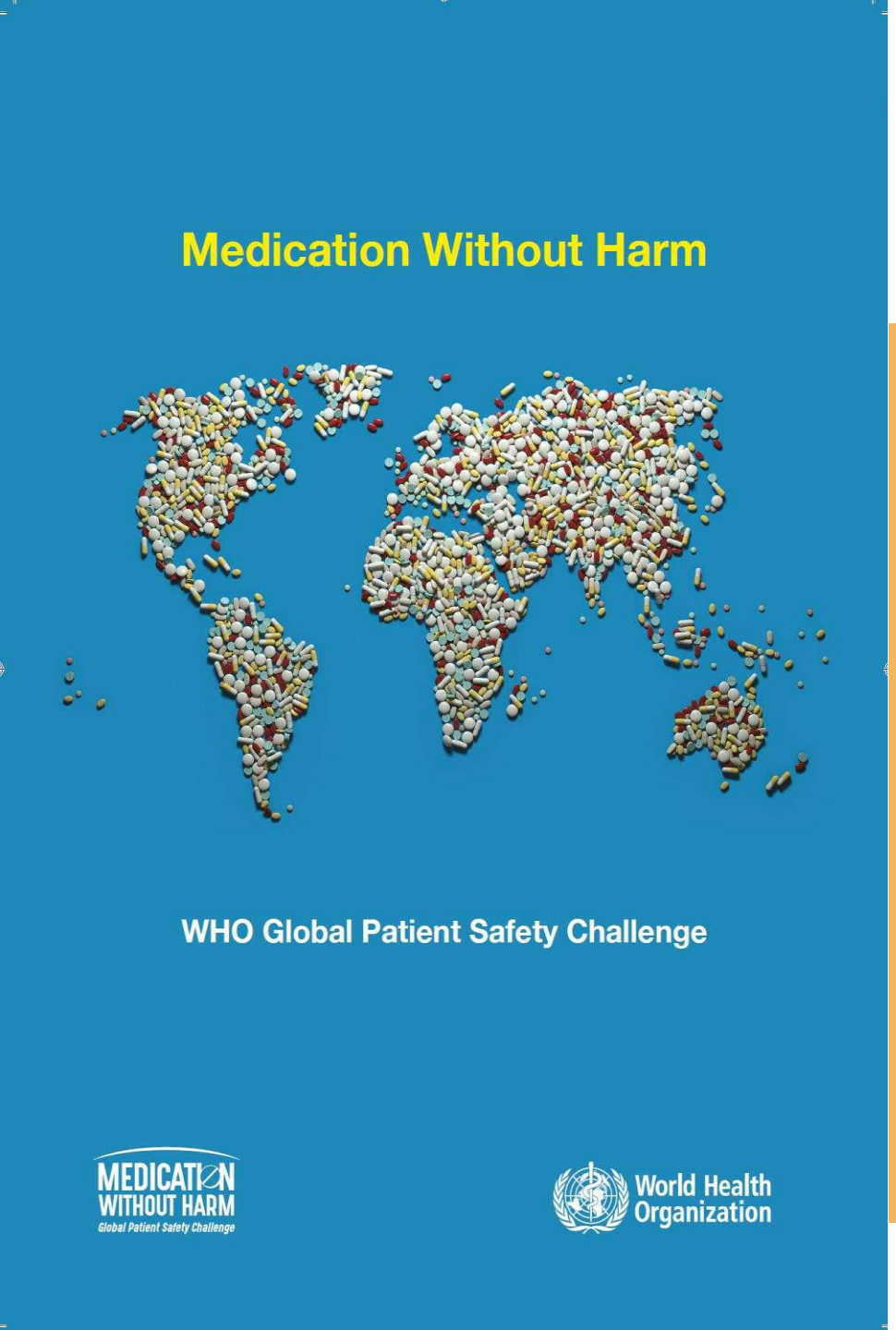

MEDICATION WITHOUT HARM
Global Patient Safety Challenge

World Health Organization

Medication error reporting and learning, and pharmacovigilance systems at the national and organizational level

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12 April 2022

Institute for Safe Medication Practices
An ECRI Institute Affiliate

ISMP Error Reporting Programs

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ISMP National Medication Errors Reporting Program

- Started in 1975, the first and only voluntary, practitioner-based medication error-reporting program
- The objectives of the ISMP MERP are:
  - Learn the underlying causes of reported medication errors or hazards
  - Disseminate valuable recommendations to individuals and organizations to prevent future errors
  - Provide guidance to the healthcare community, regulatory agencies, and pharmaceutical and device manufacturers
- Provides narratives, photos, computer screen shots.

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ISMP National Medication Errors Reporting Program

- National Medication Error Reporting Program
- National Vaccine Error Reporting Program
- Consumer Error Reporting Program

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Why we operate the program

- Capitalize on provider and consumer altruism
- Reporters need to trust in identity non-disclosure
- To provide a personal response to reporting errors (how we use the information)
- To demonstrate we are non-critical of individuals
- To provide expert and credible analysis of reported errors

Why we operate the program

- To share de-identified reports with the US Food and Drug Administration (FDA), the United States Pharmacopeia (USP), drug manufacturers, etc.
- Program operates independent of regulatory/accrediting bodies
- Impact is visible; changes based on reports (“Thanks to your reporting”)
- Program not operated for commercial gain

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July 2014 • Volume 2, Issue 7

Long-Term Care Advise*ERR*™

Educating the Healthcare Community About Safe Medication Practices

ISMP

As U-500 ... to rethink

As the obesity ep... larger doses of ... goals of people ... insulin when dose requi... per mL) is more concent... use has grown, ISMP ha... medication error reports ... present, U-500 insulin us...

Communicating doses i... a recent report, a physi... planning to use a tuberc... culated to be 0.05 mL. Th... asked if the order could ... ever, the prescriber indic... and that he had ordered ...

Confusion such as this ... misunderstand the dose ... might be prepared by me... units," resulting in a dose... derstand the difference ... report the dose, saying ... meaning 40 "syringe un... This can lead to hypergl...

Another type of insulin d... have mistakenly conside... due to a documentation e... glucose level of 150 mg ...

Provided fre...

July 2014 • Volume 12, Issue 7

Nurse Advise*ERR*®

Educating the Healthcare Community About Safe Medication Practices

ISMP

From the hospital to long-term care: Protecting vulnerable patients during handoffs

More than 3 million Americans will rely on services provided by long-term care (LTC) facilities during the year, and greater than 1.4 million will live in the nearly 16,000 LTC facilities on ... Approximately one third of these residents will take an average of ... creasing the risk of medication errors, partic... to a LTC facility.[2-4]

If you do not work in a LTC facility, you m... with me?" Medication errors that occur d... facility often originate in the hospital.[1,2] Lap... along with documentation and transcriptio... care. Studies have demonstrated that inform... fer/referral forms do not match for more t... one medication discrepancy in 70% of all ... continuation of medications intended for a... hospitalized,[2] along with the omission of ... have been continued. Thus, it is not surpri... been reported during transitions between h... these errors have been serious, life-threater...

After being discharged from the hospital, ... During the initial assessment of the patient ... viewed the transfer information faxed to th... of the inpatient medication administration ... charge summary, and the referral/transfer ... cluded the most recent morning and evening ... fer form, discharge summary, and MAR di... the concentration of insulin, 100 units per ... after the drug name. The LTC nurse referred ... sulin dose as 100 units per mL when she ... nurse then contacted the patient's LTC pl... course of hospitalization, and he instructed ... The nurse transcribed the list of medicatio... pharmacy where the order was filled deap... units in the morning and evening). The patie... perienced severe hypoglycemia. The patien... died a short time after arrival.[4]

As demonstrated with this error, poor com... takes during order transcription are the m... during transitions from hospitals to LTC f... originated during the initial documentation ...

We have a *new look!*

We are very excited to launch our revamped newsletter, designed with a fresh new look. Everything needs a change from time to time... we hope you like it!

July 31, 2014 • Volume 19, Issue 15

Acute Care ISMP Medication *Safety Alert!*®

Educating the Healthcare Community About Safe Medication Practices

ISMP

Safety requires a state of mindfulness (Part 1)

In an effort to make healthcare safer, many healthcare organizations are attempting to adopt the characteristics of high-reliability organizations (HROs) that have achieved impressive safety records despite operating in unforgiving environments. Several examples of HROs include nuclear power plants, air traffic control systems, naval aircraft carriers, and wildland firefighting crews. HROs consistently navigate through complex, dynamic, and time-pressured conditions in a nearly error-free manner.[1,2] Research suggests that HROs achieve their exceptional performance through a collective behavioral capacity to detect and correct errors and adapt to unexpected events despite a changing environment.[3,4]

Reliability in healthcare

In healthcare, errors and adverse events are often viewed as deviations from established practices and system failures. To increase reliability, organizations strive for wider adoption of best practices and improved system performance. We attribute unreliability to unwanted variability in tasks, and reliability to consistency with established routines. To improve reliability, our efforts have focused primarily on error *prevention*, which requires identifying lapses in care, understanding their causes, and implementing strategies that prevent lapses from recurring or causing harm. Lapses in care can be defined broadly as something that has gone wrong in the care of a patient regardless of the outcome. While this approach to reliability is certainly worthy of continuation, it only addresses part of the problem given that lapses in care have been found to be highly variable, novel, and often unexpected, making prevention ahead of time difficult.[7]

Reliability in HROs

HROs approach reliability from a different angle. HROs believe that variability in practices in the form of timely adjustments and moment-to-moment adaptations to work is exactly what improves reliability.[8] While HROs have established procedures to guide their work, HROs argue that requiring strict compliance to a single standard of performance at all times may not help workers cope with an unexpected event. To deal with unexpected events, HROs are alert to the possibility of errors and share a collective mindset necessary to detect, understand, and recover from unexpected events before they cause harm.[1,9] These cognitive processes are driven by a deep, chronic sense of unease that arises from admitting the possibility of failure even with familiar, well-designed, stable procedures.[1,2] People in HROs expect surprises and consider them a valuable resource because they encourage learning and discovery, and discourage complacency or inertia.[1] Workers are empowered to act on surprises to achieve reliable outcomes (first-order problem solving). They are also encouraged to go beyond first-order problem solving by taking action to prevent problem recurrence.[8] This, called second-order problem solving, includes reporting the problem to those who are in a position to address the underlying causes. Second-order problem solving is required for lasting improvement.[8]

Principles of mindfulness

At the core of HROs is a set of principles that enable organizations to focus attention on evolving problems and to address those problems before they escalate.[10] These principles,

continued on page 2—Mindfulness >

SAFETY briefs

Positive change, negative consequence. Given the long list of products that use a suffix to describe the drug release rate (e.g., XL, SR, XR) and the lack of standardization as to their exact meaning, it's nice to have it spelled out on the manufacturer's label. But this can lead to unintended consequences. In the following case, specification of "once daily" on a label was misunderstood.

Figure 1. Manufacturer's bottle of Astagraf XL 1 mg.

A renal transplant patient had been taking oral tacrolimus 3 mg every 12 hours. For convenience, this was converted to a once-daily tacrolimus product, ASTAGRAF XL (Figura 1). The patient was told to take 6 mg orally once daily, and blood levels were measured after a week of therapy.

continued on page 2—Safety Briefs >

Look at How Far We've Come

Each year, ISMP celebrates individuals and organizations that have set a standard of excellence in the prevention of medication errors during the previous 12 months. Nominations for this year's Chears Awards will be accepted through September 14. Join us at the Astor Classics Event Center Living Automotive & Communication Museum in Anaheim on December 9 as we celebrate this year's winners! Please visit www.ismp.org/Chears/ to submit a nomination, register for the gala, or make a donation to support ISMP medication safety efforts.

July 2014 • Volume 13, Issue 7

Community/Ambulatory Care ISMP Medication *Safety Alert!*®

Educating the Healthcare Community About Safe Medication Practices

ISMP

With oral ch...

Problem: Although o... with an oral agent can ... therapy. Just last mont... brain cancer, died a slo... of oral lomustine therap... single dose (150 mg). S... she received from the ... capsules each month. ... weeks pending blood t... had also been dispens... the pharmacy as a sing... condition and likely led ...

Figure 1. A lomustine overdo... caused by dispensing more t... a single dose hastened the ... death of Ruth Ann Collins.

supply of the drug, poss... was able to procure lon... dosa. It is uncertain wh... the typical 3-month supp... cies dispense. It is also ... played a role in the dec... once might be less cos... single lomustine dosa... doses.

The mail order pharmac... bottle contained three 10... three 40 mg capsules; ... capsules. The labels on ... a dose from each bottle ...

Brand medicines appear in green: Generic...

July / August 2014 • Volume 12, Issue 4

*SAFE*Medicine®

Protect Yourself from Medication Errors

ISMP

FDA approves home-use auto-injector to treat opioid overdoses

In April, the US Food and Drug Administration (FDA) approved the first home-use naloxone auto-injector, Evzio (Figure 1), for people who accidentally overdose on an opioid (narcotic). The lifesaving ... to quickly inject the medicine to tempora... until emergency medical assistance is ... adult or a child.

According to FDA, drug overdoses, caus... leading cause of death in the US among ... accidents. In a 2013 report by the Center ... opioid overdoses lead to an estimated 1... of opioids and products that contain op... volved in overdose deaths include mor... Kadian, Avinza, MS Contin), oxycod... Percocet, OxyContin), hydrocodone ... codin), methadone, fentanyl, hydron... codeine, and street drugs such as hero...

About naloxone. The medicine in the E... injector is naloxone. This medicine rapi... the effects of opioids. It is the same me... to opioid overdose victims by trained ar... sponders, and nurses and doctors in th... department. Evzio is the first drug avail... auto-injector to treat opioid overdoses ... given outside the hospital by family me... givers, or friends in an emergency. Nalo... previously available for use outside of h... only in kits that contain vials of the med... syringes. Training was required to learn ... rings and inject it properly. But making ... for easy use could save many lives. Unf... the treatment of other drug overdoses—...

Evzio is not a substitute for emergency ... injected, emergency medical assistance ... son that emergency follow-up care is ne... the body than naloxone. So, the naloxo... cause life-threatening symptoms that m...

We have a *new look!*

We are very excited to launch our revamped newsletter, designed with a fresh new look. Everything needs a change from time to time...

ISMP Medication *Safety Alert!*® Ambulatory *Surgery Centers*

Educating the Healthcare Community About Safe Medication Practices

ISMP

September 2021 □ Volume 1, Issue 1

Surgical fires caused by skin preps and ointments: Rare but dangerous and preventable

Problem: Surgical fires that ignite in or around patients can have devastating consequences, particularly if oxygen sources are present during head, face, neck, or upper chest surgeries.[1] It is estimated that up to 240 surgical fires occur each year in the US in operating rooms or during procedures in physicians' offices or clinics, making the frequency of their occurrence comparable to that of other surgical mishaps such as wrong-site surgery or retained instruments.[2-5] Surgical fires are considered rare but very dangerous events given the millions of surgical procedures performed each year. About 30 fires per year cause disfiguring or disabling injuries to patients, and one or two fires each year result in fatalities, most often from airway fires. A US Food and Drug Administration (FDA) analysis of thermal injuries and deaths associated with energy-based devices used in virtually every operation found that surgical fires were most common with monopolar "Bovie" instruments when they were used in head and neck operations.[2]

Although a centralized database of surgical fires in the US does not exist, agencies such as ECRI, which has extensive experience in surgical fire investigation and prevention, suggest that the incidence of surgical fires has decreased in the last decade.[3] The decline is due in large part to national initiatives promoted by professional organizations such as the American Society of Anesthesiologists (ASA), Anesthesia Patient Safety Foundation (APSF), American College of Surgeons (ACS), American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), ECRI, Association of perIOperative Registered Nurses (AORN), The Joint Commission (TJC), and FDA.[1] Despite this decline, attention must be paid to this very real threat to patient and staff safety, as virtually all surgical fires are preventable.[1,6]

How surgical fires start

Surgical fires occur when the three elements that support combustion—an ignition source, a fuel source, and an oxidizer—come together under the right conditions.[4,5,6] Ignition sources, which are often under the control of the surgeon, can be anything that produces heat, such as electrosurgical units and electrocautery devices, lasers, fiberoptic cables and light sources, drills, saws, and defibrillators. Even static electricity can serve as an ignition for a flammable fuel source. Almost anything flammable can be a fuel source, including linens, drapes, gowns, hair, and flammable pharmaceutical products (**Table 1**). The primary oxidizers leading to surgical fires are oxygen and nitrous oxide.

Table 1. Examples of common pharmaceutical-based fuels used during surgery and procedures[1,11]

Aerosol adhesives
Alcohol (also in suture packs)
Collodion
Degreasers (ether, acetone)
Numbing agents (ethyl chloride)
Skin preps with high alcohol (70% or greater) content
Tinctures (e.g., benzoin with 74-80% alcohol)
Petrolatum-based dressings/ointments (petroleum jelly)
Paraffin, white wax

Most reported surgical fires involve electrosurgical units and lasers as the ignition source, oxygen-rich atmospheres as the oxidizer, and alcohol-based surgical preps as the fuel.[1] However, because enriched oxygen and nitrous oxide environments can vastly increase the flammability of potential fuels,[1,6] organizations investigating surgical fires have sometimes incorrectly assumed

continued on page 2 — Surgical fires >

Welcome!

Welcome to the premier issue of the *ISMP Medication Safety Alert!® for Ambulatory Surgery Centers*, a medication safety newsletter from the Institute for Safe Medication Practices (ISMP). Written by medication safety professionals and edited by a diverse, expert perioperative advisory board, this peer reviewed newsletter is designed to:

- Alert ambulatory surgery center (ASC) practitioners to serious medication hazards
- Inform ASC practitioners about the deeply rooted causes of perioperative medication errors
- Empower ASC practitioners to protect patients from medication errors
- Engage ASC practitioners as integral members of interdisciplinary medication safety teams

To achieve these goals, we will bring you anonymous medication safety stories—sometimes amusing, sometimes tragic, but always memorable—that ISMP has received. We will talk about why mistakes happen, and offer practical advice on how to avoid errors.

Just as important, you will have a chance to share your safety stories, ask questions, and participate in surveys so we can learn about you, your medication safety concerns, and the innovative ways that you make patients safe.

We are glad you are joining us on this very important journey to prevent medication errors.

to *the* point

"Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it is the only thing that ever has."
—Margaret Mead

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NATIONAL ALERT NETWORK (NAN)

NAN ALERT 1

October 15, 2021

This alert is based on information from the National Medication Errors Reporting Program (MERP) operated by the Institute for Safe Medication Practices (ISMP).

Mix-ups between the influenza (flu) vaccine and COVID-19 vaccines

Since the 2021-22 influenza (flu) vaccine became available last month, the Institute for Safe Medication Practices (ISMP) has received 16 cases of accidental influenza and coronavirus disease 2019 (COVID-19) vaccine mix-ups. All reports were sent by consumers or healthcare practitioners via one of the ISMP national error reporting programs (www.ismp.org/report-medication-error). Most of the mix-ups occurred in patients who consented to a flu vaccine but received one of the COVID-19 vaccines instead. In three cases, patients received the flu vaccine instead of the intended COVID-19 vaccine. All the events occurred in community/ambulatory care pharmacies.

In the October 7, 2021, *ISMP Medication Safety Alert!* (www.ismp.org/node/27847), ISMP reviewed several errors with vaccine mix-ups and noted several possible contributing factors. Given that flu season is a busy time for vaccinations, many pharmacies are facing an increased demand for vaccination services. Since many of the errors were reported by consumers, details about the contributing factors were not provided in many cases. However, the possible causative factors we have gleaned from the reports include the following:

Increased demand and coadministration of the vaccines. Flu season is already a busy vaccination time for community pharmacies. And, with the approval of the Pfizer-BioNTech vaccine booster and the surge in COVID-19 cases, pharmacies can barely keep up with the vaccination demand. Also, the ability to administer the flu and COVID-19 vaccines during the same visit (www.ismp.org/ext/784) may be a contributing factor.

Syringes near each other. Two vaccine providers indicated that they had picked up a COVID-19 vaccine instead of the flu vaccine syringe, which were right next to each other in the vaccination area. Bringing both vaccines into a patient vaccination area when they are not needed sets the vaccine provider up for a possible mix-up.

Unlabeled syringes. While many vaccine providers purchase the flu vaccine in manufacturer prefilled syringes, which are labeled, COVID-19 vaccines are available in multiple-dose vials and must be prepared in a syringe for administration to patients. It is possible that these prepared COVID-19 vaccine syringes were not labeled. Also, COVID-19 vaccine doses may be prepared in an unlabeled syringe by one healthcare provider and administered by another; as a result, the person who administers the vaccine may not visually verify the empty vial if it remains with the person who prepared the dose.

Distractions. After a vaccine mix-up, one vaccine provider told the patient that he had become distracted by their conversation. Interruptions and other distractions in a busy pharmacy could also lead to mix-ups.

Staffing shortages. Because most healthcare providers are experiencing staffing shortages, it is possible that current vaccine providers are multitasking and are hurried/rushed, even when patients are scheduled for vaccinations. For example, a pharmacist who was working alone in a busy pharmacy recently told us that she needed to administer more than 50 vaccinations during her shift, in addition to dispensing prescriptions.

continued on page 2 >

International Medication Safety

intmedsafe.net

Gmail Tube Maps Acute Care Newslet... Bookmarks bar Brighton Beach Bag...

IMSN INTERNATIONAL MEDICATION SAFETY NETWORK

HOME ABOUT IMSN IMSN ADVOCACY BEST PRACTICES REPORTING PORTAL PUBLIC EVENTS RESOURCES MEMBERS ONLY

REPORTING FORM
EXISTING NRLS
YOUR REPORTS AT WORK

The **International Medication S** n international network of establis ce centres, operating medication err d producing guidance to minimise pr ntable harms fr medicine use in practice.

IMSN promotes safer medication practice to improve patient safety internationally. About IMSN

MAIN IMSN EVENTS

Our Covid-19 Vaccine Safety initiative

IMSN INTERNATIONAL MEDICATION SAFETY NETWORK CVSIG

IMSN CVSIG issues Recommendations for Global Implementation of Safe COVID-19 Immunization Practices

During the fall of 2020, as the world waited in anticipation for the emergency use/conditional marketing authorization of COVID-19 vaccines, members of the **International Medication Safety Network (IMSN)** began to discuss safety issues that might impact global immunization roll out efforts with regard to the knowledge on vaccination errors already gathered by the IMSN.

With the goal of sharing experience and learning from member countries to address COVID-19 vaccine safety issues, the I**MSN Executive Committee** formed the **IMSN COVID-19 Vaccine Safety Interest Group (CVSIG)** in February 2021.

IMSN INTERNATIONAL MEDICATION SAFETY NETWORK

PREVENTION OF FATAL VINCRISTINE (AND OTHER VINCA ALKALOIDS) ADMINISTRATION

VinCRIStine (and other vinca alkaloids) should only be given intravenously via a minibag

Prepare and dispense vinca alkaloids

https://www.intmedsafe.net/the-international-medication-error-reporting-portal/

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