The International Medication Safety Network

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President, Institute for Safe Medication Practices

Presentation objectives

- Provide background information about the International Medication Safety Network (IMSN)
- Discuss how IMSN can be of benefit to the pharmacovigilance community to enhance reporting and learning systems that address medication errors
- Present IMSN Global Targeted Medication Safety Best Practices
  - Describe ongoing safety issues with targeted items
  - Provide IMSN prevention recommendations
  - Discuss role of pharmacovigilance centers

https://www.intmedsafe.net/

IMSN INTERNATIONAL MEDICATION SAFETY NETWORK

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The **International Medication Safety Network (IMSN)** is an international network of established safe medication practice centres, operating medication error reporting programmes and producing guidance to minimise preventable harms from medicine use in practice.
IMSN promotes safer medication practice to improve patient safety internationally. About IMSN

IMSN Introduces New Global Targeted Medication Safety Best Practices

An international medication safety call to action is aimed at preventing fatalities due to medication errors with concentrated potassium injection, inadvertent intraspinal injection of vincristine, and accidental daily instead of weekly dosing of methotrexate in patients with psoriasis or rheumatoid arthritis.

The International Medication Safety Network (IMSN) has published its first set of **Global Targeted Medication Safety Best Practices** to identify, inspire, and mobilize widespread international improvement in error prevention. The inaugural best practices address issues that are well known to cause fatal and harmful medication errors despite repeated warnings and are intended to help focus global safety efforts for the next two years on those specific sources of patient harm.

The best practices highlight strategies that can have a higher impact on preventing errors because they are "high leverage" and do not rely on attention and vigilance by individuals. They call for healthcare practitioners and organizations to:

MAIN IMSN EVENTS

14th Annual IMSN Meeting & Eastern Mediterranean Countries Workshop on Medication Errors

14-15 October 2019
Rabat, Morocco **Information & registration** read more....

THE IMSN GLOBAL INITIATIVE ON DRUG PRODUCT LABELLING AND PACKAGING SAFETY

October 2018 - Cascais Global Meeting on Drug Product Labelling and Packaging Safety

June 2018 - White Oak FDA/IMSN Joint Global Summit on Labelling and Packaging

October 2016 - Toronto Global Regulatory Meeting

October 2013 - Paris Conference on safer naming, labelling and packaging of medicines


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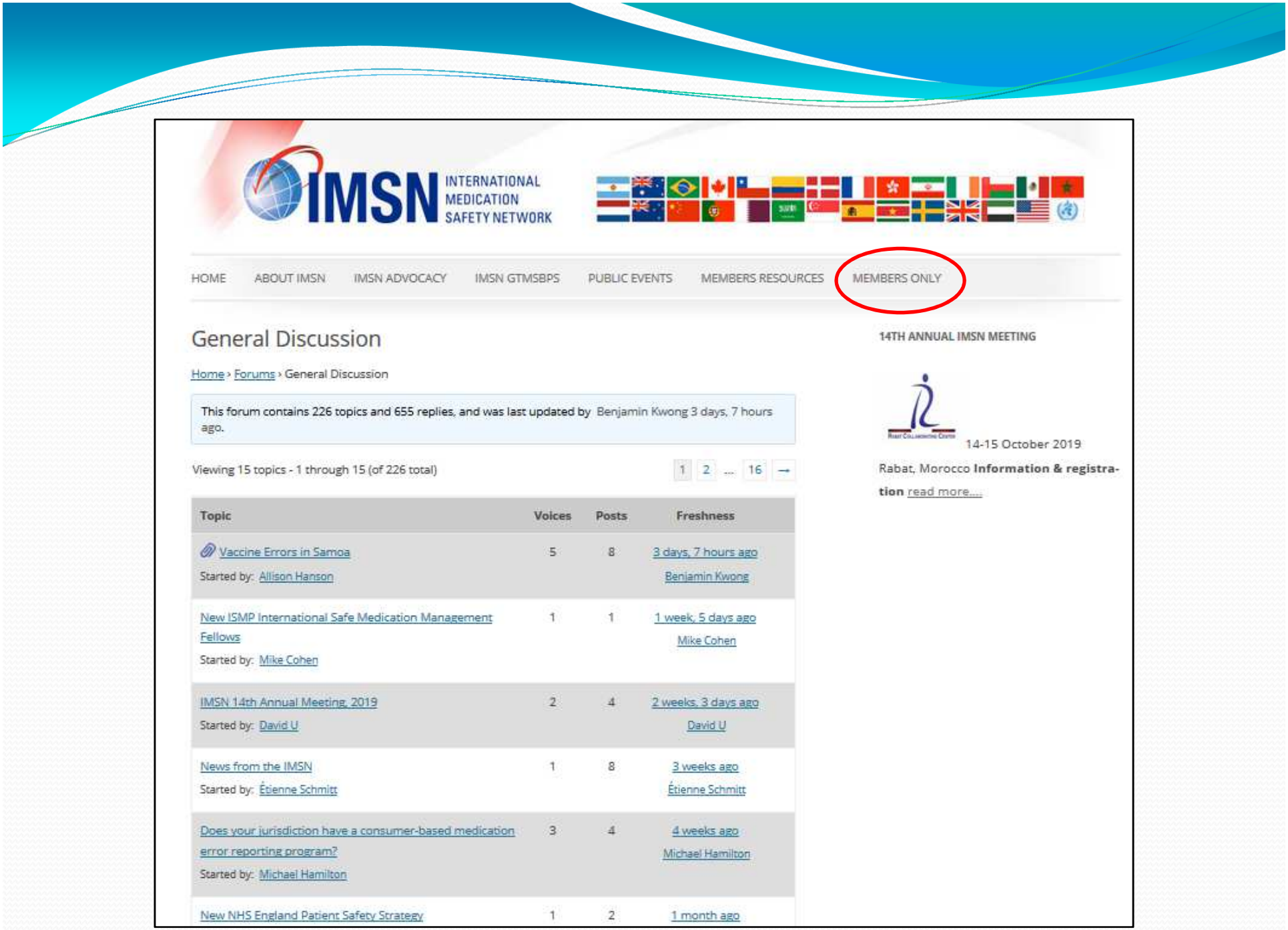
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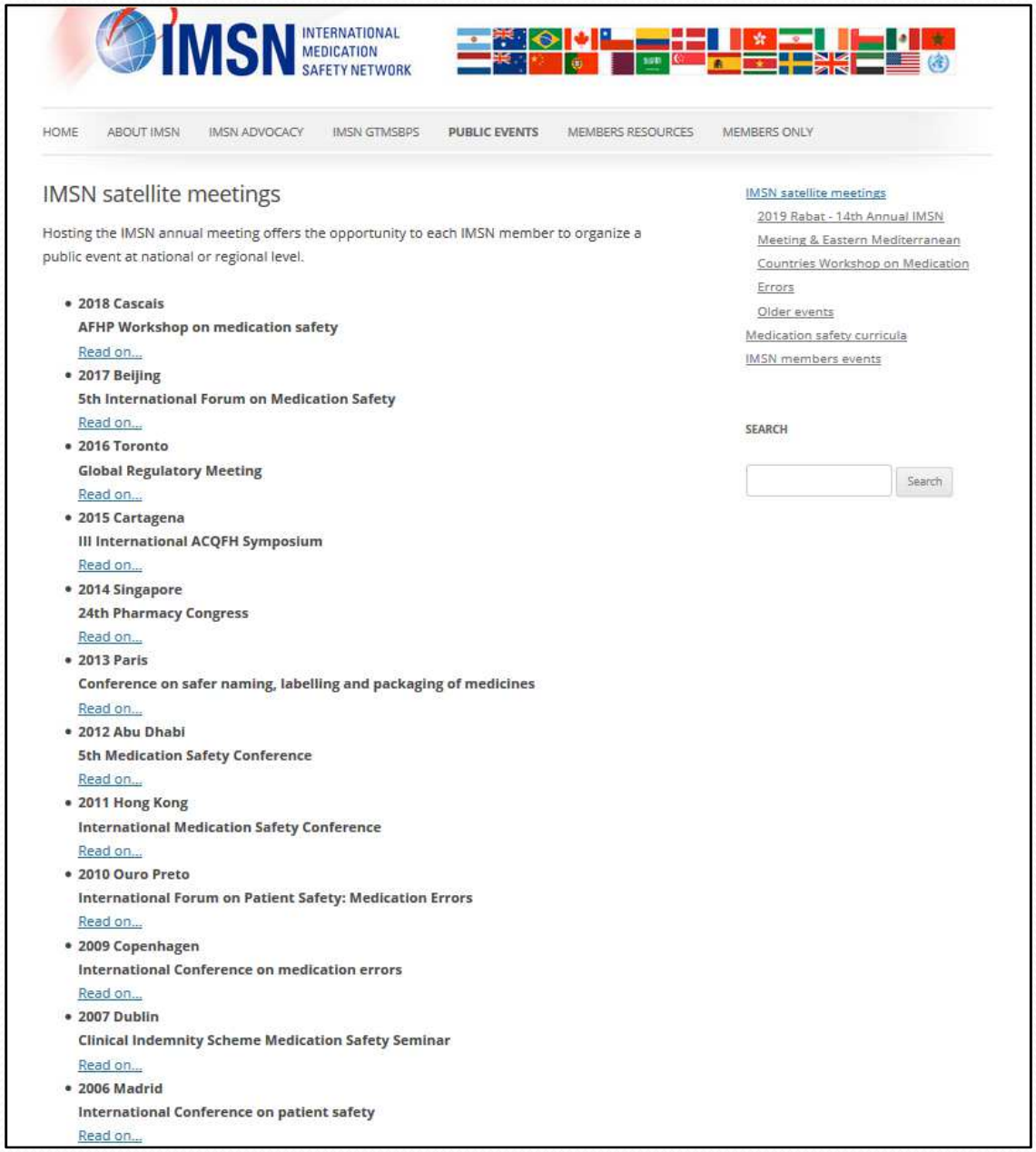
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IMSN satellite meetings
Hosting the IMSN annual meeting offers the opportunity to each IMSN member to organize a public event at national or regional level.
2018 Cascais
AFHP Workshop on medication safety
Read on...
2017 Beijing
5th International Forum on Medication Safety
Read on...
2016 Toronto
Global Regulatory Meeting
Read on...
2015 Cartagena
III International ACQFH Symposium
Read on...
2014 Singapore
24th Pharmacy Congress
Read on...
2013 Paris
Conference on safer naming, labelling and packaging of medicines
Read on...
2012 Abu Dhabi
5th Medication Safety Conference
Read on...
2011 Hong Kong
International Medication Safety Conference
Read on...
2010 Ouro Preto
International Forum on Patient Safety: Medication Errors
Read on...
2009 Copenhagen
International Conference on medication errors
Read on...
2007 Dublin
Clinical Indemnity Scheme Medication Safety Seminar
Read on...
2006 Madrid
International Conference on patient safety
Read on...
IMSN satellite meetings
2019 Rabat - 14th Annual IMSN Meeting & Eastern Mediterranean Countries Workshop on Medication Errors
Older events
Medication safety curricula
IMSN members events
SEARCH
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Global regulators and safety advocates meet about drug container labelling and packaging

FDA/IMSN SUMMIT *with* INTERNATIONAL DRUG REGULATORS *on*

LABELING & PACKAGING

to ADDRESS MEDICATION ERRORS

Sponsored by:

FDA U.S. FOOD & DRUG ADMINISTRATION

IMSN INTERNATIONAL MEDICATION SAFETY NETWORK

Participating regulators:

- Anvisa (Brasil)
- COFEPRIS (Mexico)
- European Medicines Agency
- Health Canada
- INFARMED (Portugal)
- Medicines Evaluation Board of Netherlands
- Medicines & Healthcare products Regulatory Agency (United Kingdom)
- Saudi Food and Drug Authority
- United States Food and Drug Administration
- World Health Organization

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2019 Rabat – 14th Annual IMSN Meeting & Eastern Mediterranean Countries Workshop on Medication Errors

The **Morocco Poison Control and Pharmacovigilance Centre** is pleased to host the **14th Annual IMSN Meeting** on October 14 and 15, 2019 in Rabat, Morocco. A special **Workshop on medication errors** dedicated to participants from Eastern Mediterranean Countries will be held on October 12 (Basic principles of medication errors management) and October 13 (Case studies and prevention), offering the opportunity to share prevention strategies experiences with IMSN members.

SEARCH

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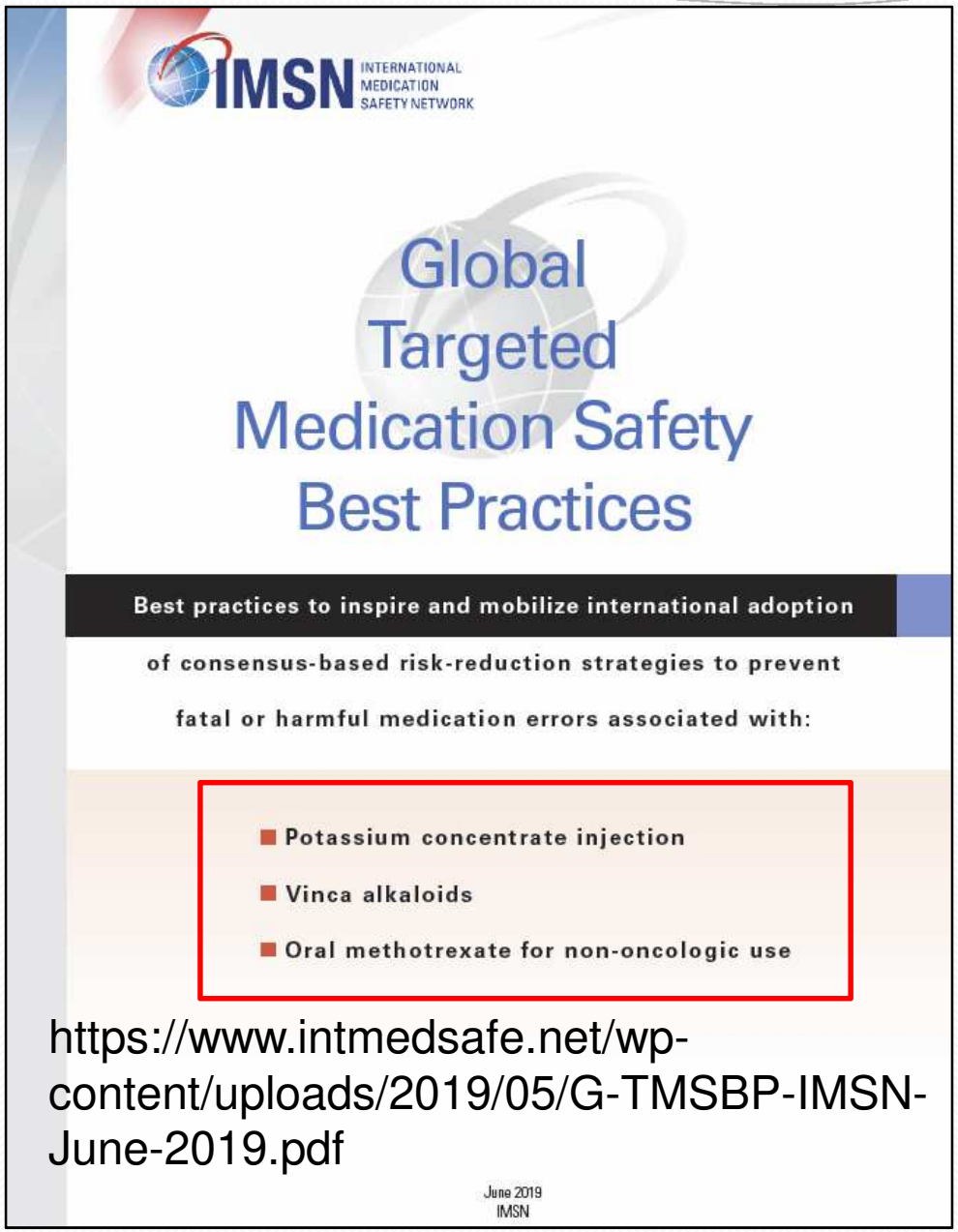
Calendar of Events

- October 13 - Eastern Mediterranean Countries Workshop on medication errors
  Case studies and sharing prevention strategies experiences with IMSN Members
- October 14 and 15 - **14th Annual IMSN Meeting**
  2019 IMSN annual meeting Agenda updated on August 21 Download

Venue

- **Morocco Poison Control and Pharmacovigilance Centre**
  WHO Collaborating Centre
  Rabat Instituts Madinate Al Irfane
  Rue Lamfedel Cherkaoui, Rabat

RABAT COLLABORATING CENTER



https://www.intmedsafe.net/wp-content/uploads/2019/05/G-TMSBP-IMSN-June-2019.pdf

Global Targeted Medication Safety Best Practices

- Specific medication safety issues are well known to cause harmful and fatal errors in patients despite knowledge of repeated occurrence and warnings. These deadly events have the following common characteristics:
  - They are recurring, likely to happen to another patient if not addressed
  - They are identifiable, easily recognized, clearly defined, and attributable to known causes
  - They are avoidable by appropriate practices, measures, and organizational barriers

G-TMSBP #1

Remove potassium concentrate injection from drug storage areas on all inpatient nursing units/wards.

Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

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ISMP Canada Safety Bulletin

Volume 19 · Issue 1 · January 16, 2019

Preventable Tragedies: Two Pediatric Deaths Due to Intravenous Administration of Concentrated Electrolytes

Take action to check the following:

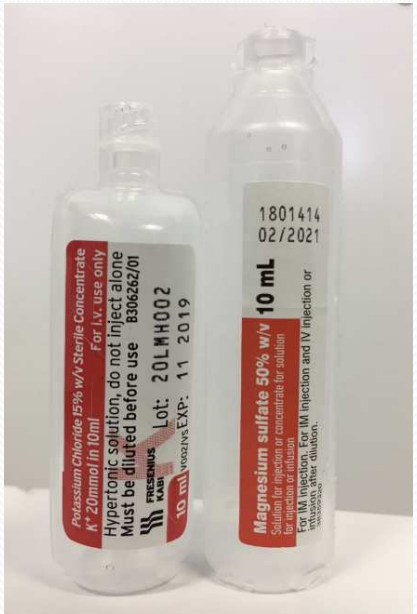
- *Compliance with current standards for the storage and availability of concentrated injectable electrolytes is mandated.*
- *Robust safeguards are included in procedures for prescribing, dispensing, preparing, and administering IV electrolyte solutions.*
- *The need for calculations and additional manipulations in the patient care area is minimized. Standardized doses of IV electrolytes that align with premixed concentrations of commercially available solutions are prescribed.*
- *Staff and prescribers are educated about strategies to prevent "never events," such as IV administration of a concentrated potassium solution during orientation and continuing education activities.*

Intravenous (IV) administration of a concentrated potassium solution (≥ 2 mmol/mL) is considered to be a pharmaceutical "never event".[1] "Never events" are defined as "patient safety incidents that result in serious patient harm or death, and that can be prevented by using organizational checks and balances."[1] The World Health Organization has focused on high-risk situations, such as these pharmaceutical "never events"[1] and the use of high-alert[2] concentrated electrolytes, as 1 of 3 key areas in its Third Global Patient Safety Challenge, "Medication Without Harm".[3]

ISMP Canada has published information about the dangers of IV administration of concentrated electrolyte solutions, including potassium chloride and potassium phosphates, in safety bulletins dating as far back as 2001.[4-9] Other health quality and patient safety organizations,[10,11] as well as healthcare accreditation bodies,[12,13] have made practice recommendations intended to reduce instances of patient harm caused by inadvertent IV administration of concentrated electrolytes.

Evaluation surveys have shown a decrease in the number of deaths due to inadvertent IV administration of concentrated electrolytes following medication safety improvement efforts.[14]

Despite the recommendations and the trend of decreased deaths, there have been 2 recent fatal incidents involving children and the IV administration of concentrated potassium phosphates or potassium chloride. These cases illustrate the need for sustained, nationwide vigilance to recognize the threat to patient safety when concentrated injectable electrolyte solutions are not appropriately stored, monitored, and administered.



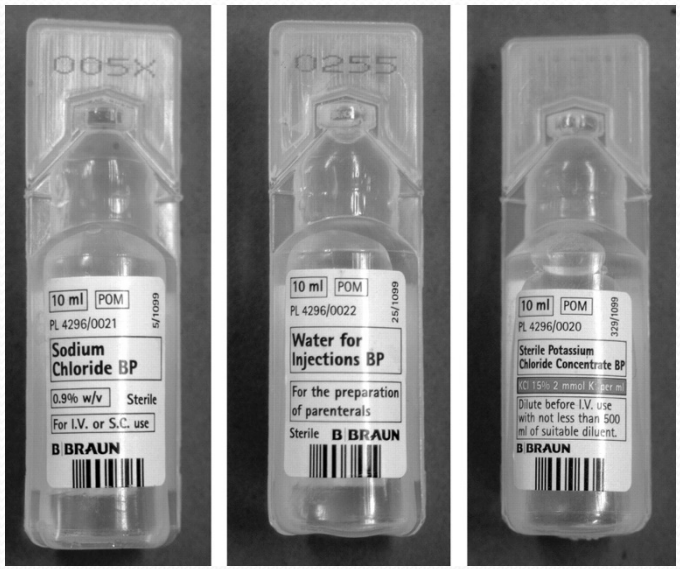
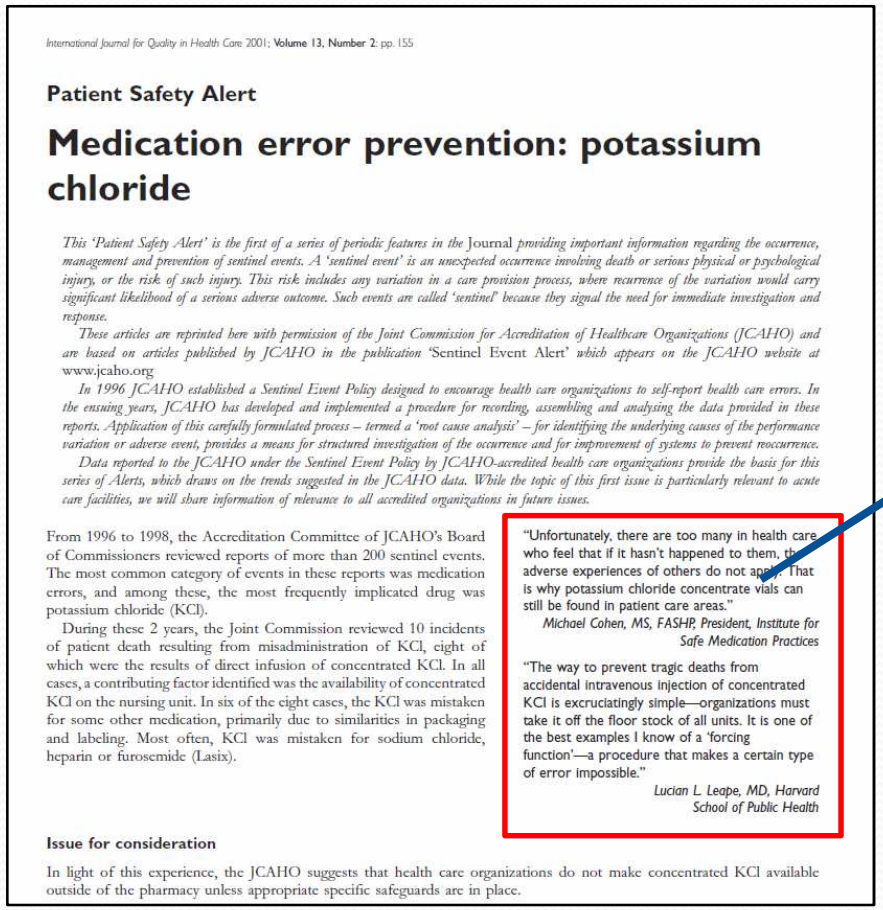


Figure 1 Ampoules of isobaric 0.5% bupivacaine (left) and 7.45% potassium chloride (right).



International Journal for Quality in Health Care 2001; Volume 13, Number 2: pp. 155

Patient Safety Alert

Medication error prevention: potassium chloride

This 'Patient Safety Alert' is the first of a series of periodic features in the Journal *providing important information regarding the occurrence, management and prevention of sentinel events. A 'sentinel event' is an unexpected occurrence involving death or serious physical or psychological injury, or the risk of such injury. This risk includes any variation in a care provision process, where recurrence of the variation would carry significant likelihood of a serious adverse outcome. Such events are called 'sentinel' because they signal the need for immediate investigation and response.*

These articles are reprinted here with permission of the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) and are based on articles published by JCAHO in the publication 'Sentinel Event Alert' *which appears on the JCAHO website at* www.jcaho.org

In 1996 JCAHO established a Sentinel Event Policy designed to encourage health care organizations to self-report health care errors. In the ensuing years, JCAHO has developed and implemented a procedure for recording, assembling and analysing the data provided in these reports. Application of this carefully formulated process – termed a 'root cause analysis' – for identifying the underlying causes of the performance variation or adverse event, provides a means for structured investigation of the occurrence and for improvement of systems to prevent reoccurrence.

Data reported to the JCAHO under the Sentinel Event Policy by JCAHO-accredited health care organizations provide the basis for this series of Alerts, which draws on the trends suggested in the JCAHO data. While the topic of this first issue is particularly relevant to acute care facilities, we will share information of relevance to all accredited organizations in future issues.

From 1996 to 1998, the Accreditation Committee of JCAHO's Board of Commissioners reviewed reports of more than 200 sentinel events. The most common category of events in these reports was medication errors, and among these, the most frequently implicated drug was potassium chloride (KCl).

During these 2 years, the Joint Commission reviewed 10 incidents of patient death resulting from misadministration of KCl, eight of which were the results of direct infusion of concentrated KCl. In all cases, a contributing factor identified was the availability of concentrated KCl on the nursing unit. In six of the eight cases, the KCl was mistaken for some other medication, primarily due to similarities in packaging and labeling. Most often, KCl was mistaken for sodium chloride, heparin or furosemide (Lasix).

"Unfortunately, there are too many in health care who feel that if it hasn't happened to them, the adverse experiences of others do not apply. That is why potassium chloride concentrate vials can still be found in patient care areas."

Michael Cohen, MS, FASHP, President, Institute for Safe Medication Practices

"The way to prevent tragic deaths from accidental intravenous injection of concentrated KCl is excruciatingly simple—organizations must take it off the floor stock of all units. It is one of the best examples I know of a 'forcing function'—a procedure that makes a certain type of error impossible."

Lucian L. Leape, MD, Harvard School of Public Health

Issue for consideration

In light of this experience, the JCAHO suggests that health care organizations do not make concentrated KCl available outside of the pharmacy unless appropriate specific safeguards are in place.

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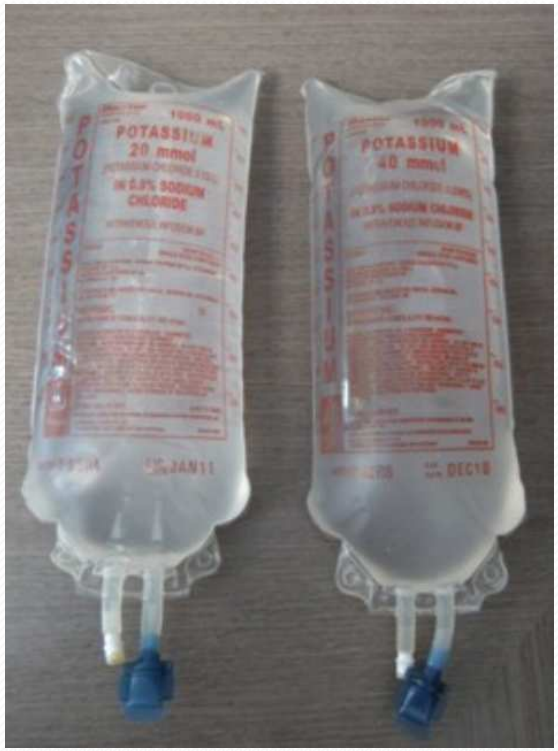
Remove potassium chloride concentrate injection

- Purchase and use premixed potassium solutions (already diluted in typical strengths for IV potassium replacement)
- Wherever possible, standardize potassium solution concentrations to eliminate the need for preparing potassium solutions that are not premixed or pharmacy-prepared.
- When necessary, prepare potassium solutions in the pharmacy for distribution internally within each hospital.


40 mEq POTASSIUM
40 mEq
POTASSIUM CHLORIDE
in 5% Dextrose and 0.9% Sodium Chloride Injection, USP
20 mEq POTASSIUM
20 mEq
POTASSIUM CHLORIDE
in 5% Dextrose and 0.9% Sodium Chloride Injection, USP


Potassium Chloride
10 mEq per 50 mL


POTASSIUM
20 mmol
IN 5.0% SODIUM CHLORIDE
POTASSIUM
40 mmol

Remove potassium chloride concentrate injection

- In scenarios where premixed solutions are not commercially-available, when a pharmacist and pharmacy preparation area is not available to prepare these solutions, or when 24-hour pharmacy service is unavailable:
  - Potassium concentrate vials or ampules should not be stored on nursing units/wards but instead be stored centrally, outside the pharmacy, in a locked cabinet.
  - Potassium concentrate vials or ampules should be placed in a clear plastic bag with warning stickers and instructions for dilution.
  - Only qualified and trained individuals (e.g., physician, nurse) should have access to these vials or ampules to prepare potassium solutions.
- Segregate and label storage locations of concentrated potassium injections in pharmacy preparation areas

G-TMSBP #2

Prepare and dispense vinca alkaloids in a minibag, never in a syringe

Prepare and dispense vinca alkaloids in a minibag, never in a syringe

- Deaths have been reported throughout the world when a vinca alkaloid was dispensed in a syringe but administered into the spinal fluid instead of IV
- The inadvertent intrathecal administration of vinca alkaloids leads to the destruction of the central nervous system radiating from the injection site. Most of the time, the outcome is fatal
- Vincristine is most frequently reported error because it is often ordered in conjunction with medications that are administered intrathecally (e.g., methotrexate, cytarabine, and/or hydrocortisone)

Prepare and dispense vinca alkaloids in a minibag, never in a syringe

- ISMP reported 135 fatalities worldwide due to inadvertent intrathecal administration – none reported in minibag
- Despite warnings ("For Intravenous Use Only—Fatal If Given by Other Routes") and extensive labeling requirements in some countries, inadvertent intrathecal administration of vincristine still occurs today

TRUSTED 2:07 / 28.01.2019 GUYANA CHRONICLE

GPHC conducting 'thorough' investigation into children's deaths

Roshnie Seegobin and Sharezer Mendonca

– sources say deaths possibly caused by misadministration of treatment drug

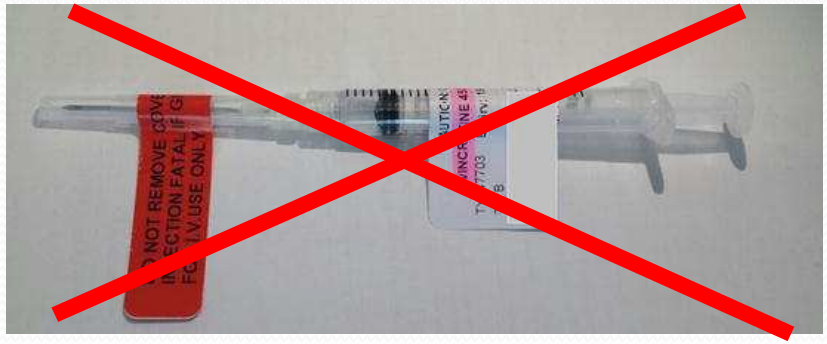
THE Georgetown Public Hospital Corporation (GPHC) has assured all concerned that it is conducting a "thorough" investigation into the circumstances surrounding the deaths of three children who were receiving treatment for leukaemia at the hospital.

"The Board of Directors of the Georgetown Public Hospital Corporation (GPHC) expresses sincere condolences to the parents, family members and relatives of Curwayne Edwards, Roshani Seegobin and Sharezer Mendonca, the three children diagnosed with leukaemia [and] who died subsequent to receiving chemotherapy at GPHC," a release from the hospital stated.

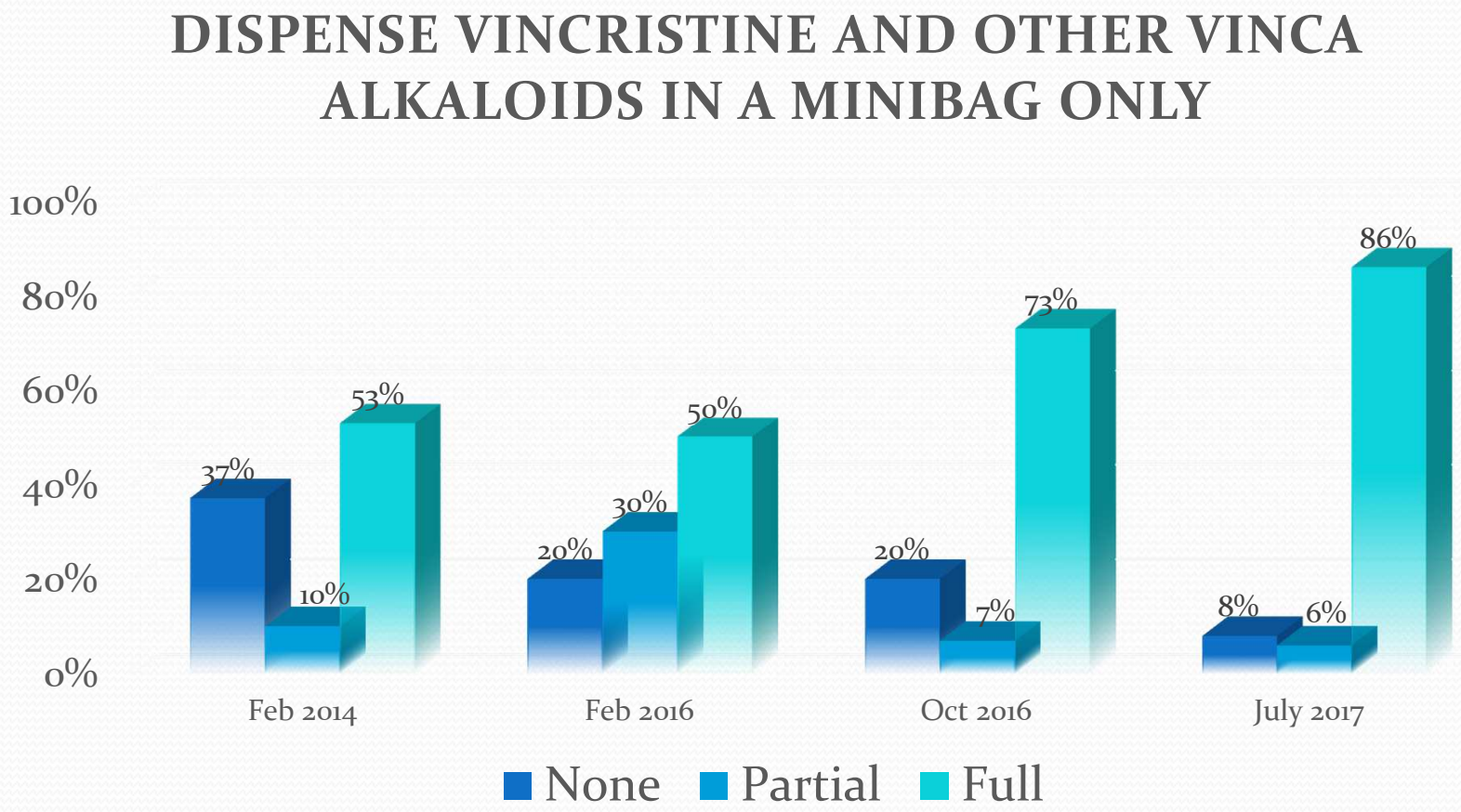
Seven-year-old Edwards succumbed on January 14; Seegobin, three, died on January 18 and Mendonca, six, passed away on January 24. The trio succumbed after an alleged adverse reaction to medication, which was administered to them as part of the treatment for leukaemia.

Prepare and Dispense Vinca Alkaloids in a Minibag, Never in a Syringe

- Alleviate risk of inadvertent intrathecal administration by adopting the preparation and administration of vinca alkaloids in minibags.
- WHO, The Joint Commission, ISMP, UK National Health Service (NHS), ISMP Canada, Australia Commission on Safety and Quality in Health Care, French Medicines Agency, ISMP España, ISMP Brasil, and others



Best Practice 2



G-TMSBP #3

Prevent inadvertent daily dosing of oral methotrexate for non-oncologic conditions.

Prevent daily dosing of oral methotrexate for non-oncologic conditions

- When used to treat disorders such as psoriasis and rheumatoid arthritis, low doses are administered weekly by the oral route
- Doctors may inadvertently prescribe and pharmacists may inadvertently dispense daily doses
- At high doses, oral methotrexate is known to be associated with serious and sometimes fatal blood dyscrasias
- Similar adverse outcomes have been associated with the use of low-dose oral methotrexate when given daily
- Fatal dosing errors reported since 1996, occurring both during hospitalization and after discharge

August 9, 2018 ▪ Volume 23 Issue 16

ISMP

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Call to action: Longstanding strategies to prevent accidental daily methotrexate dosing must be implemented

Methotrexate is a folic acid antagonist that was originally approved to treat a variety of cancers. Used for oncologic indications, methotrexate is administered in cyclical frequencies and in variable doses based on body surface area and the type of cancer being treated—for example, 12 g/m² per dose when treating osteosarcoma. The labeled indications for methotrexate later expanded to include the treatment of nononcologic conditions, including psoriasis (approved in 1971) and rheumatoid arthritis (approved in 1988). Other nononcologic off-label uses include the treatment of Crohn's disease, multiple sclerosis, inflammatory myositis, reactive arthritis (Reiter's syndrome), graft-versus-host disease, Takayasu arteritis, uveitis, and ectopic pregnancy. For most nononcologic indications, a low dose of methotrexate is administered just once or twice weekly—for example, 7.5 mg per week when treating rheumatoid arthritis.

Relatively few medications are dosed weekly; thus, accidental daily dosing of oral methotrexate has occurred all too frequently. This type of wrong frequency error has originated in all stages of the medication use process, from prescribing to self-administration. These errors have resulted in serious methotrexate overdoses that led to vomiting, mouth sores, stomatitis, serious skin lesions, liver failure, renal failure, severe myelosuppression, gastrointestinal bleeding, life-threatening pulmonary symptoms, and, in some cases, death.

Since early 1996, harmful or fatal errors with daily oral methotrexate for nononcologic use have been reported to ISMP and published in more than 60 of our *ISMP Medication Safety Alert!* newsletters. Thus, oral methotrexate for nononcologic use has been included on the ***ISMP List of High-Alert Medications*** (www.ismp.org/node/103) since the inception of the list in 2003. Although the risk of errors with oral methotrexate for nononcologic use has been known for a long time, harmful and fatal errors are still occurring today. Descriptions of recently reported events follow.

Methotrexate Errors

Medication reconciliation and transition-in-care error

The most recent event involved an error that was caught during hospitalization but continued upon discharge when an incorrect entry for daily methotrexate on a patient's home medication list was not corrected. An elderly man with rheumatoid arthritis was admitted to a hospital with renal failure. At home, he had been taking oral methotrexate 2.5 mg twice weekly (Mondays and Wednesdays). The admitting nurse began creating a list of the patient's home medications. The admitting physician noticed that methotrexate was missing from the home medication list in the patient's electronic health record and added it. However, he mistakenly documented that the patient had been taking 2.5 mg of oral methotrexate twice daily instead of twice weekly. He then made this an active order during the patient's hospitalization.

Noticing the daily order for methotrexate, a pharmacist in the central pharmacy contacted the physician to let him know that he must prescribe daily methotrexate on a hospital-mandated chemotherapy order template. However, the pharmacist did not verify that the patient had an appropriate oncologic indication for the order.

continued on page 2—Methotrexate >

SAFETY briefs

Eligard label improvements needed. **ELIGARD (leuprolide acetate for injectable suspension) is a gonadotropin-releasing hormone (GnRH) agonist indicated for the palliative treatment of advanced prostate cancer. The drug is given subcutaneously, which provides continuous release of leuprolide acetate over a 1-, 3-, 4-, or 6-month treatment period based on one of four available dosage strengths (see below).**

Dosage	Recommendation
7.5 mg	1 injection every month
22.5 mg	1 injection every 3 months
30 mg	1 injection every 4 months
45 mg	1 injection every 6 months

The Eligard carton contains two syringes in separate overwraps that must be mixed together prior to injection. Syringe A is prefilled with ATRIGEL, a polymeric (non-gelatin containing) delivery system. Syringe B is prefilled with leuprolide acetate powder. However, it is easy to miss the wording on the front of the carton, "Must be constituted before use," and a full description of the syringe contents is only mentioned in small print on the back of the carton (Figure 1). Also, the Atrigel overwrap emphasizes the name Eligard, not the Atrigel delivery system.

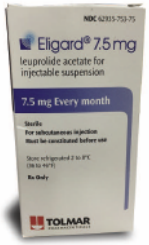


Figure 1. Eligard outer carton front panel does not clearly indicate the contents of the two syringes.

continued on page 2—SAFETY briefs >

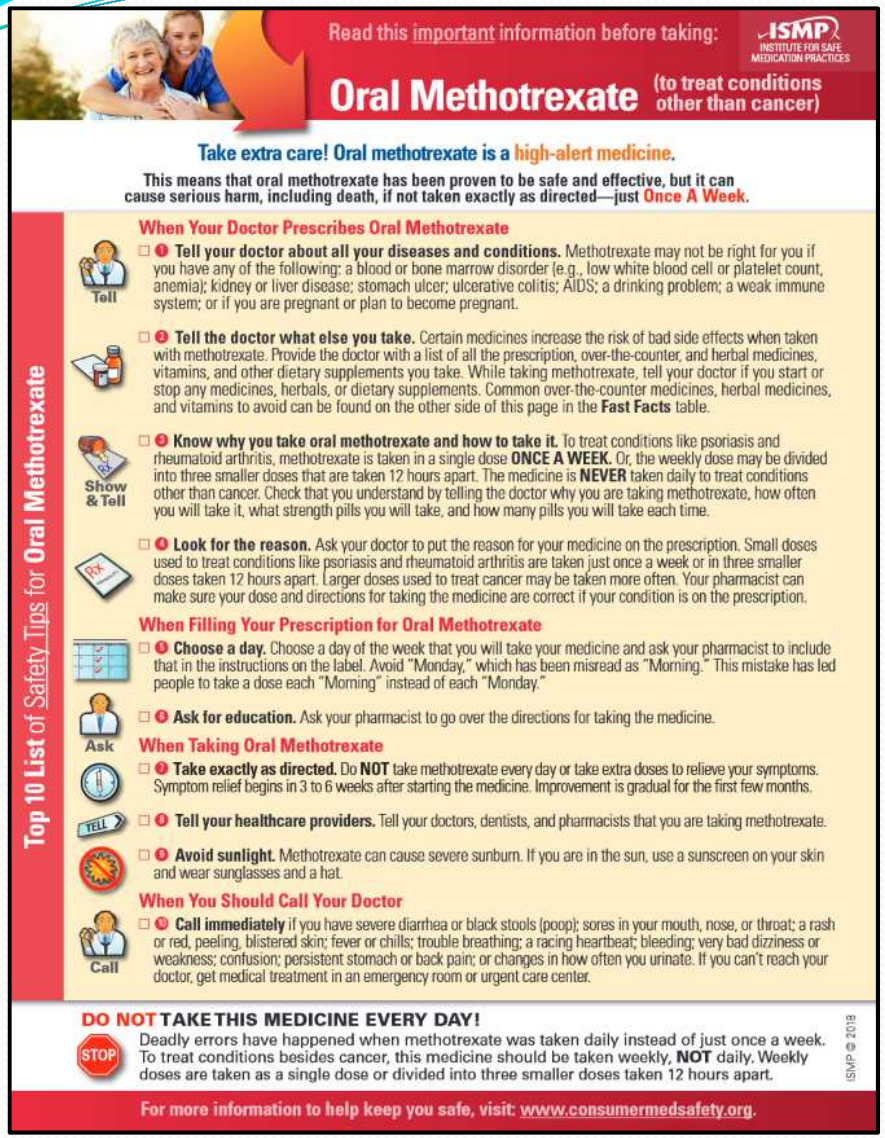
https://www.ismp.org/resources/call-action-longstanding-strategies-prevent-accidental-daily-methotrexate-dosing-must-be

Prevent daily dosing of oral methotrexate for non-oncologic conditions

- Prescribe, dispense, and administer oral methotrexate ONCE WEEKLY
  - Specify day of the week but not Mondays
  - Enter weekly dosage regimen as default in electronic systems
- In the hospital setting, remove methotrexate from nursing units/ward stock and “after hours” cupboards
- Dispense only the needed doses in safety packaging such as a dose pack, patient pack, or calendar pack
- For outpatients, dispense a maximum of 1 month’s supply

Prevent daily dosing of oral methotrexate for non-oncologic conditions

- Provide specific patient and/or family/caregiver education for all oral methotrexate orders or new prescriptions
- Require the patient to repeat back the instructions to validate that the patient understands dosing and toxicities
- Provide all patients with consumer leaflets on oral methotrexate (e.g., free ISMP high-alert medication consumer leaflet on oral methotrexate can be found at: www.ismp.org/ext/221)
- Educate clinical staff on the safe and appropriate use of methotrexate



Read this important information before taking:

ISMP INSTITUTE FOR SAFE MEDICATION PRACTICES

Oral Methotrexate (to treat conditions other than cancer)

Take extra care! Oral methotrexate is a high-alert medicine.

This means that oral methotrexate has been proven to be safe and effective, but it can cause serious harm, including death, if not taken exactly as directed—just Once A Week.

Top 10 List of Safety Tips for Oral Methotrexate

When Your Doctor Prescribes Oral Methotrexate

Tell

☐ ❶ **Tell your doctor about all your diseases and conditions.** Methotrexate may not be right for you if you have any of the following: a blood or bone marrow disorder (e.g., low white blood cell or platelet count, anemia); kidney or liver disease; stomach ulcer; ulcerative colitis; AIDS; a drinking problem; a weak immune system; or if you are pregnant or plan to become pregnant.

☐ ❷ **Tell the doctor what else you take.** Certain medicines increase the risk of bad side effects when taken with methotrexate. Provide the doctor with a list of all the prescription, over-the-counter, and herbal medicines, vitamins, and other dietary supplements you take. While taking methotrexate, tell your doctor if you start or stop any medicines, herbals, or dietary supplements. Common over-the-counter medicines, herbal medicines, and vitamins to avoid can be found on the other side of this page in the **Fast Facts** table.

Show & Tell

☐ ❸ **Know why you take oral methotrexate and how to take it.** To treat conditions like psoriasis and rheumatoid arthritis, methotrexate is taken in a single dose **ONCE A WEEK.** Or, the weekly dose may be divided into three smaller doses that are taken 12 hours apart. The medicine is **NEVER** taken daily to treat conditions other than cancer. Check that you understand by telling the doctor why you are taking methotrexate, how often you will take it, what strength pills you will take, and how many pills you will take each time.

☐ ❹ **Look for the reason.** Ask your doctor to put the reason for your medicine on the prescription. Small doses used to treat conditions like psoriasis and rheumatoid arthritis are taken just once a week or in three smaller doses taken 12 hours apart. Larger doses used to treat cancer may be taken more often. Your pharmacist can make sure your dose and directions for taking the medicine are correct if your condition is on the prescription.

When Filling Your Prescription for Oral Methotrexate

☐ ❺ **Choose a day.** Choose a day of the week that you will take your medicine and ask your pharmacist to include that in the instructions on the label. Avoid "Monday," which has been misread as "Morning." This mistake has led people to take a dose each "Morning" instead of each "Monday."

Ask

☐ ❻ **Ask for education.** Ask your pharmacist to go over the directions for taking the medicine.

When Taking Oral Methotrexate

☐ ❼ **Take exactly as directed.** Do **NOT** take methotrexate every day or take extra doses to relieve your symptoms. Symptom relief begins in 3 to 6 weeks after starting the medicine. Improvement is gradual for the first few months.

TELL

☐ ❽ **Tell your healthcare providers.** Tell your doctors, dentists, and pharmacists that you are taking methotrexate.

☐ ❾ **Avoid sunlight.** Methotrexate can cause severe sunburn. If you are in the sun, use a sunscreen on your skin and wear sunglasses and a hat.

When You Should Call Your Doctor

Call

☐ ❿ **Call immediately** if you have severe diarrhea or black stools (poop); sores in your mouth, nose, or throat; a rash or red, peeling, blistered skin; fever or chills; trouble breathing; a racing heartbeat; bleeding; very bad dizziness or weakness; confusion; persistent stomach or back pain; or changes in how often you urinate. If you can't reach your doctor, get medical treatment in an emergency room or urgent care center.

DO NOT TAKE THIS MEDICINE EVERY DAY!

STOP

Deadly errors have happened when methotrexate was taken daily instead of just once a week. To treat conditions besides cancer, this medicine should be taken weekly, **NOT** daily. Weekly doses are taken as a single dose or divided into three smaller doses taken 12 hours apart.

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For more information to help keep you safe, visit: www.consumermedsafety.org.

Oral Methotrexate

Brought to you by the Institute for Safe Medication Practices

Once a WEEK is the Only Way!

Read this important story!

Methotrexate is a cancer medicine. However, it is also used to treat other conditions like rheumatoid arthritis and psoriasis. It works well for these conditions if you take the medicine just once a **WEEK** and in smaller doses.

Most medicines are taken daily, but not methotrexate. If you take methotrexate every day by accident, you could be harmed. Sadly, some people have even died when taking methotrexate daily for conditions other than cancer.

In one case, an older man with arthritis mistakenly took one tablet each morning, but the directions said to take one tablet each Monday. In another case, the prescription label said to take the medicine every 12 hours for just three doses. But a woman took the medicine every 12 hours for 6 days in a row. Another man took many extra doses to help relieve arthritis pain, something that should never be done.

Serious harm, even death, could occur if you take methotrexate daily for conditions other than cancer.

Read the **Top 10 List of Safety Tips** on the other side of this handout to help avoid mistakes.

Topics	Fast Facts
Generic name	■ methotrexate (pronounced meth-o-TREKS-ate)
Common brand names	■ Trexall (tablets), Xatmep (oral liquid) (generic available for tablets)
Common uses (to treat conditions other than cancer)	■ Rheumatoid arthritis, juvenile arthritis, psoriasis, multiple sclerosis, lupus, difficult-to-treat asthma, inflammatory bowel disease (Crohn's disease), other inflammatory diseases
Usual dose	■ Most common strength of pills is 2.5 mg ■ Usual dose is 5 mg to 30 mg **weekly** (higher doses are used only if treating cancer) ■ **Weekly** doses are taken as a single dose or divided into three smaller doses taken 12 hours apart (no more than three doses should be taken 12 hours apart each week) ■ If you forget to take a dose, call your doctor for instructions
Special instructions and precautions	■ Your doctor may prescribe folic acid with methotrexate; your doctor may instruct you to skip the folic acid on the day you take methotrexate ■ Avoid drinking alcohol while taking this medicine ■ This medicine may affect fertility in both men and women
Safety during pregnancy/ breastfeeding	■ Methotrexate is known to cause birth defects in the children of both men and women who take it ■ Women should not take methotrexate during pregnancy; to be safe, talk to your doctor about how long to wait after treatment to become pregnant (usually 1 to 3 months) ■ Men should wait at least 3 months after stopping treatment before getting their partner pregnant ■ Do not take methotrexate while breastfeeding, as it can harm your baby
Storage	■ Store at room temperature and protect from light ■ Keep the lid of the medicine tightly closed ■ Keep oral methotrexate and all medicines out of the reach of children
Side effects	■ Minimal side effects (e.g., nausea, vomiting, drowsiness) occur with low doses (30 mg or less each week) ■ A very bad skin reaction (Stevens-Johnson syndrome) may happen; get medical help right away if you develop red, peeling, blistered skin; a skin rash; or sores in your mouth, nose, or throat
Over-the-counter medicines, herbals, or vitamins that should NOT be taken with methotrexate UNLESS prescribed by your doctor	■ Vitamins that contain folic acid or echinacea ■ Aspirin and aspirin-containing products; ask your doctor before starting, continuing, or stopping low dose aspirin (81 mg daily) ■ Check with your doctor if you take medicines for acid reflux or heartburn (e.g., Prevacid, Prilosec, Nexium) ■ Check with your doctor if nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Motrin, Advil) and naproxen (Aleve) can be taken safely with methotrexate
Prescription medicines that should NOT be taken with methotrexate	■ Check with your doctor; some medicines that may be a problem include: vaccines, acitretin, cyclosporine, foscarnet, sulfonamides, tacrolimus, pimecrolimus, clozapine ■ Do not take methotrexate with antibiotics that contain trimethoprim and sulfa (e.g., Bactrim, Sulfatrim); your doctor may tell you to skip your dose of methotrexate that week
Special tests your doctor may prescribe	■ If you can get pregnant, a pregnancy test will be done to be sure you are not pregnant before starting methotrexate ■ Your doctor may check your kidney and liver function and make sure your body is making enough blood cells with a blood test every 1 to 3 months

https://www.ismp.org/sites/default/files/attachments/2018-11/Methotrexatefinal.pdf

Common Barriers

- Lack of buy-in from others: MD/RN/Leaders/RPh
  - Not convinced, not a priority
- Unwillingness/inability to change culture/practice
- Lack of perceived risk - not an issue at our hospital
- EHR limitations – lack of IT support, shared IT, EHR capability?
- Workload concerns, inadequate staffing
- Cost

Common Barriers

- Lack of space
- Need for perfection to implement
- Inability to validate implementation, inconsistent implementation
- Lack of understanding of the best practice
  - Not understanding alternative to EHR/automation


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HOME
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IMSN GTMSBPS
PUBLIC EVENTS
MEMBERS RESOURCES
MEMBERS ONLY