The Patient Safety Education Program™
CANADA

Module 12c: Interventional Care: Medication Safety

Emanuel LL, Taylor L, Hain A, Combes JR, Hatlie MJ, Karsh B, Lau DT, Shalowitz J, Shaw T, Walton M, eds. *The Patient Safety Education Program – Canada (PSEP – Canada) Curriculum*.

This module was revised in 2018 by Paul Filiatrault and by Julie Greenall of the Institute for Safe Medication Practices Canada. Acknowledgements to Joan Fernandez, Canadian Patient Safety Institute for review and editorial contributions of the revised module.

PSEP – Canada is a partnership between the Canadian Patient Safety Institute (CPSI) and the Patient Safety Education Program, which is housed at MedStar Institute for Quality and Safety (MIQS), a division of MedStar Health, Columbia, Maryland, USA. The PSEP – Canada Curriculum is an adaptation of the PSEP Core Curriculum. PSEP has received support from the Jewish Healthcare Foundation, the Pittsburgh Regional Health Initiative, the Zell Center for Risk Research, California Healthcare Foundation, The Commonwealth Fund, and the Health Research and Education Trust in the form of the 2008 Edwin L. Crosby Fellowship that was awarded to Dr. Emanuel. PSEP is a not-for-profit educational program. It began as a collaboration among Linda Emanuel, Martin Hatlie, John Combes, and Joel Shalowitz.

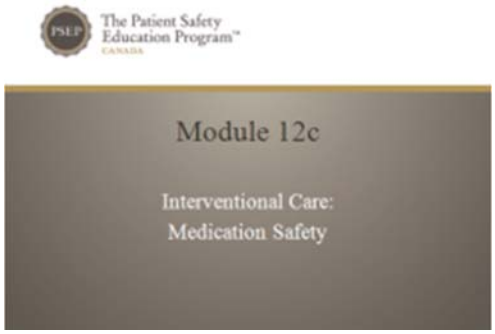
Those who have become certified PSEP – Canada Trainers by taking a 'Become a PSEP – Canada Trainer' course that was provided by PSEP – Canada may use the title of PSEP – Canada Trainer, as well as template materials, such as fliers, that are provided by PSEP – Canada and also use the appropriate designated marks to hold educational seminars using the PSEP – Canada *Core Curriculum*. The Patient Safety Education Program in the US reserves the sole right to designate Master Facilitators who teach at 'Become a PSEP – Canada Trainer' conferences.

Visit **www.patientsafetyinstitute.ca** for further information.
Contact PSEP – Canada by e-mail at **PSEPCanada@cpsi-icsp.ca**, or
PSEP – Canada
Canadian Patient Safety Institute, #410,
1150 Cyrville Road,
Ottawa, KIJ 7S9
Phone: 613-730-7322

[Revised 2018]

PSEP – Canada Objectives	Related CPSI Safety Competencies
The knowledge elements include an understanding of: • The definition of medication incident, adverse drug events and other key terms • The components of the medication use system • Common vulnerabilities in the medication system. • Strategies to enhance safety in the medication use system The performance elements include the ability to: • Identify multi-system failures that lead to medication incidents • Understand the importance of clear communication • Identify how technology may provide system safeguards	**Domain 1: Contribute to a culture of patient safety** Health care professionals who contribute to a culture of patient safety understand: • key patient safety concepts, such as adverse events, close calls, no-harm events and just culture • the creation, application, dissemination and translation of patient safety principles, practices, behaviours, attitudes and knowledge **Domain 3: Communicate effectively for patient care** Health care professionals who apply communication technologies appropriately and effectively to provide safe patient care: • Employ critical thinking tools and structured approaches to communications **Domain 4: Manage Safety Risks** Health care professionals who effectively manage safety risks have an understanding of: • system design and its impact on event evolution • safety practices that reduce the risk of adverse events **Domain 5: Optimize Human and Environmental Factors** Health care professionals who optimize human and environmental factors for patient safety: • appreciate that human performance is affected by one's behaviour within a system constructed by resources, culture and policy

Slide 1



Abstract

The frequency of preventable patient safety incidents signifies a serious concern for patient safety. Patient safety experts from Johns Hopkins reported that medical error is the third leading cause of death in the USA (Martin AM, Daniel M. Medical error - the third leading cause of death in the US. BMJ 2016;353:i2139. http://www.bmj.com/content/353/bmj.i2139)

The 2004 Canadian Adverse Events study estimated that as many as 24,000 Canadians die every year from medical errors in acute care hospitals. Problems with medication or fluid administration accounted for nearly one-quarter of these events (Baker GR, Norton PG, Flintoft V, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada, CMAJ May 25, 2004. www.cmaj.ca/content/cmaj/170/11/1678.full.pdf). Similar studies have also been completed in Australia, England and other countries.

Adverse drug events are one of the most common type of medical errors. This module introduces the frequency of medication-related events and the cultural aspects that help fuel the problem; it describes the medication system and some common vulnerabilities; and explores strategies for improving medication safety, including the essential and most important need for engaging patients in their care and in the design of care. (Baker GR & Dennis JL, A Comparative Study of Three Transformative Healthcare Systems: Lessons for Canada, Canadian Health Services Research Foundation, Sept 2011; www.chsrf.ca)

Keywords

Adverse drug event, medication incident, medication error, medication incident and adverse event reporting, medication reconciliation, computerized prescriber order entry, bar coding, automated dispensing systems, electronic medication administration record.

Teaching methods

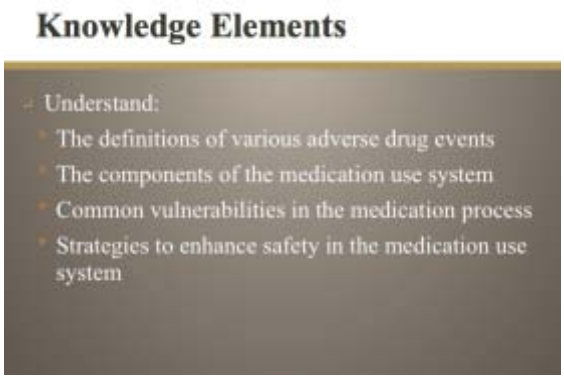
Small group, case-based discussions, role play

Module outline

- Learning objectives
- Clinical case example
- Introduction
- Canadian culture
- The pharmaceutical development and use system
- The medication use process
    - Prescribing
    - Order processing and transcription
    - Dispensing
    - Administration
    - Monitoring
- Improving medication safety
- Patient safety stakeholders
- Summary
- Potential Pitfalls
- Pearls
- Toolkits and Resources
- References

Learning objectives

Slide 2



Knowledge Elements

The knowledge elements include an understanding of foundational elements:

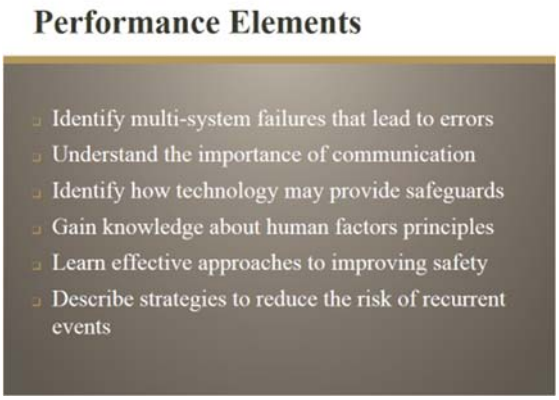
- The definitions of medication incidents, adverse drug events and other key terms;
- The components of the overall medication use system;

- Common vulnerabilities in the medication use process including the system and human factors; and
- Strategies to enhance safety in the medication use system

Further, healthcare practitioners need to recognize:

- the essential and most important need for engaging patients in their care, and in the design of care (Baker & Dennis, Sept 2011), in order to make significant progress in reducing the rate of medication events
- that medication use is extensive and engrained,
- the scope of the medication error as a subset of medical error,
- the reality that medication errors are largely invisible to the public
- medication errors, as a subset of medical errors, are a global problem
- the causes of medication errors are multifactorial
- errors occur at every stage of the medication use system

Slide 3



Performance Elements

The performance elements include the ability to:

- Identify multi-system failures that lead to medication incidents;
- Understand the importance of clear communication;
- Identify how technology may provide system safeguards;
- Gain knowledge about human factors principles and use this understanding to learn effective approaches to improving safety;
- Learn the optimal approach to improving safety; and
- Describe effective strategies to reduce the risk of recurrent events

Slide 4

Trigger tape

A chemotherapy dosage error resulted in the death of Betsy Lehman at a Boston hospital in 1995. Betsy was a health reporter for the newspaper, the *Boston Globe*. Jim Conway, the hospital's incoming Chief Operating Officer at the time, describes the impact of a patient death on the institution, and the wake-up call it sent to the medical community at large. He also describes measures taken to prevent similar events in the future. Dr. Lucian Leape, named as one of the 30 people who have had the most impact on healthcare in the past 30 years, discusses how the hierarchy of medicine was a significant barrier to learning from medication errors. (https://www.youtube.com/watch?v=ruyAsaZE6ys)

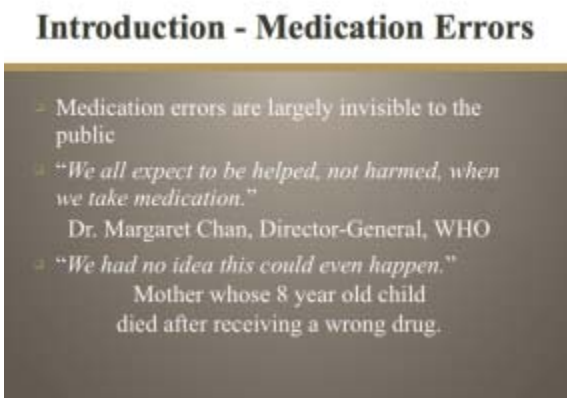
Other Examples

There have also been fatal medication incidents in Canada. In May 2017, ISMP Canada published a report about an 8 year old boy who was found dead the morning after he had the first dose of his usual drug suspension that had been refilled with the wrong medication. (Institute for Safe Medication Practices Canada. Death Due to Pharmacy Compounding Error Reinforces Need for Safety. *ISMP Medication Safety Alert!*. Volume 17 • Issue 5 • May 25, 2017. https://www.ismp-canada.org/download/safetyBulletins/2017/ISMPCSB2017-05-Tryptophan.pdf).

Many other harmful medication incidents have been described in the Institute for Safe Medication Practices Canada (ISMP Canada) Safety Bulletins; see: https://www.ismp-canada.org/ISMPCSafetyBulletins.htm.

Two publicly available detailed root cause analyses can be found at: https://www.ismp-canada.org/rca.htm. One of these describes learning from a fatality associated with incorrect programming of an ambulatory infusion pump for cancer chemotherapy and the other describes a fatality resulting from administration of hydromorphone instead of morphine in an emergency department. Events such as these have generated substantial learning about system failures, which has been incorporated into various guidelines and standards, including Medication Management standards published by Accreditation Canada. (https://store.accreditation.ca)

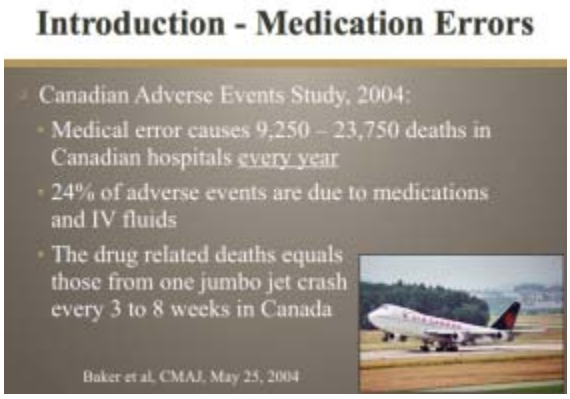
Slide 5



Healthcare delivery is not infallible. Hundreds of thousands of deaths and harmful events are due to systems failure accidents in healthcare every year worldwide. Medication-related incidents are very common. Interviews with the mother of an eight-year-old child who died after getting the wrong drug told a reporter "We had no idea this could even happen." This reflects the fact that, to the general public, these events are largely invisible.

The World Health Organization (WHO) is calling for change in medication-associated harm around the world. In March 2017, it launched a global initiative aimed at reducing severe, avoidable medication-associated errors by 50 per cent over the next five years. The initiative is called the Global Patient Challenge on Medication Safety. "We all expect to be helped, not harmed, when we take medication," said WHO Director-General Dr. Margaret Chan. "Apart from the human cost, medication errors place an enormous and unnecessary strain on health budgets. Each medication error has been shown to cost $400-$600 per event. Preventing errors saves money and saves lives." (Medication Without Harm - Global Patient Safety Challenge on Medication Safety. Geneva: World Health Organization, 2017. http://www.who.int/patientsafety/medication-safety/en/)

Slide 6



The 2004 Canadian Adverse Events study, the first national study of adverse events in Canadian hospitals, reported that as many as 24,000 Canadians die every year from adverse events in acute care facilities. Medications and IV fluid administration was identified as the second most common type, accounting for nearly one-quarter of all events (surgical events were the most common event type). The number of drug/fluid related deaths per year in Canada would be equivalent to having one jumbo jet crash every 3 to 8 weeks. (Baker GR, Norton PG, Flintoft V, et al., The Canadian

Adverse Events Study: the incidence of adverse events among hospital patients in Canada. CMAJ 2004;170(11):1678-86 http://www.cmaj.ca/content/cmaj/170/11/1678.full.pdf)

More recently, a joint effort between the Canadian Patient Safety Institute (CPSI) and the Canadian Institute for Health Information (CIHI) produced a new measure for hospital harm in Canada and estimated that one of every eighteen patients in Canadian hospitals experience a preventable incidence of harm (Canadian Patient Safety Institute, Canadian Institute for Health Information. Measuring Patient Harm in Canadian Hospitals 2016. http://www.patientsafetyinstitute.ca/en/toolsResources/Hospital-Harm-Measure/Documents/CIHI%20CPSI%20Hospital%20Harm%20Report%20EN.pdf)

Similar studies were completed in other countries. In 1999, the US Institute of Medicine published their report, *To Err is Human,* which identified medication errors as the most common type of adverse event in healthcare. This report highlighted that preventable medication errors resulted in up to 7,000 deaths per year in hospitals and tens of thousands more in outpatient facilities. (To Err is Human: Building A Safer Health System, Institute of Medicine, November 29, 1999. http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf)

Slide 7

Defining medication incidents and adverse drug events

See: https://www.ismp-canada.org/definitions.htm

An **adverse drug event** is defined as "an injury from a medicine or lack of an intended medicine. This includes adverse drug reactions and harm from medication incidents" (Collaborating parties of the Canadian Medication Incident Reporting and Prevention System, CMIRPS 2005). Adverse drug events that result in "serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk there of" are called **critical incidents or sentinel events**.

A **medication incident (error)** is defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/ packaging/ nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use (similar term: medication error)".

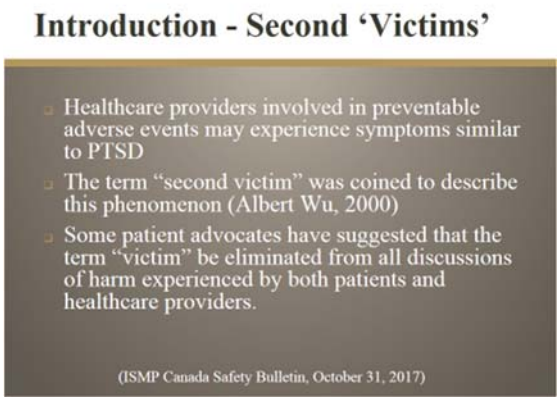
Simplified definition: A mistake with medication, or a problem that could cause a mistake with medication.

A potential adverse event may also be referred to as a **near miss or close call**: "an event that could have resulted in unwanted consequences, but did not because either by chance or through timely intervention the event did not reach the patient" (Collaborating parties to the CMIRPS, 2005). These are also sometimes called **near hits or good catches**.

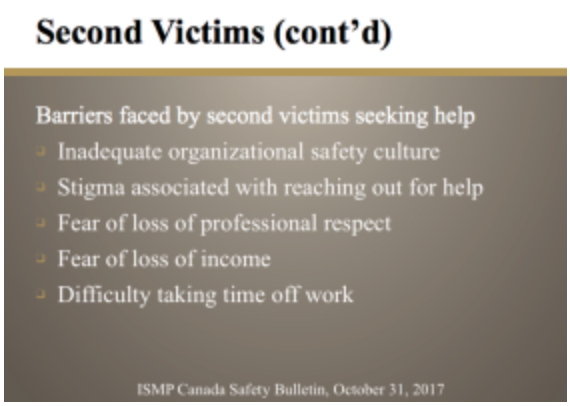
Adverse drug reactions occur in the absence of a medication error. These are the most common type of adverse drug event. The harm experienced by the patient is judged as being caused by the drug itself. Some adverse drug reactions are well-known and can be anticipated and prevented, however many are not predictable and occur without warning (e.g., allergic reactions).

Medication safety is usually considered to be related to the medication management process (freedom from preventable harm) rather than drug molecule safety which is the purview of Health Canada.

Slide 8



Slide 9



When a patient experiences harm as a result of a medication error, the healthcare providers involved can experience severe and long-lasting psychological effects, which can be equivalent to post-traumatic stress disorder (PTSD). The instant patient harm occurs, the involved caregiver also becomes a patient who may face numerous barriers when seeking help. (Institute for Safe Medication Practices. The Second Victim: Sharing the Journey toward Healing. *ISMP Medication Safety Alert!*. Volume 17 • Issue 9 • October 31, 2017. https://www.ismp-canada.org/download/safetyBulletins/2017/ISMPCSB2017-10-SecondVictim.pdf)

The term "second victim" was coined to describe caregivers who are involved in preventable adverse events. (Wu, 2000) Healthcare providers should be aware that the use of the term "victim" for patients, families and healthcare providers and the suggestion that victims can be ranked has caused sensitivity among patients and families, and some have advocated that this terminology not be used.

Canadian Culture

In June 2014, Statistics Canada published the first national, population-based study that detailed current prescription drug use among community-dwelling Canadians aged 6 to 79. Results showed prescription medications are widely used in many Canadian households. (Statistics Canada, Health Reports, June 2014, Prescription medication use by Canadians aged 6 to 79. http://www.statcan.gc.ca/pub/82-003-x/2014006/article/14032-eng.pdf).

Slide 10

In a 2012 article, twenty-seven per cent of seniors reported taking five or more medications on a regular basis. Within the past year, 12% of seniors taking five or more medications experienced a side effect that required medical attention compared with 5% of seniors taking only one or two medications. Even when controlling for age and number of chronic conditions, the number of prescription medications was associated with the rate of emergency department use. Less than half of all seniors reported having received medication reviews and having the possible side effects of their prescription medications explained to them by their physician. (Reason B, Terner M, McKeag AM, et al. The impact of polypharmacy on the health of Canadian seniors. Family Practice 2012; 29: 427-432. http://fampra.oxfordjournals.org/content/early/2012/01/05/fampra.cmr124)

Slide 11

Slide 12

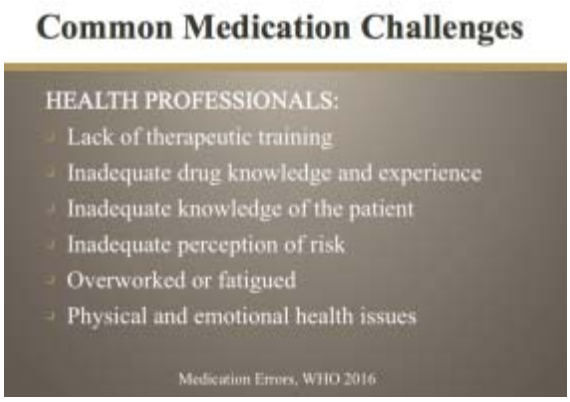
Polypharmacy—taking more medications than clinically necessary—is likely the strongest risk factor for medication error. For example, critically ill patients are prescribed twice as many medications as compared to those outside of the intensive care unit (ICU) and nearly all will suffer a potentially life-threatening error at some point during their stay. (Moyen E et al. Clinical review: Medication errors in critical care. Critical Care 2008,12:208 https://ccforum.biomedcentral.com/articles/10.1186/cc6813)

Patients and the public are not always medication-wise. ISMP Canada has published three newsletters on common misconceptions about medicines that could be deadly on the SafeMedicationUse.ca website. (Institute for Safe Medication Practices Canada. Misconceptions about Medicines That Could Be Deadly: Part 1. SafeMedicationUse.ca Newsletter. Volume 7 • Issue 1 • January 18, 2016. https://safemedicationuse.ca/newsletter/downloads/201601NewsletterV7N1Misconception1Storage.pdf. Institute for Safe Medication Practices Canada. Misconceptions about Medicines That Could Be Deadly: Part 2. SafeMedicationUse.ca Newsletter. Volume 7 • Issue 4 • May 31, 2016. https://safemedicationuse.ca/newsletter/downloads/201605NewsletterV7N4Misconception2ExtraDoses.pdf. Institute for Safe Medication Practices Canada. Misconceptions about Medicines That Could Be Deadly: Part 3. SafeMedicationUse.ca Newsletter. Volume 7 • Issue 5 • June 7, 2016. https://safemedicationuse.ca/newsletter/downloads/201606NewsletterV7N5Misconception3SharingMedicines.pdf)

Patients, and their families, are too often passive recipients of medicines and not informed and empowered to play their part in decreasing the risk of medication errors. The Institute of Medicine report Preventing Medication Errors, states "**the most powerful strategy** for improving safety may be motivating providers and organizations to support the full engagement of patients and surrogates in improving the safety of medication use." (Bootman JL, Cronenwett LR. Co-Chairs. Committee on Identifying and Preventing Medication Errors, Institute of Medicine. Preventing Medication Errors, Institute of Medicine (IOM) July 2006. The National Academies Press: http://nap.edu/11623)

Common Medication Challenges

Slide 13



Challenges can, and do, occur at all stages of the medication use process. Causes of errors are multi-factorial. In 2016, the WHO published a document (Medication Errors: Technical Series on Safer Primary Care. Geneva: World Health Organization; 2016. http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf) which has identified factors that may influence medication errors:

- healthcare professionals (e.g., training, knowledge, experience, fatigue);
- patients (e.g., poor communication, complexity of case, literacy and language barriers);
- work environment (e.g., workload and time pressures; distractions and interruptions; lack of standardized protocols; physical environment [e.g., temperature, noise levels]; availability of supportive technology; clinical decision support; appropriate staffing);
- department/institution (e.g., absence of a safety culture); and
- the need for policies and practice protocols that integrate these factors and prioritize safety.

These factors individually and collectively contribute to the potential for medication and other safety incidents for each patient. Availability and timely communication of patient information (e.g., medication history, current laboratory and diagnostic test results) are fundamental to care and monitoring decisions by all disciplines.

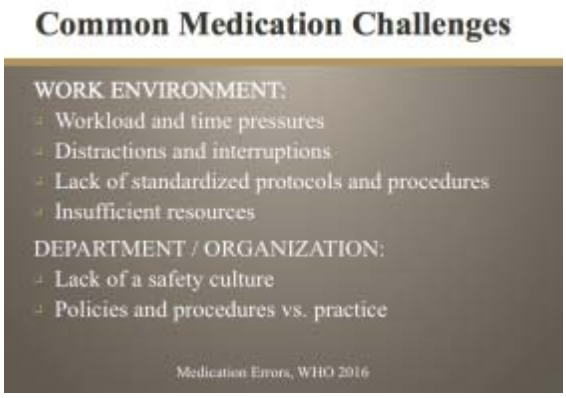
Slide 14

Transition points of care, such as admission, transfer and discharge, are known areas of risk, in particular for medication incidents.

Decision-making by individual providers is impacted by their own level of experience and expertise, as well as factors such as stress and fatigue. In addition, local cultural factors such as the level

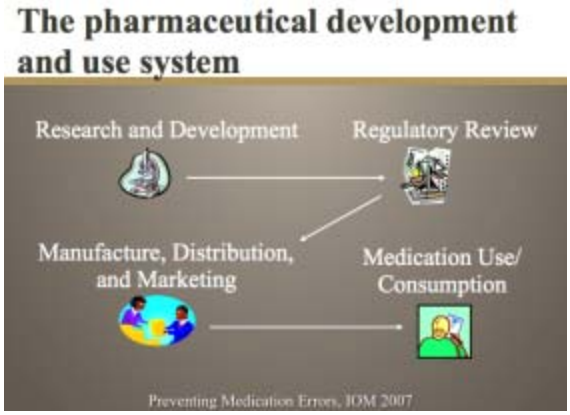
of teamwork and presence or absence of a safety culture influence the likelihood of clinicians "speaking up" or asking for help in a given situation.

Slide 15



The pharmaceutical development and use system

Slide 16



The pharmaceutical development and use system is highly complex and encompasses the entire cycle of medication procurement, prescribing, order processing and transcription, preparation, dispensing, transportation, administration, documentation and monitoring.

Regulatory review

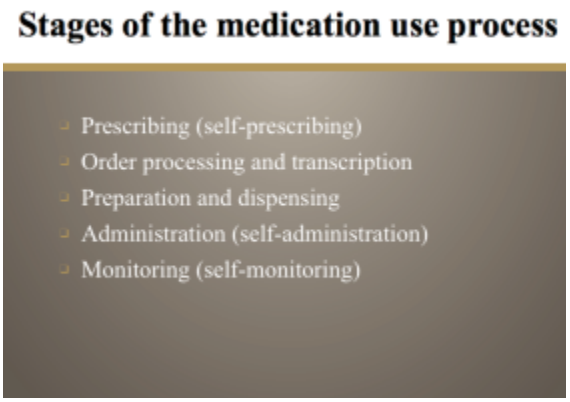
During the regulatory review stage, Health Canada evaluates drug research findings in order to ensure safety and efficacy for the intended indications.

Health Canada is also responsible for approval of drug naming and labelling.

ISMP Canada worked with Health Canada to develop the Good Label and Packages Practices Guides for Prescription and Non-Prescription Products to enhance the pre-market evaluation of drug naming and labelling. (See: https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-non-prescription-drugs-natural-health-products.html and https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-prescription-drugs.html).

The medication use process

Slide 17

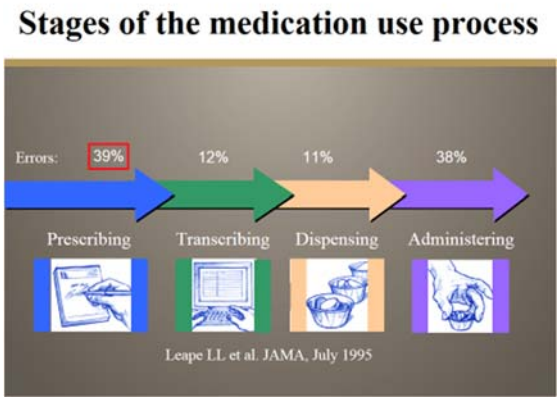


The medication process involves 5 broad stages: prescribing, order processing and transcription, preparation and dispensing, administration and monitoring. These stages will be referred to as the "medication use" system. Some of these steps are also undertaken by patients without health professional participation, advice or knowledge.

Providing one critically ill patient with a single dose of a medication requires correctly executing 80–200 steps. (Pharmacy-nursing shared vision for safe medication use in hospitals: executive summary session. Am J Health Syst Pharm 2003;60:1046-52. https://www.medscape.com/viewarticle/455700)

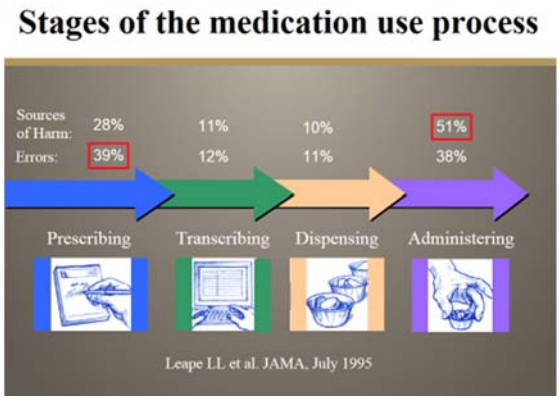
Medication errors, defined as any error in the medication process regardless of whether a patient experiences an adverse consequence, can occur at any step.

Slide 18



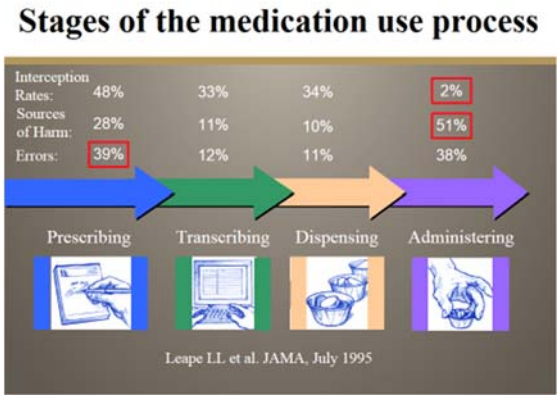
A landmark study conducted by Lucian Leape and colleagues is frequently quoted as it identified the frequency of occurrence of error at each stage of the process: prescribing 39%, order processing and transcription 12%, pharmacy dispensing 11%, and administration 38%. (Leape L et al. Systems analysis of adverse drug events. JAMA 1995;274:35-43 https://jamanetwork.com/journals/jama/article-abstract/389137?redirect=true).

Slide 19



In addition to identifying the stages where errors occurred, the Leape study (Systems analysis of adverse drug events. JAMA 1995) also looked at the potential for interception, or correction, of errors occurring at each stage. Nearly half of the prescribing errors were intercepted by nurses and pharmacists and about one third of transcription errors were identified and corrected prior to administration. However, only 2% of errors occurring at the administration stage were intercepted; this has been a key driver for the introduction of bar code verification of patient and medication identity at the bedside.

Slide 20

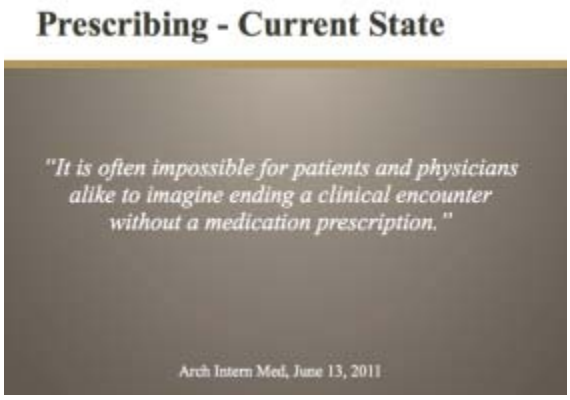


The Leape study did not assess the monitoring stage, however a later Canadian study identified prescribing and monitoring as the most frequent types of errors in geriatric patients. (Gurwitz JH, Field TS, Judge J, et al. The study concluded that special focus was needed on the ordering and monitoring stages of pharmaceutical care for preventing adverse drug events in the long-term care setting Am J Med. 2005 Mar;118(3):251-8. https://www.sciencedirect.com/science/article/pii/S0002934304007181

The medication use system is influenced by environmental factors, including physical environment and workflow design, staff education and competence, interdisciplinary team communication skill, and quality processes and risk management.

Patients are encouraged to actively participate in their own care, in partnership with their health professionals, at all stages of the medication use system. They also may undertake all of these steps when they purchase over-the-counter ("OTC") medications, a number of which used to be available by prescription only.

Slide 21

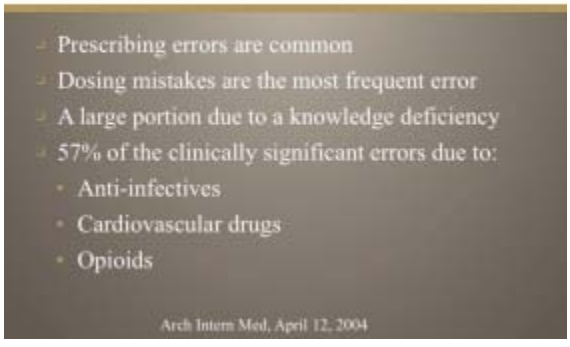


The authors of an article on the principles of conservative prescribing stated, "It is often impossible for patients and physicians alike to imagine ending a clinical encounter without a medication prescription." (Schiff GD, Galanter WL, Duhig J, et al. Principles of Conservative Prescribing. Arch Intern Med 2011; 171(16):1433-1440

https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1105913)

At the beginning of the medication-use process, there is often a knowledge gap about how the drugs being prescribed will work in specific patient populations. Medications are sometimes prescribed in ways and circumstances that increase the risk of harm to patients. (Principles of Conservative Prescribing. Arch Intern Med 2004).

Slide 22

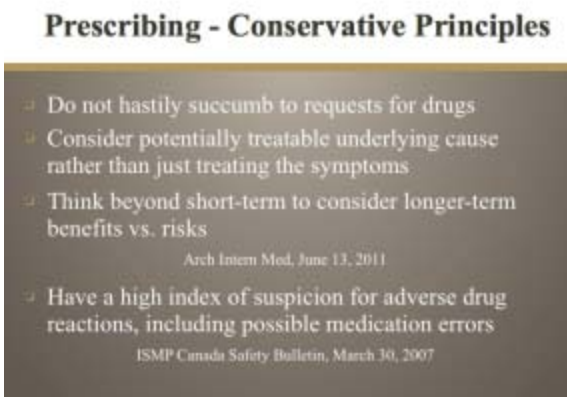


The knowledge gap about drug indications, contraindications and drug interactions is a source of error during prescribing. Lack of drug knowledge by prescribers was identified as a potential risk factor for medication errors in the ICU. (Systems analysis of adverse drug events. *JAMA* 1995).

Computerized prescriber order entry (CPOE) with decision support and the availability of web-based drug information resources at the point of care may reduce the risks of medication errors at the prescribing stage.

Principles of Conservative Prescribing

Slide 23

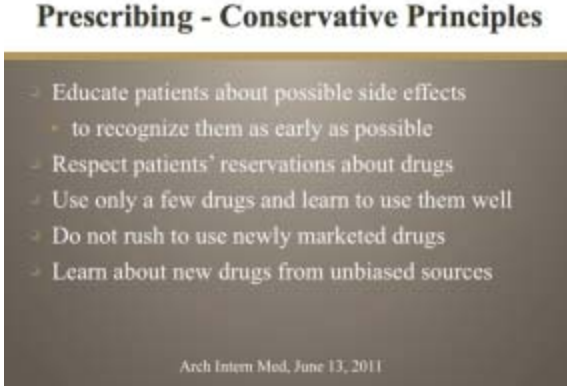


Some of the conservative prescribing principles promoted in the article by Schiff et al include:

1. Do not hastily succumb to requests for drugs:
   - consider non-drug therapy
   - treatable underlying causes
2. Consider potentially treatable underlying cause rather than just treating the symptoms
3. Think beyond short-term to consider longer-term benefits vs. risks
4. Have a high index of suspicion for adverse effects
   - be aware of adverse drug reactions or withdrawal-type symptoms
   - suspect drug error

   (ISMP Canada. Unexpected hypoglycemia. Consider medication error in the differential diagnosis. ISMP Canada Safety Bulletin, March 30, 2007. https://www.ismpcanada.org/download/safetyBulletins/ISMPCSB2007-01Hypoglycemia.pdf)

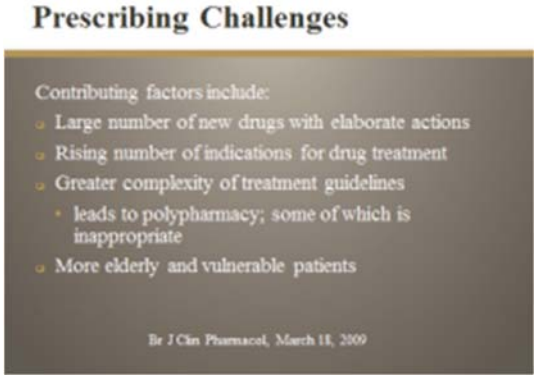
Slide 24



1. Educate patients about possible side effects so they recognize them as early as possible
2. Respect patients' reservations about drugs
3. Use only a few drugs and learn to use them well
4. Do not rush to use newly marketed drugs (e.g. free samples)
5. Learn about new drugs and new indications from trustworthy, unbiased sources:

- exercise caution and skepticism
- wait until drugs have sufficient time on the market
- be skeptical about surrogate rather than true clinical outcomes
- avoid seduction by elegant molecular pharmacology
- beware of selective drug trial reporting

Slide 25



Prescribing is a complex skill that depends on a sound knowledge of medicines, an understanding of the principles of clinical pharmacology, the ability to make judgments concerning risks and benefits, and ideally experience. It is not surprising that errors occur.

The availability of new active substances has become an increasing problem given the thousands of prescription medications currently in use, in addition to an average of 100 new patented drug products that are introduced each year onto the Canadian market (The Patented Medicine Prices Review Board. Annual Report 2016. Available at http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1334).

Use of free drug samples, a significant promotional tool used by the pharmaceutical industry for new drugs, may compromise medication safety as:

- the practice influences decision-making during prescribing because physicians are more likely to use a sample medication even if that is not otherwise their first choice. (The High Cost of "Free" Drug Samples, *Clinical and Translational Gastroenterology*, Dec 2014. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4274368/)
- it bypasses standard safety checks provided by the screening for drug interactions, drug allergies, appropriateness of drug and dose by pharmacists. (Preventing Medication Errors, IOM 2006)
- the lack of documentation means the medication record is incomplete

The challenge of being a prescriber is probably greater now than ever before. Historically, prescribers maintained competence through education and personal vigilance but although they report spending a considerable amount of time in continuing medical education (CME) activities, studies have shown a sizeable difference between real and ideal performance, suggesting a lack of effect of formal CME. (Davis D, Thomson O'Brien MA, Freemantle N, et al. Impact of Formal Continuing Medical Education: Do Conferences, Workshops, Rounds, and Other Traditional Continuing Education Activities Change Physician Behavior or Health Care Outcomes? *JAMA* 1999;282(9):867-874. http://www.med.unc.edu/aging/fellowship/current/curriculum/research-academic-work/qi-work/QI_and_CME.pdf).

Systems analysis of errors suggests that knowledge and training are relevant factors in causation and that focused education improves prescribing performance. (Maxwell S. Prevention of

Medication Errors: teaching and training. *Br J Clin Pharmacol,* March 2009. http://europepmc.org/articles/PMC2723205).

Clinical Implications – Case Example

Prescribing decisions are often made based on information provided at education events sponsored by the pharmaceutical industry and further influenced by availability of drug samples and promotional materials. Presentations and promotional materials may not always include information such as adverse drug reactions, drop out rates, and inclusion and exclusion criteria, which would help prescribers determine if the generalizability of the findings are applicable to their patient(s).

An example of a new medication which generated a strong safety signal within the first few months after approval was the new oral anticoagulant dabigatran (PRADAXA). It was approved by the US FDA in October 2010. Unexpectedly large numbers of serious and fatal bleeding reports, particularly in older patients with a median age of 80, were reported in the following few months. During the first quarter of 2011, 932 serious adverse events were linked to dabigatran, including **120 deaths**, 25 cases of permanent disability, and 543 cases requiring hospitalization. Of the 932 events, 505 cases involved hemorrhage, more than any other monitored drug. The total included 120 cases that described the event with terms indicating hemorrhagic stroke, which is particularly problematic given that the drug's primary indication is to prevent ischemic strokes. ISMP QuarterWatch published an analysis, noting that by the end of 2012, the FDA had received 7,387 domestic reports of serious injury associated with dabigatran, including **1,158 patient deaths.** (Institute for Safe Medication Practices. QuarterWatch, First Quarter 2011, Signals For Dabigatran And Metoclopramide, ISMP Medication Safety Alert, Jan 2012. http://www.ismp.org/Newsletters/acutecare/showarticle.aspx?id=12)

It is unknown how commercial marketing may have positioned dabigatran and whether this may have contributed to the number of adverse events with this medication; however it illustrates the importance of patient selection and monitoring criteria for newly available medications.

Self-prescribing

Self-prescribing has an important role to play in healthcare. With the continued improvement in people's education, general knowledge and socio-economic status it is expected that people will take an increased role in their own care. (World Health Organization. Drug Information Vol. 14, No. 1, 2000. http://apps.who.int/medicinedocs/en/d/Jh1462e/1.html)

Slide 26

Over-the-counter (OTC) medications are produced, distributed and sold to consumers for use on their own initiative. Many OTC drugs used to be available only by prescription.

When self-prescribing with OTC medications, the patient (or family member) makes a decision based on their own assessment of their health condition and determination of which OTC medication to take. Responsible self-medication can be used to prevent and treat symptoms and ailments that do not need medical consultation or oversight, which reduces pressure on medical services. (WHO Drug Information, Vol 14, 2000)

Medication information is available to patients through a variety of sources including the internet, television and print media advertisements. While an informed and engaged patient is an important component of safe care, due to the marketing nature of much of the available information, patients may be unduly influenced towards requesting or self-selecting a particular medication for their condition, when another, or in some cases, no medication at all might be more appropriate (e.g. cold remedies for children).

There are several concerns involving self-prescribing. Patients may consume OTC products for inappropriate reasons due to:

- Lack of knowledge about medication use.
- Lack of suitable consumer information.
- Insufficient understanding of the risk.
- Misconception that the ready availability means they are not toxic.
- Bypassing the safety checks provided by pharmacists (e.g., screening for drug interactions, drug allergies, appropriateness of drug and dose, etc) for prescribed products.

Font style and type size of instructions on medication packaging limits readability, and literacy barriers may also be a factor in incorrect dosing of both non-prescription and prescription products. Dosing information is often provided on the outside of a box or as part of a package insert, which can easily be separated from the medication. A SafeMedicationUse.ca consumer alert described a case in which a consumer took twice the recommended dose of an allergy medication because the box had been discarded (Institute for Safe Medication Practices Canada. Removing Medicines from Original Packaging Can Lead to Errors. Safe-MedicationUse.ca Alert , Feb 22, 2011. https://www.safemedicationuse.ca/alerts/dowloads/ISMPC_alert_2011_02.pdf).

Another problem identified with patient self-selection of medications in the community is the increasing trend towards brand name extensions. Another SafeMedicationUse.ca alert described the inadvertent self-selection of Gravol® Ginger in place of Gravol® containing dimenhydrinate. (Look-Alike Gravol Ginger Product Causes Confusion for Consumers. SafeMedicationUse.ca alert August 17, 2010. https://www.safemedicationuse.ca/alerts/alerts_gravol.html)

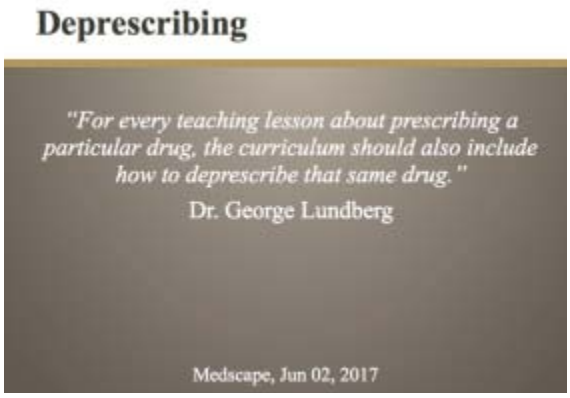
Deprescribing

Slide 27

Deprescribing is the planned process of reducing or stopping medications that may no longer be of benefit or may be causing harm. The risk of harmful drug related problems and hospitalizations increases when taking many prescription medications. The goal of deprescribing is to reduce medication burden while improving quality of life. Deprescribing should be done in partnership with a health care provider and close supervision may be needed to safely stop certain medications (e.g., to avoid withdrawal reactions).

71% of Canadian seniors are willing to stop a medication if their doctor says it is possible. (Canadian Deprescribing Network. Deprescribing Fact Sheet for patients. http://deprescribing.org/CADEN/)

Slide 28

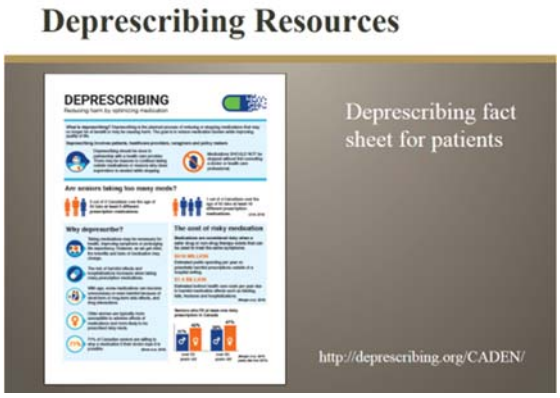


Slide 29

With age, some medications can become unnecessary or even harmful because of short-term or long-term side effects, and drug interactions.

Deprescribing is part of good prescribing practices as it optimizes medication use and is vital to managing chronic diseases.

Slide 30



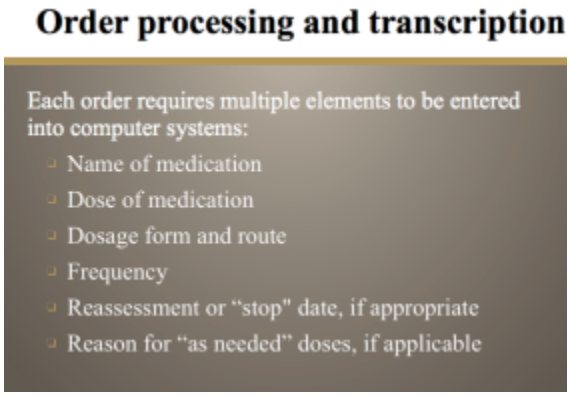
Slide 31

Resources to support making decisions about tapering or stopping medications are available at www.deprescribing.org and at www.medstopper.com

Order Processing and Transcription

In hospital and long-term care settings, it is common for medication orders that have been written into the chart by prescribers to be transcribed by nursing and/or pharmacy staff into a medication administration record (MAR). The MAR is used to keep track of medications administered to patients. These MARs may be hand-written, computer-generated from the pharmacy medication profile and printed (cMAR) or fully electronic with documentation in real time (eMAR).

Slide 32

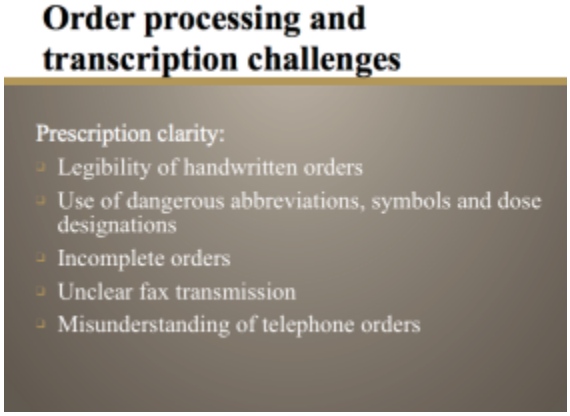


Pharmacists typically screen medication orders prior to their entry into the pharmacy information system and also rely on modern pharmacy computer systems, which are programmed to detect drug allergies and interactions. With integrated information systems, alerts about laboratory monitoring results that may necessitate dosing adjustments can also be automated.

The order processing stage of the medication use system provides an important safety check by both nurses and pharmacists for the appropriateness of the medication order and is where nearly half of prescribing errors are discovered. (Systems analysis of adverse drug events. *JAMA* 1995).

In computerized prescriber order entry systems, the nursing processing step is eliminated, along with the associated safeguard of order checking by another healthcare professional who knows the patient; however this is anticipated to be offset by other benefits such as improved legibility and ability to incorporate clinical decision support at the front end of the process for prescribers.

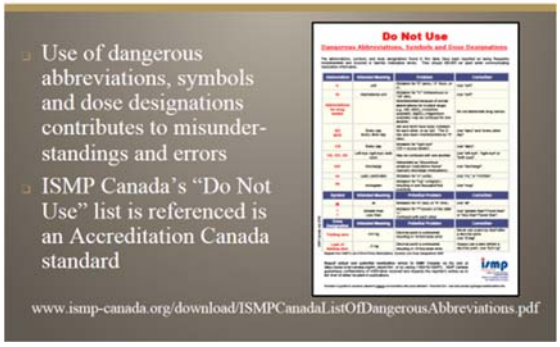
Slide 33



Order processing and transcription challenges

Handwritten prescription orders and prescription orders with missing key drug characteristics are common problems in systems that rely on manual order writing by prescribers and/ or manual transcription by nurses and pharmacy staff. Many transcription-related medication incidents occur when a drug name is illegible, if a drug name looks or sounds like that of another drug, dosages are unclear, or concentrations are not specified. The large number of look-alike, sound-alike drugs also contribute to order processing and transcription challenges.

Slide 34 **Order processing & transcription challenges**



The use of known error-prone abbreviations such as "qd" for every day versus "qid" for 4 times per day, creates circumstances that can easily lead to misunderstandings. Miscommunications also commonly occur due to use of trailing zeroes (e.g., 1.0 mg instead of 1 mg) or the failure to use leading zeroes (e.g., .1 mg instead of 0.1 mg).

Confusing dose designations

- Use of trailing zeroes (e.g., 1.0 mg instead of 1 mg)
- Failure to use leading zeroes (e.g., .1 mg instead of 0.1 mg)

Confusing instructions

- OD (*oculus dexter* or right eye) confused with "once daily" (QD)
- AD (*aura dexter* or right ear) confused with "as directed"
- "U" for "units", mistaken for "0" (zero), "4" (four) or cc
- "qd" for "every day" confused with "qid" for "4 times per day"

Confusing symbols

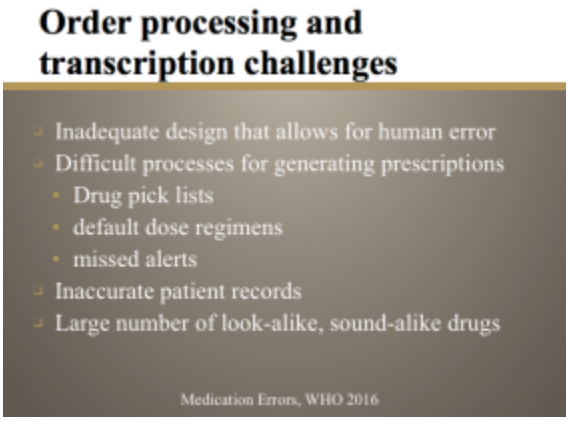
- Ampersand (&) and slash mark (/) can be misidentified as numbers or letters

ISMP Canada publishes a list of "Do Not Use" dangerous abbreviations, symbols and dose designations. (Institute for Safe Medication Practices Canada. Do Not Use Dangerous Abbreviations, Symbols and Dose Designations, July 2006. http://www.ismp-canada.org/download/ISMPCanadaListOfDangerousAbbreviations.pdf).

These are referenced by Accreditation Canada in their standards for medication management (Medication Management Standards 2017, Accreditation Canada).

Verbal (in-person) or telephone orders for sound-alike medications can be misinterpreted, even when the order is written out and read back to the prescriber. Workload, local culture and difficult interpersonal relationships between and among practitioner groups can have negative influences on patient safety; for example, decreasing the likelihood that unclear orders will be clarified prior to implementation.

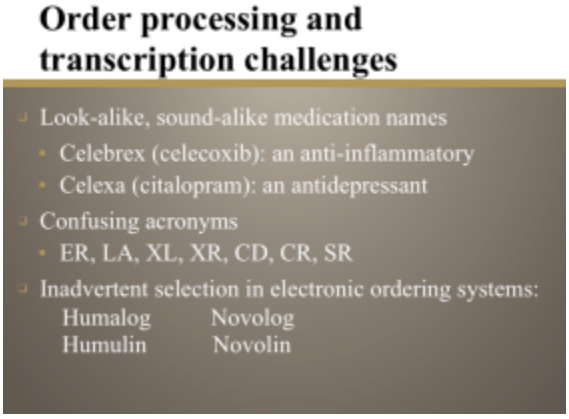
Slide 35



Key factors during order processing that are associated with medication errors include:

- Inadequate design that allows for human error
- Difficult processes for generating first prescriptions (e.g. drug pick lists, default dose regimens and missed alerts)
- processes for generating correct repeat prescriptions
- Lack of accuracy of patient records (World Health Organization. Medication Errors: Technical Series on Safer Primary Care. Geneva: World Health Organization; 2016. http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf?ua=1)

Slide 36



Look-alike/sound-alike names

- Celebrex (celecoxib): a nonsteriodal anti-inflammatory drug
- Celexa (citalopram): an antidepressant

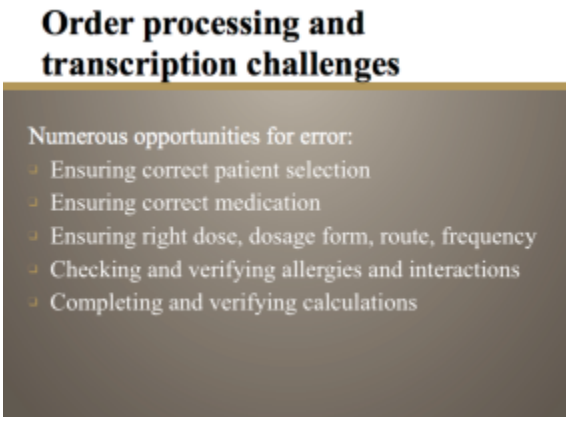
Insulin mixtures

- Humalog Mix 75/25
- Novolog Mix 70/30
- Humulin 50/50
- Novolin 70/30

Abbreviations/acronyms for long-acting or slow, delayed, or extended release

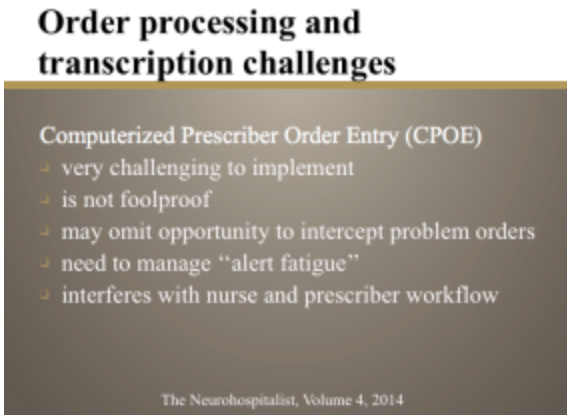
- LA, XL, XR, CD, ER, CR, SR

Slide 37



The numerous repetitive-type tasks associated with order processing and transcription present numerous opportunities for error. Manual or electronic selections are required for the correct patient, drug, dose, form, route, and frequency. Medication allergies and interactions have to be checked and validated. If calculations are required, these need to be verified, often by another individual if a high-alert medication is involved.

Slide 38



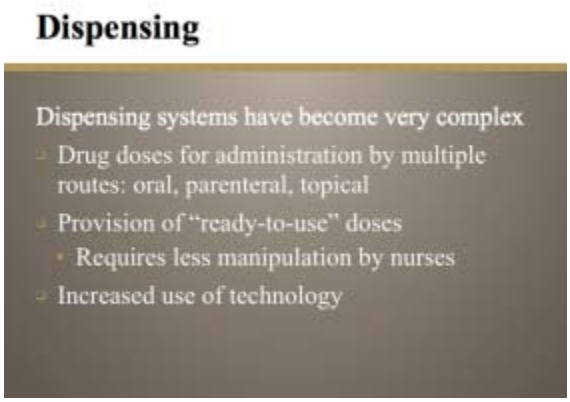
Computerized prescriber order entry (CPOE) will become a progressively more important part of the institutional and primary care landscape. Every implementation of CPOE is associated with both generally recognized and unique local factors that can facilitate or confound its rollout. CPOE systems share the following features:

- prescribers entering the orders directly into a computer system (not through a unit secretary);
- prescribers working through a digital interface (no handwriting);
- standardization/structure (for example, not through free text documents).

CPOE affects health care delivery in complex ways, with benefits as well as risks including:

- may omit opportunity to intercept problem orders
- need to proactively consider "alert fatigue"
- introduction of asynchrony between nurse and prescriber workflow
- "a corresponding reduction in face-to-face communication led to the generalized feelings of disempowerment" (Khanna R, Yen T. Computerized Physician Order Entry: Promise, Perils, and Experience. The Neurohospitalist, 2014,Vol 4(1), 26-33. http://journals.sagepub.com/doi/abs10.1177/1941874413495701?journal-Code=nhoa)

Slide 39



Medication administration errors can occur when nurses must manipulate medications prior to administration. One important safety strategy is the provision of the medication in a ready-to-use format to reduce the complexity of the medication delivery system. Mixing solutions, cutting tablets, pouring liquids, and drawing solutions into syringes are all steps that may introduce errors into the medication administration process, especially in the midst of busy, noisy patient care units or when time is short. Much of the preparation and manipulation of medication for acute care inpatients that was previously done by nurses is being shifted to the pharmacy. By dispensing each dose from the pharmacy in a single unit that is ready for administration without further steps, the risk of an administration error leading to an adverse drug event can be significantly reduced. (Institute for Healthcare Improvement. Dispense Medications in Ready-to-Use Single Doses. http://www.ihi.org/resources/Pages/Changes/DispenseMedicationsinReadytoUseSingleDoses.aspx)

For example, one best practice is to ensure that all oral liquids that are not commercially available as a unit dose product, are dispensed by the pharmacy in a ready-to-use oral syringe. This prevents dosing errors as well as the unintended administration of oral products by the intravenous route. (Institute for Safe Medication Practices. ISMP 2018-2019 Targeted Medication Safety Best Practices for Hospitals. http://ismp.org/Tools/BestPractices/TMSBP-for-Hospitalsv2.pdf).

In Canadian hospitals, oral solid medications are now commonly provided in unit dose packaging (i.e., one tablet/ capsule in an individually labelled package). Adoption of unit dose packaging was accelerated when Accreditation Canada made this a standard.

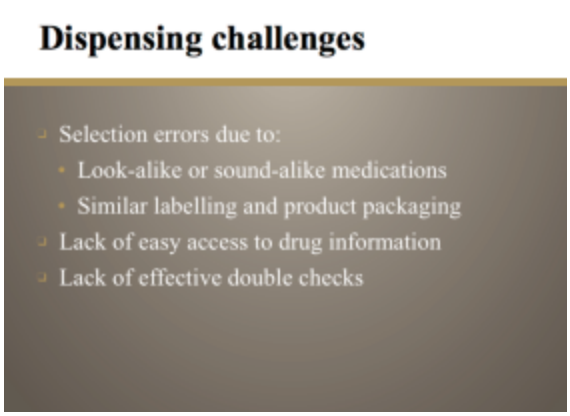
In long-term care other residential care settings, oral solid medications are commonly provided in modified unit-dose packaging – both daily "multi-packs" and 30 day "blister cards" in which several medications to be administered at the same time are packaged in the same container.

Slide 40

The introduction of technology, such as packaging machines and robotic dispensing and compounding has added to the complexity of pharmacy activities.

Dispensing challenges

Slide 41



Regardless of the setting, there are many opportunities for error in the dispensing process, beginning with selecting the patient in the pharmacy information system, selecting the medication and dosage form during order entry, entering the prescription directions, checking and verifying allergy status and potential drug interactions, performing and verifying required dose calculations, selecting and preparing the medication, and finally, ensuring correct labelling.

Slide 42

Contributing factors to errors in the dispensing process include (but are not limited to):

- problematic packaging and labelling (e.g., look alike packaging, obscure placement of critical safety information);
- distractions and interruptions during processing;
- poorly designed work areas (e.g., inadequate lighting and counter space) and workflow;
- failure to use, or ineffective independent double check processes;
- lack of process standardization;
- outdated or inaccessible drug reference files, texts, and/or database systems; and
- high workload and insufficient staffing or inappropriate skill mix.

In addition, there are special considerations in each setting, based on the services provided and the level of automation in place.

Slide 43

Slide 43 provides an example of an error that occurred when dispensing medications in a long term care home. Chloral hydrate liquid was dispensed instead of potassium chloride liquid, leading to a fatality. (Institute for Safe Medication Practices Canada. System Vulnerabilities across the Spectrum of Care: Another Mix-up between Choral Hydrate and Potassium Chloride, *ISMP Canada Safety Bulletin*, Sept 15, 2005: https://www.ismp-canada.org/download/safetyBulletins/ISMP-CSB2005-07ChloralHydrate.pdf)

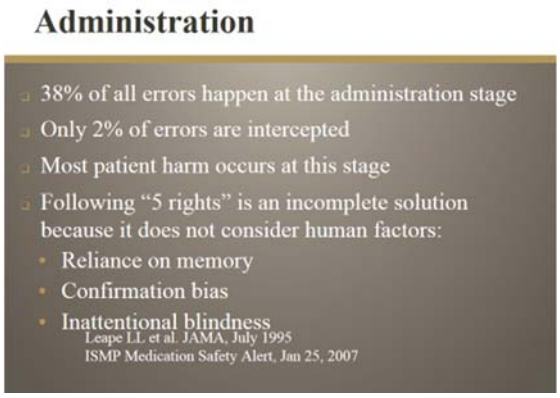
Slide 44

Use of technology in the dispensing phase, while beneficial in terms of safety and efficiency overall, is not foolproof, and may introduce new opportunities for medication errors. Once a medication has been repackaged, added to an automated dispensing machine or compounder, it may be dispensed to **hundreds of patients**, creating the potential for an error to be widely propagated prior to discovery; different safeguards are thus required for these devices than for

traditional manual dispensing methods, where prescriptions are prepared and dispensed for one patient at a time.

Administration

Slide 45



The process of giving a patient medicine – the right drug, in the right dose, via the right route, in the right form, to the right patient, at the right time – appears to be simple and straight-forward and practitioners are often told if they follow the "five rights" (now updated by some regulators and educators to seven or eight rights), they will not make a mistake. However, things are never as simple as they seem. ISMP (US) has referred to the five rights as "a destination without a map", commenting that "they are merely broadly stated goals, or desired outcomes, of safe medication practices that offer no procedural guidance on how to achieve these goals" (Institute for Safe Medication Practices. The five rights: A destination without a map. *ISMP Medication Safety Alert!*. 2007;12(2). http://www.ismp.org/newsletters/acutecare/articles/20070125.asp). The five rights do not take system issues or human factors into consideration.

There are few system-based safeguards between the practitioner administering a medication and the patient receiving the medication. The landmark study by Lucian Leape and colleagues (Systems analysis of adverse drug events. JAMA 1995), mentioned earlier, identified the interception rate for errors occurring at the administration stage as only 2%. Historically when errors happened, attention was focused on the actions of the individual provider (most commonly a nurse) – part of the reason this part of the process is often referred to as the "sharp" end.

Administration challenges

The administration stage is highly sensitive to human factor engineering concepts such as confirmation bias, inattentional blindness, fatigue, and reliance on memory, as well as individual practitioner competence and adherence to best practice. This helps to explain why following the "five rights" (right patient, right drug, right time, right dose, right route) is an incomplete solution in helping nurses to prevent errors. In fact, the five rights are the goal, not the methodology to achieve it.

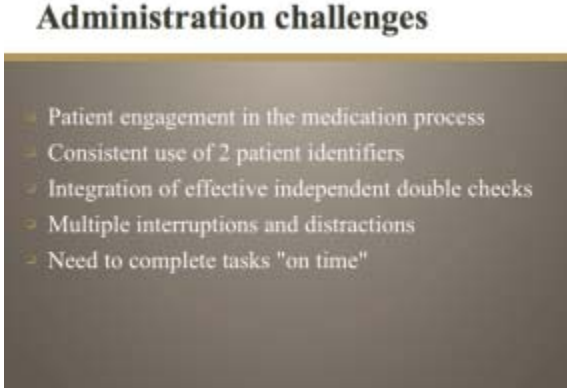
Slide 46

Slide 47

Slide 47 provides a link to a video that explains the phenomenon of inattentional blindness, which is the failure to see something that should have been clearly visible. (https://www.youtube.com/watch?v=IGQmdoK_ZfY)

Preparing medications for administration can range from retrieval of an individual unit dose from an automated dispensing machine or a patient's medication bin to calculation of the dilution and required infusion rate for an inotropic agent ordered in mcg/kg/minute in an intensive care unit. While many medications are supplied to patient care areas in ready-to-use formats, this is more prevalent for less complex items such as tablets and capsules, and injectable items for which doses can be standardized. This means that medication preparation for the most complex and vulnerable patients in a hospital can remain the sole responsibility of the bedside nurses.

Slide 48



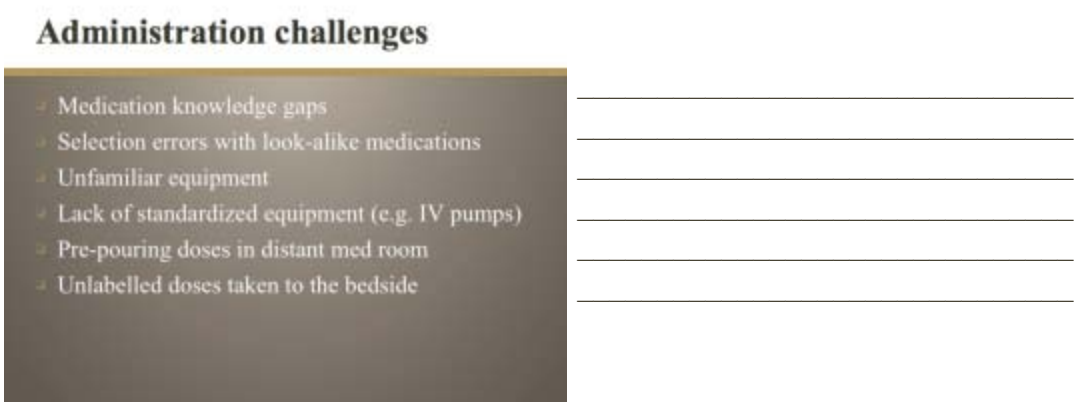
Errors occurring at the administration stage are similar to those that occur in the pharmacy (e.g., incorrect medication selection, incorrect dose, incorrect calculations, incorrect patient identification, as well as others).

A standardized methodology for ensuring correct patient identification is an important step to avoiding the inadvertent administration of medications to patients other than those for whom they were intended. Accreditation Canada now requires that two unique identifiers be checked prior to administration of any medication (Medication Management Standards 2017, Accreditation Canada).

Some effective system-based strategies to decrease the risk of inadvertent administration of the medications to the wrong patient include:

1. Medication, MAR and patient in same location for verification; i.e., always taking the MAR to the bedside;
2. Labelling of any medication doses prepared in the patient care area, to ensure medications can be identified up to the point of administration;
3. Opening of unit dose packages only after arrival at the bedside;
4. Scanning of drug bar codes at the bedside; and
5. Engaging patients by talking with them about medications being given.

Slide 49



Omission of ordered doses is also a frequently reported error; these may be due to memory lapses, but more often are related to the multiplicity of tasks nurses are required to keep track of in highly distracting environment where systems are still primarily manual. An observational study identified that nurses carry on, on average, more than 15 discrete tasks in their short term memory at any given time during a shift (Potter P, Boxerman S, Wolf L, et al. An Analysis of Nurses' Cognitive Work: A New Perspective for Understanding Medical Errors. Advances in Patient Safety 2004;1:39-51. https://www.ahrq.gov/downloads/pub/advances/vol1/Potter.pdf). This can be overwhelming, considering the limits of the average human's short term memory capacity (seven +/- two pieces of information can be held when attention is full) (Miller GA. The magical number seven, plus or minus two: some limits on our capacity for processing information. *Psychological Review*. 1956;63(2):81-97. http://psychclassics.yorku.ca/Miller/). Our ability to remember things is also impacted by stress, fatigue, and other physiological factors.

Misreading of handwritten medication administration records (MARs) can also be a problem; similarly to problems described in the prescribing section, any handwritten document can be misread or misinterpreted due to legibility issues.

As in other parts of the healthcare system, new technology is being introduced and the technology itself can be a source of error. Pump programming errors are common (e.g., entering incorrect information, such as wrong rate, or entering information into the incorrect field, such as transposing infusion rate and volume to be infused). A root cause analysis of a fatal medication error in which a chemotherapy medication was administered over 4 hours instead of 4 days identified the complexity of the programming sequence for the ambulatory infusion pump as a significant contributing factor to the event (Institute for Safe Medication Practices Canada. Fluorouracil Root Cause Analysis. http://www.ismp-canada.org/download/reports/FluorouracilIncidentMay2007.pdf).

Errors related to infusion pumps have been discussed in several ISMP Canada Safety Bulletins:

July 2003 www.ismp-canada.org/download/safetyBulletins/ISMPCSB2003-07InfusionPumps.pdf), Institute for Safe Medication Practices Canada;

Jan 2004 (https://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2004-01InfusionPump.pdf), Institute for Safe Medication Practices Canada; and,

September 2006 (http://www.ismpcanada.ca/fr/dossiers/bulletins/BISMPC2006-06.pdf), Institute for Safe Medication Practices Canada.

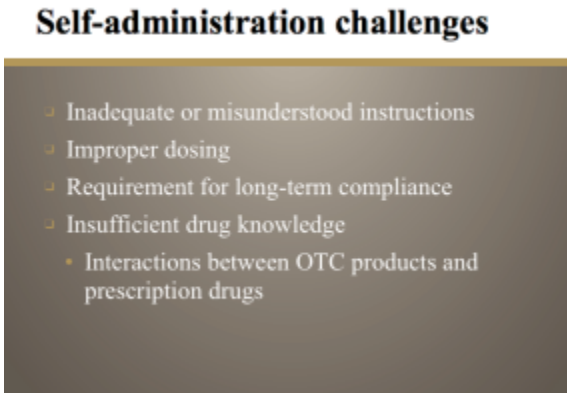
To address the potential for errors related to infusion pump technology, Accreditation Canada requires that organizations provide ongoing, effective training on infusion pumps for staff and service providers (Medication Management Standards 2017, Accreditation Canada).

The work environment for nurses is demanding, with constant distractions and interruptions. Patients turn over quickly and are cared for by multiple providers over different shifts. Nursing staff shortages are not uncommon, resulting in overtime shifts as well as use of agency nurses who may not be familiar with local policies and procedures.

Self-administration challenges

Patients require sufficient education and understanding of the medication regimen and administration procedures (e.g., inhalers, injections) to be able to manage this aspect of the process at home. Non-adherence to prescribed medications can be a safety concern.

Slide 50



During self-administration, the most common types of medication events are wrong dosages; taking medications that are unnecessary; interactions with other prescription and non-prescription medications; and non-adherence. Overdosing or under-dosing may occur due to inadequate

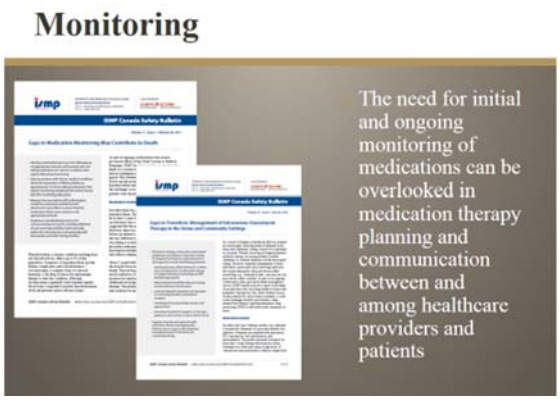
instructions and use of improper measuring devices (e.g., using a household teaspoon versus an oral syringe or other device designed for use with medications). Other types of incidents that have occurred include misinterpreting instructions (e.g., confusing teaspoons with tablespoons), and misreading dosing charts. The risk of harm associated with incorrect dosing increases with medications that have narrow therapeutic indices (also called high-alert medications), such as oral chemotherapy agents, opioids, and insulin. Other types of dosing incidents have been associated with frequency or duration of treatment.

Monitoring

Monitoring (or assessment, evaluation, observation, surveillance) involves obtaining and evaluating clinical indicators and both desired and undesired drug effects on an individual patient basis. The need for initial and ongoing monitoring of medications can be overlooked in medication therapy planning and communication between and among healthcare providers and patients because it is sometimes seen as an informal process. However, lack of monitoring can be a source of error and patient harm; for example, if laboratory tests are omitted such as INR for warfarin, this can lead to internal bleeding.

The effect of medications administered can be assessed through direct observation of the patient, laboratory testing and use of monitoring devices (e.g., blood pressure, heart rate, oxygen saturation). In acute care hospitals, bedside monitoring of the patient includes monitoring vital signs, airway, infection, fluid intake and output, electrolytes, pain, cognition etc. In intensive care units, monitoring is more frequent, invasive, and technologically complex. In long-term and home care, other indicators are evaluated, including cognition, ability to communicate, psychological well-being, and ability to perform daily activities.

Slide 51



In the ambulatory setting, self-monitoring by patients (or family members) is encouraged. They can be educated to assess physiological and psychological responses to prescription medications, over-the-counter products and dietary supplements. Advances in monitoring equipment, such as blood glucose meters for diabetic patients, mean that many patients are able to monitor their condition and adjust their medication doses accordingly. Patients now have computerized access to lab work in many provinces.

The goal of effective monitoring is the early detection of a decrease in a patient's health status or the incidence of an adverse event so that an appropriate response can be initiated to restore a patient's health.

Monitoring challenges

Slide 52

Studies of medication incidents causing harm found that in both hospital and ambulatory care settings, contributing factors included inadequate laboratory monitoring, as well as delayed responses, or failure to respond to, signs and symptoms of drug toxicity or laboratory evidence of drug toxicity. Lack of patient involvement in their own monitoring may be due to cultural and language barriers.

To be active partners in their healthcare, patients and families need the right information in order to use medications safely. CPSI and ISMP Canada teamed up with Patients for Patient Safety Canada, the Canadian Pharmacists Association, and the Canadian Society for Hospital Pharmacists to create a list of top questions to help patients have an informed conversation about medications with their healthcare provider. They are encouraged to use the widely endorsed tool "5 Questions to Ask About Your Medications" whenever attending a doctor's appointment (e.g., family physician or specialist, dentist, optometrist), interacting with a community pharmacist, when leaving the hospital to go home and when being visited by home care services. The following 2 slides show the *5 Questions* and a video that explains them. The *5 Questions* poster is now available in 20 languages and has been widely endorsed by healthcare institutions and organizations in Canada and internationally. See: https://www.ismp-canada.org/medrec/5questions.htm and the 2 minute YouTube video https://www.youtube.com/watch?v=BJI1ToB-Dv8.

Slide 53

Slide 54

Self-monitoring challenges

With decreased lengths of stay for hospital admissions and shortages of family physicians, a large part of monitoring for effectiveness and adverse effects rests with the patient and their family members or other caregivers. The vulnerability associated with being ill along with the subjective nature of self-monitoring along makes this a highly complex issue. Additionally, patients may not be given sufficient instructions regarding what to expect, or may misunderstand or forget verbal instructions that are not reinforced with written information. Critical information such as when to seek medical attention may not be provided or understood.

Slide 55

A key concern related to monitoring is the introduction of new medications to an existing medication regimen. This concern exists with both prescription and non-prescription medications. An ISMP Canada Safety Bulletin described a fatality that was determined to be related to an interaction between fentanyl patches taken to manage chronic pain and Kaletra® (lopinavir plus ritonavir) provided to the patient as part of an HIV post-exposure prophylaxis kit (Institute for Safe Medication Practices Canada. Drug Interaction Incident with HIV Post-exposure Prophylaxis. *ISMP Canada Safety Bulletin*. 2008;8(3):1-2. http://www.ismp-canada.org/download/safetyBulletins/ISMP-CSB2008-03HIVPEP.pdf).

A study published in 1999 identified that ritonavir treatment results in approximately a three-fold increase in fentanyl concentrations. (Olkkola KT, Palkama VJ, Neuvonen PJ. Ritonavir's role in reducing fentanyl clearance and prolonging its half-life. *Anesthesiology* 1999 Sep;91(3):681-5. https://www.ncbi.nlm.nih.gov/pubmed/10485779). The patient in this case experienced severe drowsiness but did not know that this symptom necessitated medical evaluation.

The number of OTC medications has increased and many of them previously required a prescription. Warnings about interactions are often listed on product labels, but difficulty in understanding (and even reading) the labels can increase the probability of an adverse effect.

Some prescription medications have a particularly high likelihood of drug and food interactions. Examples include warfarin, an anticoagulant, and monamine oxidase (MAO) inhibitors, an older class of antidepressant.

Intensive self-monitoring is required for patients with certain conditions, such as diabetes, which requires frequent self-monitoring of blood glucose levels and adjustments to insulin therapy. Depression also requires self-assessment of changes in psychosocial affect.

Some studies have found that the use of self-monitoring devices in conjunction with extensive education has resulted in positive health outcomes. It is important to develop well-designed programs to assist patients to self-monitor for both positive and negative effects of medications, and to help them understand how to respond to adverse health events.

Improving medication safety

Patient and family centred care

The patient and family need to be an integral part of the healthcare team as advocated in the revised Accreditation Canada standards – care is not something that is done "to" or "for" patients; it is something that is done "with" them. The importance of the patient and/or family's full participation in care decisions and processes cannot be overstated.

Patient rights are THE FOUNDATION for the safe and ethical use of medications. This requires a significant shift from the conventional approach to care toward a true patient and family-centred model. When patients are not be able to participate fully in care decisions and management, due to their underlying condition(s) or cognitive abilities, a member of their family should represent them in all decisions regarding their care. This should be the standard expectation of all members of the care team.

Refer to PSEP – Canada Module 7A – Patients as Partners: Engaging Patients and Families:Patient and Family Centred Care for further content on Patient and Family Centred Care (PFCC).

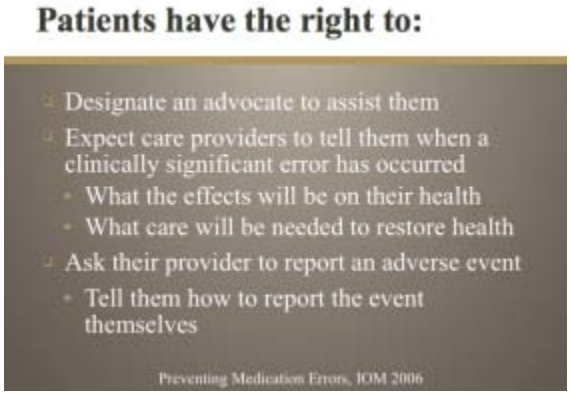
Slide 56 **Improving medication safety**

Patient Rights

Gains will only be made in the reduction of medication errors when patients are empowered to play an active role in their care through the establishment of patient rights. (Preventing Medication Errors, IOM 2006).

Slide 57

Slide 58



Patients have the right to:

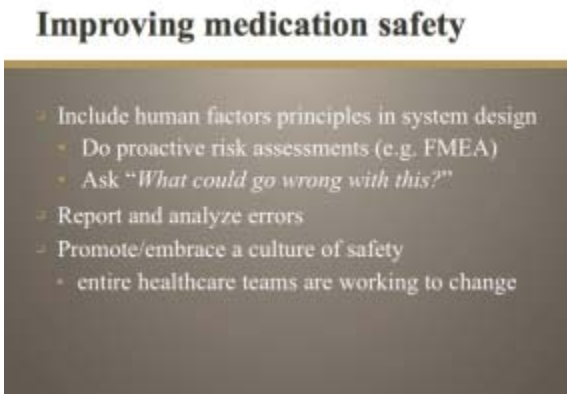
- be the source of control for all medication management decisions that affect them;
- accept or reject medication therapy on the basis of personal values;
- be adequately informed about their medication therapy and alternative treatments;
- ask questions to better understand their medication regimen;
- receive consultation about their medications at all points along the medication use system;
- designate a surrogate or representative to assist them with all aspects of their medication management;
- expect to tell them when a clinically significant error has occurred, what the effects of the event on their health will be and what care they will receive to restore their health; and
- ask their provider to report an adverse event and give them information about how they can report the event themselves (Preventing Medication Errors, IOM 2006).

Human Factors

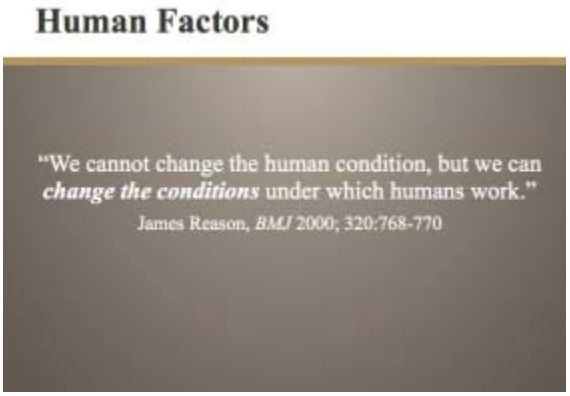
The team needs to consider how to integrate system-based strategies for safety that are based on human factors engineering principles, into all aspects of the medication use system. Additional work is still needed on better incorporating the principles of human factors engineering for combating fatigue (e.g., adequate staffing of professionals involved in medication use); elimination of redundancies (e.g., identifying when double-checks add value in decreasing errors); read-back; the use of reminders, constraints, and colour differentiation. (Preventing Medication Errors, IOM 2006).

Refer to PSEP – Canada Module 2: Human Factors Design: Applications for Healthcare for further content on Human Factors.

Slide 59



Slide 60

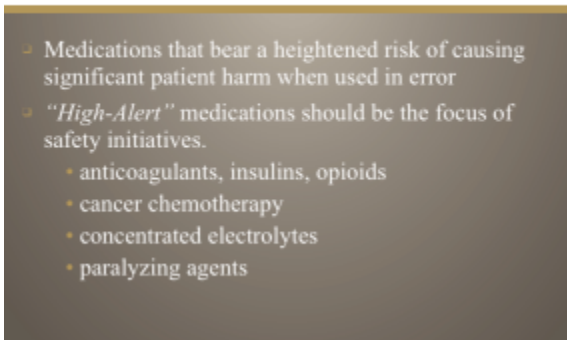


The entire healthcare team should be working to make medication use safer; this is not a role that can be delegated to a few people. A helpful tip is to promote the mindset where team members are always thinking, "What could go wrong with this?" when changes are introduced into their work routine or environment. As James Reason says, "We cannot change the human condition, but we can change the conditions under which humans work". (Reason J. Human error: models and management. *BMJ* 2000; 320:768-770. http://www.bmj.com/content/320/7237/768)

High-Alert Medications

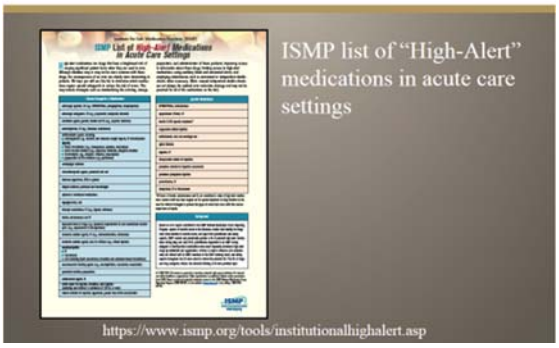
High-alert medications are those that bear a heightened risk of causing significant patient harm when they are used in error. High-alert (or high-risk) medications have a very narrow margin of safety and although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. Some high-alert medications are also narrow therapeutic index drugs, meaning that the difference between the therapeutic and toxic dose is small but not all high-alert medications are in this category. In the 2017 Medication Management standards, Accreditation Canada requires that hospitals address high-alert medications as a high priority.

Slide 61 **"*High-Alert*" medications**



ISMP publishes a list of high-alert medications for acute care settings. (Institute for Safe Medication Practices. ISMP's List of High-Alert Medications. www.ismp.org/Tools/highalertmedications.pdf). Lists are also available at the www.ISMP.org for long-term care and community/ambulatory care settings.

Slide 62 **"*High-Alert*" medications**



Common high-alert medications include:

- anticoagulants, such as heparin and warfarin;
- cancer chemotherapy agents;
- concentrated electrolyte solutions, such as potassium chloride;
- insulin;
- opioid analgesics, such as morphine, hydromorphone and fentanyl; and

- paralyzing agents (neuromuscular blockers).

The most common types of harm associated with these medications are an extension of their intended pharmacologic effects or known side effect profile; for example, anticoagulant overdoses cause serious bleeding, incorrect insulin doses cause either hypo or hyperglycemia; opioid overdoses cause respiratory depression.

Safeguards to reduce the risk of adverse events with high-alert medications include:

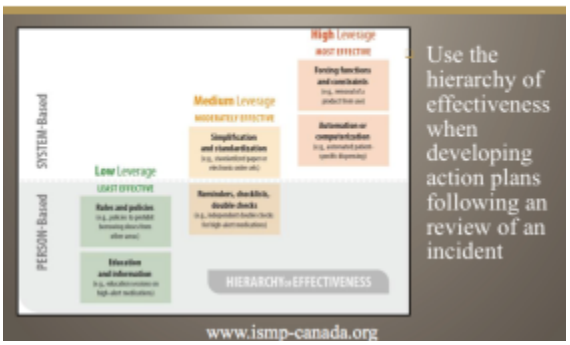
- limiting access (e.g., removing concentrated electrolytes, insulins and high-concentrations of opioids and heparins from ward stock, deploy automated dispensing cabinets);
- segregating high-alert medications from other medications with which they may be confused (e.g., storing paralyzing agents in separate containers in refrigerators);
- implementing independent double checks (or automated checks, such as bar code verification) prior to administration of all high-alert medications;
- standardizing procedures for ordering, preparing, and administering these products (e.g., using standard order sets and protocols);
- using auxiliary labels (e.g., Warning – paralyzing agent); and
- automated alerts in electronic systems coupled with clinical decision support systems that check for dosing limits (e.g., CPOE, pharmacy information system, "smart" pumps).

With the Medication Management standards, Accreditation Canada has helped raise awareness of the need for additional safeguards for high-alert medications.

Hierarchy of Effectiveness

It's important to recognize that certain types of risk-mitigation strategies are more effective than others. Person-based strategies, such as education and policy development, are most often implemented because they are relatively easy; however, they are also low leverage and are often not effective in preventing a recurrence of an incident. Mitigation strategies can be ordered by hierarchy of effectiveness as shown in Slide 63. Higher leverage strategies are always system-based and often require long term planning and capital investment. (Institute for Safe Medication Practices Canada. Designing Effective Recommendations. Ontario Critical Incident Learning. Issue 4, April 2013. https://www.ismp-canada.org/download/ocil/ISMPCONCIL2013-4_EffectiveRecommendations.pdf)

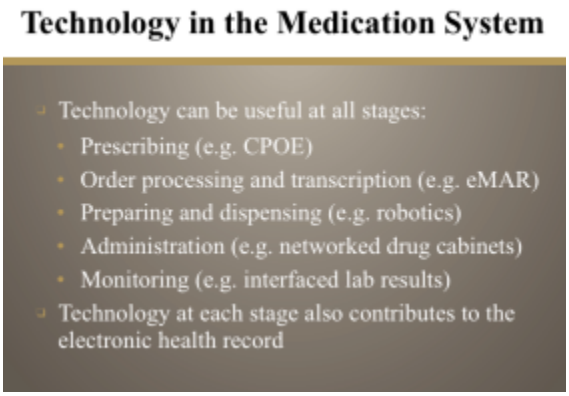
Slide 63



System-based recommendations have a higher likelihood of success because they do not rely on individual attention and vigilance. A small number of higher-leverage, more effective recommendations addressing the contributing factors determined from an incident analysis will be more likely to improve patient safety than a larger number of less effective strategies.
It is important to ensure that recommendations from an incident analysis are specific, measurable, attainable, realistic, and timely (SMART). Continuously monitor and assess the effectiveness of any recommendations arising from incident analyses is also critical as well as providing feedback to staff about quality and safety improvement initiatives and achievements undertaken.

Use of Technology in the Medication System

Slide 64



Judicious use of technology can be an important safeguard at all stages of the medication system to enhance medication safety. Various technologies are available to support each stage of the medication use process. (for more, see PSEP – Canada Module 6: Technology: Impact on Patient Safety).

However, any technology can introduce errors as well as prevent them. Problems associated with technology, such as overriding warnings produced by computerized systems, can undermine the safeguard provided by these systems. Usability testing by staff who will be using the technology PRIOR to purchase is one effective method of ensuring new technology will be compatible with existing organizational processes and achieve the desired outcomes.

Prior to introducing new technology, it is essential to evaluate existing processes to ensure that the technology will not introduce unexpected vulnerabilities into the process; and also that opportunities for process improvement are considered, rather than simply automating the existing process(es). Diligent incident reporting is key to monitoring unexpected effects of technology implementation. Sufficient resources for ongoing maintenance and staff support are critical to success with any technology.

Patient Safety Stakeholders

All stakeholders, from patients to organizational leaders, have responsibilities for ensuring medication safety. Each team member can take definitive actions and uphold safeguards in the medication use process. Many recommended strategies are outlined in the IOM's Quality Chasm Reports (Aspden P, Wolcott J, Bootman JL, Cronenwett LR, eds. Institute of Medicine. Preventing

medication errors: quality chasm series. Washington, DC: National Academy Press, 2006. http://www.iom.edu/?id=35961) - some of which are listed in the following section.

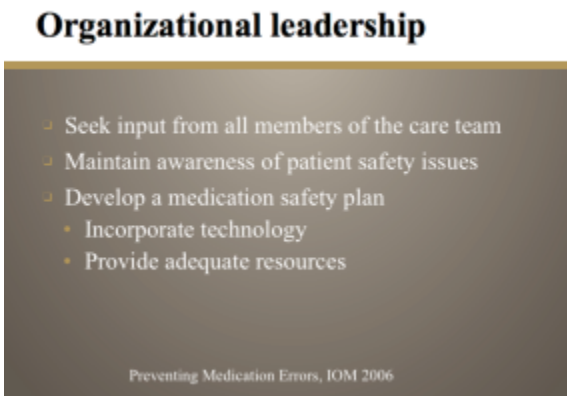
Slide 65

Organizational Leadership

Slide 66

There are steps that can be taken by organizational leadership to aid in reducing medication-related adverse events.

Slide 67



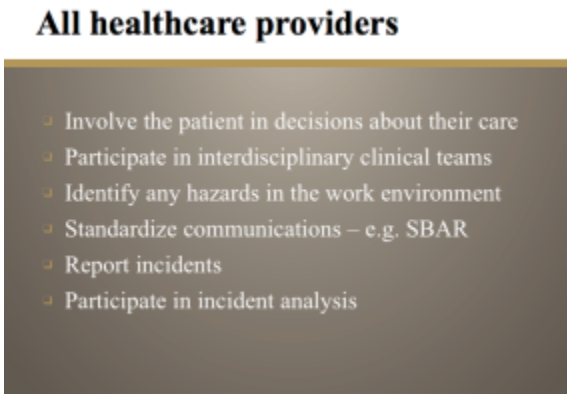
The senior leadership team can:

- promote the full engagement of patients and their families in improving the safety and effectiveness of medication use. (Preventing Medication Errors, IOM 2006);
- promote a culture of high reliability and provide strong leadership for multidisciplinary teams of clinicians and staff to work together to provide safe and effective care;
- model a "just culture", where staff are encouraged and expected to report safety concerns, and make good behavioural choices in their day to day work (e.g. focus on safety vs. speed);
- implement 'Leadership Walkrounds' to provide opportunity for staff to express their concerns and ensure issues brought forward are addressed. (Frankel A, Graydon-Baker E, Neppl C, et al. Patient Safety Leadership WalkRounds. *Jt Comm J Qual Saf*. 2003 Jan;29(1):16-26. https://psnet.ahrq.gov/resources/resource/1272/patient-safety-leadership-walkrounds);
- support the inclusion of patient safety as a core value of the organization, reflecting this position by including safe care in the organizational mission statement;
- devote resources to establishing safe work environments for all stages of the medication use process (e.g. appropriate lighting, reducing distractions, addressing workload issues);
- introduce system safeguards in the medication delivery process, such as simplifying and standardizing processes to reduce reliance on memory, reducing hand-offs, establishing forcing functions where possible, and developing standardized protocols and checklists;
- invest in well-designed technologies, such as computerized prescriber order entry (CPOE) with clinical decision support, bar code verification of medication dispensing and administration, and electronic health records, and ensure sufficient staffing to ensure appropriate use and ongoing maintenance; and
- foster ongoing monitoring and reporting of medication incidents and adverse drug events, including electronic monitoring and detection systems, spontaneous reporting to external agencies, and internal reporting for safety improvement purposes while providing resources for retrospective analysis of patient safety incidents and for prospective analysis (e.g., using Failure Mode and Effects Analysis) to target improvements before adverse events occur.

All Healthcare Providers

All healthcare providers must 'buy in" to the patient and family-centred care vision by engaging them as active partners in all decisions affecting their care.

Slide 68

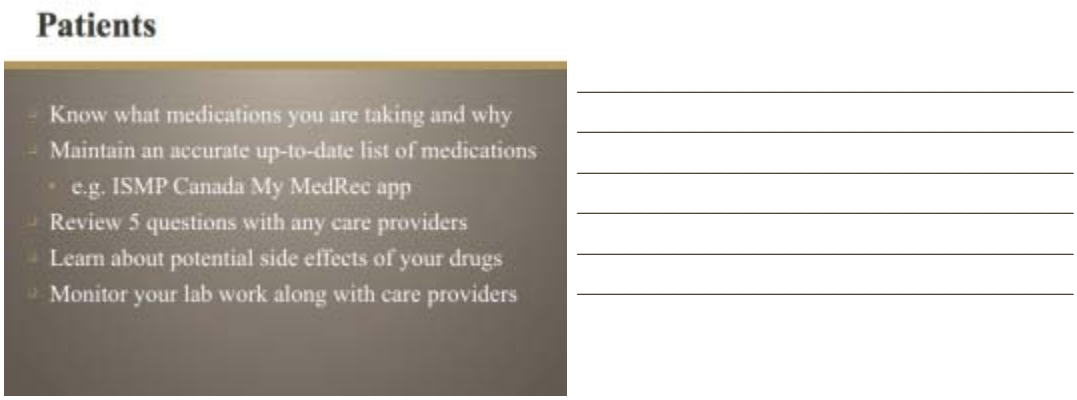


Medication safety efforts are not confined only to patient interactions. Healthcare providers can also take steps during interactions with other health professionals; for example:

- work as a team with other prescribers, pharmacists and nurses;
- standardize verbal and written communication about prescriptions within the practice and improve handoffs to other healthcare providers (e.g., SBAR - Situation, Background, Assessment, Recommendations);
- actively participate in reconciling medications and resolving discrepancies with patient records and share the list of medications (e.g,, Best Possible Medication History) with patients and other providers, especially at transition points (i.e., admission, transfer and discharge); and
- identify high-risk situations (e.g., when feeling stressed, sleep-deprived, frustrated or angry, or when supervising inexperienced personnel) and take appropriate action to avoid adverse patient outcomes, including acknowledging when unable to continue working and arranging for a replacement team member.

Patients

Slide 69



- maintain an up-to-date list of all your medications (prescribed, non-prescribed, over-the-counter complementary and alternative) e.g. ISMP Canada's app: MyMedRec; see: https://www.knowledgeisthebestmedicine.org/index.php/en/app/;
- bring the list of medications (and the medications in their original containers) to all visits with a provider for review; and
- use the brochure: *5 Questions to Ask About Your Medications*, in all settings such as:
    - at the doctor's office
    - in a care clinic
    - at the pharmacy
    - at the hospital

Barriers to Patient Engagement

Slide 70

Many patients are not comfortable taking an assertive role with their care providers and have not been made to feel that this is their role. Language and literacy barriers also need to be considered. Health status may also limit their ability to be fully engaged in care planning and decision-making.

There are also barriers on the provider side that inhibit the ability of providers to engage in an effective partnership with their patients (Cohen MR. Medication Error 2nd Edition. APHA Publications. 2007. http://www.ismp.org/products/medErrsEd2/default.asp). Sometimes, there is insufficient knowledge available about the risk, benefits, and use of drugs, and over-reliance on marketing materials for new knowledge about medications. Also, there is a lack of patient educational materials and resources to support providers in this capacity. Other barriers to the providers include:

- complex, burdensome, time-consuming, and changing documentation requirements associated with public and private reimbursement for services;
- overall lack of systems approach, including poor workflow design, inadequate use of information technologies, inadequate continuity of care, all of which compromise efficiency, effectiveness and safety; and
- attitude/cultural factors such as the lack of support and leadership required to change from the current hierarchical system to a culture of safety.

Incident Reporting

Slide 71

Incident reporting provides important opportunities to understand current system vulnerabilities and learn from system failures. The Canadian Medication Incident Reporting and Prevention System (CMIRPS), is a partnership between Health Canada, ISMP Canada and the Canadian Institute for Health Information (CIHI), supported by the Canadian Patient Safety Institute. ISMP Canada accepts reports from consumers (www.safemedicationuse.ca) and individual healthcare practitioners (www. https://www.ismp-canada.org/err_ipr.htm). Health service organizations can report incidents to the CIHI National System of Incident Reporting (NSIR). More information about NSIR is available at: https://www.cihi.ca/en/national-system-for-incident-reporting-nsir-faq .

Several provinces also have provincial patient safety reporting and learning systems.

Tools and Resources

A number of tools and resources are available to assist Canadian organizations and individual practitioners to assess vulnerabilities and identify and implement system-based strategies to enhance medication safety; a list of selected resources is available at the end of this module.

Summary

Slide 72

Current healthcare is not universally centred around patients and families, who are not fully engaged as full partners in their own healthcare plan.

Medication errors are a very common occurrence requiring ongoing awareness and attention.

Healthcare providers in all settings should seek to emulate **high reliability organizations** that constantly improve the safety and quality of medication use. To this end, they should **implement active internal monitoring programs** so that progress toward improved medication safety can be accurately demonstrated. (Preventing Medication Errors, IOM 2006)

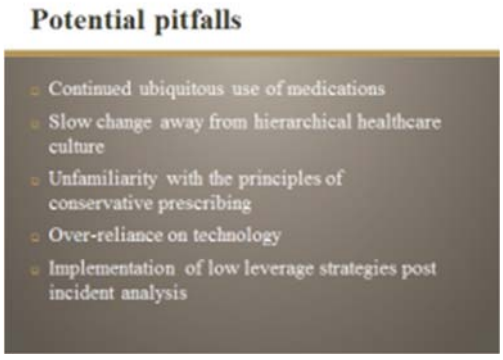
Medication safety is everyone's responsibility, starting with the organization's leaders who shape organizational culture and make resource allocation decisions; practitioners who prescribe, transcribe, dispense, administer and monitor the effects of medications; and including patients who receive medications from care providers and who also self-manage medications in the home.

Understanding the importance of the systems approach to medication management and the impact of human factors engineering principles on error potential and system design are foundational to patient safety and form the basis of processes for prospectively evaluating processes to prevent errors and learning from errors that have occurred in order to prevent recurrence. Those who work in healthcare can learn from high-reliability industries, such as aviation and nuclear power, where leaders and staff have learned to manage risk more effectively. A key concept present in high-reliability industries is "mindfulness" – reflecting that safety is always the "top of mind" priority. Continually ask "What can go wrong with this?"

Education and training are important components of safety awareness, but on their own are low leverage strategies because they rely on individual awareness and retention of specific information. Human factors principles focus on how to provide people with the information they need, when they need it; procedures are developed in such a way that steps follow a logical and intuitive sequence to reduce reliance on individual care and vigilance to prevent errors. Technology has great potential to assist in enhancing medication safety and patient safety in general; however it is important that sufficient resources are provided to test, maintain and monitor systems to avoid workarounds that circumvent the intended safeguards.

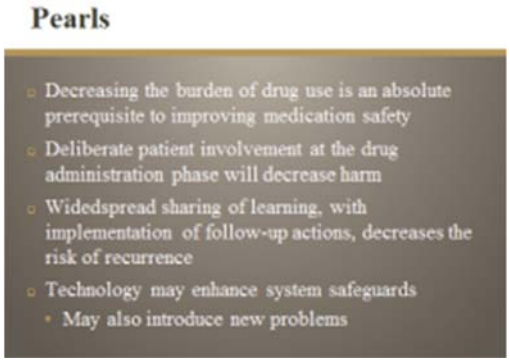
Potential Pitfalls

Slide 73



1. The continued ubiquitous use of medications.
2. Slow change away from hierarchical healthcare cultures.
3. Failure to actively engage and educate patients about medication use.
4. Unfamiliarity with the principles of conservative prescribing.
5. Over-reliance on technology: Technology is not a panacea for eliminating medication events. Technologies must be well designed and clinicians must be properly trained to ensure improved patient care.
6. Implementation of low-leverage strategies (e.g., reliance on education and policy development) post incident analysis will result in the continual recurrence of medication errors. Implementation of ineffective strategies post incident analysis is unlikely to be successful in avoiding recurrence of medication errors.

Slide 74



- Preventable harm due to medication use is a significant problem. Decreasing the burden of drug use is an absolute prerequisite to improving medication safety. Patients and family members should take an active role in their care and should expect to receive information related to their medication treatment. Patients and families also need to understand that all medication use carries a certain level of risk.
- Medication incidents are common in all healthcare settings and at all stages of the medication use process. The medication use system is complex; errors can occur at any of the five stages in the process – prescribing, order processing and transcription, dispensing, administration and monitoring. Deliberate patient engagement at the final administration phase will decrease the likelihood of harm due to errors.
- To achieve the safety levels that are seen in the airline industry, medication errors must be reported and analyzed, with liberal sharing of the learning to local, national and international audiences. ISMP Canada Safety Bulletins (https://www.ismp-canada.org/ISMPCSafetyBulletins.htm) and CPSI's Global Patient Safety Alerts (http://www.patientsafetyinstitute.ca/en/NewsAlerts/Alerts/Pages/default.aspx) are examples of sharing mechanisms.
- Technologies appropriate for each stage of the medication use process should be adopted with sufficient resources for ongoing support and maintenance.

Slide 75

Toolkits and Resources

Refer to the Toolkit and Resource Compendium (PSEP – Canada Appendix 1c) for additional resources.

- **Canadian Medication Incident Reporting and Prevention System (CMIRPS) Program**: The Canadian Medication Incident Reporting and Prevention System (CMIRPS) Program has been developed through the collaborative efforts of Health Canada, the Institute for Safe Medication Practices Canada (ISMP Canada), and the Canadian Institute for Health Information (CIHI), with input from stakeholders across Canada. http://www.patientsafetyinstitute.ca/English/toolsResources/ReportingAndLearning/CanadianMedicationIncidentReportingAndPreventionSystem/Pages/default.aspx

  Système canadien de déclaration et de prévention des incidents médicamenteux (SCDPIM); https://www.ismp-canada.org/fr/scdpim.htm

- **ISMP Canada Safety Bulletins;** published 10 times per year; see: https://www.ismp-canada.org/ISMPCSafetyBulletins.htm ; francais: https://www.ismp-canada.org/fr/dossiers/bulletins/

- **CPSI Global Patient Safety Alerts:** Alerts, advisories, and recommendations from patient safety, quality, and healthcare organizations from around the world. See: http://www.patientsafetyinstitute.ca/en/NewsAlerts/Alerts/Pages/default.aspx

  Alertes mondiales sur la sécurité des patients; http://www.patientsafetyinstitute.ca/fr/newsalerts/alerts/pages/default.aspx

- **Medication Safety Self-Assessment® (MSSA) programs** are available from ISMP Canada for acute care, long-term care, home care, and community and ambulatory pharmacy. Several specialty assessments are also available, including a Medication Safety Checklist for the Operating Room, an MSSA for Oncology and for Anticoagulant Safety. More information on Medication Safety Self-Assessment Programs is available from: https://www.ismp-canada.org/mssa.htm. https://www.ismp-canada.org/ISMPCSafetyBulletins.htm

- **The Canadian Incident Analysis Framework (CIAF)**, released in 2012, replaced the 2006 Canadian Root Cause Analysis Framework. The CIAF was developed collaboratively by the Canadian Patient Safety Institute, the Institute for Safe Medication Practices Canada, Saskatchewan Health, Patients for Patient Safety Canada (a patient-led program of the Canadian Patient Safety Institute), Paula Beard, Carolyn E. Hoffman and Micheline Ste-Marie. The CIAF is a resource to support those responsible for, or involved in, managing, analyzing and/or learning from patient safety incidents in any healthcare setting with the goal of increasing the effectiveness of analysis in enhancing the safety and quality of patient care. The CIAF can be downloaded from: http://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF

- **Canadian Incident Analysis Framework online toolkit:** is a set of online resources developed to supplement the Canadian Incident Analysis Framework document. See: http://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Pages/Tools.aspx

- **The Canadian Failure Mode and Effects Analysis Framework: Proactively Assessing Risk in Healthcare,** Version 2, was released in 2017. This framework is intended to be used by interdisciplinary teams and focuses on preventing adverse events through proactive identification and correction of system vulnerabilities. More information is available at: https://www.ismp-canada.org/fmea.htm.

- **Getting Started Kits for Medication Reconciliation** have been developed by ISMP Canada with support from CPSI. See below and https://www.ismp-canada.org/medrec/ for additional resources

    - **Medication Reconciliation in Acute Care**: Getting Started Kit (Version 4, 2017); available from: https://www.ismp-canada.org/download/MedRec/MedRec-AcuteCare-GSK-EN.pdf; Le bilan comparatif des médicaments en soins aigus: trousse de depart (Version 4); disponible depuis: https://www.ismp-canada.org/download/MedRec/MedRec-AcuteCare-GSK-FR.pdf
    - **Medication Reconciliation in Long Term Care**: Getting Started Kit (Version 3, 2017). Available from: https://www.ismp-canada.org/download/MedRec/MedRec-LTC-GSK-EN.pdf; Le bilan comparatif des médicaments pour les soins de longue durée trousse de depart (Version 3, 2017); disponible dupuis: https://www.ismp-canada.org/download/MedRec/MedRec-LTC-GSK-FR.pdf
    - **Medication Reconciliation in Home Care**: Getting Started Kit (Version 2, 2015); available from: https://www.ismp-canada.org/download/MedRec/Medrec_HC_English_GSK_v2.pdf; Le bilan comparatif des médicaments en soins à domicile trousse de depart (Version 2, 2015): disponible depuis: https://www.ismp-canada.org/download/MedRec/Medrec_HC_French_GSK_v2.pdf

    Paper to electronic Med Rec implementation Toolkit, 2nd edition, 2017; available from: https://www.ismp-canada.org/download/MedRec/PtoE/Paper_to_Electronic_MedRec_Implementation_ToolKit.pdf. ; Boîte à outils pour le remplacement du bilan comparatif des medicaments sur papier par sa version électronique (2e edition, 2017); disponible dupuis: https://www.ismp-canada.org/download/MedRec/PtoE/Paper-to-Electronic-MedRec-Implementation-ToolKit-FR.pdf

    - **Med Safety Exchange Webinars** – ISMP Canada and CPSI; https://www.ismp-canada.org/MedSafetyExchange/
    - **Opioid stewardship**; infographics and other resources: https://www.ismp-canada.org/opioid_stewardship/

Consumer programs for medication safety:

- **SafeMedicationUse.ca:** newsletters and alerts designed specifically for consumers; see: https://www.safemedicationuse.ca/

  MédicamentSécuritaires.ca; http://www.medicamentssecuritaires.ca/

- **Knowledge is the Best Medicine.** (Consumer awareness program designed to promote healthy living and educate Canadians about the safe and appropriate use of medicines and vaccines) Available from: https://www.knowledgeisthebestmedicine.org/index.php/en/ ; francais: https://www.knowledgeisthebestmedicine.org/index.php/fr/

- **MyMedRec app:** https://www.knowledgeisthebestmedicine.org/index.php/en/app/; francais: https://www.knowledgeisthebestmedicine.org/index.php/fr/application/

ISMP (United States)

- **Medication safety newsletters**; see: http://www.ismp.org/Newsletters/default.asp
- **Guidelines** have been developed on a variety of topics; see: http://www.ismp.org/Tools/guidelines/default.asp
- **Targeted Medication Safety Best Practices for Hospitals**; see: http://www.ismp.org/Tools/BestPractices/Default.aspx

  The Targeted Medication Safety Best Practices for Hospitals were developed to identify, inspire, and mobilize widespread adoption of consensus-based best practices for specific medication safety issues that continue to cause fatal and harmful errors.

References

Accreditation Canada. Required Organizational Practices Handbook, February 2017. Available from: https://store.accreditation.ca/products/required-organizational-practices-handbook-2017-version-2

Aspden P, Wolcott J, Bootman JL, Cronenwett LR, eds. Institute of Medicine. Preventing medication errors: quality chasm series. Washington, DC: National Academy Press, 2006. http://www.iom.edu/?id=35961.

Baker GR, Dennis JL. A Comparative Study of Three Transformative Healthcare Systems: Lessons for Canada, Canadian Health Services Research Foundation, Sept 2011. www.chsrf.ca.

Baker GR, Norton PG, Flintoft V, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ*. 2004 May 25;170(11):1678-86. http://www.cmaj.ca/content/cmaj/170/11/1678.full.pdf

Bennett J, Harper-Femson LA, Tone J, Rahmohamed Y. Improving medication administration systems: an evaluation study. *Canadian Nurse*. 2006;102(8):35-9.

Bootman JL, Cronenwett LR. Co-Chairs. Committee on Identifying and Preventing Medication Errors, Institute of Medicine. Preventing Medication Errors, Institute of Medicine (IOM) July 2006. The National Academies Press: http://nap.edu/11623

Camiré E, Moyen E, Stelfox HT. Medication errors in critical care: risk factors, prevention and disclosure. *CMAJ*. 2009;180(9):936-43. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2670906/?tool=pubmed.

Canadian Deprescribing Network. Deprescribing Fact Sheet for patients. http://deprescribing.org/CADEN/

Canadian Patient Safety Institute, Canadian Institute for Health Information. Measuring Patient Harm in Canadian Hospitals 2016. http://www.patientsafetyinstitute.ca/en/toolsResources/Hospital-Harm-Measure/Documents/CIHI%20CPSI%20Hospital%20Harm%20Report%20EN.pdf

Canadian Patient Safety Institute, Institute for Safe Medication Practices Canada, Patients for Patient Safety Canada, Canadian Pharmacists Association, Canadian Society for Hospital Pharmacists. 5 Questions to Ask About Your Medications. Institute for Safe Medication Practices Canada 2016. https://www.ismp-canada.org/medrec/5questions.htm.

Cohen MR. Medication Error 2nd Edition. APHA Publications.2007. http://www.ismp.org/products/medErrsEd2/default.asp

Davis D, Thomson O'Brien MA, Freemantle N, et al. Impact of Formal Continuing Medical Education: Do Conferences, Workshops, Rounds, and Other Traditional Continuing Education Activities Change Physician Behavior or Health Care Outcomes? *JAMA* 1999;282(9):867-874. http://www.med.unc.edu/aging/fellowship/current/curriculum/research-academic-work/qi-work/QI_and_CME.pdf

Field TS, Gilman BH, Subramanian S, et al. The costs associated with adverse drug events among older adults in the ambulatory setting. *Med Care*. 2005 Dec;43(12):1171-6. https://www.ncbi.nlm.nih.gov/pubmed/16299427

Frankel A, Graydon-Baker E, Neppl C, et al. Patient Safety Leadership WalkRounds. *Jt Comm J Qual Saf*. 2003 Jan;29(1):16-26. https://psnet.ahrq.gov/resources/resource/1272/patient-safety-leadership-walkrounds

Gurwitz JH, Field TS, Judge J, et al. The incidence of adverse drug events in two large academic long-term care facilities. Am J Med. 2005 Mar;118(3):251-8 https://www.sciencedirect.com/science/article/pii/S0002934304007181

Health Canada. Good Label and Package Practices Guide for Prescription Drugs. June 2016. https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-prescription-drugs.html.

Health Canada. Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products. May 2017. https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-non-prescription-drugs-natural-health-products.html

Institute for Healthcare Improvement. Dispense Medications in Ready-to-Use Single Doses. http://www.ihi.org/resources/Pages/Changes/DispenseMedicationsinReadytoUseSingleDoses.aspx

Institute for Safe Medication Practices Canada. Death Due to Pharmacy Compounding Error Reinforces Need for Safety. *ISMP Medication Safety Alert!*. Volume 17 • Issue 5 • May 25, 2017. https://www.ismp-canada.org/download/safetyBulletins/2017/ISMPCSB2017-05-Tryptophan.pdf.

Institute for Safe Medication Practices Canada. The Second Victim: Sharing the Journey toward Healing. *ISMP Medication Safety Alert!*. Volume 17 • Issue 9 • October 31, 2017. https://www.ismp-canada.org/download/safetyBulletins/2017/ISMPCSB2017-10-SecondVictim.pdf.

Institute for Safe Medication Practices Canada. Collaborating parties to the development and implementation of the Canadian Medication Incident Reporting and Prevention System: Institute for Safe Medication Practices Canada, Canadian Institute for Health Information and Health Canada, 2001. http://www.ismp-canada.org/definitions.htm.

Institute for Safe Medication Practices Canada. Misconceptions about Medicines That Could Be Deadly: Part 1. SafeMedicationUse.ca Newsletter. Volume 7 • Issue 1 • January 18, 2016. https://safemedicationuse.ca/newsletter/downloads/201601NewsletterV7N1Misconception1Storage.pdf

Institute for Safe Medication Practices Canada. Misconceptions about Medicines That Could Be Deadly: Part 2. SafeMedicationUse.ca Newsletter. Volume 7 • Issue 4 • May 31, 2016. https://safemedicationuse.ca/newsletter/downloads/201605NewsletterV7N4Misconception2ExtraDoses.pdf

Institute for Safe Medication Practices Canada. Misconceptions about Medicines That Could Be Deadly: Part 3. SafeMedicationUse.ca Newsletter. Volume 7 • Issue 5 • June 7, 2016. https://safemedicationuse.ca/newsletter/downloads/201606NewsletterV7N5Misconception3SharingMedicines.pdf

Institute for Safe Medication Practices Canada. Unexpected hypoglycemia . Consider medication error in the differential diagnosis. ISMP Canada Safety Bulletin, March 30, 2007. https://www.ismpcanada.org/download/safetyBulletins/ISMPCSB2007-01Hypoglycemia.pdf.

Institute for Safe Medication Practices. QuarterWatch, First Quarter 2011, Signals For Dabigatran And Metoclopramide, ISMP Medication Safety Alert, Jan 2012. http://www.ismp.org/Newsletters/acutecare/showarticle.aspx?id=12.

Institute for Safe Medication Practices Canada. Removing Medicines from Original Packaging Can Lead to Errors. Safe-MedicationUse.ca Alert, Feb 22, 2011. https://www.safemedicationuse.ca/alerts/dowloads/ISMPC_alert_2011_02.pdf.

Institute for Safe Medication Practices Canada. Look-Alike Gravol Ginger Product Causes Confusion for Consumers. SafeMedicationUse.ca alert August 17, 2010. https://www.safemedicationuse.ca/alerts/alerts_gravol.html.

Institute for Safe Medication Practices Canada. Do Not Use Dangerous Abbreviations, Symbols and Dose Designations, July 2006. http://www.ismp-canada.org/download/ISMPCanadaListOfDangerousAbbreviations.pdf.

Institute for Safe Medication Practices. ISMP 2018-2019 Targeted Medication Safety Best Practices for Hospitals. http://ismp.org/Tools/BestPractices/TMSBP-for-Hospitalsv2.pdf

Institute for Safe Medication Practices Canada. System Vulnerabilities across the Spectrum of Care: Another Mix-up between Choral Hydrate and Potassium Chloride, *ISMP Canada Safety Bulletin*, Sept 15, 2005: https://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2005-07ChloralHydrate.pdf.

Institute for Safe Medication Practices. The five rights: A destination without a map. *ISMP Medication Safety Alert!*. 2007;12(2). http://www.ismp.org/newsletters/acutecare/articles/20070125.asp

Institute for Safe Medication Practices Canada. Report of a Near Miss With Succinylcholine Warrants Action. *ISMP Canada Safety Bulletin*, April 2005. https://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2005-04Succinylcholine.pdf.

Institute for Safe Medication Practices Canada. Fluorouracil Root Cause Analysis. http://www.ismp-canada.org/download/reports/FluorouracilIncidentMay2007.pdf.

Institute for Safe Medication Practices Canada. ALERT: Potential for "Key Bounce" with Infusion Pumps. *ISMP Canada Safety Bulletin*. 2006;6(6):1-2. http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2006-06KeyBounce.pdf.

Institute for Safe Medication Practices Canada. Infusion Pumps – Opportunities for Improvement. *ISMP Canada Safety Bulletin*. 2003;3(7):1-2. http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2003-07InfusionPumps.pdf.

Institute for Safe Medication Practices Canada. Infusion Pump Project: Survey Results and Time for Action. *ISMP Canada Safety Bulletin*. 2004;4(1):1-2. http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2004-01InfusionPump.pdf.

Institute for Safe Medication Practices Canada. Drug Interaction Incident with HIV Post-exposure Prophylaxis. *ISMP Canada Safety Bulletin*. 2008;8(3):1-2. http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2008-03HIVPEP.pdf.

Institute for Safe Medication Practices. ISMP's List of High-Alert Medications. www.ismp.org/Tools/highalertmedications.pdf.

Institute for Safe Medication Practices Canada. Designing Effective Recommendations. Ontario Critical Incident Learning. Issue 4, April 2013. https://www.ismp-canada.org/download/ocil/ISMPCONCIL2013-4_EffectiveRecommendations.pdf.

Institute for Safe Medication Practices. FDA and ISMP Lists of Look-Alike Drug Names with Recommended Tall Man Letters, 2011. http://www.ismp.org/Tools/tallmanletters.pdf. Accessed July 2011.

Institute for Safe Medication Practices Canada. Application of TALLman lettering for Drugs Used in Oncology. *ISMP Canada Safety Bulletin*. 2010;10(8). http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2010-08-TALLmanforOncology.pdf.

Institute for Safe Medication Practices Canada. Removing Medicines from Original Packaging Can Lead to Errors. *SafeMedicationUse.ca Alert*. 2011;2(1). http://www.safemedicationuse.ca/alerts/downloads/ISMPC_alert_2011_02.pdf.

Institute for Safe Medication Practices Canada. Look-Alike Gravol Ginger Product Causes Confusion for Consumers. *SafeMedicationUse.ca Alert*. 2011;1(3). http://www.safemedicationuse.ca/alerts/alerts_gravol.html.

Khanna R, Yen T. Computerized Physician Order Entry: Promise, Perils, and Experience. The Neurohospitalist, 2014,Vol 4(1), 26-33. http://journals.sagepub.com/doi/abs10.1177/1941874413495701?journal-Code=nhoa

Kohn LT, Corrigan JM, Donaldson MS, eds. To Err Is Human: Building a Safer Health System. Institute of Medicine Committee on Quality of Health Care in America. National Academy Press, Washington DC; 1999. http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf

Lahey T. The High Costs of "Free" Drug Samples, *Clinical and Translational Gastroenterology*, (2014) 5, e67; doi:10.1038/ctg.2014.16. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4274368/

Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA*. 1995 Jul;274(1):35-43. https://jamanetwork.com/journals/jama/article-abstract/389137?redirect=true.

Likic R, Maxwell S. Prevention of Medication Errors: teaching and training. *Br J Clin Pharmacol* March 2009. http://europepmc.org/articles/PMC2723205

Martin AM, Daniel M. Medical error - the third leading cause of death in the US. BMJ 2016;353:i2139. http://www.bmj.com/content/353/bmj.i2139

Miller GA. The magical number seven, plus or minus two: some limits on our capacity for processing information. *Psychological Review.* 1956;63(2):81-97. http://psychclassics.yorku.ca/Miller/

Moyen E, Camire E, Stelfox HT. Clinical review: Medication errors in critical care. Critical Care 2008,12:208 https://ccforum.biomedcentral.com/articles/10.1186/cc6813

Olkkola KT, Palkama VJ, Neuvonen PJ. Ritonavir's role in reducing fentanyl clearance and prolonging its half-life. *Anesthesiology* 1999 Sep;91(3):681-5. https://www.ncbi.nlm.nih.gov/pubmed/10485779

Orser B. Reducing medication errors. *CMAJ Canadian Medical Association Journal*. 2000; 162(8):1150-1. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1232368/?tool=pubmed.

The Patented Medicine Prices Review Board. Annual Report 2016. Available at http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1334.

Pharmacy-nursing shared vision for safe medication use in hospitals: executive session summary. *Am J Health Syst Pharm* 2003;60:1046-52. https://www.medscape.com/viewarticle/455700

Potter P, Boxerman S, Wolf L, et al. An Analysis of Nurses' Cognitive Work: A New Perspective for Understanding Medical Errors. Advances in Patient Safety 2004;1:39-51. https://www.ahrq.gov/downloads/pub/advances/vol1/Potter.pdf

Reason B, Terner M, McKeag AM, et al. The impact of polypharmacy on the health of Canadian seniors. Family Practice 2012; 29: 427-432. http://fampra.oxfordjournals.org/content/early/2012/01/05/fampra.cmr124

Reason J. Human error: models and management. *BMJ* 2000; 320:768-770. http://www.bmj.com/content/320/7237/768

Schiff GD, Galanter WL, Duhig J, et al. Principles of Conservative Prescribing. *Arch Intern Med* 2004;164:785-792 https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1105913

Statistics Canada, Health Reports, June 2014, Prescription medication use by Canadians aged 6 to 79. http://www.statcan.gc.ca/pub/82-003-x/2014006/article/14032-eng.pdf.

The Patented Medicine Prices Review Board. Annual Report 2016. Available at http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1334.

The Patented Medicine Prices Review Board. Annual Report 2015. Available at http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1273.

The Patented Medicine Prices Review Board. Annual Report 2014. Available at http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1217.

The Patented Medicine Prices Review Board. Annual Report 2013. Available at http://www.pmprb-cepmb.gc.ca/view.asp?ccid=938.

The Patented Medicine Prices Review Board. Annual Report 2012. Available at http://www.pmprb-cepmb.gc.ca/view.asp?ccid=892.

World Health Organization. Medication Without Harm - Global Patient Safety Challenge on Medication Safety. Geneva: World Health Organization, 2017. http://www.who.int/patientsafety/medication-safety/en/

World Health Organization. Medication Errors: Technical Series on Safer Primary Care. Geneva: World Health Organization; 2016. http://apps.who.int/iris/bitstream10665/252274/1/9789241511643-eng.pdf

World Health Organization. Drug Information Vol. 14, No. 1, 2000. http://apps.who.int/medicinedocs/en/d/Jh1462e/1.html

Wu A. Medical error: the second victim. BMJ 2000;320:726. Available from: http://www.bmj.com/content/320/7237/726

Principal message

The single most important message your audience should come away with is that *there are many error prone features of the medication use process*. As a part of this insight, the participant should realize that *all members of the healthcare team plus patients, families and healthcare administrators have a role in improving medication safety*.

Module overview

Adverse drug events are one of the most common type of medical errors. The medication use process is a highly complex system involving physicians, nurses, pharmacists, patients, and their caregivers, all of whom play a role in ensuring medication safety. Additionally, senior hospital management play a critical role by fostering a safety culture and investing in well-designed technology. Despite the best efforts of the individuals involved, improved medication safety requires a systems approach to analyzing sources of error at each step of the medication use process.

This module introduces the frequency of medication-related events and the cultural aspects that help fuel the problem; it describes the medication system and some common vulnerabilities; and explores strategies for improving medication safety, including the essential and most important need for engaging patients in their care and in the design of their care.

Preparing for a presentation

1. Assess the needs of your audience

Choose from the material provided in the module according to the needs of your expected participants. It is better for participants to come away with a few new pieces of information, well learned, than to come away with a deluge of information from which they can remember little or nothing.

2. Presentation timing

The suggested timing for each part of this module is:

Introduction	5 minutes
Trigger tape & discussion	10 minutes
Presentation	30 minutes
Debrief about teaching methods	5 minutes
Summary	10 minutes
Total	60 minutes

3. Number of slides: 75

4. Preparing your presentation

The text in the module was not designed to be used as a prepared speech. Instead, the text provides material you may want to use. The slides have been designed to trigger your presentation. Although the slides closely follow the text of the module, they do not contain all of the content. Their use presumes that you have mastered the content.

You may want to make notes on the slide summary pages to help you prepare your talk in more detail and provide you with notes to follow during your presentation.

Remember that you can adjust the slides to suit your presentation content, your style, and to make it feel fully familiar and your own.

Practice your presentation using the slides you have chosen, and speaking to yourself in the kind of language you expect to use, until it is smooth and interesting and takes the right amount of time. The most accomplished presenters and teachers still practice prior to a presentation; don't miss this step.

5. Preparing a handout for participants

The module text and slides were designed to be reproduced and provided to participants as a handout. Take the portion you need; they can be used in their entirety, module by module, or for just one specific topic. Please ensure to acknowledge the source of the material, the PSEP – Canada Acknowledgment Page at the front of the module provides the formal citation.

6. Equipment needs

- Screen, computer and projector
- Flipchart and markers for recording discussion points

Test your equipment beforehand to ensure that it works.

Review your video to assess which portions you would like to use.

Have a back-up plan so that if there is any equipment failure you can move without panic to your back-up plan. For instance, have in mind that:

- if the video fails, you can read the vignette of the trigger tape story;
- if the slides cannot be shown, you can refer to the hand out slides; and
- if the markers do not work, you can have participants list items on their hand outs that you would have written up for all to see.

Making the presentation

1. Introduce yourself

If you have not already done so, introduce yourself. Include your name, title, and the organization(s) you work for. Briefly describe your professional experience related to the information you will be presenting.

2. Introduce the topic

Show the title slide for the module. To establish the context for the session, make a few broad statements about the importance of topic as a patient safety matter. Tell participants the format and time you will take to present the session. Identify the teaching styles that you intend to use.

3. Review the session objectives

Show the slide with the session objectives listed. Read each objective and indicate those that you are planning to emphasize.

4. Show the trigger tape

After reviewing the objectives for the session, show the trigger tape. The trigger tape should engage the audience and provide appropriate context for the session. The trigger tape does not need to demonstrate an ideal interaction, but to "trigger" discussion.

Trigger tape content

A chemotherapy dosage error results in the death of Betsy Lehman, a health reporter for the *Boston Globe*. Jim Conway, incoming Chief Operating Officer at the time, describes the impact of a high-profile patient death on the institution, and the wake-up call it sent to the medical community at large. He also describes measures taken to prevent similar dosage errors in the future.

Keep in mind that the facilitator may choose to use any one of the trigger tapes for this cluster of modules. Since the vignettes are rich and overlap in their teaching points, it may make sense to do this, for instance if an audience has seen the trigger tape already or if a trigger tape from another module is easier for the audience to identify with.

A teachable moment: discussion after the trigger tape

After the trigger tape, ask the participants for their comments about the issues and the interaction they have just seen. To affirm what they contribute, consider recording the important points on a flipchart.

If the discussion is slow to start, you may want to ask more direct questions, like:

- Has serious patient harm resulting from a medication incident ever occurred in your institution? How did you deal with it?
- What specific problems have you encountered in the medication use process?
- How does your organization use technology to improve medication safety? Have there been instances were technology was harmful rather than helpful?
- What barriers have you encountered in improving medication safety?

Use the discussion to set the stage for the material to follow. Do not let the discussion focus on a critique of the technical quality of the video or how "real" the players seemed. If the participants do not like something that was said or done in the video, acknowledge that there is always room for improvement and ask them how they would do it themselves.

Setting limits to discussion time

It is usually best to limit discussion of the video to no more than five minutes, then move on to the presentation. To help move on if the discussion is very engaged, try saying something like:

- let's hear two last points before we move on, and
- now that you have raised many of the tough questions, let's see how many practical answers we can find.

For the more advanced facilitator who is very confident of both the patient safety material and his or her pedagogic skills, it is possible to use the trigger tape as a form of case-based teaching and to facilitate the discussion to draw out the teaching points of the module. The hazard of this approach is that the discussion will not yield the desired teaching points. Feel free to return to the slides if this happens. If this approach is used, it is essential to write up the points on a flip chart as they arise, to fill in any gaps and to summarize at the end.

5. Present the material

Recommended style: interactive lecture

An interactive lecture will permit you to engage your audience, yet cover your chosen material within the time. You can use as your interactive components the trigger tape stimulated discussion and an interactive exercise. To foster discussion, ask participants for examples from their institutions or experiences. Look for examples of both failed and successful technology implementations, focusing on the underlying reasons for failure or success of each case. Ideally, the examples could be linked to one of the major teaching points.

Interactive exercise

Case-based teaching

Use the case below and/or the trigger tape as a guide to delivering key teaching points from the module. To help participants feel involved and invested, you may invite them to give you a case from their institution or experience. However, it is usually best to return to the given case or the trigger tape to draw out analytic points for teaching since the case is known to you and you do not need to 'think on your feet' too much.

Case example

Barbara, a 67-year-old woman, has breast cancer and is participating in a dose-escalating phase 1 clinical trial in which higher-than-normal doses of cyclophosphamide, a toxic chemotherapy agent, are administered. Barbara has been responding well to the treatment during the first two rounds of therapy. While at a cancer center for her third round of therapy, Barbara receives the wrong dose of cyclophosphamide. Even though the correct dose is supposed to be a total of 4,000 mg/m^2 infused over a 4-day period (or 1,000 mg/m^2 each day for 4 days), a physician fellow writes the order as "4,000 mg/m^2 x 4 days." While the clinical trial protocols are not easily available, the physician fellow does not have time to find and double check the dosage due to patient workload. The dispensing pharmacist has more-than-normal workload that day and does not check the dosage before dispensing the chemotherapy agent. The existing computer systems does not check for overdosing or alert to the pharmacist of any inconsistencies among the different rounds of therapy.

When the drug arrives, the charge nurse sees the higher-than-normal doses that Barbara is receiving compared to other patients in the clinical trial. The clinical trial protocols, however, are not easily available to the nurse. The nurse also cannot double check the dosages for Barbara in the medication administration records because the notations are not clearly written. In addition, without any standard protocol to follow, the nurse does not question the attending physician or the fellow, thinking that it is not her place to question the physician's prescribed order. The erroneous dosing has gone unnoticed, and Barbara suffers multiple seizures and dies a few days later due to the overdose. It is another ten weeks after the incident before the error is discovered when her treatment data for the clinical trial are entered into the computer.

Key teaching points – common problems in the medication use process

This case can be used to highlight the errors that occur at each stage of the medication use process. You may want to ask the participants to try to come up with these errors on their own. For the above case, the following key factors contributed to the error:

Problems in Prescribing

- Physician fellow had insufficient experience in prescribing cyclophosphamide and did not know the maximum dosage allowable for this chemotherapy agent.
- Physician fellow did not double check the doses prescribed to Barbara in her previous rounds of therapy.
- An attending physician did not double check and sign off the order written by the physician fellow.
- Clinical trial protocols were not clear, not current, and not easily available to the physician fellow at the prescribing stage.
- In a stressful work environment, the physician fellow was not able to double check the prescription.

Problems in Transcribing and Ordering

- Some dosages were written in total dose while others in daily dose formats, often in the same protocol.
- Double-checks were minimal.

Problems in Preparing and Dispensing

- Clinical trial protocols were not clear, not current, and not easily available to the pharmacists at the dispensing stage.
- The pharmacy computer system did not check for maximum allowable dosages or alert the pharmacist of any inconsistencies in prescriptions.
- Due to more-than-normal workload, the dispensing pharmacist did not check the dosage before dispensing the chemotherapy agent.

Problems in Administering

- Illegible handwritten documentation in the medication administration records prevented the nurse from double checking dosage information from previous rounds of therapy.
- Clinical trial protocols were not clear, not current, and not easily available to the nurses or to Barbara and her family at the administration stage.
- Work-related factors, such as distractions and caseload, compromised the minimum required standard of care that should have been provided, such as reviewing patient medical records or administering drugs.

- The lack of standard procedure and limited communication channels across hierarchical levels inhibited nurses from questioning prescribing decisions made by the physicians.

Problems in Monitoring

- The nurse initially was not aware of Barbara's deteriorating health condition as a reaction to the overdose and therefore did not inform the physician right away.
- It took 10 weeks after the incident before the overdose error was discovered. Protocols for reporting were not clear to the healthcare team or Barbara's family. When reporting did occur, it did not move up the organization in a timely manner.
- Barbara and her family were not aware of their rights as patients and were not informed of what actions they could take to pursue an investigation.

Key teaching points – safeguards to prevent medication errors

This case can be used to highlight the safeguards that can be implemented to prevent medication errors. You may want to ask the participants to try to come up with these safeguards on their own. For the above case, the following are specific examples of safeguards that can prevent the adverse event from reoccurring:

Educate Patients and Surrogates on Drug Information

- Every patient should be notified of his/her rights to be informed, to play an active role in their care, and to question their providers about their care and treatment received.

All Stakeholders Should Take Definitive Actions

- Attending physicians should sign off on all cancer chemotherapy prescriptions.
- Dosages should be written in terms of daily dose.
- Written documentation of any drugs in the medication administration records should be double-checked between shifts.
- Clinicians who enter information into patient records should write their names in capital block letters so that follow-up inquiries can be conducted, if necessary.
- All members of the healthcare team, administrative or clinical, should be explicitly authorized by senior management to perform independent checks of prescribed doses, and to question openly any presumed dosing error.
- The work environment should be improved by adding additional healthcare staff to alleviate workload and giving pharmacists their own working station to minimize unnecessary distractions.

Invest in Well-Designed Technology

- The computerized provider order system should be extensively supported by online protocols and templates.
- Computer system warnings should prevent physicians from placing drug orders that exceed the maximum limit. Alerts, such as a red "WARNING: HIGH CHEMOTHERAPY DOSE," should appear on the screen. To override the computer, physicians must document new scientific findings that prove a higher dose may be safe and effective for the patients at hand.
- Electronic surveillance systems should monitor patients around the clock and detect some adverse drug events early enough to prevent their progression.

6. Key take-home points

1. The drug use process is a complex system. Problems can occur at any of the five stages in the process – prescribing, transcribing and ordering, dispensing, administering, and monitoring.
2. Patients and family should take active roles in their care and should be educated on drug-related information related to the treatment they receive.
3. All stakeholders of the healthcare team, both clinical and administrative, should take definitive action toward ensuring medication safety.
4. Well-designed technologies should be adopted with proper on-going maintenance and appropriate use at each stage of the medication use process.
5. Medication incidents are common across healthcare settings and special attention should target high-alert medications that have the highest risk for patient harm.
6. Clinicians should ensure patients know the name, purpose, and instructions of each prescribed medication, therapeutic and side effects, problems with other medications and substances, and the importance of adherence.
7. In prescription orders, the clinician should provide complete details on the drug regimen (patient name, drug name, dosage, formulation, route, frequency, units, flow rates, and duration).
8. Technology is not a panacea for eliminating medication error. Technologies must be well designed and clinicians must be properly trained to ensure improved patient care.

7. Summarize the discussion

Briefly, review each part of the presentation. Recap two or three of the most important points that were discussed.