

TAANA2015
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THE INSTITUTE FOR SAFE MEDICATION PRACTICES:
THE EXPERT WITNESS



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2

Objectives

- ▶ Explain the mission and function of the Institute for Safe Medication Practices
- ▶ Explain how ISMP can help defend adverse licensing Board actions for practitioners who have made medication errors
- ▶ Describe ISMP materials that have been used as evidence in licensing Board proceedings
- ▶ Discuss the use of ISMP as an expert witness for reports and testimony at Board hearings



3



Institute for Safe Medication Practices
A Nonprofit Organization Educating the Healthcare Community and Consumers About Safe Medication Practices

- 501(c)(3) nonprofit organization founded in 1994
- Mission: To advance patient safety worldwide by empowering the healthcare community, including consumers, to prevent medication errors
- Seven primary activities
 - Consulting
 - Collaboratives
 - Education
 - Error reporting
 - Publications
 - Research
 - Advocacy
- **NOT a standards-setting/accrediting organization**
- **NOT supported by government or pharmaceutical industry**
- **Interdisciplinary**



4

ISMP Collaborations

- Food and Drug Administration
- United States Pharmacopeia
- Centers for Medicare & Medicaid Services
- State licensing boards
- Departments of health
- Centers for Disease Control and Prevention
- The Joint Commission
- Professional organizations
 - Pharmacists
 - Nurses
 - Physicians
 - Consumers
- National Patient Safety Foundation
- Consumers Advancing Patient Safety
- ECRI Institute
- PhRMA
- Health insurers
- Systems engineering
- Medication Safety Officers Society
- Healthcare providers
- World Health Organization
- ISMP Canada
- ISMP Brazil
- ISMP Spain




6



ISMP NATIONAL MEDICATION ERRORS REPORTING PROGRAM

Thank you for your willingness to report to the ISMP National Medication Errors Reporting Program (NERP). When reporting an error or hazard:

- Tell us the story of what went wrong or could go wrong, the causes or contributing factors, how the event or condition was discovered or intercepted, and the actual or potential outcome of the involved patient(s).
- Be sure to include the names, dosage forms, and dose/strength of all involved products. For product-specific concerns (e.g., labeling and packaging risks), please include the manufacturer.
- Share your recommendations for error prevention.
- If possible, submit associated materials (e.g., photographs of products, containers, labels, de-identified prescription orders) that help support the report being submitted.

Please complete the form below and click on the "Submit" button to report the error or hazard to the ISMP National Medication Errors Reporting Program.

Name: (optional)
Email:
Confirm email:
Error Description: Please describe the incident as best you can. This information will be handled in confidence.

Upload Images (optional):
Up to three images can be uploaded. Input area will appear after each image is selected up to 3.

<https://www.ismp.org/orderforms/healthcaremerp.aspx>

7

FDA MedWatch and FAERS



QuarterWatch monitors domestic, serious adverse drug events reported to the FDA. We identify trends in drug safety, report signals for specific drugs, and seek to improve the system.

- Chantix and hostile behavior
- Bleeding episodes with new anticoagulants without a reversal agent, lower dosing option, test to identify excessive anticoagulation
- High prevalence of psychiatric side effects in children and teens taking Singulair and Claravis



8




9

National Alert Network (NAN)

Widely distributed by NAN partners




10

Medical product error-prevention efforts need to be shared and harmonized internationally

Unsafe labeling, packaging, and product information can sometimes be imported into the US by global pharmaceutical companies. In medical journals and advertising mailed to many of us last week, Sanofi expressed the strength of their new high concentration insulin product **TOUJEO** as "300U/mC" (Figure 1). Not only is the abbreviation "U" discouraged here in the US, but the lack of a space between 300 and U sets a terrible example for prescribers and electronic prescribing system vendors that might be unaware that this practice might lead to a dangerous, 10-fold insulin overdose. Sanofi is a French company that's done business in the US for many years. So, it's disappointing that US executives were either unaware of the potential for an overdose when abbreviating units with a "U" (and that The Joint Commission has "U" on their "Do Not Use" abbreviation list), or the US executives were otherwise powerless to stop an ad campaign designed in France.



Figure 1. The advertisement for Toujeo lists the strength as 300U/mC, using the error-prone abbreviation U for units.

Your Reports at Work

Notice to use the change. Thanks to Sanofi, for addressing use of the dangerous abbreviation "U" for the word "units" (April 23, 2015 issue) in the advertisements for TOUJEO (insulin glargine). The photo of the original advertisement (on the left) has been changed. The new advertisement (on the right) is how the strength will appear in all labeling and advertising for Toujeo in the future (Figure 1).

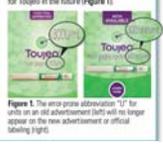


Figure 1. The error-prone abbreviation "U" for units on an old advertisement (left) will no longer appear on the new advertisement or official labeling (right).

ISMP Acute Care Medication Safety Alert! June 4, 2015.

ISMP Acute Care Medication Safety Alert! April 23, 2015.

11

Other Resources







12




13

ISMP Guidelines

ISMP Safe Practice Guidelines for Adult IV Push Medications
A compilation of safe practices from the ISMP Adult IV Push Medication Safety Summit

Prepared by the Institute for Safe Medication Practices (ISMP)
MEMBER OF THE AMERICAN ACADEMY OF CRIMINAL JUSTICE EXPERTS

ISMP Acute Care Guidelines for Timely Administration of Scheduled Medications

Background
The Institute for Safe Medication Practices (ISMP) is a national, non-profit organization dedicated to the prevention of medication errors and the promotion of safe medication practices. ISMP's mission is to reduce the number of medication errors and improve patient safety through education, research, and advocacy. ISMP's guidelines are based on a comprehensive review of the literature and input from experts in the field.

How to Use the Guidelines
These guidelines are intended to provide a framework for safe medication practices. They are not intended to be a substitute for professional judgment or clinical judgment. They are intended to be used in conjunction with other safety practices and procedures. They are intended to be used as a guide to help prevent medication errors and improve patient safety.

Advisory Group
The ISMP Acute Care Guidelines for Timely Administration of Scheduled Medications were developed by a multidisciplinary advisory group consisting of experts in the field of medication safety, including pharmacists, nurses, physicians, and other healthcare professionals.

14

How ISMP Can Help

- Evidence
- Written expert report
- Testimony at hearing
- Met with Boards outside of hearings
- Help frame arguments in response to the statement of charges
- Provide a framework for decision support within a Just Culture
- Provide emotional support for "second victims"

15

How ISMP Can Help

- Evidence
 - Publication of similar medication errors
 - Other media on topic (e.g., slide presentation)
 - System-based causes of errors
 - Root cause analysis
- Human factors
 - Perceptual biases
 - Cognitive biases
 - Human error rates
- At-risk behaviors (procedural violations)
- Just culture

16

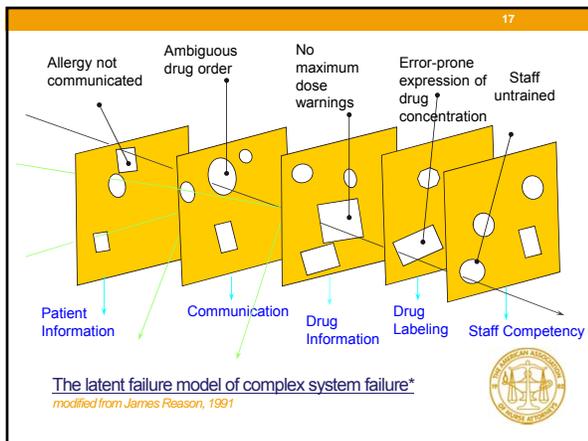
Examples

NurseAdvise
What happens next after a medication error?

Medication Safety Alert!
Double checks for amblyopia and exotropia errors

What happens next after a medication error?
A medication error is a preventable event that may cause harm to a patient. It is a failure in the medication process, from the time the medication is prescribed to the time it is administered. Medication errors can occur at any point in the process, and they can have serious consequences for the patient. It is important for healthcare professionals to be aware of the signs and symptoms of medication errors and to take steps to prevent them from occurring.

Double checks for amblyopia and exotropia errors
Amblyopia and exotropia are common eye conditions that can lead to vision loss if not properly treated. Medication errors in the treatment of these conditions can have serious consequences for the patient. It is important for healthcare professionals to be aware of the signs and symptoms of these conditions and to take steps to prevent medication errors from occurring.



18

System Analysis

The Joint Commission Journal on Quality and Patient Safety

Root Cause Analysis: Shaping Systems for Better Behavioral Choices: Lessons Learned from a Fatal Medication Error

Lesson from the Denver Medication Error/Criminal Negligence Cases: Look Beyond Blaming Individuals

Julia Swann, R.N., B.S.N., Christine Baker, R.N., Ph.D., David D. Rowe, M.D., Michael J. Golan, R.N., B.S., S.D.

Article at-a-glance
Background: In the wake of the Denver medication error, the authors sought to understand the system factors that contributed to the error. The authors conducted a root cause analysis (RCA) of the error and identified several system factors that contributed to the error. These factors included inadequate medication reconciliation, inadequate communication, and inadequate staff training. The authors recommend several strategies to prevent similar errors from occurring, including improved medication reconciliation, improved communication, and improved staff training.

The Event
The event described in this article involved a fatal medication error in a Denver hospital. The error occurred when a nurse administered a medication to a patient who was allergic to the medication. The error was caused by a combination of system factors, including inadequate medication reconciliation, inadequate communication, and inadequate staff training.

For additional, see pages 142-151.

19

Human Error Probabilities

Unfamiliar task performed at speed/no idea of consequences	50%
Task involving high stress levels	30%
Complex task requiring high comprehension/skill (knowledge)	15%
Select ambiguously labeled control/package	5%
Failure to perform a check correctly (rule-based)	5%
Error in routine operation when care required (skill-based)	1%
Well designed, familiar task under ideal conditions	0.04%
Human performance limit	0.01%
Team performance limit	0.001%



20

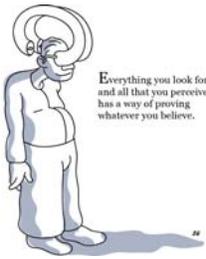
Human Error and At-Risk Behavior Rates



21

Confirmation Bias

Selectively search for information that confirms one's beliefs, reject information that does not



Everything you look for and all that you perceive has a way of proving whatever you believe.

- Judge likelihood by how easily the idea sprang to mind (**availability heuristic**)
- Stick to our initial assumptions (**anchoring heuristic**)
- Downplay contrary evidence, reluctant to pursue alternatives (**premature closure**)
- When we look "here," we risk missing "there"

Jim Gill: www.cognitiveBiasParade.com



Confirmation Bias



Not a big deal when you confuse cereal products...



Confirmation Bias



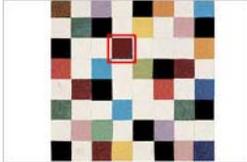
But it is a big deal when you confuse these



24

Change Blindness

Inability of visual system to detect alterations to something in plain view.




www.nytimes.com/interactive/2008/03/31/science/20080331_ANGIER_GRAPHIC.html#step1

http://www.youtube.com/watch?v=FWsXSQspIQ&feature=player_embedded

<http://www.theinvisiblegorilla.com/videos.html>



25

Inattentional Blindness



Why do intelligent, diligent, thorough people fail to see the obvious?



26

Inattentional Blindness

- Consider what we see to be true representation of external world
- Brain, working with eyes, constructs the outside world inside our heads using memories and knowledge
- We see only what the brain tells us to see
- Attention acts as filter to examine sensory input and select small percent for full processing
- Inattentionally blind to rest of information since never reaches consciousness
- The world shifts under our gaze
- "The Grand Illusion"



27

Cognitive Biases: How We Make Decisions

- **Frequency illusion**
 - Thing recently brought to attention appears with improbable frequency
- **Hindsight bias**
 - Tendency to see past events as being predictable
- **Status quo bias**
 - Disfavor change and keep what have
- **Normalcy bias**
 - Never happen here
- **Identifiable victim effect**
 - Tendency to respond more strongly to person at risk than groups
- **Current moment bias**
 - Stronger preference for immediate rewards



28

At-Risk Behaviors

- **A behavioral choice**
 - Desire to accomplish more
 - Faded perception of risk
 - Unknowingly create unjustifiable risk
 - First order problem solving
- Behavior driven by perception of consequences
 - Rewards more immediate, positive, strong
 - Delayed and uncertain consequences are weak
 - Rules are generally weak
- With experience, precautions fall by the wayside
 - Driving
- Not choosing to put people in harm's way, but subtle drifting that becomes habitual



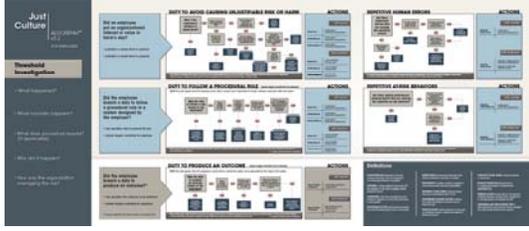
29

At-Risk Behaviors

- **Examples of At-Risk Behaviors**
 - Technology work-arounds/failure to engage
 - Rushed communication during shift change
 - Carrying medications in pockets
 - Bypassing computer alerts
 - Illegible handwriting
 - Grab and go
 - Not labeling syringes
 - Borrowing medications
 - Disregarding patient concerns




JUST CULTURE ALGORITHM



Decision Tree



31

How ISMP Can Help

- Written Expert Report
 - Basis of report (what was reviewed)
 - Description of event
 - Allegations
 - Why the event happened
 - Additional observations
 - Frequency of similar events
 - Corrections to Board report
 - Summary
 - Conclusions
 - Recommendations
 - Credentials
 - Attachments



32

Example

- Programming error with fentaNYL patient-controlled analgesia
 - Infrequent use of fentaNYL
 - Changed from HYDROmorphine to fentanyl without clinical reason
 - PCA device design flaw
 - Pump would automatically default to a prior setting if the current setting was not confirmed by pressing "Enter" within 20 seconds
 - Hidden default to prior settings if "New Patient" was not selected
 - Complex programming process
 - Trailing zero misread
 - PCA Order did not match programming requirements
 - Multiple pumps in use leading to unfamiliarity
 - Failed double check systems



33

How ISMP Can Help

- Testimony at hearings
 - Credentials acceptable if same profession
 - May need to provide a written report if testifying
 - Experiences vary based on state and culture of Board
 - Many cases settled before testimony
 - Expert testimony is not a revenue source for ISMP
 - Unavailability may be an issue
 - Have met with Boards informally on behalf of practitioners



34

Questions

