Encouraging pharmacy involvement in pharmacovigilance; an international perspective.

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Medication errors and pharmacovigilance

- Pharmacovigilance is defined as a system for monitoring the safety and effectiveness of medicines.
- As part of the overall effort, analysis of medication errors represents a critical component
- Knowledge of the medication use system is required to understand root causes of medication errors, including medical product issues

Medication errors and pharmacovigilance

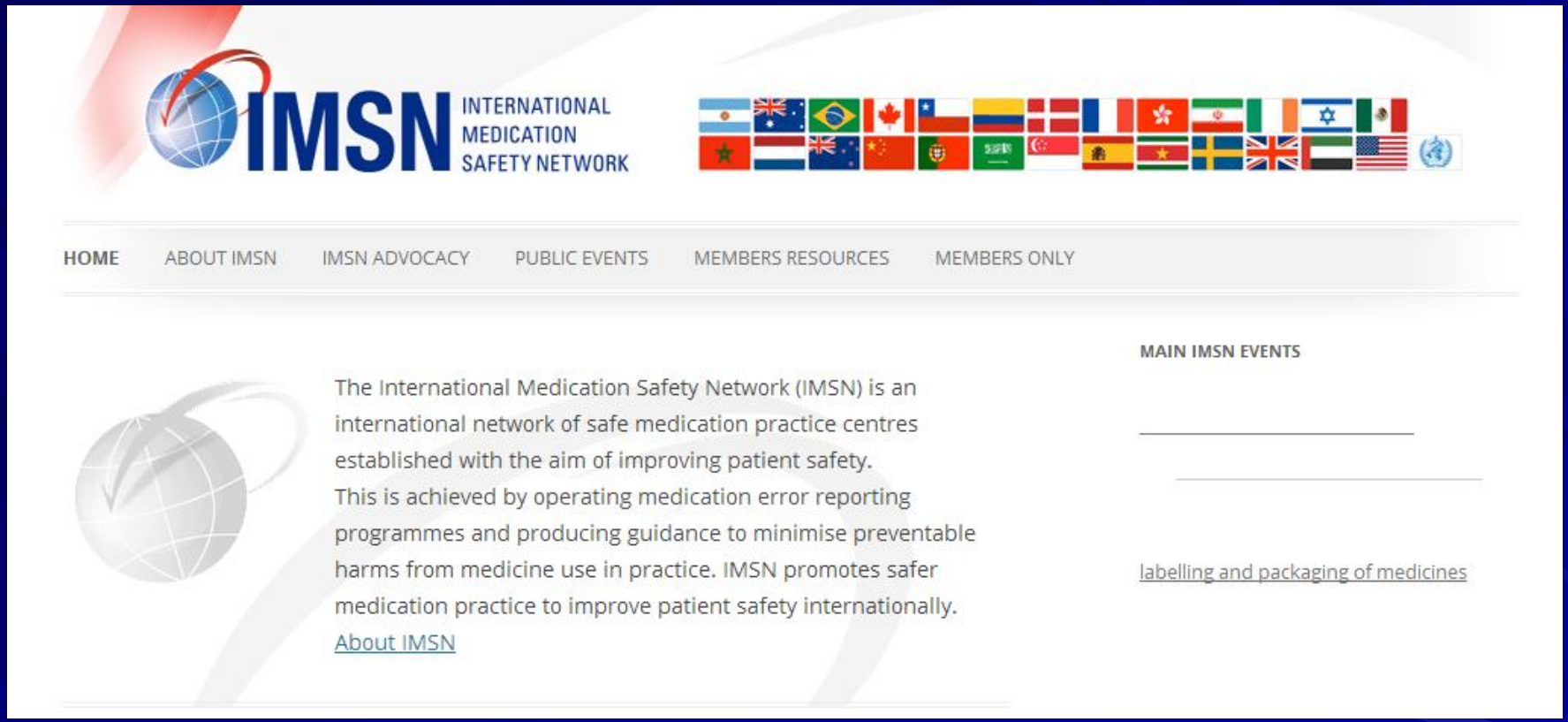
- Medication errors are a public health issue
- Patient harm arises from both adverse drug reactions and medication errors
- Medication error reporting and learning must be part of international pharmacovigilance efforts
- Similar adverse outcomes arise from medication errors globally

Medication errors and pharmacovigilance

- Because of their knowledge of medication use systems, familiarity with regulated products, and ultimate responsibility for medication safety, pharmacists are ideal health professionals to assume roles in pharmacovigilance
- Such medication safety expertise must be incorporated into pharmacovigilance efforts in a collaborative way
- The main purpose is to share learning, identify unsafe conditions and support implementation of product and practice improvement strategies that serve to prevent patient harm

- Established to support and facilitate the transfer of information to benefit medication error prevention efforts in participating countries

www.intmedsafe.net



WHO Initiative

- Support and strengthen consumer reporting of ADRs and adverse events
- Expand the role and scope of national pharmacovigilance centres to prevent medicine-related adverse events
- Promote better and broader use of existing pharmacovigilance data for patient safety
- Develop additional methods of pharmacovigilance to complement data from spontaneous reporting systems

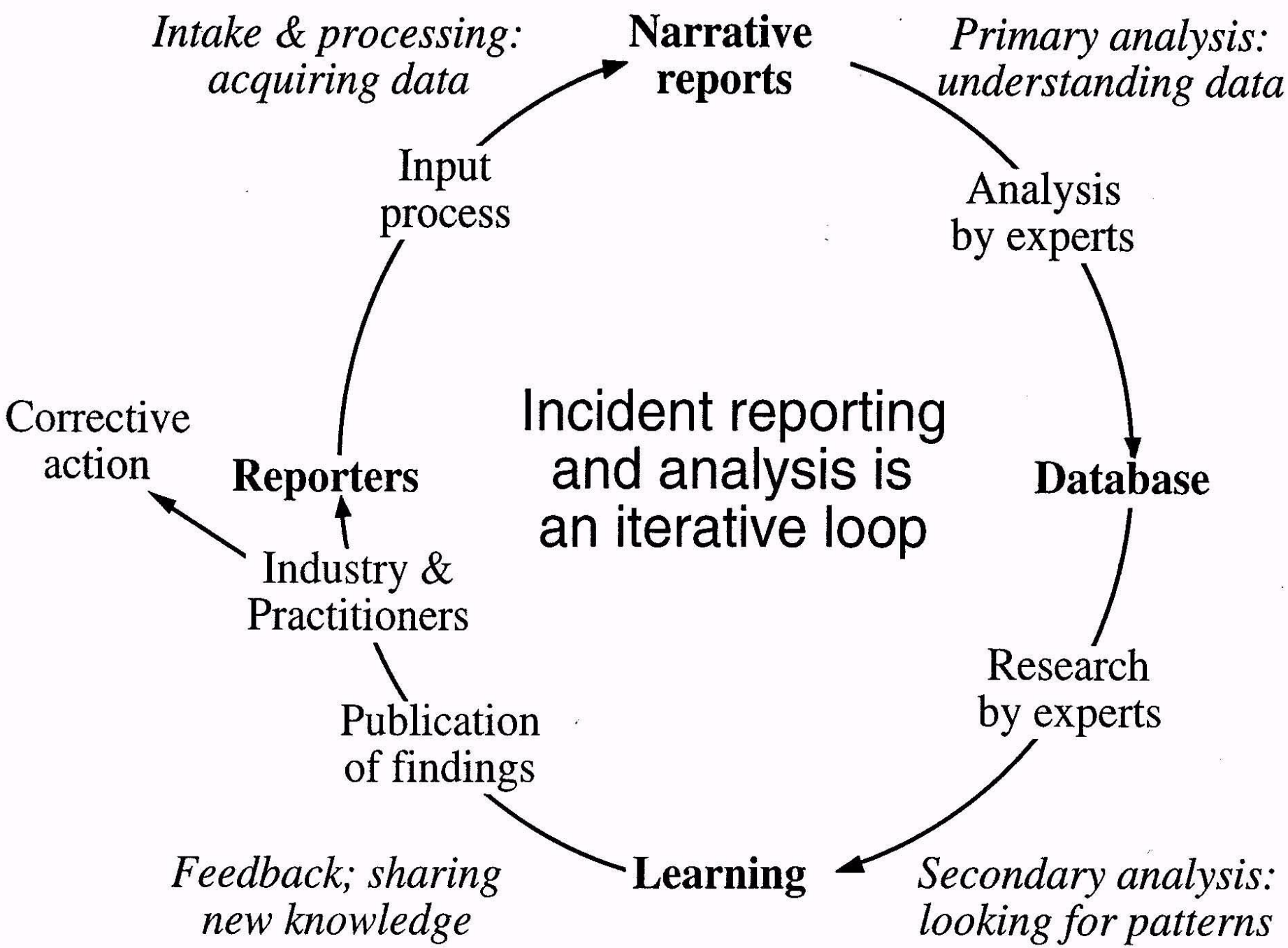
IMSN – WHO
PV training – Morocco

National Medication Errors Reporting Program

Operated by the
Institute for Safe Medication Practices
www.ismp.org

ISMP is a federally certified patient safety organization (PSO)

Pennsylvania Patient Safety Reporting Program


Intake & processing:
acquiring data
Narrative
reports
Primary analysis:
understanding data
Input
process
Analysis
by experts
Corrective
action
Reporters
Incident reporting
and analysis is
an iterative loop
Database
Industry &
Practitioners
Research
by experts
Publication
of findings
Feedback; sharing
new knowledge
Learning
Secondary analysis:
looking for patterns

Institute for Safe Medication Practices

ISMP Canada

ISMP Spain

ISMP Brazil

Pa-PSRS = Pennsylvania Patient Safety Reporting

Medication Error Reporting System


July '12, 2014 ; Volume 19 Issue 14

ISMP

Acute Care

ISMP Medication Safety Alert!

Educating the Healthcare Community About Safe Medication Practices

With oral chemotherapy, we simply must do better!

SAFETY briefs


August 2014 ; Volume 13 Issue 8

ISMP

Community/Ambulatory Care

ISMP Medication Safety Alert!

Educating the Healthcare Community About Safe Medication Practices

In medicine, be wary of "misspeakers" who "shoot from the hip"

SAFETY briefs

- Early warning system
  - Issue nationwide hazard alerts and press releases
- Learning
  - Dissemination of information and tools
- Change
  - Product nomenclature, labeling, and packaging changes, device design, practice issues
- Standards and Guidelines
  - Advocates for national standards and guidelines

Error Reporting Programs

- Not just focused on quantitative data
- Learning is from qualitative information in the reports
- Allows national alerts after just a single report of a major safety issue
- Generally reaches audiences long before FDA, CDC, industry actions
- However, all too often, practitioners and organizations don’t act until it happens to them

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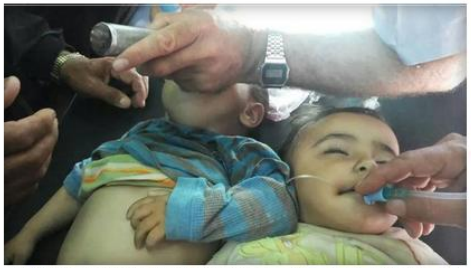
ebay TAKE A STEP IN THE RIGHT DIRECTION

AP / September 17, 2014, 5:31 PM

15 Syrian children die after measles vaccinations



Two Syrian children receive treatment after they were given a second round of measles vaccinations in Idlib province in this photo released Wednesday, Sept. 17, 2014, by Edlib News Network (ENN), an activist group opposed to Bashar Assad's government. EDLIB NEWS NETWORK

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BEIRUT -- At least 15 children died after receiving vaccinations in rebel-held parts of northwestern Syria, while the death toll from two days of government airstrikes on a central city climbed to nearly 50, a heavy toll even by the vicious standards of the country's civil war, activists said.

The children, some just babies, all exhibited signs of "severe allergic shock" about an hour after they were given a second round of measles vaccinations in Idlib province on Tuesday, with many suffocating to death as their bodies swelled, said physician Abdullah Ajaj, who administered the vaccinations in a medical center in the town of Jarjanaz.

nomophobia \nō-mō-'fō-bē-ə\
noun 1. The fear of being out of cell phone signal range. 2. The anxiety relating to the sudden loss of a cellular connection.

endnomophobia.com
#wehavethecure

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September 25, 2014 ▪ Volume 19 Issue 19

ISMP

Acute Care ISMP Medication Safety Alert!®

20 YEARS ADVANCING MEDICATION SAFETY

Educating the Healthcare Community About Safe Medication Practices

Quarterwatch™ Report: Quarters 2 and 3, 2013

Signals for Chantix, Xyrem, Gilenya, and Tecfidera

The new issue of ISMP's Quarterwatch™ (see **Box** below) on adverse drug events (ADEs) reported to the US Food and Drug Administration (FDA) focuses on safety signals involving four drugs. The report examines cases of homicidal, self-injurious, and suicidal ideation for varenicline (**CHANTIX**); multiple adverse effects on the brain with sodium oxybate (**XYREM**); cardiac, ocular, infection, and pregnancy risks with fingolimod (**GILENYA**); and severe gastrointestinal (GI) toxicity and hypersensitivity associated with dimethyl fumarate (**TECFIDERA**).

Varenicline (Chantix): Thoughts of suicide/self-injury and homicide

In October 2014, FDA will move the smoking cessation drug varenicline back into the drug safety spotlight. The agency has scheduled a joint public meeting of two advisory committees to review the current Boxed Warning and Medication Guide. Thus far, FDA has revealed little about why it scheduled this special meeting. The inaugural issue of

continued on page 2—Quarterwatch >

What is Quarterwatch™?

SAFETY briefs

Tragic vaccine diluent mix-ups in Syria have also happened here. You may have seen news reports last week about a terrible tragedy in Syria where 15 children died after being vaccinated against measles. The diluent turned out to be atracurium. Don't think that something similar couldn't happen here. It has, many times.

Apparently in the Syrian incident, the manufacturer shipped vials of vaccine as a lyophilized powder along with separate glass ampuls of diluent. Somehow, a mix-up occurred either before shipment from the manufacturer or at the central area where the vaccines and diluents were stored in a refrigerator, prior to distribution to other areas. The diluent ampuls were

Two chamber vial used for medications with diluents

Liquid diluent or vaccine component B

Lyophilized powder or vaccine component A

The following information is intended for healthcare professionals only:

Instructions for use – Dual chamber syringe (See diagram overleaf)

VIATIM, Suspension and solution for suspension for injection in pre-filled syringe

Hepatitis A (inactivated, adsorbed) and Typhoid polysaccharide vaccine

1. Remove the tip-cap (A).
2. Attach needle and needle shield (B) to the syringe.
3. Screw the plunger rod (C) into the plunger stopper (Stopper 2).
4. Shake the syringe; then mix the vaccine components by slowly pushing the plunger, keeping the needle upwards. The vaccine in the lower chamber moves into the upper chamber by means of the by-pass channel.
5. Shake vigorously until a homogeneous suspension is achieved.
6. Holding the needle shield at the tip, remove by pulling upwards without twisting.
7. Proceed immediately with the injection. A vein test may be carried out by pulling slightly on the plunger. The stoppers may separate but ensure that Stopper 2 does not reach the by-pass channel in order to avoid any leakage of liquid. If a blood vessel has been penetrated, blood will be pulled back into the syringe.

September / October 2014 • Volume 12 Issue 5

SAFEMedicine®

Protect Yourself from Medication Errors

Most accidental poisonings in children occur when medicine is not in its normal storage location

Anyone who takes care of children knows that they have to make their home safe. Whether it's putting up a gate to keep an adventurous child from falling, or covering electrical outlets to keep a curious child away from danger, a safe home is job one. The risk of child poisonings with medicines in the home, however, may not be considered and addressed.[1]

Every minute of every day, a poison control center answers a call about a young child that has accidentally ingested a medicine.[2] The American Association of Poison Control Centers (AAPCC) receives more than half a million reports of medicine poisonings in children less than 6 years of age *every year*.[1] On top of that, one child is treated in an emergency department for accidental medicine poisoning every 8 minutes. That's more than 60,000 children rushed to the hospital each year for evaluation.[1] In almost all cases, the children have taken the medicines themselves, unwitnessed by an adult. Only 5% of child medicine poisonings are due to dosing errors made by parents or caregivers.[1]

A recent study provides parents with insights regarding accidental child poisonings with medicines.[1] The purpose of the study was to identify deep-rooted causes of accidental poisonings with medicines. To do this, the researchers conducted interviews with caregivers who reported child poisonings, asking questions that may have been overlooked in prior studies, such as:

- When did the poisoning occur *in relation to the last proper dose*?
- In what *room* did the poisoning occur?
- Was the medicine in its *usual storage location* when the poisoning occurred?

The most remarkable finding from this study was that most child poisonings occurred when the medicine was **not** in its normal storage location. Instead, the medicine had been removed from its storage location so it could be taken by an adult or given to a child. Then, the medicine was not immediately returned to its usual storage location. During this time, children were able to access the medicine. Thus, no matter how securely medicines are usually stored, this study suggests that there is a period of great risk for child poisonings shortly after removing or taking medicines, before they are put away again.

The study looked at 220 cases of child poisonings involving over-the-counter (OTC) medicines reported to McNeil Consumer Healthcare during a 4-month period. McNeil is a company that markets a wide range of OTC products, including **Tylenol** (acetaminophen), **Benadryl** (diphenhydramine), **Zyrtec** (cetirizine), **Imodium** (loperamide), **Motrin** (ibuprofen), and **Sudafed** (phenylephrine and/or **pseudoephedrine**, may contain **dextromethorphan**).

All the children involved in these 220 cases were less than 7 years old. The children were the intended recipient of the medicine in about half the cases. Children's medicines were involved more often than adult medicines, and liquid medicines were ingested more often than chewable or regular tablets. At the time

continued on page 2—Poisonings >

check it out

To prevent harm from accidental medicine poisonings in children, consider these recommendations.

Store safely

- Keep all medicines in a secure (and preferably locked) cabinet, up and away and out of reach and view of children. This includes medicines you take every day, such as vitamins, as well as potentially toxic products you might not think of as medicines, such as diaper rash remedies or eye drops.
- Keep medicines currently in use in a secure location and under close observation during the entire administration period to prevent a child from accessing the medicine while taking a dose or while giving a dose to another child.
- Return medicines to a secure location, high and out of sight, **immediately** after use—not letting children see where you put them.
- Don't leave medicine containers out as a reminder. If you need a reminder to take doses of medicine, set an alarm on your watch or cell phone, or write a note.
- Never leave medicines on counters, night-

continued on page 2—check it out >

Get your flu vaccine now!

The Centers for Disease Control and Prevention (CDC) reports that manufacturers are now shipping flu vaccines for the 2014-2015 flu season. Vaccine distribution will continue through the fall. For more information, go to: www.cdc.gov/flu/about/season/index.htm. Call your doctor or pharmacy to get your flu vaccine today!

Brand medicines appear in ***green****. Generic medicines appear in* ***red****.*

August 2014 • Volume 13 Issue 8

Community/Ambulatory Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

In medicine, be wary of "misspeakers" who "shoot from the hip"

Have you ever answered a question even though you were not sure of the answer? Perhaps the fear of looking dumb was so overwhelming that any answer was thought to be better than no answer? Under this pressure, we may "shoot from the hip," forming an answer to a question in seconds and talking no time to weigh options or look at the question in-depth. If the answer is wrong—which it often is—we "misspeak." Speaking off the cuff with authority when you are not certain of the answer is a prescription for disaster in healthcare.

Recently, a patient encountered several instances of "misspeaking" by healthcare workers. The patient had just undergone dental work, including a root canal. Her dentist had prescribed amoxicillin to prevent an infection. However, the patient had a documented allergy to penicillin, which was listed in her dental record. When the patient received the handwritten prescription, she asked the dentist's receptionist if it was safe to take amoxicillin given her penicillin allergy. The receptionist assured the patient that the dentist had verified the prescription. When the patient dropped off the prescription to be filled at the pharmacy, she asked the pharmacy technician to verify that the medication ordered was not penicillin since she was allergic to penicillin. The technician quickly replied, saying, "No, it's not. That's why your doctor prescribed it." Trusting the healthcare workers, she took the medication. Several days later, she began to notice a rash that extended over her entire body, which was diagnosed as an allergic reaction to amoxicillin. She was fortunate that she did not experience an anaphylactic reaction.

Healthcare workers are often pressured to give an answer instantly. Pressure to meet time constraints may contribute to this. And with busy schedules and time constraints, staff may be only too happy to oblige. For pharmacists, managing dispensing time expectations while juggling incoming prescriptions, insurance adjudication issues, and clinical clarifications with prescribers may contribute to this pressure. Prescribers may be pressured to manage high patient volumes and wait times. Nurses may be multi-tasking to provide care for multiple patients in a fast-moving, ever-changing healthcare setting. This pressure and an expectation from others for instantaneous responses may lead to "misspeaking."

Additionally, answering questions can take time, a precious commodity in today's world, particularly in healthcare. Thus, healthcare practitioners may "shoot from the hip" and "misspeak" when trying to placate a patient or quickly answer a patient's question because they simply need to move forward with their work. This may involve the provision of misinformation, such as telling a patient who questions the appearance of a medication that it is just a different generic product, without taking the time to notice that it's the wrong drug. Or, the answer may have some truth to it but not enough details to really answer the question.

"Shooting from the hip" sometimes hits the target, but it is seldom precise. Serious errors are possible when imprecision and misinformation are introduced into patient care. To reduce these behaviors, consider the following.

continued on page 2—Misspeak

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 may 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

continued on page 2—SAFETY briefs >

Look at How Far We've Come

Each year, ISMP celebrates individuals, organizations, non-profit associations, companies, and others that have set a standard of excellence in the prevention of medication errors during the previous 12 months. Nominations for this year's **Chiem Awards** will be accepted through **September 14**. Join us at the **Astor Classics Event Center** in Anaheim, CA on **December 8** as we celebrate this year's winners! Please visit www.ismp.org/Chiem/ to submit a nomination, register for the gala, or make a donation to support ISMP medication safety efforts.

August 28, 2014 • Volume 19 Issue 17

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

VARIZIG dilution problems reported

An issue came to our attention recently regarding varicella zoster immune globulin (**VARIZIG**), indicated for post-exposure prophylaxis against chickenpox in high-risk individuals, such as children and adults who are immunocompromised. The product is available as a kit (**Figure 1**) that contains a single vial of diluent along with a vial of 125 units of lyophilized powder (labeled as international units or IU, which ISMP deems an unsafe and unnecessary expression that is sometimes misread as IV). The diluent is packaged as a single-dose vial containing 8.5 mL. VARIZIG is approved in the US for IM use only but approved in Canada for IM or IV use. According to the US label, only 1.25 mL of diluent is necessary for reconstitution of the 125 unit vial for IM use, resulting in a solution of 100 units per mL. In Canada where IV use is approved, 2.5 mL of diluent must be added to the vial.

Recently, in a US hospital emergency department (ED), a 5-year-old pediatric patient was to receive 125 units IM. However, a nurse misunderstood the instructions and used the entire volume of diluent (8.5 mL) to reconstitute the product. Rather than waste the dose, the nurse decided to divide the dose into two 3 mL injections and one 2.5 mL injection—for a total of 3 IM injections, which is bound to be traumatizing, particularly for a 5-year-old child. It is unclear why the instructions were misunderstood, but since only a fraction of the diluent (1.25 of the 8.5 mL) is necessary, it is likely that the packaging contributed to the error. We could also foresee a situation where the entire diluent is used to reconstitute the powder, and the practitioner assumes this provides the labeled 100 units per mL concentration, which would lead to a subtherapeutic dose.

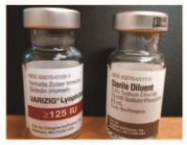


Figure 1. Lyophilized vial of VARIZIG and diluent.

The product is distributed in the US by Emergent Biosolutions and manufactured by its subsidiary, Cangene Biopharma, in Canada. According to Emergent Biosolutions, the diluent vial presently contains 8.5 mL because higher doses were originally used in Canada, and stability studies were conducted with larger diluent volumes. The company told us that Cangene has a new liquid form of the product under development that will not require reconstitution. The dosing for the new formulation is also weight-based and may require more than one vial according to a dosing chart in the package insert. For now, if you stock the lyophilized product, consider adding an auxiliary label that reminds practitioners to reconstitute with the volume listed in the labeling (1.25 mL per 125 unit vial, which provides 100 units per mL), and then to discard the remaining diluent.

We also had a pharmacist express concern regarding the amount of sodium phosphate administered based on the diluent vial label. The label states that it contains "10 mM" of sodium phosphate, which seems to be a high dose of sodium phosphate for treating hypophosphatemia. But don't confuse mM with mmol (as we did along with the reporter).

continued on page 2—VARIZIG >

SAFETY briefs

Nitroglycerin injection shortage issue.

Caution: During the intravenous (IV) nitroglycerin shortage, if you have had to jockey between Baxter and Hospira for available premixed nitroglycerin bottles, you may already know how this can lead to errors. The Baxter container label expresses the nitroglycerin strength primarily as the mg of drug per total volume in the container (e.g., 100 mg/250 mL), followed by the amount in micrograms per

Figure 1. Strength communicated in mg per total volume in the vial, followed by mcg per mL.

Figure 2. Strength communicated in mcg per mL, followed by mg per total volume in the vial.

mL listed within parentheses (**Figure 1**). On the other hand, Hospira labels its premixed infusion of nitroglycerin primarily in micrograms per mL (e.g., 100 mcg/mL), with the mg of drug per total volume in parentheses (**Figure 2**). This is a long-standing problem that ISMP has brought to the attention of the product manufacturers and the US Food and Drug Administration (FDA) in the past.

Errors are more likely during product shortages because infusion pumps may need to be reprogrammed. For example, nurses familiar with Hospira's 100 mcg/mL label as the primary display may confuse this with a Baxter bottle labeled as 100

continued on page 2—SAFETY briefs >

September 2014 • Volume 12 Issue 9

Nurse Advise ERR®

Educating the Healthcare Community About Safe Medication Practices

Recommendations for practitioners to address system-based causes of vaccine errors (Part 2)

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. According to the World Health Organization (WHO), immunizations prevent 2 to 3 million deaths per year. Despite this success, some children and adults in the US remain vulnerable to the 17 vaccine-preventable diseases targeted with specific immunization recommendations.

The failure to vaccinate due to lack of information or misinformation is the primary reason for the existence of susceptible populations in the US. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others.

In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (ISMP VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In our June 2014 newsletter (www.ismp.org/so?id=391), we provided a summary analysis of error reports submitted to the ISMP VERP during its first year.

The vaccinations most frequently involved in errors included:

- Influenza
- *Haemophilus influenzae* type b conjugate (Hib)
- Diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV)
- Tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap)
- Diphtheria and tetanus toxoids and acellular pertussis adsorbed (DTaP)
- Hepatitis A (HepA)
- Hepatitis B (HepB)
- Human papillomavirus (types 6, 11, 16, 18), recombinant (HPV4)
- Zoster
- Measles, mumps, rubella, and varicella (MMRV)

The most common contributing factors with the reported vaccine errors included:

- Mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases
- Unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (e.g., combination vaccines; diluent and powder)
- Failure to check or verify the patient's age, health record, or state vaccine registry
- Similar vaccine names and abbreviations
- Similar and confusing vaccine labeling and packaging
- Unsafe storage conditions (e.g., stored near other similar vaccines, unwanted temperature fluctuations)
- Expiration dates not noticed or misunderstood

continued on page 2—Vaccine errors >

SAFETY wires

Nitroglycerin injection shortage issue. Caution: Due to shortages of intravenous (IV) nitroglycerin, your hospital may have had to switch back and forth between bottles of Baxter and Hospira premixed nitroglycerin infusions. If so, you may already know that switching between the two products can lead to errors, depending on which product was available. The Baxter infusion label expresses the nitroglycerin strength primarily as the mg of drug per total volume in the container (e.g., 100 mg/250 mL), followed by the amount in micrograms

Figure 1. Strength communicated in mg per total volume in the bottle, followed by mg per mL.

Figure 2. Strength communicated in mcg per mL, followed by total mg per container.

per mL (e.g., 400 mcg/mL) listed within parentheses (**Figure 1**). On the other hand, Hospira labels its premixed infusion of nitroglycerin primarily in micrograms per mL (e.g., 100 mcg/mL), with the mg of drug per total volume in parentheses (**Figure 2**). The differences in the labels of these products have been a longstanding problem that ISMP has brought to the attention of the product manufacturers and the US Food and Drug Administration (FDA) in the past.

continued on page 2—SAFETY wires >

Baxter

Supported by educational grants from Baxter and BD

BD

September 2014 • Volume 2 Issue 9

Long-Term Care Advise ERR™

Educating the Healthcare Community About Safe Medication Practices

URGENT! Health systems need to plan NOW for upcoming changes in enteral feeding device connectors

Are you ready for the design changes coming soon for enteral feeding device connectors? While ISMP and other organizations have repeatedly publicized the upcoming global changes with all enteral device connectors, we are not confident that healthcare organizations, including long-term care (LTC) facilities, are adequately preparing for such a significant change. The new International Organization for Standardization (ISO) enteral connector design will no longer be Luer-compatible and will require major changes in enteral nutrition practices, policies, procedures, and processes that need planning. These changes were implemented to prevent accidental misadministration of oral solutions via the intravenous route. These new connectors will impact nurses, pharmacists, physicians, dieticians, caregivers, and patients/residents across the continuum of care. We are concerned that LTC facilities and pharmacies will be ill-prepared when the new enteral connectors begin to be systematically introduced later this year and into 2015. Our concern is heightened by several unresolved process dilemmas that the change will undoubtedly trigger, particularly related to preparation, dispensing, and administration of enteral medications.

Enteral device connector changes

In the first phase of changes, which have been in place since 2012, enteral feeding administration sets with the new enteral-only fitting at the proximal end have been introduced. This connector fits into the feeding substance container (**Figure 1**). In the next phase, which will begin by the fall of 2014, manufacturers will distribute administration sets with the new enteral-only connector at the other end that connects to the feeding tube (PEG-tube, G-tube, etc.). Because the feeding tubes with the new connector (named "ENFit") will not be available until the second quarter of 2015, a temporary transition adapter will be attached to the administration set (**Figure 2**). The new

Enteral Connectors—continued on page 2 >

Figure 1. Enteral feeding administration sets already have an enteral-only connector that fits into the feeding container (bottle end). (Picture by GEDSA)

Figure 2. The ISMP Transition Connector will connect the feeding tube to the administration set until new feeding tubes with ENFit connectors are available (second quarter 2015). (Picture provided by GEDSA.)

check it out

Follow these recommendations to prepare for the new enteral device connectors.

- **Form an implementation team.** Form an interdisciplinary team that includes prescribers, frontline nurses, and pharmacists to assess the existing systems, processes, and protocols that may need to be changed during and after transition to the new enteral connectors.
- **Establish a communication plan.** Have the implementation team reassess/improve/create a plan for communication between the LTC facility and the pharmacy when liquid medications are required for residents and how they will be administered (e.g., oral or enteral).
- **Plan a dispensing process.** Have the implementation team reassess how enteral liquid medications will be dispensed from the pharmacy. ISMP strongly recommends that the pharmacy dispense resident-specific unit doses in enteral syringes and has been in contact with manufacturers about the need for enteral syringe caps and bottle adapters for this purpose. While we are reasonably optimistic about the availability of these devices once enteral syringes are on the market, organizations should determine an alternative process for safely dispensing resident-specific doses in labeled, barcoded, unit-dose cups or vials.

continued on page 2—check it out >

Time's Running Out!

We need your input! Don't forget to complete our survey on the ***Use of Computerized Medication Order Entry Systems in Long-Term Care Facilities***. The last day to participate is **September 10, 2014**. Go to: www.surveymonkey.com/s/ISMP-CMOE.

Provided free to long-term care facilities in the US thanks to corporate sponsorship from Lilly

NATIONAL ALERT NETWORK (NAN)

NANALERT

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

April 25, 2012

Proper disposal of fentaNYL patches is critical to prevent accidental exposure

On April 18, 2012, the U.S. Food and Drug Administration (FDA) alerted healthcare providers and consumers about the importance of proper storage, application, and disposal of transdermal fentaNYL (fentaNYL patch) to prevent dangerous, accidental pediatric exposure (www.fda.gov/Drugs/DrugSafety/ucm300747.htm). FDA noted 26 cases of accidental pediatric exposure during the past 15 years, including 10 that resulted in death and 12 that resulted in hospitalization. Sixteen events involved children 2 years old or younger. Incidents have occurred in the home but can also originate within a healthcare institution, where children may accompany adults who are visiting patients.

On the heels of a heartbreaking event recently reported to the ISMP National Medication Errors Reporting Program (ISMP MERP) by a grieving mother, this alert is intended to complement the recent FDA alert by focusing on safe disposal of fentaNYL patches in hospitals and long-term care facilities.

Last November, a 2-year-old boy, Blake (see photo in upper right corner), died after accidental exposure to a used fentaNYL patch hastily discarded in a long-term care facility. The family was visiting the boy's great-grandmother at a nursing home. Two days after the visit he was found unconscious, in respiratory arrest, and was unable to be resuscitated. A medical examiner later found a small, white, 1 inch by ½ inch piece of what appeared to be tape in the boy's throat. Later, a toxicology report came back indicating that a lethal dose of fentaNYL was in Blake's system. The "tape" was sent to a laboratory for processing and turned out to be a used fentaNYL patch, with a high concentration of the potent opioid fentaNYL still remaining.

Blake's parents spoke with authorities and related a history of the boy's visit to the nursing home. County detectives and the state health department officials began an investigation. At the facility, authorities found that medication patches were not being disposed of properly. A used fentaNYL patch was seen on a bedside table and, according to the mother, patches had been disposed of in the trash pail in the boy's great-grandmother's room. Authorities also found used medication patches in other patient rooms on the floor, stuck to bed railings, and in other unsecured patient areas.

Blake was only 2 years old when he died.

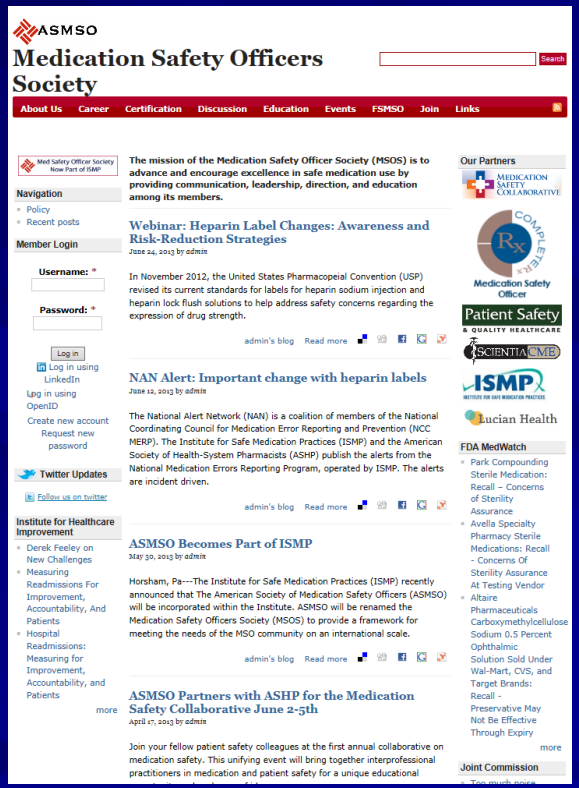
A theory emerging about the child's death is that he may have run over a used fentaNYL patch on the floor of his great-grandmother's room with his Tonka truck wheels. After the visit, he may have peeled off the patch and stuck it in his mouth. Used fentaNYL patches can still contain a large quantity of unabsorbed medicine after they are removed, so both new and used patches can be dangerous to children and pets.

The theory is quite feasible given that other children have been exposed to patches in a similar manner. In another case received through the ISMP MERP, a child sat on a used fentaNYL patch that had fallen off a family member, and it stuck to her thigh, causing drug-related symptoms. Another child

continued on page 2—Fentanyl patches

ISMP Websites

www.ismp.org



www.asmso.org/

www.consumermedsafety.org

Look-alike products


SULFATRIM®
SUSPENSION
POVIDINE
SURGICAL SCRUB
POVIDINE
TOPICAL SOLUTION
CHILDREN'S
APAP ELIXIR
ALPHARMA


PLIVA
NDC 50111-563-01
Cyclobenzaprine HCl
Tablets, USP
10 mg
Rx only
100 Tablets
PLIVA
NDC 50111-314-01
Cyproheptadine HCl
Tablets, USP
Rx only
100 Tablets


METRONIDAZOLE
TABLETS, USP
METFORMIN
HYDROCHLORIDE
TABLETS

Which Concentration to Select?


HEP-LOCK U/P
PRESERVATIVE-FREE
Heparin Lock
Flush Solution, USP
10 USP units/mL
Heparin
Sodium Inj., USP
10,000 USP units/mL


Heparin
Sodium Inj., USP
10,000 USP units/mL
Heparin
Sodium Inj., USP
10,000
USP units/mL

Opticlik Pen Device

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TUESDAY, AUGUST 28, 2012

Insulin safety for people who inject with a 'pen'

by Michael R. Cohen, R.Ph., M.S.

With millions of Americans suffering from diabetes, there's been tremendous growth in the use of insulin. For convenience, many insulin dependent diabetics carry their insulin in a prefilled syringe available from drug manufacturers. The device is called an insulin pen because it sort of looks like a pen and can be carried in your pocket. But it's actually a sophisticated device designed for multiple injections of insulin until the cartridge within the pen needs to be replaced.

Unfortunately, not every insulin dependent patient knows how to use their pen in the proper way and they sometimes place themselves at dangerous risk of complications. We received an interesting report from a certified diabetes educator/RN about a patient who suffered an insulin overdose by misreading the amount dialed. With some of the most popular insulin pens now in use, you have to turn a dose selector dial to set the pen to deliver the prescribed dose. The dose then appears in a little built-in window on the pen. Once you set the dose you inject the pen's needle into your skin and push a button to release the dose. In the picture below you can see what that looks like where the insulin dose that has been dialed is 46 units.

In this actual case that happened when a new patient was giving herself Novolog insulin for the first time, the patient ultimately wound up in a hospital emergency room, unconscious and with a dangerously low blood sugar of just 20 mg/dL. A normal blood sugar would be above 70 to around 100. A blood sugar that low risks permanent brain injury of not caught in time.

About Check Up

Check Up is your guide to health and medicine across the Philadelphia region.

Brought to you by Philly.com/health and the Philadelphia Inquirer's Health and Science team, this blog covers major health events in our region and offers everything from personal health advice to an expert look at health reform.

Our guest bloggers include:

- Michael Cohen -- Medication Safety
- Robert Field -- Health Policy
- Daniel R. Hoffman -- Pharma

Blog Roll

- Health News blogs:

Get It Now

FDA Center for Drug Evaluation and Research

- Office of Surveillance and Epidemiology
  - Office of Medication Error Prevention and Risk Management
    - Division of Medication Error Prevention and Analysis

Figure 1. Unapproved Morphine Sulfate Oral Solution 20 mg/mL previously marketed by Roxane.

Figure 2. Morphine Sulfate Oral Solution 20 mg/5 mL by Roxane.

Figure 1. Unapproved Morphine Sulfate Oral Solution 20 mg/mL previously marketed by Roxane.

Figure 2. Morphine Sulfate Oral Solution 20 mg/5 mL by Roxane.

Before

After

FDA Medication Error Prevention Guidances

- Safety Considerations for Product Design to Minimize Medication Errors (December 2012)
- Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors (April 2013)
- Best Practices in Developing Proprietary Names for Drugs (May 2014)

Forthcoming ISO standards to prevent healthcare catheter misconnections

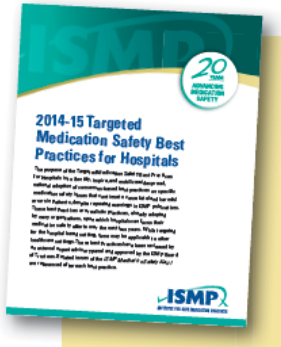
- Enteral applications (feeding tubes and formula delivery systems)
- Breathing systems and driving gases applications (oxygen and ventilators)
- Urethral and urinary applications
- Limb cuff inflation applications
- Neuraxial applications (spinal and epidural catheters and infusions)
- Intravascular or hypodermic applications

ISMP Launches Targeted Medication Safety Best Practices for Hospitals

Deciding what to focus your safety efforts on during the next year?

ISMP is encouraging adoption of consensus-based best practices on specific issues that continue to cause harmful errors despite repeated warnings.

For more information and a printable copy of the best practices, visit **www.ismp.org**.



The 2014-15 ISMP best practices address:

- VinCRIStine
- Oral methotrexate
- Patient weights in metric units
- Oral syringes
- Oral liquid dosing devices
- Glacial acetic acid

www.ismp.org

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

20 YEARS
ADVANCING MEDICATION SAFETY

Examples of Continuing Medication Safety Issues

- Wrong-route errors
- Order communication errors
  - oral, written, CPOE
- Look-alike packaging
- Look-alike/sound-alike drug name confusion
- PCA-related errors
- IV compounding errors
- Vaccine errors

Causes of medication errors

- **Critical patient information missing?** (age, weight, allergies, lab values, pregnancy, patient identity, location, renal/liver impairment, diagnoses, etc.)
- **Critical drug information missing? (**outdated/absent references, inadequate computer screening, inaccessible pharmacist, uncontrolled drug formulary, etc.)
- **Miscommunication of drug order?** (illegible, ambiguous, incomplete, misheard, or misunderstood orders, intimidation/faulty interaction, etc.)
- **Drug name, label, packaging problem?** (look/sound-alike names, look-alike packaging, unclear/absent labeling, faulty drug identification, etc.)
- **Drug storage or delivery problem?** (slow turn around time, inaccurate delivery, doses missing or expired, multiple concentrations, placed in wrong bin, etc.)

Causes of Medication Errors

- **Drug delivery device problem?** (poor device design, misprogramming, free-flow, mixed up lines, IV administration of oral syringe contents, etc.)
- **Environmental, staffing, or workflow problems?** (lighting, noise, clutter, interruptions, staffing deficiencies, workload, inefficient workflow, employee safety, etc.)
- **Lack of staff education?** (competency validation, new or unfamiliar drugs/devices, orientation process, feedback about errors/prevention, etc.)
- **Patient education problem?** (lack of "counseling," noncompliance, not encouraged to ask questions, lack of investigating patient inquiries, etc.)
- **Lack of quality control or independent check systems?** (equipment quality control checks, independent checks for high alert drugs/high risk patient population drugs etc.)

Use of storytelling

- Powerful communication strategy
  - package experiences in an interesting way
  - share lessons learned
  - people remember information that evokes emotion, captures attention, involves personalization
  - people who remember stories also remember the rationale behind specific error-reduction strategies, thus improving compliance

Communicating low frequency, high harm events

October-December 2013

ISMP Quarterly Action Agenda

ISMP One of the most important ways to prevent medication errors is to learn about problems that have occurred in other organizations and to use that information to prevent similar problems at your practice site. To promote such a process, the following selected items from the October-December 2013 issues of the *ISMP Medication Safety Alert!* have been prepared for an interdisciplinary committee to stimulate discussion and action to reduce the risk of medication errors. Each item includes a brief description of the medication safety problem, a few recommendations to reduce the risk of errors, and the issue number to locate additional information as desired. Look for our high-alert medication icon under the issue number if the agenda item involves one or more medications on the ISMP's **List of High-Alert Medications** (www.ismp.org/Tools/highalertmedications.pdf). The Action Agenda is also available for download in a Microsoft Word format (www.ismp.org/Newsletters/acutecare/articles/ActionAgenda1401.doc) that allows expansion of the columns in the table designated for organizational documentation of an assessment, actions required, and assignments for each agenda item. Many product-related problems can also be viewed in the *ISMP Medication Safety Alert!* section of our website at: www.ismp.org. Continuing education credit is available for nurses at: www.ismp.org/Newsletters/acutecare/actionagendas.asp.

Key: ⚠ – ISMP high-alert medication

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/ Assignment	Date Completed
Understanding and managing IV container overfill					
(23) ⚠	More than 1,100 patients received less potent chemotherapy than intended. Large bags of chemotherapy had been prepared and divided into smaller doses for multiple patients. Overfill in the large bags was not considered when listing the concentration on the label because the compounding pharmacy thought each large bag was to be used as a single dose. Although the full dose in each bag was listed on the label, the actual concentration on the label was incorrect. There are several methods that can be used to prepare sterile products, each with specific means for managing the overfill volume to avoid confusion.	Choose the most appropriate method of preparing each medication infusion according to whether or not the volume/concentration is critical. Obtain a list of overfill amounts of commonly used products from vendors for reference as necessary. For continuous infusions titrated to effect, ensure standardization in the preparation process in order to avoid variations in concentration and inconsistencies with the dose delivered. For a single dose drug infusion, the most critical aspect of the process is ensuring that the entire contents in the container are administered; the label should include a reminder, "Infuse entire contents for full dose."			
Safety concerns surrounding the use of U-500 insulin					
(22) ⚠	As the use of U-500 insulin grows, so do the number of errors, mostly related to dosing confusion caused by not having a syringe with a U-500 scale. Healthcare providers and patients rely on syringes meant for U-100 insulin to measure U-500 insulin doses. This results in communicating the dose by the number of units that correspond to the U-100 syringe. Another source of confusion is name similarity since **HUMULIN R** is the name used for both U-100 insulin and U-500 insulin.	Until U-500 syringes or pens are available, use tuberculin syringes to measure doses by volume, using a dosing conversion chart (available at: www.ismp.org/sc?id=260). Total doses should be expressed in both units and volume (i.e., 200 units [0.4 mL]). To minimize name confusion, ensure the strength is listed with each **HUMULIN R** insulin product during order entry. Separate U-100 insulin and U-500 insulin vials in storage areas.			
Initiative to eliminate tubing misconnections					
(23)	Catheter misconnections happen when tubing from one type of delivery system is connected to another delivery system that serves a different function. An international effort is underway to standardize the various types of connectors used in healthcare, making them incompatible with each other.	A phased-in approach to launch the new connectors, starting with enteral devices, will occur in 2014. Organizations should review the publication, **Stay Connected**, for Frequently Asked Questions (www.ismp.org/sc?id=267) and to begin the initial steps to prepare for these changes.			

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Making error reporting work

- Capitalize on altruism
- No public disclosure of involved staff
- Personal response to reporters
- Feedback and changes communicated
- Non-critical of individuals – it's the system
- Expert and credible analysis
- De-identified information forwarded to authorities
- Regulator and manufacturer advocacy

Data Elements

- Possible causes
  - Critical patient information missing?
  - Critical drug information missing?
  - Miscommunication of drug order?
  - Drug name, label, packing problem?
  - Drug storage or delivery problem?
  - Drug delivery device problem?
  - Environmental, staffing, or workflow problems.
  - Lack of staff education?
  - Lack of patient education?
  - Lack of quality control or independent check systems?

(Assess-ERR™ www.ismp.org/Tools/AssessERR.pdf)

ASSESS - ERR ™

Medication System Worksheet

Patient MR# _____ Incident # _____
(if error reached patient)
√ if no callback identified: _____
Date of error: _____ Date information obtained: _____ Patient age: _____

Drug(s) involved in error: _____

Non-formulary drug(s)? ☐ Yes ☐ No
Drug sample(s)? ☐ Yes ☐ No
Drug(s) packaged in unit dose/unit of use? ☐ Yes ☐ No
Drug(s) dispensed from pharmacy? ☐ Yes ☐ No
Error within 24 hours of admission, transfer, or after discharge? ☐ Yes ☐ No
Did the error reach the patient? ☐ Yes ☐ No
Source of IV solution: ☐ Manufacturer premixed solution ☐ Pharmacy IV admixture ☐ Nursing IV admixture

Brief description of the event: (what, when, and why) _____

Possible causes	Y/N	Comments
Critical patient information missing? (age, weight, allergies, VS, lab values, pregnancy, patient identity, location, renal/liver impairment, diagnoses, etc.)		
Critical drug information missing? (outdated/absent references, inadequate computer screening, inaccessible pharmacist, uncontrolled drug formulary, etc.)		
Miscommunication of drug order? (illegible, ambiguous, incomplete, misheard, or misunderstood orders, intimidation/faulty interaction, etc.)		
Drug name, label, packaging problem? (look/sound-alike names, look-alike packaging, unclear/absent labeling, faulty drug identification, etc.)		
Drug storage or delivery problem? (slow turn around time, inaccurate delivery, doses missing or expired, multiple concentrations, placed in wrong bin, etc.)		
Drug delivery device problem? (poor device design, misprogramming, free-flow, mixed up lines, IV administration of oral syringe contents, etc.)		
Environmental, staffing, or workflow problems? (lighting, noise, clutter, interruptions, staffing deficiencies, workload, inefficient workflow, employee safety, etc.)		
Lack of staff education? (competency validation, new or unfamiliar drugs/devices, orientation process, feedback about errors/prevention, etc.)		
Patient education problem? (lack of information, noncompliance, not encouraged to ask questions, lack of investigating patient inquiries, etc.)		
Lack of quality control or independent check systems? (equipment quality control checks, independent checks for high alert drugs/high risk patient population drugs etc.)		

Did the patient require any of the following actions after the error that you would not have done if the event had not occurred?
☐ Testing ☐ Additional observation ☐ Gave antidote ☐ Care escalated (transferred, etc.) ☐ Additional LOS ☐ Other_____

Patient outcome:
_____

Role of voluntary error reporting programs

- Programs should NOT have a regulatory role or even direct connection with regulators – examples Pa-PSRS; ISMP national MERP)
- Reporting inversely proportional to publicity generated for specific event types
- Reporter satisfaction/reward when actions communicated widely or changes visible; knowledge that others will benefit

How do you ensure representative reporting?

- Difficult with mandatory reporting
  - Hospital incident reporting
  - Serious reportable events
  - Allowance for “whistle blowers”
- Voluntary can be open to all (e.g., ISMP MERP) or closed (e.g., specialty such as blood or laboratory)
  - Practitioners (ismp.org)
  - Consumers (consumermedsafety.org)
- Specialty organizations
  - (ISMP has links to other organizations for reporting of diabetes medication incidents, nutrition-related incidents, others)

How are errors investigated?

- May/may not be
  - Mandatory reporting may be for data collection or public accountability vs. detail needed for action by reporting program
  - Voluntary reporting allows free discussion with reporter
    - Materials such as photographs, screen prints, information from product manuals, etc. often retrievable
      - Note: IT vendors have sometimes prohibited such communications via signed agreement/contract
    - Expert analysis applied
    - Reporting agency gathers facts from external sources as required
    - More detailed reporting encouraged via responses communicated with individuals and constituency

How are results from analyses and investigations distributed?

- Direct communication with reporter/organization
- Published data analysis
- Anecdotal reports/story telling more possible with voluntary reporting
- Published in newsletters/journal articles; websites; media releases; news columns/blogs; social media; meetings with constituents; webcasts, etc.
- Multiple journal columns; Medscape;
- Communication with regulatory agencies, product vendors, accreditation agencies
- Communication with consumers

Public health benefits

- Minimal cost, little work for health-systems
- Manufacturers and regulatory agencies receive follow-up and improvement ideas
- Practice related reports are processed
- Data analysis and trending
- Practitioner education
- Useful in developing drug standards and drug information