MSOS Member Briefing
November 2020

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November 2020

Moderated by: E. Robert Feroli, PharmD, FASHP

MSOS
MEDICATION SAFETY OFFICERS SOCIETY

1

Medication Safety Strategic Planning: Saudi Medication Safety Center (SMSC)

Ghadeer Banasser, PharmD, CPHQ, FISMP
Medication Safety Specialist
Saudi Medication Safety Center (SMSC)
Ministry of National Guard - Health Affairs (MNG-HA)

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Outline

- Organizational Structure: An Overview
- Strategic Plan Development Process
- Medication Safety Strategic Plan Review

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Ministry of National Guard- Health Affairs (MNG-HA)

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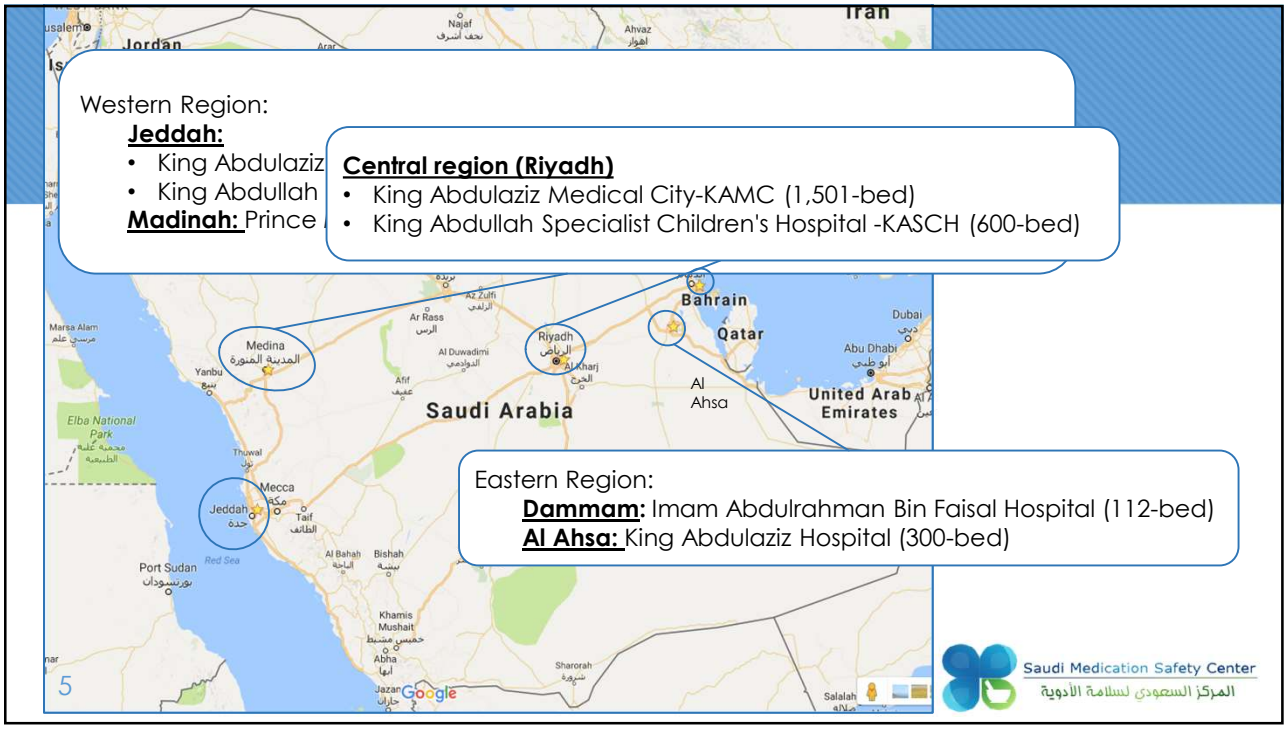

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MNG-HA Facilities

- Medical Cities
  - **Oncology Centers**
  - **Cardiac Centers**
  - **Children Hospitals**
- Primary Health Care (PHC) Centers
- King Saud University for Health Sciences
- King Abdullah International Medical Research Center (KAIMRC)

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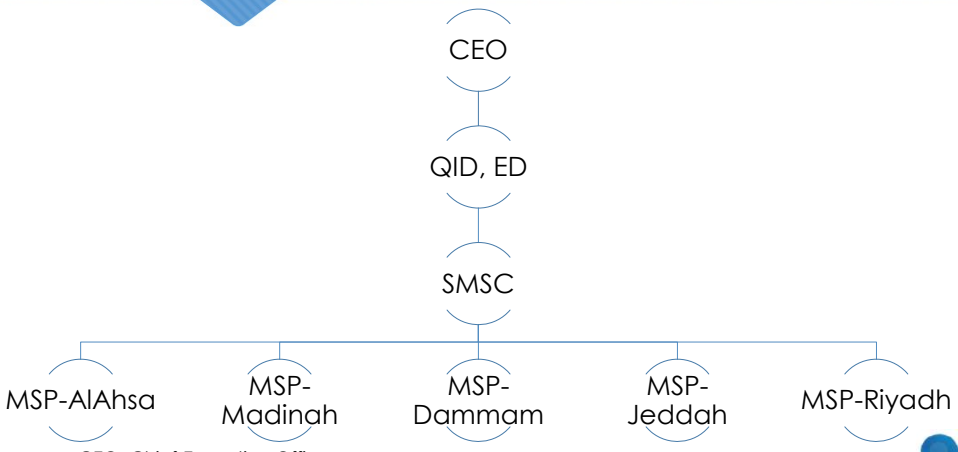
Medication Safety Reporting Structure



7 CEO: Chief Executive Officer
QID, ED: Quality Improvement Department, Executive Director
MSP: Medication Safety Program

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MSP Membership

- **Chairman:** Director, Quality Improvement Department
- **Co-Chairman:** Director, Pharmaceutical Care Services (or equivalent)
- **Members:**
  - Medication Safety Officer/Specialist (or equivalent), Quality Improvement Department
  - Physician Representative(s)
  - Pharmaceutical Care Services Representative(s)
  - Nursing Services Representative(s)
  - Clinical Information Management System, ISID Representative
  - Pharmaceutical Planning, Logistics and Contracts Management Representative
  - Chair, Medication Use Process Error Subcommittee (MUPES)
  - Chair, Adverse Drug Reaction (ADR) Team
  - Chair, Regional Medication Pump Team
  - Chair, Regional Automated Dispensing Cabinet (ADC)Team

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Strategic Plan Development

- Involve Key People
- Assess your Current Position
- Review the Model Plan
- Map a Strategy for the Future
- Select Change Projects
- Implement the Strategic Plan
- Monitor Performance

9 *ISMP. Pathways for Medication Safety - Leading a Strategic Planning Effort. 2002. available at: https://www.ismp.org/resources/strategic-planning*
Medication Errors. 2nd ed. Washington, DC: APhA; 2007

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SWOT analysis

Strengths
- Positive Reputation
- Qualified Expertise
- National Representative at the IMSN

Weaknesses
- Manpower Shortage
- Hiring Turnaround
- Lack of Qualified Candidates

Opportunities
- National Expansion in Med Safety activities
- Collaboration with the ISMP

Threats
- Leadership Support
- Local Accreditation Standards
- Low Med Safety Literacy

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10 IMSN: International Medication Safety Network

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Medication Safety Strategic Plan
Reporting, Learning, and Sharing
Evidence-Informed Practices
Partnering with Patients
Technology
Promote the Advancement of Med Safety
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Medication Safety Strategic Plan
Reporting, Learning, and Sharing
2021
Q1: ISMP Assess-ERR™
2022
Q1: Triggers/error detection
Q1: MSOs Training
Q2: Annual safety rounds
Q3: Training Program (interns/students, residents, other healthcare providers)
2023
Q1: Award "Lifesaver" Report
2024
Q1: Review of outcome input on reported incidents
2025
Q1: Med safety innovation applications
Q1: Residency training program
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Medication Safety Strategic Plan
Evidence-Informed Practices
2021
2022
2023
2024
2025
• Q1: Standing Agenda item on SMSC Board (tasks)
• Compliance with national and international accreditation standards
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Medication Safety Strategic Plan
Partnering with Patients
2021
2022
2023
2024
2025
• Q3: Community Representative
• Q3: Annual community health fair
• Q3: Engage patients/families in Med Safety Initiatives
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Medication Safety Strategic Plan
Technology
2021
Q3: Patient reporting portals
2023
2025
Q1: Automation and HIT use in Med Safety
Q1: Improve the utilization of ADCs, Smart Pumps, and BCMA
2022
2024
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Medication Safety Strategic Plan
Promote the Advancement of Med Safety
Q3: Collaborate with national and international patient/med safety org
2021
2023
2025
Q1: Contribute to medication safety literature
2022
2024
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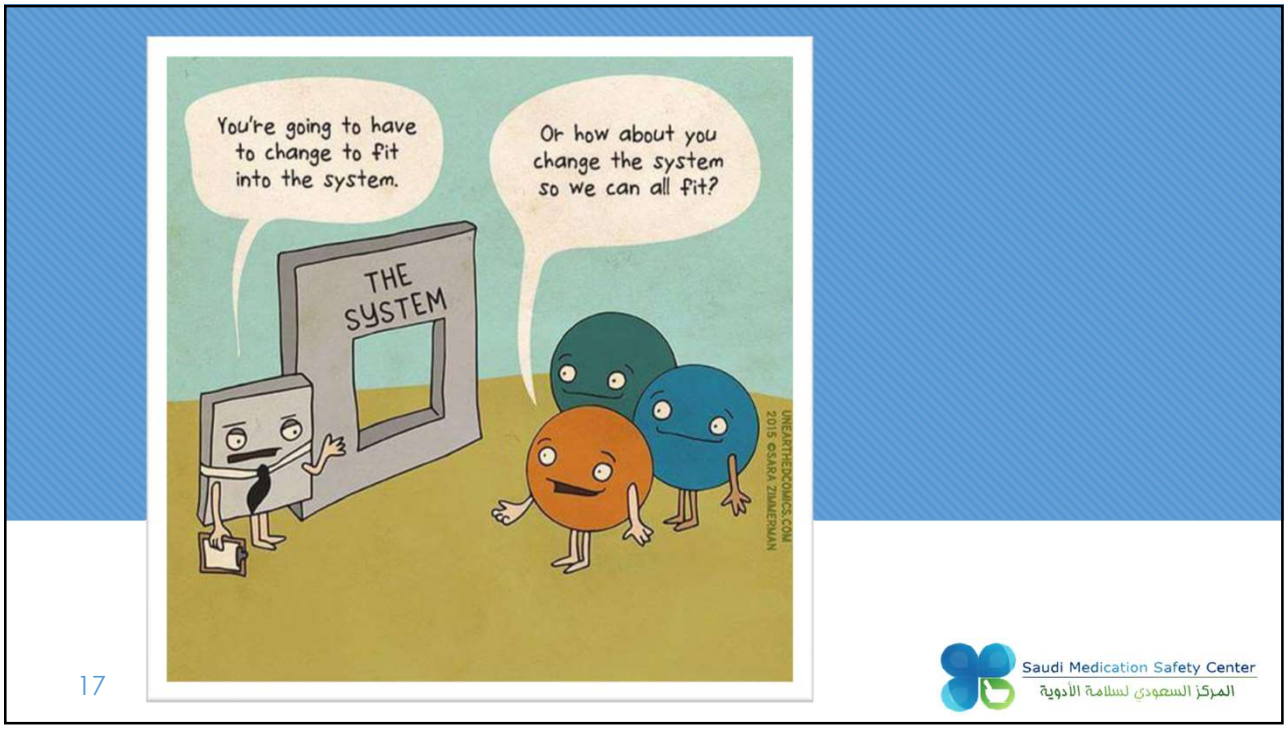
You're going to have to change to fit into the system.
Or how about you change the system so we can all fit?
THE SYSTEM
UNEARTHEDCOMICS.COM
2015 ©SARA ZIMMERMAN
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Saudi
Welcome to Arabia
السعودية
أهلاً بالعالم
THANK YOU
#VISITSAUDI
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Hidden Medication Losses: A discovery on patient care rounds

Dan Sheridan, MS, RPh, CPPS

Medication Safety Pharmacist
OhioHealth Marion General Hospital & Hardin Memorial Hospital
Marion, OH

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OhioHealth Marion General Hospital

250-bed, not-for-profit, community hospital

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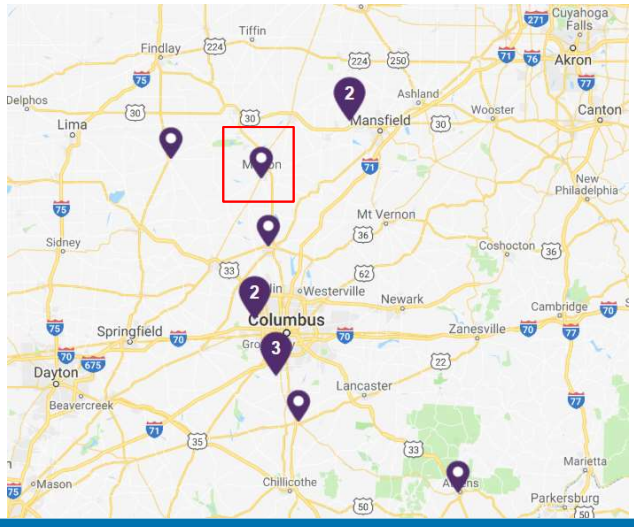
The OhioHealth Corporation



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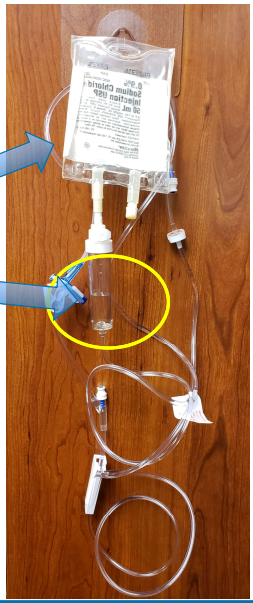
Patient Care Rounds

Safety issue spotted:

- Empty 50 mL bag of piperacillin/Tazobactam on IV pole
- 27 mL primary tubing was still full
- Patient received about 46% of dose
- 4 hour extended infusion only lasted 2 hours
- Secondary tubing should have been used



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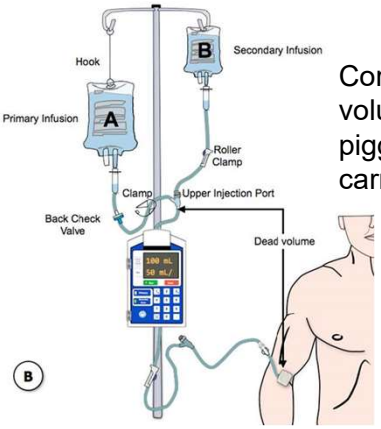
Intermittent infusions

Incorrect: Small volume intermittent spiked with long primary tubing



Correct: Small volume intermittent piggybacked into carrier fluid.

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Key point

A large primary tubing in a small bag may lead to substantial hidden drug loss.

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Assuming a 25 mL primary set

Can lose:

- 50% of a 50mL bag
- 25% of a 100 mL bag
- 10% of a 250 mL bag
- 5% of a 500 mL bag

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Quality Metric Selected as a Marker

From IV pump data:

50 mL intermittent infusions given via secondary

---

50 mL intermittent infusions given via secondary and primary

Chemotherapy excluded - special short primary tubing used

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Measuring the extent of the problem

1) Download pump data, limited to:

VTBI (mL)	=	50
Start Reason Code	contains	infusion started
Infusion Type	contains	intermittent
Profile Name	contains	adult
Diluent Volume	=	50

2) Use Excel filters to quickly see how many run as secondary, out of how many? 2607 of 4118 records found

Blossoming scope of the problem

- Two patients on one unit
- Hospital-wide: 28.5% given correctly Jan 2019
- System-wide: 35.7% given correctly Jan 2019
- 30,000+ monthly opportunities for improvement just with 50 mL intermittent infusions

Why does it happen?

- Unclear policies
- Shortage of large volume parenterals
- Intermittent IV medications ordered without carrier fluid orders
- Orders to stop IV fluids, but still on intermittent IV medications
- Nurses can't hang carrier fluids without an order

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Corrective Strategies

Problem: Nurses can't hang "carrier fluid" without an order.

Our approach:

1) Embed orders for carrier fluid into "insert IV" orders
2) Embed orders for carrier fluid into admission order sets
3) P&T authority for pharmacists to enter carrier fluids

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Corrective Strategies

Problem: Lack of awareness of issue

Our approach:

1) "Tip of the week" educational document
2) Engaged nurse educators
3) Slogan: "If the IV bag is the small kind, put it on a secondary line!"

"Just in time" education

1) Pop-up warnings on dispensing cabinets
"This drug must be given with a SECONDARY set"

2) "Infuse via secondary set" labels for a few months

Appeal to Emotions

Find real people within the data, and tell their story.

"*A 54 year old patient was admitted to the ICU with Pneumonia. The patient was started on Zosyn every 8 hours. The patient's first 6 doses were given via primary tubing, so the patient likely only received half the doses. If the IV bag is the small kind, put it on a secondary line!"*

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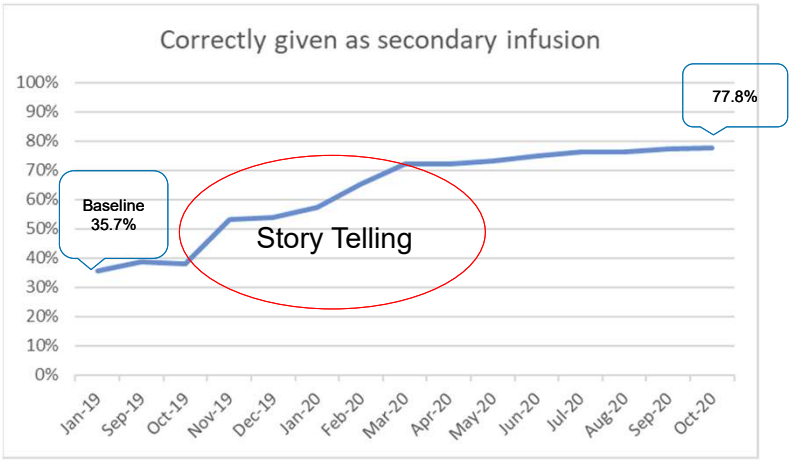
Our journey



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Lessons Learned

- Go to Gemba, see the problem
- Use data to measure the problem
- Build carrier fluids into order sets
- Seek partners across professions
- Tell stories to humanize the problem
- Create accountability at site and unit level

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Celebrate Success!

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Questions?

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Standard Auxiliary Labels

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Nov 19, 2020

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Medication Safety Events

Bupivacaine continuous nerve block almost administered IV

Bupivacaine epidural administered via IV pump

Vecuronium vial left unused at bedside

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Observations

- >80 labels
- Duplicates/overlaps
- Inconsistent use
- No written guidance

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Project Goals

- ✓ Decrease number of labels by 50%
- ✓ Improve consistency
- ✓ Develop label management process

★ **Approved labels list**
★ **Pharmacy procedure**

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Planning

- ✓ Research publications & resources
  - ISMP 2/2019 “Your attention please… designing effective warnings”
  - MSOS forum
- ✓ Collect & organize
- ✓ Review
  - Pharmacy leadership group
  - Front-line/end-user
  - Medication Management Committee
- ✓ Approval
  - Med Management Committee
  - Nursing Practice and Quality Council

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Review

- **Is the label necessary?**
  - Likelihood & severity of event
  - Clinical significance
  - Reported errors
  - Published recommendations
  - Redundancy
  - End user feedback
  - Frequency of use

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Review

- **Design**
  - Easy to understand
  - Affirmative wording
  - Color standards
  - Behavior based

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Label Placement

1. Patient-specific doses dispensed from pharmacy *
2. Pharmacy bins - excludes carousel, ADCs, CII Safe
3. On every medication in all areas- pharmacy, kits/trays, procedural areas, etc. *

* Directly on the product and over closures when possible

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Label	Situation	Placement
	Pharmacy- compounded epidurals	Pharmacy bins Directly on each bag
	When RN must administer a partial tablet, vial, etc.	Patient-specific doses
	Double/quadruple or non-standard IV infusions	Pharmacy bins Directly on each bag
	Premixed parenteral nutrition IV bags if contents require activating/mixing	Patient-specific doses
	NICU oral solutions	Patient-specific doses

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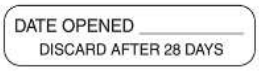
Eliminated Labels	Use Instead
  	
    	
	NA

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Procedure: Label Management

- ✓ Review labels annually
- ✓ Approve changes through Med Management and Nursing Practice Committees
- ✓ Align with design standards when possible
- ✓ Only Pharmacy Buyer will purchase
- ✓ Use commercially-available labels when possible
- ✓ Responsibilities for label placement
- ✓ Annual audit

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Final Steps

- Purchase labels
- Purchase dispensers
- Remove old labels – hide and seek
- Place dispensers in convenient locations
- Communicate & educate
  - Emails,
  - Newsletters,
  - Meetings/huddles
  - Posters

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Looking Back & Forward

- 80 ⟶ 30 in 8 months
- Effectiveness?
- Maintenance
- Round 2?
  - Design
  - Label of the month
  - 2nd look
  - Requests - IM Only, Central line only

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Questions? Comments?

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ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

ISMP Update
MSOS Briefing November 2020

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

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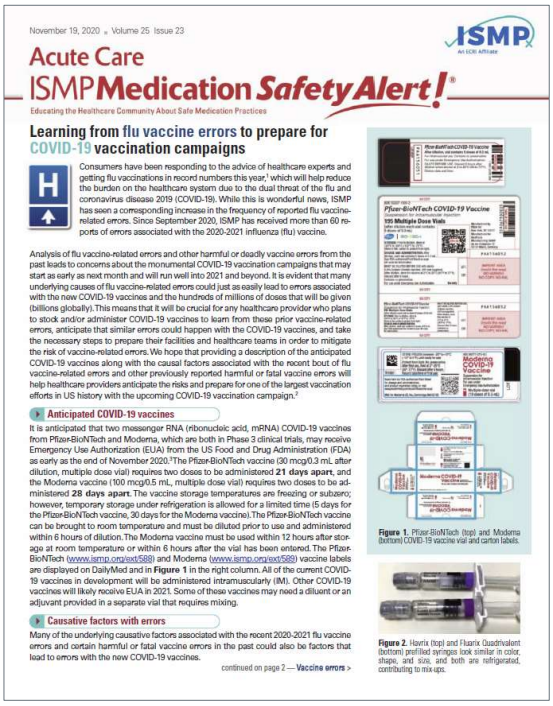
November 2020



November 19, 2020 • Volume 25 Issue 23

ISMP An ECRI Affiliate

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Learning from flu vaccine errors to prepare for COVID-19 vaccination campaigns

Consumers have been responding to the advice of healthcare experts and getting flu vaccinations in record numbers this year,[1] which will help reduce the burden on the healthcare system due to the dual threat of the flu and coronavirus disease 2019 (COVID-19). While this is wonderful news, ISMP has seen a corresponding increase in the frequency of reported flu vaccine-related errors. Since September 2020, ISMP has received more than 60 reports of errors associated with the 2020-2021 influenza (flu) vaccine.

Analysis of flu vaccine-related errors and other harmful or deadly vaccine errors from the past leads to concerns about the monumental COVID-19 vaccination campaigns that may start as early as next month and will run well into 2021 and beyond. It is evident that many underlying causes of flu vaccine-related errors could just as easily lead to errors associated with the new COVID-19 vaccines and the hundreds of millions of doses that will be given (billions globally). This means that it will be crucial for any healthcare provider who plans to stock and/or administer COVID-19 vaccines to learn from these prior vaccine-related errors, anticipate that similar errors could happen with the COVID-19 vaccines, and take the necessary steps to prepare their facilities and healthcare teams in order to mitigate the risk of vaccine-related errors. We hope that providing a description of the anticipated COVID-19 vaccines along with the causal factors associated with the recent bout of flu vaccine-related errors and other previously reported harmful or fatal vaccine errors will help healthcare providers anticipate the risks and prepare for one of the largest vaccination efforts in US history with the upcoming COVID-19 vaccination campaign.[2]

Anticipated COVID-19 vaccines

It is anticipated that two messenger RNA (mbonucleic acid, mRNA) COVID-19 vaccines from Pfizer-BioNTech and Moderna, which are both in Phase 3 clinical trials, may receive Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA) as early as the end of November 2020.[3] The Pfizer-BioNTech vaccine (30 mcg/0.3 mL after dilution, multiple dose vial) requires two doses to be administered **21 days apart**, and the Moderna vaccine (100 mcg/0.5 mL, multiple dose vial) requires two doses to be administered **28 days apart**. The vaccine storage temperatures are freezing or subzero; however, temporary storage under refrigeration is allowed for a limited time (5 days for the Pfizer-BioNTech vaccine, 30 days for the Moderna vaccine). The Pfizer-BioNTech vaccine can be brought to room temperature and must be diluted prior to use and administered within 6 hours of dilution. The Moderna vaccine must be used within 12 hours after storage at room temperature or within 6 hours after the vial has been entered. The Pfizer-BioNTech (www.ismp.org/ext/588) and Moderna (www.ismp.org/ext/589) vaccine labels are displayed on DailyMed and in **Figure 1** in the right column. All of the current COVID-19 vaccines in development will be administered intramuscularly (IM). Other COVID-19 vaccines will likely receive EUA in 2021. Some of these vaccines may need a diluent or an adjuvant provided in a separate vial that requires mixing.

Causative factors with errors

Many of the underlying causative factors associated with the recent 2020-2021 flu vaccine errors and certain harmful or fatal vaccine errors in the past could also be factors that lead to errors with the new COVID-19 vaccines.

continued on page 2 — Vaccine errors >

Figure 1. Pfizer-BioNTech (top) and Moderna (bottom) COVID-19 vaccine vial and carton labels.

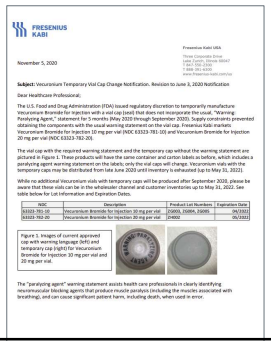
Figure 2. Havrix (top) and Fluarix Quadrivalent (bottom) prefilled syringes look similar in color, shape, and size, and both are refrigerated, contributing to mix-ups.

Bamlanivimab infusion rate issue in fact EUA sheet

Remdesivir error update to FDA Advise-ERR article

Update on "fuzzy matching" in Epic

ASPEN statement on filtration for total nutrient dextrose-amino acids admixtures and lipid injectable emulsions (ILE).



FRESENIUS KABI

November 5, 2020

Subject: Vecuronium Temporary Vial Cap Change Notification. Revision to June 3, 2020 Notification

Dear Healthcare Professional:

The U.S. Food and Drug Administration (FDA) issued regulatory discretion to temporarily manufacture Vecuronium Bromide for Injection with a vial cap (seal) that does not incorporate the usual, "Warning Paralyzing Agent" statement from May 2020 through September 2020. Supply constraints prevented obtaining the components with the warning statement on the cap. Fresenius Kabi marketed Vecuronium Bromide for Injection 10 mg per vial (NDC 63323-781-10) and Vecuronium Bromide for Injection 20 mg per vial (NDC 63323-782-20).

The vial cap with the required warning statement and the temporary cap without the warning statement are pictured in Figure 1. These products will have the same container and carton labels as before, which includes a paralyzing agent warning statement on the labels; only the vial caps will change. Vecuronium vials with the temporary caps may be distributed from late June 2020 until inventory is exhausted (up to May 31, 2022).

While no additional Vecuronium vials with temporary caps will be produced after September 2020, please be aware that these vials can be in the wholesaler channel and customer inventories up to May 31, 2022. See table below for Lot Information and Expiration Dates.

NDC	Description	Product Lot Numbers	Expiration Date
63323-781-10	Vecuronium Bromide for Injection 10 mg per vial	20A01, 20B04, 20J05	04/2022
63323-782-20	Vecuronium Bromide for Injection 20 mg per vial	20A02	05/2022

Figure 1. Images of current approved cap with warning language (left) and temporary cap (right) for Vecuronium Bromide for Injection 30 mg per vial and 20 mg per vial.

The "paralyzing agent" warning statement assists health care professionals in clearly identifying neuromuscular blocking agents that produce muscle paralysis (including the muscles associated with breathing), and can cause significant patient harm, including death, when used in error.

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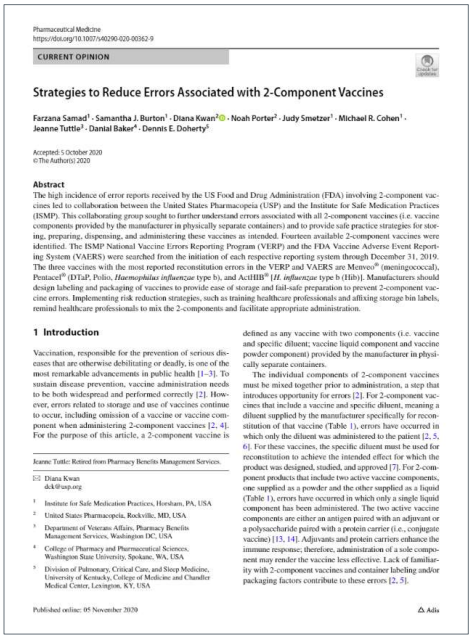

Pharmaceutical Medicine
https://doi.org/10.1007/s40290-020-00362-9

CURRENT OPINION

Strategies to Reduce Errors Associated with 2-Component Vaccines

Farzana Samad[1] · Samantha J. Burton[1] · Diana Kwan[2] · Noah Porter[2] · Judy Smetzer[1] · Michael R. Cohen[1] · Jeanne Tuttle[3] · Danial Baker[4] · Dennis E. Doherty[5]

Accepted: 5 October 2020

Abstract
The high incidence of error reports received by the US Food and Drug Administration (FDA) involving 2-component vaccines led to collaboration between the United States Pharmacopeia (USP) and the Institute for Safe Medication Practices (ISMP). This collaborating group sought to further understand errors associated with all 2-component vaccines (i.e. vaccine components provided by the manufacturer in physically separate containers) and to provide safe practice strategies for storing, preparing, dispensing, and administering these vaccines as intended. Fourteen available 2-component vaccines were identified. The ISMP National Vaccine Errors Reporting Program (VERP) and the FDA Vaccine Adverse Event Reporting System (VAERS) were searched from the initiation of each respective reporting system through December 31, 2019. The three vaccines with the most reported reconstitution errors in the VERP and VAERS are Menveo® (meningococcal), Pentacel® (DTaP, Polio, *Haemophilus influenzae* type b), and ActHIB® [*H. influenzae* type b (Hib)]. Manufacturers should design labeling and packaging of vaccines to provide ease of storage and fail-safe preparation to prevent 2-component vaccine errors. Implementing risk reduction strategies, such as training healthcare professionals and affixing storage bin labels, remind healthcare professionals to mix the 2-components and facilitate appropriate administration.

1 Introduction

Vaccination, responsible for the prevention of serious diseases that are otherwise debilitating or deadly, is one of the most remarkable advancements in public health [1–3]. To sustain disease prevention, vaccine administration needs to be both widespread and performed correctly [2]. However, errors related to storage and use of vaccines continue to occur, including omission of a vaccine or vaccine component when administering 2-component vaccines [2, 4]. For the purpose of this article, a 2-component vaccine is defined as any vaccine with two components (i.e. vaccine and specific diluent; vaccine liquid component and vaccine powder component) provided by the manufacturer in physically separate containers.

The individual components of 2-component vaccines must be mixed together prior to administration, a step that introduces opportunity for errors [2]. For 2-component vaccines that include a vaccine and specific diluent, meaning a diluent supplied by the manufacturer specifically for reconstitution of that vaccine (Table 1), errors have occurred in which only the diluent was administered to the patient [2, 5, 6]. For these vaccines, the specific diluent must be used for reconstitution to achieve the intended effect for which the product was designed, studied, and approved [7]. For 2-component products that include two active vaccine components, one supplied as a powder and the other supplied as a liquid (Table 1), errors have occurred in which only a single liquid component has been administered. The two active vaccine components are either an antigen paired with an adjuvant or a polysaccharide paired with a protein carrier (i.e., conjugate vaccine) [13, 14]. Adjuvants and protein carriers enhance the immune response; therefore, administration of a sole component may render the vaccine less effective. Lack of familiarity with 2-component vaccines and container labeling and/or packaging factors contribute to these errors [2, 5].

Jeanne Tuttle: Retired from Pharmacy Benefits Management Services.

✉ Diana Kwan
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5 Division of Pulmonary, Critical Care, and Sleep Medicine, University of Kentucky, College of Medicine and Chandler Medical Center, Lexington, KY, USA

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November 2020

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Patient Safety

Medication Safety

Reduce the number of drug-related safety events

Medication safety events impact nearly 1 in 20 (5%) patient experiences, resulting in approximately 2 million hospital stays, and up to 9,000 deaths per year in the US. Medication events are a leading cause of medical malpractice claims each year. While medication errors are common, they are also preventable. Our Medication Safety online membership can help you stay informed about high-alert medications, new technologies and best practices, and create real safety improvements that help you reduce risk in your facility.

Driven by data and expertise from the Institute for Safe Medication Practices (ISMP), a global leader in medication safety which has extensive experience in determining the system-based causes of medication errors and driving change, this membership provides actionable guidance and practical strategies for anyone involved in handling risk throughout the medication management process.

Medication Safety membership includes:

- Guidelines and best practices
- Self-assessment questionnaires to evaluate current processes
- In-depth guidance articles with actionable recommendations
- Member question and answers
- Updates with the latest information

Topics covered include:

- Anticoagulants
- Automated Dispensing Cabinets
- Communicating Medication Orders
- Medication Administration

Learn more: **www.ecri.org/solutions/medication-safety**

Contact us: **clientservices@ecri.org** | **+1 (610) 825-6000, ext. 5891**

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www.ismp.org/ext/570

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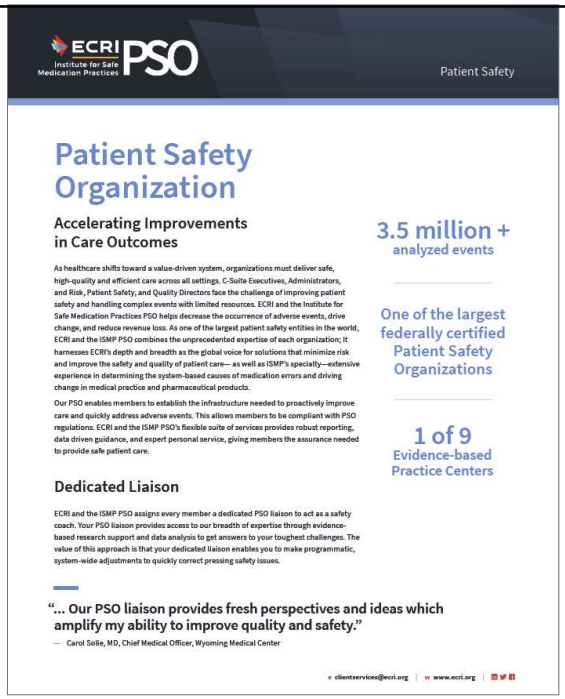

ECRI Institute for Safe Medication Practices PSO

Patient Safety

Patient Safety Organization

Accelerating Improvements in Care Outcomes

As healthcare shifts toward a value-driven system, organizations must deliver safe, high-quality and efficient care across all settings. C-Suite Executives, Administrators, and Risk, Patient Safety, and Quality Directors face the challenge of improving patient safety and handling complex events with limited resources. ECRI and the Institute for Safe Medication Practices PSO helps decrease the occurrence of adverse events, drive change, and reduce revenue loss. As one of the largest patient safety entities in the world, ECRI and the ISMP PSO combines the unprecedented expertise of each organization; it harnesses ECRI's depth and breadth as the global voice for solutions that minimize risk and improve the safety and quality of patient care— as well as ISMP's specialty—extensive experience in determining the system-based causes of medication errors and driving change in medical practice and pharmaceutical products.

Our PSO enables members to establish the infrastructure needed to proactively improve care and quickly address adverse events. This allows members to be compliant with PSO regulations. ECRI and the ISMP PSO's flexible suite of services provides robust reporting, data driven guidance, and expert personal service, giving members the assurance needed to provide safe patient care.

3.5 million +
analyzed events

One of the largest federally certified Patient Safety Organizations

1 of 9
Evidence-based Practice Centers

Dedicated Liaison

ECRI and the ISMP PSO assigns every member a dedicated PSO liaison to act as a safety coach. Your PSO liaison provides access to our breadth of expertise through evidence-based research support and data analysis to get answers to your toughest challenges. The value of this approach is that your dedicated liaison enables you to make programmatic, system-wide adjustments to quickly correct pressing safety issues.

"... Our PSO liaison provides fresh perspectives and ideas which amplify my ability to improve quality and safety."

— Carol Solie, MD, Chief Medical Officer, Wyoming Medical Center

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ISMP An ECRI Affiliate

www.ismp.org/ext/591

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Questions?

- A copy of today's slides will be posted on our website
- Next MSOS Briefing date – January 28, 2021.
  Register: https://ecri.zoom.us/webinar/register/WN_YTUR1_JWS-CKALq3Zm8Dvw

MSOS
MEDICATION SAFETY OFFICERS SOCIETY

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