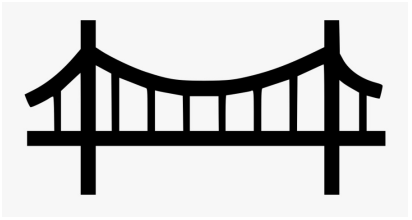
Protocol Content Administrators (PCA)

IRB
- Protocol – High level
- Ethics, objectives/aims, feasibility

PCA
- All research documents (protocol, lab manual, pharmacy manual)
- Detail, all assessments and drug(s)

IDS
- Pharmacy Manual
- Drug(s) only



IRB | PCA: Bridges the gap | IDS

City of Hope. **IRB**: Institutional Review Board; **PCA**: Protocol Content Administrator; **IDS**: Investigational Drug Services

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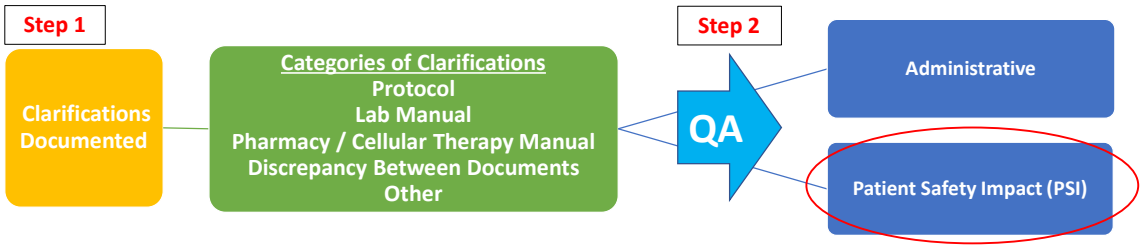
Project: Research Protocol Clarifications

Captures team efforts in identifying and resolving research protocol discrepancies / issues



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Defining "Patient Safety Impact"

- **World Health Organization (WHO)[1]**
  - Preventing harm, particularly 'avoidable harm'
  - Reduction of risk of unnecessary harm
- **Questions to ask:**
  - What was the resolution?
  - What's the worst thing that could happen to the patient if NOT clarified?

	Considered PSI	NOT PSI
Drug Dosing, Administration, Frequency	Any	
Dispensing Discrepancies	Incorrect bottle count Incorrect dispensing timepoints	Giving extra tablets due to requirement of dispensing full bottle
Procedures	Excessive or inconsistent timepoints	A discrepancy in procedure window
Labs	Collection discrepancies (extra blood stick, extra tube of blood, extra blood volume)	Processing discrepancies would not affect patient safety
Terminology	Unclear terminology Ex: "biweekly" can mean twice weekly OR twice a month	

City of Hope. 1. https://www.who.int/patientsafety/about/en/

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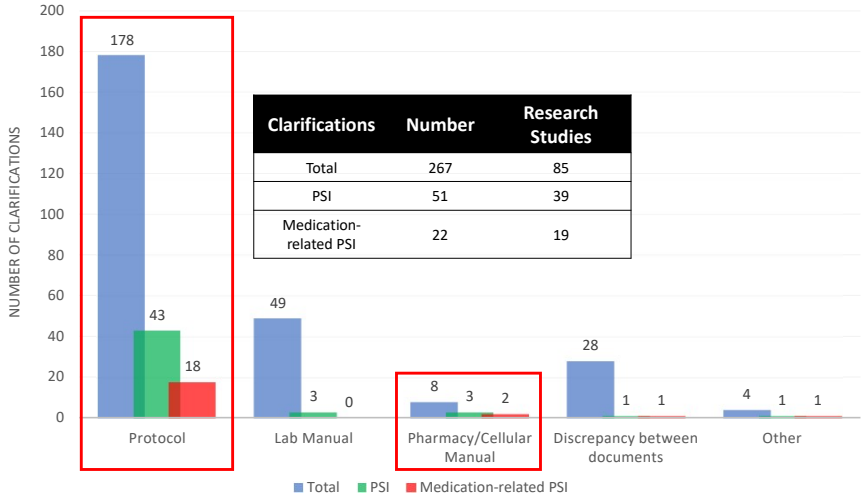
Clarifications Results

Feb 22, 2021 to May 4, 2021



Clarifications	Number	Research Studies
Total	267	85
PSI	51	39
Medication-related PSI	22	19

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Medication-Related PSIs

Type of Medication-Related PSIs	Number (%)	Examples
Drug Dosing	**7 (32%)**	• Inconsistent weight-based dosing guidance • Allowable pediatric intrathecal drugs unclear • Nivolumab dosing only notes GREATER than or LESS than 18 years old • Dose-reducing fosaprepitant due to DDI with encorafenib
Drug Frequency	**7 (32%)**	• Start, stop, duration, schedule of therapy
Drug Administration	**6 (27%)**	• Method of rinsing transplant cells in IV bag at end of infusion • Infusion duration discrepancy • Allowable pre-medication agents • Infusion-related reaction management
Drug Dispensing	**2 (9%)**	• Incorrect # bottles to dispense • Drug dispensed every 3 cycles, but patient is evaluated for continuation each cycle

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Summary and Next Steps

Goal is to decrease number of PSI

- Highlights importance of having clinical study personnel dedicated to comprehensive review of research documents prior to patient start
  - In-depth review of protocol and pharmacy manual documents for drug information sections
  - Contributing to validity of clinical trial results
- Involvement in investigator-initiated trials (IIT) protocol writing to prevent PSIs
- Potential incorporation of our team with Institutional Review Board (IRB)
- Financial impact

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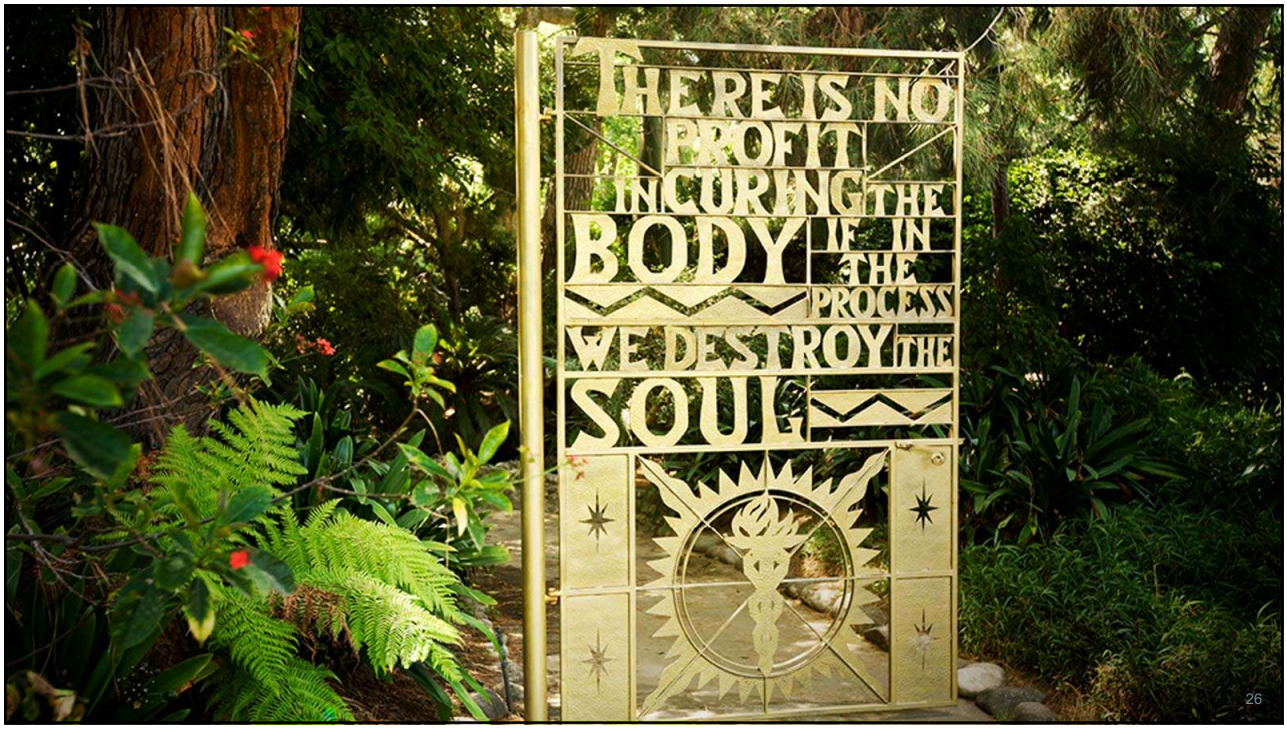

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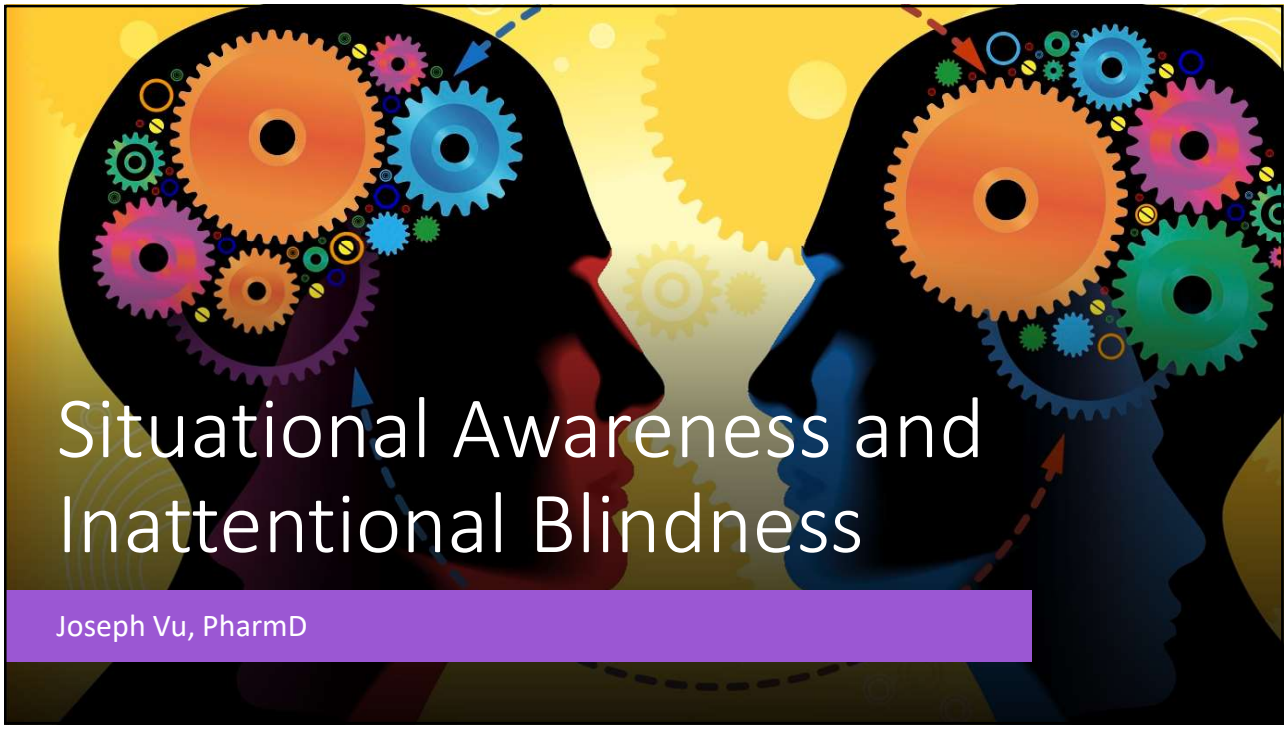

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Learning Objectives

Understand	Understand the general concept behind situational awareness and explain the three-level model as proposed by Endsley (1995)
Compare	Compare situational awareness to inattentional blindness and assess the dynamic relationship of these in the healthcare setting
Discuss	Discuss situational awareness practices/strategies that have been integrated in daily workflow to mitigate the risk of inattentional blindness

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Situational Awareness

- According to the Agency for Healthcare Research and Quality (AHRQ), situational awareness is the state of knowing the conditions that affect one's work
- It may be achieved by actively monitoring the dynamic nature of the task at-hand
- In the healthcare setting, it may include:
  - Knowing the status of the patient
  - Knowing the status of other team members
  - Being aware of environmental conditions
  - Understanding the current progress towards the goal

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Three Primary Levels

Mica Endsley, a former Chief Scientist for the United States Air Force, developed a theory for situational awareness in 1995

Her three-level model was comprised of:

1. Perception of key elements in the environment
2. Comprehension of the current situation
3. Projection of future status

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Perception of Key Elements

- This marks the first (and perhaps most important) step in achieving situational awareness
- Involves a conscious recognition of the ***relevant*** factors in the current state of affairs
- May be subject to error in the form of inaccuracy and/or incompleteness

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Comprehension of the Situation

- Builds upon and augments the mere recognition of key elements in the environment
- Involves an extensive understanding of said elements relative to the overall goal
- Deficiencies are often secondary to lack of level 1 situational awareness, inept training, and/or utilization of an incorrect mental model

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Projection of Future Status

- Defined as the ability to anticipate/foresee expected and unexpected outcomes of the current state
- Achieved by understanding how level 1 and level 2 situational awareness factors interact with each other and using this information to predict future occurrences
- Requires constant re-evaluation and adaptation of mental models in the ever-changing environment

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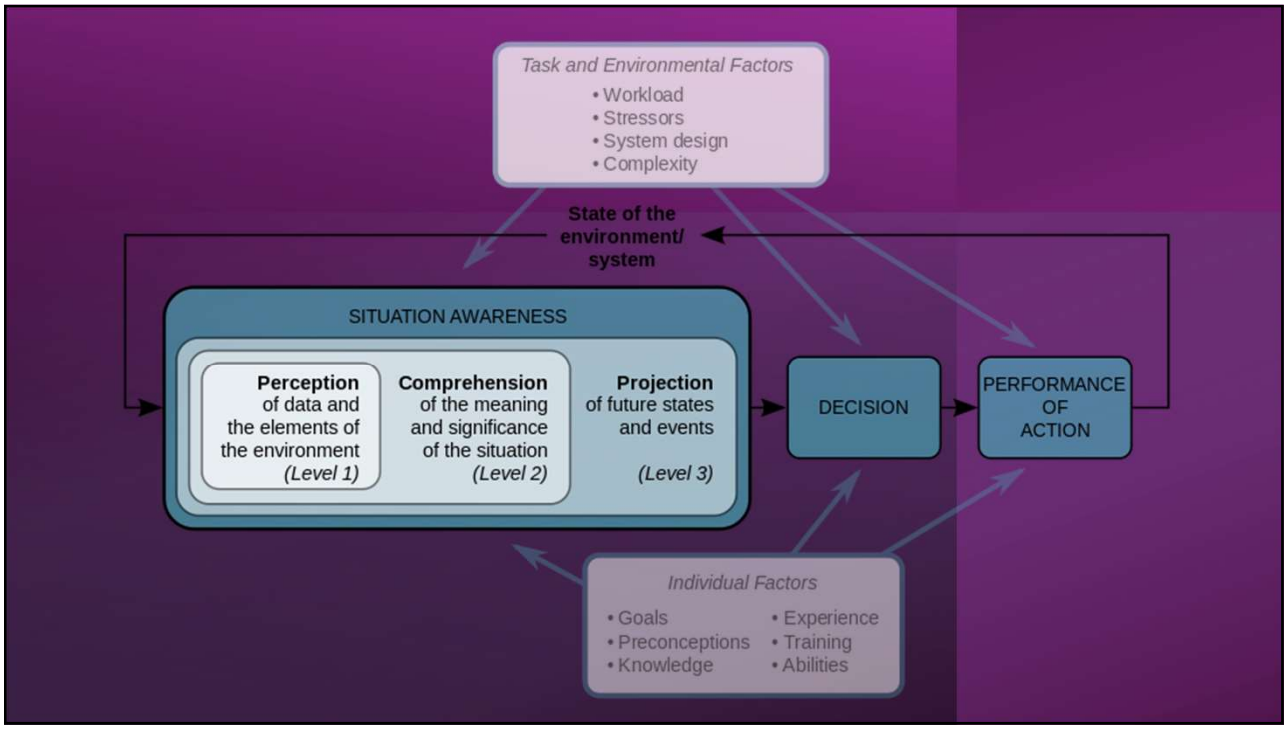

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Inattentional Blindness

- Failure to perceive a variable that is in plain sight secondary to directed focus elsewhere; the antithesis to situational awareness
- Often occurs because said variables are not expected – they do not fit the mental model currently in use
- "Humans have a finite amount of attention… We were not made to multi-task!"

The Invisible Gorilla: Simons & Chabris (1999)

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Examples in Healthcare

- An RN pulls a vial of heparin from the Pyxis machine and goes through the "7 rights" of medication administration. She proceeds to draw up the dose and gives it to an infant. Following an MRT, it was discovered that the infant had received heparin 10,000 units/mL rather than the ordered 10 units/mL.
- A pharmacist enters a prescription for methotrexate daily into the electronic health record. A dose warning appears on the screen, but the pharmacist bypasses it and dispenses the medication. The patient receives an overdose and is hospitalized.

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Conceptual Relevance

- The body's basic senses have the ability to intake unlimited information from the environment, but the brain can only process a finite amount at any given time
- The brain will then subconsciously "fill in the gaps" for anything that was omitted (sometimes erroneously)
- Adverse outcomes typically materialize when the brain misses key information and incorrectly compensates

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Relation to Situational Awareness

- Situational awareness work is traditionally centered around proper education and training
- The aforementioned types of error-reduction strategies have little utility in mitigating inattentional blindness, which is fundamentally involuntary and undetected
- Efforts should be focused on the systems level (i.e., by making important information more discernable and reducing distractions from reaching the operator)

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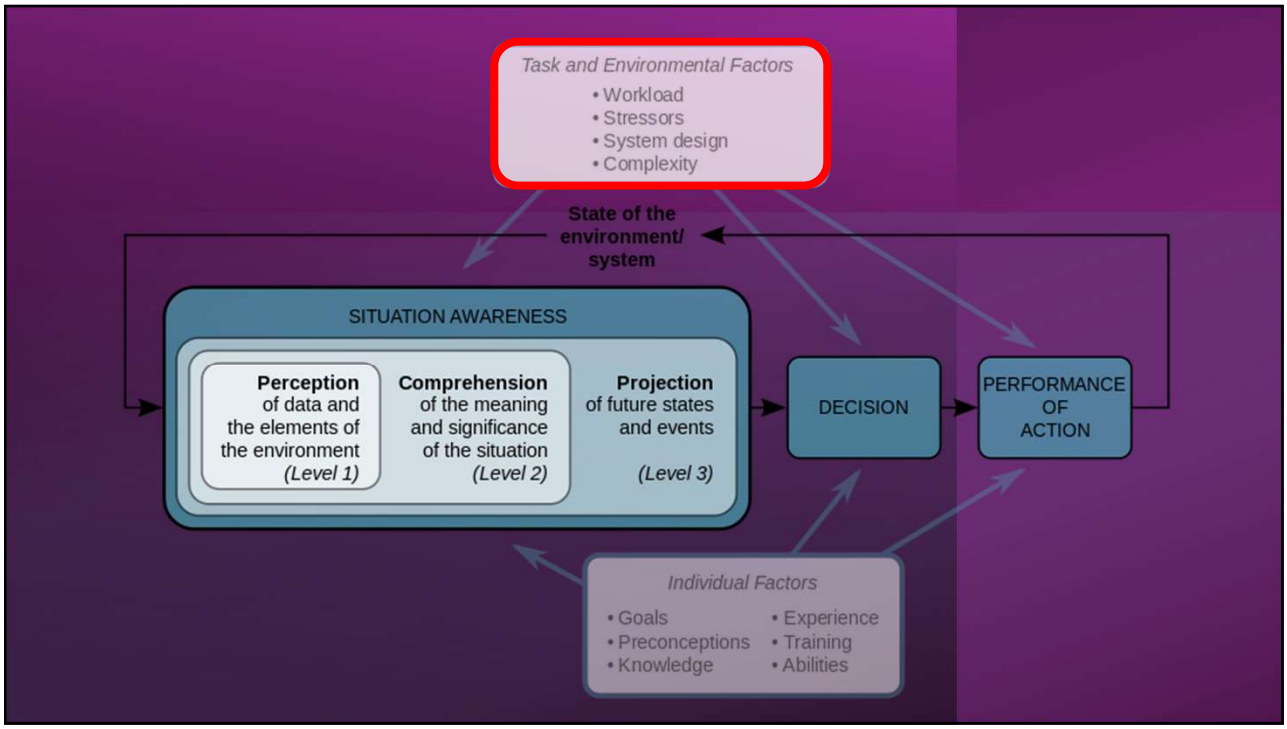

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Open Floor

- Cincinnati Children's is dedicated to the promotion of situational awareness applications to improve safety across our institution:
  - We have dedicated an entire FTE to filter/triage nursing inquiries and requests to the pharmacy
  - We have established an entire task force to actively monitor and optimize the infusion pumps
  - We have implemented many best practice alerts (BPAs) as a result of errors from safety reports
  - We have installed various measures to speed up the dispensing of time-sensitive medications (i.e., interface prioritization, STAT pass-through, red-card initiative)

What are some examples of situational awareness work at your respective facilities?

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References

1. TeamSTEPPS Fundamentals Course: Module 5. Situation Monitoring. AHRQ. https://www.ahrq.gov/teamstepps/instructor/fundamentals/module5/igsitmonitor.html. Accessed January 4, 2021.
2. Endsley MR. Toward a Theory of Situation Awareness in Dynamic Systems. Human Factors. 1995;37(1):32-64. doi:10.1518/001872095779049543.
3. Simons DJ, Chabris CF. Gorillas in our midst: sustained inattentional blindness for dynamic events. Perception. 1999;28(9):1059-74. doi: 10.1068/p281059. PMID: 10694957.
4. 4. Grissinger M. 'Inattentional blindness': what captures your attention?. *P T*. 2012;37(10):542-555.

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ISMP Update
MSOS Briefing May 2021

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

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ISMP Medication Safety Self Assessment® for Perioperative Settings

– Launched May 18th

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https://www.ismp.org/resources/medication-safety-self-assessmentr-perioperative-settings

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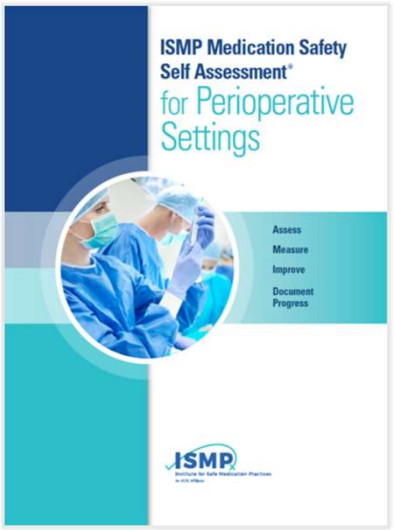
Benefits to Organizations

- Provide a standardized way for organizations to assess the safety of systems and practices associated with medication use in any phase of perioperative care
- Heighten awareness of best practices
- Compare their results with demographically similar organizations
- Create organization-specific, safety focused initiatives



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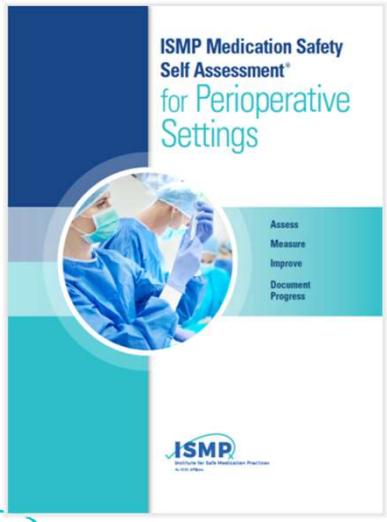
National Benefits



- Create a baseline of national efforts
- Pinpoint how currently designed systems, staff practices, and emerging challenges may impact perioperative medication safety
- Determine challenges many healthcare providers face in keeping patients safe during all perioperative phases of care
- Develop tools/resources associated with preventing harm from medication use

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Advisory Group

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- Deborah Wagner, PharmD, FASHP
- Rachel Stratman Wolfe, PharmD, MHA, BCCCP
- Nicole Yin, PharmD

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Endorsing Organizations

- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
- American Association of Nurse Anesthetists (AANA)
- American College of Clinical Pharmacy (ACCP) Perioperative Care Practice and Research Network (PRN)
- American Society for Health Care Risk Management (ASHRM)
- American Society of Health-System Pharmacists (ASHP)
- American Society of PeriAnesthesia Nurses (ASPAN)
- Anesthesia Patient Safety Foundation (APSF)
- Association of periOperative Registered Nurses (AORN)
- Children's Hospitals' Solutions for Patient Safety (SPS)
- ECRI
- Infusion Nurses Society (INS)
- Institute for Healthcare Improvement (IHI)
- National Association for Healthcare Quality (NAHQ)
- Pediatric Pharmacy Association (PPA)
- The Joint Commission (TJC)

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MSOS Member Briefing
May 2021

Potential Medication Error Risks With Investigational Drug Container Labels

FDA Public Meeting, May 18,19

Topics included:

1. The prevalence and types of medication errors attributed to container labels;
2. The impact of such errors on clinical investigations;
3. Information that should always be on the container label, and how that information should be presented to facilitate safe use;
4. Entities responsible for labeling containers;
5. Existing processes for reporting and analyzing medication errors and complaints related to container labels; and
6. Global regulatory convergence and differences for the information on container labels.

5/20/2021 US FDA Eyes New Investigational Drug Label Requirements That Bring International Harmonization :: Pink Sheet

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Printed By Amy Rowe

US FDA Eyes New Investigational Drug Label Requirements That Bring International Harmonization

19 May 2021 | NEWS

by Sarah Karlin-Smith | @sarahkarlin | Sarah.Karlin-Smith@informa.com

Executive Summary

To help reduce medication errors that can harm patients and compromise research results, FDA – pushed by clinical trial sites – looks to exert more control of the labels of investigational drug products.

CLINICAL TRIAL SITES ARE CONCERNED THE LABELS ON INVESTIGATIONAL DRUGS ARE CONFUSING

Source: photo illustration/Alamy Images

The US Food and Drug Administration is considering new regulatory action to create more consistency in the labeling of investigational drugs to help reduce medication errors and protect patients as well as the integrity of the clinical trial results.

The agency is looking at recommending a harmonized global approach to the issue.

Recent studies that have pointed to missing or confusing information on investigational drug labels as a contributing factor for medication errors have recommended global harmonization of the labels, said Gerald Dal

https://pink.pharmaintelligence.informa.com/PS144368/US-FDA-Eyes-New-Investigational-Drug-Label-Requirements-That-Bring-International-Harmon... 1/3

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Public Meeting with FDA May 18 & 19

Panel 1: Clinical Trial Site Perspectives

- **Michael R. Cohen**, RPh, MS, ScD (hon.), DPS (hon.), FASHP, President, Institute for Safe Medication Practices (ISMP)
- **Sapna R. Amin**, PharmD, BCOP, Manager, Investigational Pharmacy Services, MD Anderson Cancer Center, Houston, Texas
- **Richard Needleman**, RPh, Investigational Drug Services Pharmacist. Fox Chase Cancer Center, Philadelphia PA
- **Jamie N. Brown**, PharmD, FCCP, BCPS, BCACP, Investigational Drug Service Program Manager, Durham VA Health Care System
- **Han Feng**, PharmD, BCPS, Supervisory Pharmacist, Medication Safety National Institutes of Health
- **Raymond J. Muller,** MS, FASHP, Director of Pharmacy Quality, Safety & Training Programs, Memorial Sloan Kettering Cancer Center

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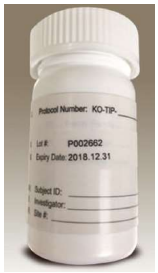
Other panels

- Panel 2: Supplier/CRO Perspectives
- Panel 3: Industry (Sponsor) Perspectives
- Panel 4: International Regulatory Perspectives
- Panel 5: Institutional Review Board Perspectives
- Panel 6: FDA Regulatory Perspectives
- Public Comment

Investigational product related issues- ISMP-2018

- License plate type product ID
- Changing product names not reflected on labels/protocols
- Unlabeled products
- Bulky "naked" boxes
- Missing, confusing or unnoticeable drug names
- Missing or hard to find strength
- Missing formulation
- International labels; multilanguage text
- Small font size; no differentiation of text
- Unsafe abbreviations and dose expressions
- Missing lot #'s and expiration dates
- No unit dose packaging for oral studies
- Multiple strengths of tablets-same color, size and shape

Some injectable investigational drugs that are light sensitive are packaged individually in bulky unlabeled white boxes that must be labeled by the clinical site prior to storage.



This investigational drug is identified by the protocol number only, although it has been assigned a generic name (tipifarnib). Also, the strength of the product (100 mg) can only be found below the peel-off label, although the drug is available in multiple strengths.

Panel 1 - Key Points

- ✓Investigational drug labeling needs to be consistent across sponsors, protocols, and formulations
- ✓Inconsistencies contribute to unsafe conditions and potential errors that could compromise research integrity or cause patient harm
- ✓Individual sites collaborate with sponsors to address safety challenges, but information & lessons learned may not be shared across phases or with other study sites
- ✓There is a need to report medication errors in a way that assures learning by all concerned

Presented at the Potential Medication Error Risks With Investigational Drug Container Labels Public Meeting 55

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Questions?

- A copy of today's slides will be posted on our website
- Next MSOS Briefing date – July 22, 2021.
  Register:
  https://ecri.zoom.us/webinar/register/WN_s6FpmZc2Ss6AoIIObhqrcA

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