MSOS Member Briefing March 2024

Moderated by: E. Robert Feroli, PharmD, FASHP





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Federal Funding Opportunities for Medication Safety Research

Medication Safety Officers Society | March 2024 Member Briefing

Farzana Samad, PharmD, FISMP, CPPS

Health Scientist Administrator

Agency for Healthcare Research and Quality (AHRQ) | Center for Quality Improvement and Patient Safety (CQuIPS)

Objectives



- Understand the role of medication safety research in practice
- Share examples of medication safety research currently funded through AHRQ Grants
- Discuss opportunities for federal (AHRQ) funding for medication safety research

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The role of medication safety research in practice



What works? How and when does it work? Where should we focus our efforts? What applies to our practice setting?

Research

Implementation

Measurement

- **User-driven research**
- Collaboration
- Dissemination

Use evidence-based research & tools to tailor interventions to your practice

Continuous learning

How do we get involved in medication safety research?



- What initiatives could benefit from research and evidence-based support?
- What could be shared so others can use your experience and results to generate ideas for their practice?
- Collaborate with your local researchers
- Collaborate with other institutions (e.g., other health-systems, academia, human factors experts)
- Collaborate with community champions (e.g., for community pharmacy services, for education, for patient experience)
- Mentored research and postdoctoral training (AHRQ NoFOs!)

Become a part of the research team!

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Stages of patient safety research initiatives



- Identification of risks, hazards, and patient harm.
- Design, implementation, dissemination and spread, and evaluation of interventions to improve patient safety.
- Establishment of strategies to sustain patient safety improvements such as culture, incident/event reporting, measurement, monitoring, and surveillance.

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Opportunities for AHRQ-funding: Sample active projects



Grantee	Title	Aims
Bykov	Drug interactions and opioid-related	1. Effects of <i>fluoxetine</i> and <i>paroxetine</i> on rates of opioid-related ER visits & hospitalizations among older adults who use <i>oxycodone</i> , <i>hydrocodone</i> , or <i>tramadol</i>
R01 HS 027623	emergency room visits and hospitalizations	 Effects of diltiazem and verapamil on rates of opioid-related ER visits & hospitalizations among older adults who use oxycodone, fentanyl, or tramadol Effects of clopidogrel and ticlopidine on rates of opioid-related ER visits and
Brigham and Women's Hospital	among older adults	hospitalizations among older adults who use tramadol

Exploratory: identification of risks, hazards, and patient harm.

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Opportunities for AHRQ-funding: Sample active projects



Grantee	Title	Aims
Becker	Optimizing OTC labels for older	1. Determine the information to be prioritized in order to reduce the likelihood of ADRs.
R01 HS 25386	adults: Empirical evaluation of labels	 Investigate formatting techniques that attract attention to critical information when accessing it is not the participant's explicit goal (bottom-up attention). Investigate formatting techniques that attract attention to critical information and
Michigan State	designed to provide older users	promote decision making when accessing that information is the participant's explicit goal (top-down attention).
University	the information they need to	4. Evaluate the information required for older consumers to make an appropriate OTC choice.
	minimize adverse drug	5. Evaluate how optimized labels (based on Aims 1-3) garner attention and support appropriate OTC drug selection by older adults.
	Events	Evaluate whether the benefits of an optimized label generalize to commercial brands.

Identification of risks, hazards, and patient harm; intervention development and testing

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Opportunities for AHRQ-funding: Sample active projects



Grantee	Title	Aims
Witt	Overcoming barriers to warfarin	1. Identify and validate potential PSM <i>barriers and facilitators</i> from the perspective of US patients and anticoagulation providers.
R18 HS 27960	patient self- management (PSM)	 Implement PSM in five US ambulatory care sites using implementation strategies developed in partnership with the Anticoagulation Forum's Centers of Excellence program and supported by rapid-cycle research methodologies to overcome
University of Utah	implementation in the US healthcare system	 identified barriers. 3. Identify specific factors associated with successful PSM implementation outcomes and quantify changes in anticoagulation therapy outcomes such as INR control, bleeding, and thromboembolism associated with PSM implementation.

Design, implementation, dissemination and spread, and evaluation of interventions to improve patient safety.

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Opportunities for AHRQ-funding: Sample active projects



Grantee	Title	Aims
Farag R18 HS 029292	Assuring Medication Safety in K-12 Schools: Implementing and	 Implement and evaluate the usability of eSMAR in a select sample of K-12 schools in the Iowa City Community School District. Understand contextual factors influencing eSMAR implementation. Evaluate the effectiveness of eSMAR (number of errors intercepted).
University of lowa	Evaluating the Electronic School Medication Administration Record (E-SMAR)	3. Evaluate the electiveness of estimate (number of errors intercepted).

Design, implementation, dissemination and spread, and evaluation of interventions to improve patient safety.

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Opportunities for AHRQ-funding: Sample active projects



Grantee	Title	Aims
Chui R18 HS 029608 The Board of Regents of the University of Wisconsin System	Engineering Resilient Community Pharmacies (ENRICH) Patient Safety Learning Lab	 Identify and define community pharmacy work system design requirements for safe medication practices to enable resilient performance. Design and develop MedSafeMap, a feasible and sustainable solution that facilitate safe medication practices through resilient performance. Implement MedSafeMap in community pharmacies and pilot test its impact on pharmacy staff attitudes, behaviors, and performance. Refine solutions and identify challenges to adoption. Assess resilience-focused attitudes, behaviors, and performance to support chronic chare management (CCM).

Design, implementation, dissemination and spread, and evaluation of interventions to improve patient safety. Establishment of strategies to sustain patient safety improvements such as culture, incident/event reporting, measurement, monitoring, and surveillance.

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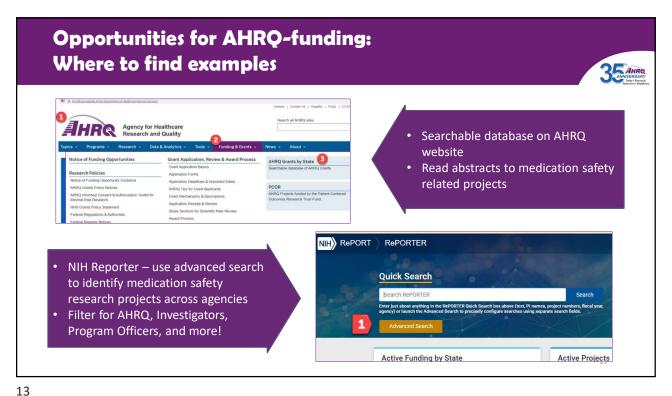
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Opportunities for AHRQ-funding: Sample active projects

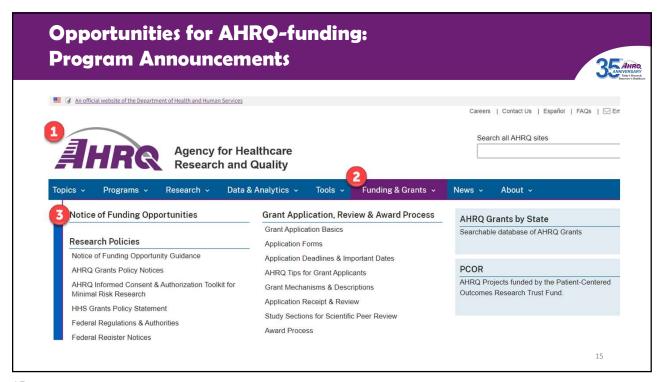


Grantee	Title	Aims
Lester	Preventing medication errors	 Refine the design of SAVE-Rx to resolve unsafe e-prescription transactions. Evaluate the implementation of SAVE-Rx for resolving unsafe e-prescription
R18 HS	due to unsafe	transactions.
028786	electronic prescription	3. Determine the effects of SAVE-Rx on medication safety outcomes.
Regents of	transactions with	*System Approach to Verifying E-Prescriptions (SAVE-Rx): algorithm uses e-prescription
the	just-in-time	transaction data to automatically identify when drug product description does not
University of Michigan	feedback	match e-prescription NDC or NDC dispensed

Design, implementation, dissemination and spread, and evaluation of interventions to improve patient safety



Opportunities for AHRQ-funding: Understanding the application process An official website of the Department of Health and Human Services Careers | Contact Us | Español | FAQs | ☐ En Search all AHRQ sites Agency for Healthcare Research and Quality Data & Analytics ~ Research ~ Tools ~ Funding & Grants 🗸 About ~ Programs v Grant Application, Review & Award Process Notice of Funding Opportunities AHRQ Grants by State Grant Application Basics Searchable database of AHRQ Grants Research Policies Notice of Funding Opportunity Guidance Application Deadlines & Important Dates AHRQ Grants Policy Notices AHRQ Tips for Grant Applicants AHRQ Projects funded by the Patient-Centered AHRQ Informed Consent & Authorization Toolkit for Grant Mechanisms & Descriptions Minimal Risk Research Application Receipt & Review HHS Grants Policy Statement Study Sections for Scientific Peer Review Federal Regulations & Authorities Award Process Federal Register Notices



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Opportunities for AHRQ-funding: Selected Notice of Funding Opportunities (NoFOs) Program Announcements: https://www.ahrq.gov/funding/fund-opps/index.html PA 24-156: Health Services Research Demonstration and Dissemination Grants PA 23-290: Improving Diagnostic Safety in Ambulatory Care: Strategies and Interventions PA 22-048: Large Health Services Research Demonstration and Dissemination Projects for Combating Antibiotic-R18 Resistant Bacteria (CARB) PA 21-267: Making Health Care Safer in Ambulatory Care Settings and Long-term Care Facilities PA 21-264: Large Health Services Research Demonstration and Dissemination Projects for Prevention of Healthcare-**Associated Infections** PA 24-154: Health Services Research Projects PA 24-093: Systems-Based Approaches to Improve Patient Safety by Improving Healthcare Worker Safety and Well-Being (Clinical Trial Optional) R01 PA 23-291: Understanding and Improving Diagnostic Safety in Ambulatory Care: Incidence and Contributing Factors PA 22-047: Large Research Projects for Combating Antibiotic-Resistant Bacteria (CARB) PA 21-265: Large Research Projects for Prevention of Healthcare-Associated Infections R03 PA 24-155: Small Health Services Research Grant Program R13 PA 22-238: Conference Grant Programs PA 21-164: Using Innovative Digital Healthcare Solutions to Improve Quality at the Point of Care (Clinical Trial R21/R33 Optional)



THANK YOU!

Thoughts?

Reach out! Farzana.Samad@ahrq.hhs.gov

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Simulation Medications The Risk is "Real"

Mara Weber PharmD, BSRT OhioHealth System, Doctors Hospital Medication Safety Pharmacist

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OhioHealth System

Not-for-profit system of hospitals and healthcare providers based in Ohio area.

- 15 hospitals, 200+ ambulatory sites, hospice, and other health services
- Spanning 47 Ohio counties



Doctors Hospital

- 213 bed, teaching hospital
- Large Osteopathic Medicine Program

BELIEVE IN WE™## OhioHealth

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Situation/Background

Healthcare simulation experiences use various types of medications and supplies.

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<u>A</u>ssessment

- Disparate simulation practices:
 - Simulation Lab Run vs Staff Educator
 - Isolated or In-Situ (on units)
 - Expired items
 - "Demo" Items
 - Self Made Items
 - Empty Boxes

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Assessment

- Each of the scenarios can present different risks:
- These items can look realistic (actually distilled water)
- Expired/Deteriorated
- Empty boxes/vials
- Reports from FDA & ISMP have shown these can make it into normal supply and have caused deaths

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Assessment



From the Foundation for Safe Healthcare Simulation: 2015 Demonstration/Simulated Sodium Chloride

<u>"The FDA report</u> estimates 45 patients received this fluid intravenously, 2 became septic, requiring ICU admission. Within all the documented incidents, 2 patients died, though the direct link to the fluid administration has not been confirmed. The FDA sent out a safety alert and continues monitoring"

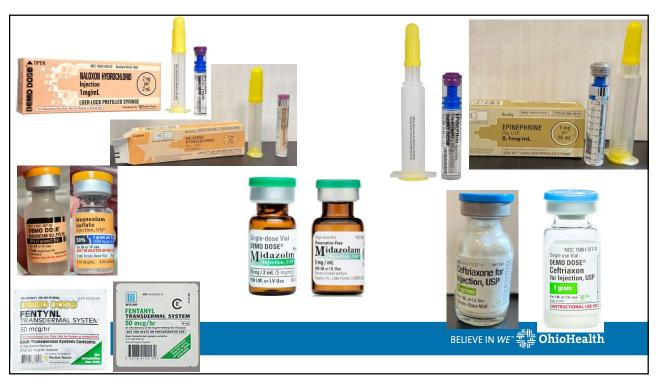
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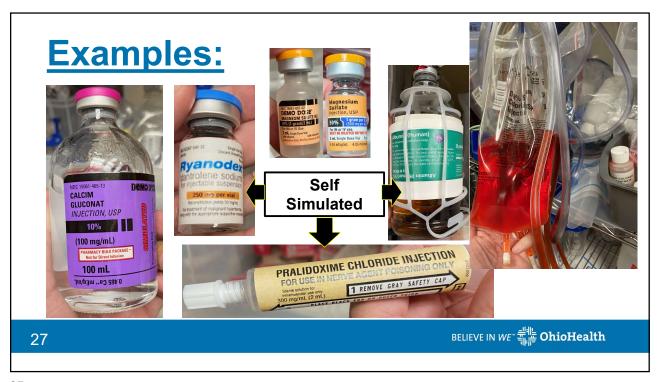
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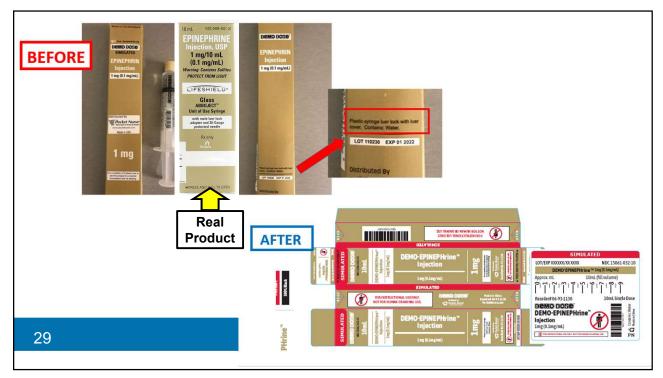


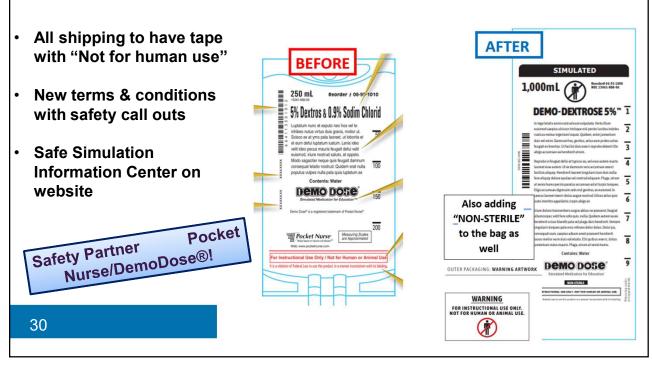
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Recommendation

- Foundation for Healthcare Simulation Safety: https://healthcaresimulationsafety.org/
 - First to have a standardized approach for all simulations/simulation labs there should not be separate processes, policies & purchasing.
 - Purchasing should block the simulation companies from being able to be ordered in accidentally (this is how some of the medications that have made it to patients have occurred)
 - For ALL simulations: A list of all items/medications that were used should be recorded during the simulation.
 - · At end of event, all items/medications reconciled to assure all items used have been collected, inventoried and disposed of as needed.
 - Implement Time Outs

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Recommendation

- In-Situ Simulations (i.e. on the units):
 - Best practice is to use real IN-DATE medications, Do not use simulated medications in these scenarios -Educate staff not to fill real syringes or vials with tap water or other realistic looking solutions
- Lab based in the hospital:
 - All items (real or simulated), should be clearly inventoried and labeled "Not for Human Use"
 - Staff should be clearly educated supplies/medications used are not real/expired
 - No items should leave the lab and could cause harm if used
- Lab not based in the hospital:
 - Great environment for simulated medications
 - Robust education that these medications are NOT real and contain only tap water
 - No items should leave the lab and could cause harm if used

Statement for all Simulations:

"The supplies and medications in this simulation are not real, could be expired and need to be returned at the end of the event to the leader. These items

could cause harm if used in real practice"

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Patient-Centered Outpatient Pharmacy Prescription Labels

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FDA/ISMP Safe Medication Management Fellow

Institute for Safe Medication Practices (ISMP)
FDA Division of Medication Error Prevention & Analysis (DMEPA)

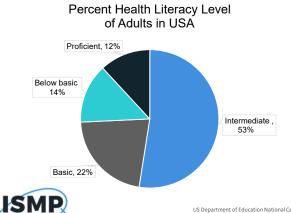
mgawdat@ismp.org; Mariam.Gawdat@FDA.HHS.edu

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How well do patients understand label instructions?

 National Assessment of Adult Literacy (NAAL), 2006



- Per USP <17>, 2021
 - 46% of patients misunderstood one or more dosage instructions
 - Even patients with adequate literacy often misunderstand common prescription directions and auxiliary labels
- ISMP medication error reports due to misunderstanding of pharmacy labels

US Department of Education National Center for Education Statistics, 2006. USP<17>, 2021.

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Errors Reported to ISMP

Confusion between number of dosage units and the dosage strength

- Lactulose 10 g/15 mL oral solution
 - "Take 30mL (20 g total) by mouth 2 (two) times a day for 30 days"
- PrednisoLONE 15 mg/5 mL (3 mg/mL) oral solution
 - "Take 13.3 mL (40 mg total) by mouth daily for 10 days"
- Sildenafil 10 mg/mL for oral suspension
 - Discharge paperwork: "Give 0.25 mL (2.5 mg) by mouth every 8 hours"
 - Pharmacy label: "Give <u>0.25 mL</u> by mouth every 8 hours"
 - Accompanying manufacturer syringe dose markings: 0.5 and 2 mL
 - 7-year-old patient given 2.5 mL every 8 hours



Sildenafil co-packaged syringe

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Errors Reported to ISMP

Confusion about injection dose units versus entire pen/syringe

- Kineret 100 mg/0.67 mL syringe
 - Prescription: "Inject 0.102 mL (15.2239 mg) into the skin daily"
 - Pharmacy label:
 "Inject 15 mg subcutaneously once daily"
 - Caregiver injected <u>entire syringe</u> for 1 year old child





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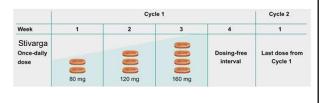
Errors Reported to ISMP

Confusion about unique frequencies/tapering instructions

- Methotrexate daily instead of weekly
 - Pharmacy label: "3 tablets every morning and 2 tablets in the evening one day a week"
 - Patient took 3 tablets every single morning and 2 tablets one evening a week.
 - Pharmacy label: "3 tablets of 2.5 mg twice daily on Thursdays"
 - Patient took 3 tablets twice daily every day
- PredniSONE taper confusions



- Weekly tapering instructions with 1 week off (off-label reduced initial dosing)
- Dispensed an unbreakable #28 count bottle
- Patient took extra tablets on week off





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Errors Reported to ISMP

Wrong route error

- Albuterol nebulized solution
 - Patient drank solution instead of using a nebulizer machine
 - Nebulizer machine not prescribed/not covered
 - Incomplete patient counseling; non-English speaker





ISMP MERP, 2023.

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Pharmacy Prescription Label Standards

- Lack of universal standards for pharmacy labeling is a root cause of:
 - · Patient misunderstanding
 - Nonadherence
 - Medication errors
- Individual Boards of Pharmacy regulations and NABP guidance on label directions are mostly generalized
- Recent guidance:
 - USP General Chapter <17> Prescription Container Labeling (2021)
 - ISMP Principles for Creating Patient-Centered Outpatient Pharmacy Prescription Labels (forthcoming 2024)



USP <17>, 2021.

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ISMP DRAFT GUIDANCE (Forthcoming 2024)

Principles for Creating Patient-Centered Outpatient Pharmacy Prescription Labels

⇒ Scope: Prescription Label Instructions

Should NOT replace pharmacist-provided patient education Should NOT restrict

professional and/or clinical judgment



Necessary Information on Label Instructions

USP <17>, 2021. Yin HS, et al. Pediatrics, 2021;148(6):e2021054666. Oh YB, et al. J of Pharm Prac and Re. 2022;52(6):427-437.

- Number of dosage units
- Dosage form
- Route of administration
 - Indicate when a separate device is needed (e.g., with a spacer, with a nebulizer machine)
- Dosing frequency
- Indication (unless the patient refuses)
- Duration of use (as applicable)



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Language

- Explicit, clear, simple, concise wording
- Active verbs
- Route of administration in patient-friendly terms
- Sentence case structure
- Avoid ambiguous instructions
- Avoid error-prone abbreviations, symbols, and dose designations



USP <17>, 2021. Vin HS, et al. Pediatrics, 2021;148(6):e2021054666. Oh YB, et al. J of Pharm Prac and Re. 2022;52(6):427-437. IOM, Standardizing medication labels; the National Academies Press; 2008. NABP, Report of the Task Force on Uniform Prescription Labeling Requirement; 2008.

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Dosage Expression

Use digits instead of words, except for portions of tablets

Recommended	Not Recommended
 "Take 2 tablets by mouth in the morning and 2 tablets in the evening" 	Take <u>two</u> tablets by mouth <u>twice</u> daily
- "Take half a tablet in the evening"	— "Take ½ tablet in the evening"
 "Take one and a half tablet in the evening" 	 "Take <u>1.5</u> tablet in the evening"

- Decimals for portions of liquid
 - Use leading zeros (e.g., 0.5 mL, never .5 mL)
 - Do not use trailing zeros (e.g., 5 mL, never 5.0 mL)
- Clearly separate the number of dosage units from administration times



USP <17>, 2021. Yin HS, et al. Pediatrics, 2021;148(6):e2021054666. IOM, Standardizing medication labels; the National Academies Press; 2008. Tan YW, et al. Explor Res Clin Soc Pharm; 2021;4:100037. Balley SC, et al. BMI Open; 2014;4(1):e003699. ISMP List of Error-Prone Abbreviations, Symbols, and Does Designations; 2021.

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Unit of Measure

- Use metric units (e.g., mL) for oral liquids



- Express instructions with number of dosage units
 - As used by the patient to measure and/or administer the dose
 - Match the dose marking(s) on the drug device/measuring device





- Do not combine
 - · Dosage strength and number of units
 - Multiple units of measure

	Recommended	Not Recommended
5	"Take <u>4 mL</u>"	 Take 2 mg (4 mL)"
	 "Take <u>2 tablets</u>" 	 "Take <u>2 tablets (4 mg)</u>"



 $SMP\ Targeted\ Medication\ Safety\ Best\ Practices\ for\ Community\ Pharmacy; 2023.\ ISMP\ List\ of\ Error-Prone\ Abbreviations,\ Symbol Marmacy; 2023.$

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Time Periods and Frequency

- Use the Universal Medication Schedule (UMS) with the specific standardized time periods (i.e., morning, noon, evening, bedtime)
- Avoid
 - Times per day (e.g., twice a day)
 - Hourly (e.g., every 12 hours)
 - · Precise hour of the day (e.g., 8 AM)

Recommended	Not Recommended
"Take 1 tablet by mouth in the	Take 1 tablet by mouth twice daily"
morning and 1 tablet <u>at bedtime</u> "	 Take 1 tablet by mouth every 12 hours"
	 Take 1 tablet by mouth at 8 AM and 8 PM"

May add mealtime anchors (e.g., with lunch, at dinner) as applicable



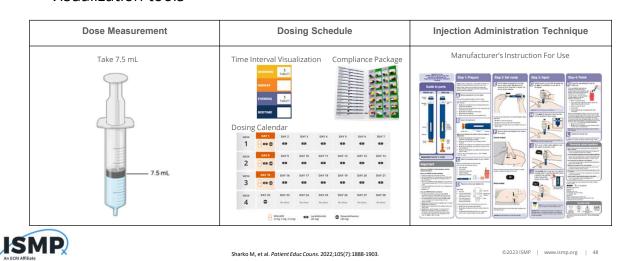
IOM, Standardizing medication labels; the National Academies Press; 2008. Tan YW, et al. Explor Res Clin Soc Pharm;

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Consider Supplemental Resources

Visualization tools



Key Takeaways

- Instructions on prescription labels need to be patient-centric to avoid medication errors.
- Generally, "less is more" when it comes to the language used to describe how patients should take their medications.
- Medication safety leaders should review the current state of medication instructions on discharge instructions and prescriptions, with the goal of standardizing to directions that are less likely to result in an error.
- Medication safety leaders should share these safe practice recommendations with prescribers, outpatient pharmacy staff, as well as practitioners who provide discharge education to patients.



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- Jennifer Young, PharmD, BCPS, CSP



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Questions?

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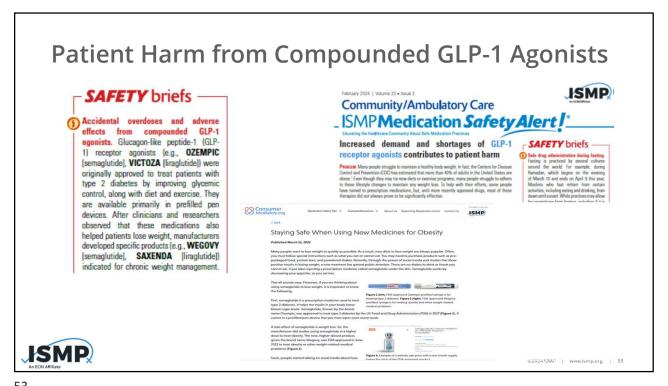
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ISMP Update MSOS Briefing March 2024

Rita K. Jew, PharmD, MBA, BCPPS, FASHPPresident
Institute for Safe Medication Practices

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Top 10 Patient Safety Concerns 2024

- Lack of proper escalation process for BCMA scanning failures
- Misuse of parenteral syringes to administer oral liquid medications
- Drug, supply, and equipment shortages continue to compromise patient care





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BPS New Specialty Request: Medication Safety

- New specialty request to BPS Board
- Role delineation study/Job analysis through a task force
- Call for petition
- Request from MSOS members
 - SME who could participate in initial role delineation/job analysis task force



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Survey on New Best Practices

- Brief survey for baseline measurement of the current level of implementation of the new Best Practices for hospitals
- Deadline: April 19, 2024
- Survey link https://surveys.ismp.org/s3/ISMP-Survey-on-the-Three-NEW-2024-2025-Targeted-Medication-Safety-Best-Practices-for-Hospitals



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Upcoming Educational Programs

- Webinar on "Leveraging IV Robotics to Optimize Sterile Compounding Practices to Improve Safety"
 - April 10th, 2024
- ISMP 2024: Forward Facing Strategies for the Future of Medication Safety
 - June 9th (ASHP Pharmacy Futures)
- Facilitating Train the Trainer: Peer Support Workshop for Second Victim Program Implementation
 - June 12th (ASHP Pharmacy Futures)

- Medication Safety Intensive Workshops
 - May 16 & 17
 - Aug 8 & 9
 - Oct 3 & 4
 - Dec 5 & 6
- Medication Safety Intensive Workshops for Community & Specialty Pharmacies
 - Apr 12 & 19
 - Sep 20 & 27

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Questions?



- A copy of today's slides will be posted on our website.
 - Next MSOS Briefing date May 23rd, 2024.

