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Mr. Mark Zigler
Co-Lead Commission Counsel
Public Inquiry into the Safety and Security of Residents in the Long-Term Care Homes System
400 University Avenue, Suite 1800C
Toronto, ON M7A 2R9

Dear Mr. Zigler;
Thank you for the opportunity to provide expert opinion for the proceedings of the *Public Inquiry into the Safety and Security of Residents in the Long-Term Care Homes System.* My letter of engagement and the questions I was requested to answer are attached as Appendix 1 to this document.

Professional background and qualifications

I am a registered pharmacist in Ontario, originally licensed to practice in 1982. I hold BScPhm and MHSc (Bioethics) degrees, both issued by the University of Toronto, in 1981 and 2006 respectively. I completed an Accredited Canadian Pharmacy Residency at Toronto General Hospital in 1981-1982. Over the course of my career, I have worked in community pharmacy, long-term care for people with developmental disabilities and hospital pharmacy. In 2004, I completed a one-year Fellowship in Safe Medication Management with the Institute for Safe Medication Practices Canada (ISMP Canada) and in January 2005, I began a full-time position as a Project Leader. My current role is Director of Projects and Education. In this role, I am responsible for consultation projects and education programs and am actively involved in completing this work as well as leading it.

In the nearly 15 years I have been with ISMP Canada, I have led numerous medication system reviews, root cause analyses of critical medication incidents and proactive risk assessment projects in a variety of sectors, including long-term care (LTC). I was involved in a project funded by the Ontario Ministry of

Health and Long-Term care in 2008-2009[1] that informed the development of the current regulations for medication management in LTC homes. I have been an expert witness for three coroner's inquests, one of which involved a death in a long-term care home.

As described in my CV (Appendix 2), I have co-authored a number of medication safety-related articles. I am actively involved in the development of ISMP Canada Safety Bulletins and have been a peer reviewer for the Canadian Journal of Hospital Pharmacy. I was a co-author of the 2006 Canadian Root Cause Analysis Framework and the revised Canadian Incident Analysis Framework released in 2012. I also have expertise in proactive risk assessment using Failure Mode and Effects Analysis.

I have been integrally involved in development of ISMP Canada's Medication Safety Self-Assessment (MSSA) programs, specifically the Hospital, Oncology, Epidural, and Hydromorphone versions. I led the work with the Canadian Society of Hospital Pharmacists to develop the Audit Tool for Aseptic Compounding, which runs on ISMP Canada's electronic platform. I am currently leading the revision of the MSSA for LTC, which will be released later this year.

Preparation of expert report

I confirm that I have prepared this report and all opinions expressed are my own. As an employee of ISMP Canada, I have used its resources and have consulted with members of our interdisciplinary team: a physician, pharmacist, and registered nurse with experience in the long-term care setting, a pharmacist with home care expertise and others with medication system safety expertise. Where the report references ISMP Canada work that I have not directly been involved with, I have familiarized myself with the material and adopted the research as reliable.

Documents reviewed

Preparation of this report included review of the following:

i) Documents provided by the Counsel for the Inquiry:
- Agreed Statement of Facts on Guilty Pleas
- Interview of EW, Vol 1, 14Feb2018
- Draft Overview Report: Facilities and Agencies
- Legislation relevant to medication management in long-term care: The Duties and Responsibilities of Long-Term Care Homes, 2007-2010 and 2010-2015
- Polices and procedures for medication management in the LTC homes in which the events under review occurred

[1] Joint Task Force on Medication Management in Long-Term Care Report, Nov 4, 2009. Available from; https://www.ismp-canada.org/download/Joint_Task_Force_Report_Nov5_Final.pdf.

ii) ISMP Canada Medication Safety Self Assessment[2] programs, aggregate responses, including areas of strength and opportunities:
- For long-term care
- for home care organizations

iii) Additional medication safety project work undertaken by ISMP Canada that may provide relevant insights, including:
- Medication diversion
- Medication storage and disposal
- Published safety bulletins with relevant content

iv) Environmental scan of recently published literature on medication management in long-term care and home care, as well as selected articles on medication diversion[3].

General background: the medication use process

There are five key steps in the medication use process: Prescribing, Transcribing, Dispensing, Administration, and Monitoring; these are described briefly below and will be used later in the report. The medication use process is interdisciplinary and each step may involve a number of different healthcare disciplines.

Prescribing refers to the act of assessing an individual's pharmacological needs and ordering appropriate medications to address these needs.

Transcribing refers to the conveyance of prescriber information into other systems necessary to acquire medications. This could be a nurse copying information onto a pharmacy order sheet, or a pharmacist/pharmacy technician/pharmacy assistant entering a handwritten order into a pharmacy computer system. As organizations become more computerized, transcribing becomes less prevalent.

Prescriber orders must be transmitted to the pharmacy for transcription into the pharmacy medication profile for dispensing and, for LTC, into a medication administration record (MAR). A paper MAR may

[2] ISMP Canada's Medication Safety Self-Assessment programs are designed to: i) Heighten awareness of the distinguishing characteristics of a safe medication system; ii) Provide an assessment tool to assist individual practice sites to evaluate the safety of systems and processes locally; iii) Assist organizations to evaluate their improvement efforts over time; and iv) Create a system-wide aggregate database that can be used for comparative purposes (anonymous site-to-site comparisons) and to identify system-wide opportunities for improvement. Information on ISMP Canada's MSSA programs is available from: https://www.ismp-canada.org/mssa.htm.

[3] Medication diversion is the use of medications for other than their intended purpose. The term is most commonly used in reference to opioids and benzodiazepines, which are common targets for individuals with substance use conditions. Institutional supplies are one source of diverted medication.

be printed from the pharmacy computer system (cMAR) or a real-time electronic record (eMAR) may be used.

Dispensing refers to the provision of medications for an individual recipient, and includes assessment of the appropriateness of the medication as ordered, for example: assessing allergies, drug interactions, dosage relative to kidney function, etc.

Administration refers to the delivery of the medication into the individual for whom it is prescribed, via oral ingestion, injection, topical application, or other means. Inherent in this step is confirmation of the correct medication to the correct recipient at the correct time. This represents a critical stage because after this point, the medication is acting pharmacologically in the individual who receives it. Nurses are commonly advised to follow the "rights" of medication administration to avoid errors (previously five rights – now eight); i.e., right person, right drug, right dose, right route, right time, right documentation, right reason and right response. These are in fact the goal, rather than the process.[4]

Monitoring refers to observation of the effects of the medication. It can refer to both the short term (e.g., observation for immediate allergic reaction) or the long term (e.g., determination of a medication' s effect on cholesterol level over a period of time). All healthcare disciplines, as well as other team members (e.g., PSWs) and the resident and family have a role in monitoring the effects of medications.

There are influences on medication use that contribute to the medication use process. Health Canada as the regulator, and the pharmaceutical industry as the manufacturers, determine the availability, format (dosage form and packaging) and dose/concentration accessible for use. In LTC in Ontario, the medications for which funding is available are determined by the provincial Drug Benefit Formulary[5]; this Formulary would also be commonly used when prescribing for people receiving home care services. Decisions about medications to be covered are made at a provincial level. Challenges can occur when the available formulation does not optimally meet the needs of the population served. Local practice patterns and practice culture also play a role in how medications are used in a facility. For example, prescribers may favour one type of medication over another, or may perform procedures at a facility that require stocking certain types of medications which would not otherwise be available.

The design of the medication use process in LTC homes is largely driven by the billing model, in which individual prescriptions for residents are filled by an external pharmacy and billed directly to the Ontario Drug Benefit program, and then provided to the LTC home for administration. The only exception to this is a small number of non-prescription items, such as antacids and laxatives, that are

[4] ISMP Medication Safety Alert! The Five Rights – A destination without a map, January 2007. Available from: https://www.ismp.org/resources/five-rights-destination-without-map
[5] Ontario Public Drug Programs; information available from: http://www.health.gov.on.ca/en/pro/programs/drugs/odbf_mn.aspx.

supplied through the Ontario Government Pharmacy. This system has implications for drug use control that will be discussed later in the report.

Questions to be answered in this report

I respond to the questions raised in your letter dated May 14, 2018 as follows:

A/ Medication Management in Long-Term Care

1. a) What are the minimum requirements for medication management systems in long-term care homes both in terms of infrastructure and oversight as the medication flows from pharmacy to resident?

Regulatory requirements and professional standards and guidelines

Provision and oversight of long-term care (LTC) homes in Ontario was regulated under the *Nursing Home Act* until July 1, 2010, when the *Long-Term Care Homes Act, 2007*[6] came into force. The Regulations to the Act[7] contain detailed provisions for medication management that include the following components:

- An interdisciplinary medication management system that provides safe medication management and optimizes effective drug therapy outcomes, including quarterly and annual evaluation of effectiveness of the medication management system; and
- Written policies and protocols developed, implemented, evaluated and updated in accordance with evidence-based practices to ensure accurate acquisition, dispensing, receipt, storage, administration, destruction and disposal of all drugs used in the Home.

Specific requirements for medication management are included in inspections of LTC homes, which include observation of medication storage and administration processes.

Every LTC home is required to retain a pharmacy service provider for the home and the contract must include provision for 24-hour access to medications, either from the contracted pharmacy service provider or from another pharmacy holding a certificate of accreditation under the *Drugs and Pharmacies Regulation Act*[8]. Provision of LTC services has evolved into a specialty area of pharmacy practice that is, to a great extent, undertaken by larger pharmacy operations; many of these pharmacies do not offer traditional pharmacy services that are open to the public. In addition to the Regulations to the *Long-term Care Homes Act*, guidance for pharmacists providing such services is

[6] Long Term Care Homes Act, 2007; available from: https://www.ontario.ca/laws/statute/07l08
[7] Regulations to Long Term Care Homes Act O.Reg 79/10:General. Available from: https://www.ontario.ca/laws/regulation/100079
[8] Drugs and Pharmacies Regulation Act; available from: https://www.ontario.ca/laws/statute/90h04

provided through *Standards of Practice for Pharmacists Providing Services to Long-Term Care Facilities*[9] issued by the Ontario College of Pharmacists and *Best Practice Guidelines for Long-Term Care* are also available from the Ontario Pharmacists Association.[10]

Prescribing

In general, no drug is allowed to be given to a resident in a LTC Facility without an order from a licensed prescriber. Both physicians and nurse practitioners prescribe medications in LTC Homes.

The prescribing process typically encompasses assessment, diagnosis, and a treatment plan in context of a patient's medical history, existing conditions, current clinical status and the goals of care. This process generally falls into one of two purposes:

i) *Ongoing treatment of chronic conditions (e.g., hypertension, diabetes, depression)*

Medications in this case are prescribed over a prolonged period and are periodically re-assessed as to effectiveness, tolerance, and continued need. These medications are prescribed therapy for the individual patient's disease and reviewed at least every three months as part of the quarterly review process.

The majority of therapies in this category are marketed drug products delivered through the pharmacy service provider. Medications can also include natural health products, or alternative health products not typically available through the pharmacy service provider. Other medications not typically available through the pharmacy include research or investigational drugs, or certain other specific therapeutics such as chemotherapy agents. In these cases, the family of the patient typically supply the therapies through hospital clinics or other practitioners.

ii) Episodic treatment of acute conditions such as acute infection, injury, or decompensation of a chronic condition.

Therapies in this case are prescribed in one of two ways:

A. From a set of medical directives
   Medical directives are a set of pre-prescribed medications that are available to be administered to a patient without the need for a prescriber's individual authorization. These are prescribed ahead of time in anticipation of occasional need and administered at the discretion of nursing staff. These therapies are typically directed towards minor ailments (e.g., mild pain, nausea, mild constipation) or to provide availability of selected

[9] Standards for Pharmacists Providing Services to Licensed Long-Term Care Facilities; available from: http://www.ocpinfo.com/regulations-standards/standards-practice/ltc-standards/

[10] Ontario Pharmacists Association. OPA Best Practice Guidelines for Long-Term Care Inspections of the Medication Management System; available from: https://www.opatoday.com/Media/Default/Tools%20and%20forms%20-%20LTC/2016-06-20%20LTC-TableUpdate_Complete.pdf

emergency drugs where delay in acquiring a prescriber's authorization may be deleterious (e.g., anaphylaxis, hypoglycemia).

Generally, medical directives are prescribed upon admission of the patient to the facility and are reviewed at least annually (some facilities review these quarterly). These directives commonly apply to all residents in a facility and are reviewed annually by the interdisciplinary committee (often called the Professional Advisory Committee) for the Home. Prescribers can tailor individual directives to the restrictions of the patient. Use of these orders is intended to address one-time use; if a resident requires ongoing treatment, the prescriber should be requested to assess the patient and write a specific order for a routine or "as needed" medication.

B. Individually prescribed medications after assessment and diagnosis of the acute condition. In this case, medications would be acquired through the usual pharmacy process.

Prescriber orders may be handwritten, or electronically entered into the resident's health record, or provided to a nurse over the telephone and co-signed on the next visit to the LTC Home. Most electronic prescribing systems currently in use in LTC Homes do not include real-time clinical decision support, such as allergy, drug interaction and lab value alerts, although these are present in pharmacy computer systems.

Transcription

Most LTC homes have an electronic health record that supports documentation of progress notes, lab values, medication administration and other functions; PointClickCare is one example. Pharmacy computer systems may or may not integrate with the software system used in the LTC Home.

Prescriber orders must be transmitted to the pharmacy for transcription into the pharmacy medication profile and into a medication administration record (MAR). Orders from physicians and nurse practitioners may be faxed to the pharmacy or electronically transmitted. A common mechanism for electronically submitting orders is a digital pen, or "digipen"; the prescriber uses a special pen to write all order and when the pen is returned to the docking station, it transmits an exact replica of the order to the pharmacy.

The pharmacy transcription of each order is usually checked by two nurses against the handwritten order in the resident's health record. The second check may be done on the night shift. Both checks are typically documented on the prescriber order; some order forms have a predefined area for this documentation. When the pharmacy is not available (e.g., evenings/weekends) new orders are still transmitted to the pharmacy using the digipen and nurses make a manual entry into the cMAR or eMAR so that medications can be administered and documented in the interim.

All medications must be reviewed every three months. Generally, the pharmacy provides three-month review forms based on the current medication profile for each resident; usually nurses review these forms prior to prescriber review. Prescribers must indicate "continue" or "discontinue" on the review form; the form is transmitted to pharmacy by the usual means and any changes are processed. When the three-month review is complete it is rechecked by two nurses against the MAR; any discrepancies are addressed with the prescriber and/or pharmacy.

Dispensing

A "monitored dosage system" is required by the *Long Term Care Homes Act*. The Ontario Pharmacists Association guidelines[11] note that such a system should allow:

- Identification of medication at the point of administration
- Ease of opening the packaging
- Tamper proof system
- Efficient time management during the medication passes
- Ease of accurate administration of medication

The use of a current medication administration record (MAR), paper or electronic, to be maintained for each resident in order to monitor and record all doses of medication.

A common approach to this is a strip package that can contain up to 5 medications in each pouch (Figure 1).

Figure 1: Monitored dose system for medications in LTC

Prescribers authorize medications for three months at a time through the quarterly medication review process described under *Prescribing.*

Most LTC homes receive medications from their pharmacy service provider on a standard schedule. A one-week supply of strips of prepackaged oral solid medications (i.e., tablets/capsules) is delivered on

[11] Ontario Pharmacists Association. OPA Best Practice Guidelines for Long-Term Care Inspections of the Medication Management System; available from: https://www.opatoday.com/Media/Default/Tools%20and%20forms%20-%20LTC/2016-06-20%20LTC-TableUpdate_Complete.pdf, p.14

the same day each week. A daily delivery is available for new medications and refills of unit-of-use/multi-dose medications such as eyedrops, inhalers, insulin pens and topical items as well as "as needed" items. These items are ordered by nursing staff as required; there is usually a standardized order form to support this.

Unit-of-use/multi-dose medications are usually supplied as single units or in the standard package size; for example, inhalers would be dispensed one at a time, insulin pens in boxes of 3 and insulin cartridges in boxes of 5.
In cases where medications are required urgently, they may be accessed by:

i) Contacting a local community pharmacy (the contracted pharmacy must have a 24-hour service arrangement per legislation)
ii) "Borrowing" doses of medicine from future doses for the same resident in the case where a prescribed drug dose is increased, with borrowed doses to be replaced by pharmacy
iii) "Borrowing" doses of medicine from another resident, with borrowed doses to be replaced by pharmacy – this is not a recommended process
iv) Use of the emergency drug box (also known as an emergency cupboard, or night box). The emergency box is a repository of medications that may need to be started on a timely basis during periods where the pharmacy service provider is closed or not able to provide the service. These supplies are limited and are designed to provide medications for an interim period only.

Government Pharmacy stock

Certain non-prescription medications are supplied from the Ontario Government Pharmacy; these include laxatives and antacids (see Appendix 3). Bulk supplies of these medications may be stored in a locked medication storage room and distributed to individual medication rooms as needed. Supplies of these items are ordered by a designated individual in each Home; these are not managed by the pharmacy service provider.

Emergency drug box

As noted above, an emergency drug box is available for medications that may be required urgently or outside regular pharmacy hours. This box includes medications for symptom management (e.g., furosemide, prednisone, injectable dimenhydrinate) rescue agents (e.g., diphenhydramine, epinephrine, glucagon, naloxone, vitamin K) and medications required outside of the daily delivery schedule (e.g., oral antibiotics). By legislation, the emergency drug box contents, and associated medical directives, are established locally and must be reviewed annually by an interdisciplinary committee.

There is usually only one emergency box for each home; it would be kept locked in one of the medication rooms – typically this would be the medication room closest to where the RN is assigned.

Emergency box medications that require refrigeration are usually stored in the refrigerator in the medication room where the emergency box is stored. If emergency narcotics are available (e.g., morphine injection) they are stored with the other narcotics and controlled drugs. An example of an emergency drug box is shown in Figure 2.

Figure 2: Example of an emergency drug box

A medication from the emergency box can be administered pursuant to a prescriber's specific order (e.g., new antibiotic) or if required for urgent symptom management according to medical directives as described under *Prescribing*. If the medication will be required on an ongoing basis, nursing staff will make arrangements to obtain sufficient supply.

The emergency drug box supply is usually audited monthly by either nursing or pharmacy staff; at this point any discrepancies (i.e., drugs used and not reordered) can be corrected. Lack of a standardized process to ensure emergency drug box items are replaced can lead to medications not being available when required.

High-alert medications

High-alert medications are medications that are more likely to cause harm if used incorrectly. ISMP (US), a sister-organization to ISMP Canada, has developed reference lists of high-alert medications for the acute care, long-term care and community/ambulatory settings.[12] The LTC list (Appendix 4) includes insulin and oral hypoglycemic agents, opioids (also called narcotics), anticoagulants (blood thinners), as well as others. With any of these medications, administration of the incorrect dose, or to the incorrect resident, has a high likelihood of causing harm.

[12] Institute for Safe Medication Practices (US). High-alert medication lists; available from: http://www.ismp.org/recommendations/high-alert-medications-acute-list; http://www.ismp.org/recommendations/high-alert-medications-community-ambulatory-list; http://www.ismp.org/recommendations/high-alert-medications-long-term-care-list.

In 2010, ISMP Canada published an analysis of medication incidents in the LTC environment[13], that were voluntarily reported. The data reviewed for the analysis spanned a period of almost 9 years (August 1, 2000, to February 28, 2009). The database search identified a total of 4740 medication incidents in the long-term care environment. Of these, 131 (2.8%) had an outcome of harm or death. Administration of an incorrect dose was the single most common type of incident, followed by dose omission, administration of the incorrect drug, and administration of a medication to the incorrect patient. The majority of the harmful incidents reported involved 1 of 3 classes of medications that are considered high-alert medications: anticoagulants, insulin, and opioids (narcotics).

A variety of precautions and safeguards to reduce the likelihood of incorrect use of high-alert medications have been implemented in hospitals and some LTC homes, including limiting available concentrations and dosage forms[14], limiting access (through reduced quantities and available dosage forms, as well as restricted access), and use of independent double checks (human or electronic [e.g., bar coding]). The purpose of such safeguards is not to suggest lack of trust in the healthcare providers responsible for dispensing and administering these agents, but to provide an additional level of safety for the individual receiving the medication, because the consequences of an incorrect administration can be severe. While opioids are subject to additional controls related to federal legislation, other high-alert medications may be readily available in institutional settings.

i) Insulin and oral hypoglycemic agents

Diabetes is a common health condition; the Canadian Diabetes Association website notes that 11 million Canadians are living with diabetes or prediabetes.[15] Individuals with diabetes may control their condition with diet alone or diet plus medications. The type of medication used depends on the underlying problem. People who are unable to produce insulin naturally must receive insulin by injection. People who are unable to produce sufficient insulin or who have become insulin resistant may be treated with oral medications designed to increase insulin production, decrease production of glucose in the liver, or decrease insulin resistance. Many people will require a combination of treatments, which may include both oral medications and insulin. There are also newer injectable drugs for diabetes that are not insulin related (e.g., liraglutide). Both insulin and oral hypoglycemic agents are considered to be high-alert medications because of the risks associated with hypoglycemia – serious hypoglycemia can progress to loss of consciousness, seizures and death.

Insulin is available in numerous formulations and dosage forms, all of which must be administered by injection; insulin is not absorbed if administered by mouth. A search of the Health Canada Drug Product Database (https://health-products.canada.ca/dpd-bdpp/index-eng.jsp) using the search terms

[13] Medication Incidents Occurring in Long-Term Care. ISMP Canada Safety Bulletin, 2010; 10(9). Available from: https://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2010-09-MedIncidentsLTC.pdf.
[14] A dosage form is the form in which a medication is supplied; e.g., tablet, capsule, liquid, topical patch or cream, injection, inhaler, etc.
[15] Canadian Diabetes Association website: https://www.diabetes.ca/about-diabetes/types-of-diabetes.

“insulin, “human”, and “marketed products” generated a list of 49 commercially available insulin products in Canada.

Response to treatment with insulin is monitored by fingertip blood glucose measurement. Devices have been designed for self-use by patients, with results available immediately; similar devices are available in LTC Homes and other institutional settings.

Insulin: availability, types and formats

Insulin is available without a prescription from any community pharmacy in Ontario to facilitate access to this life-saving medication. Insulin is stored “behind the counter”; however, no documentation or identification is required to access it. There is variability internationally in insulin accessibility; in some countries insulin is only available by prescription.

The various types and brands of insulin are mainly differentiated by their time of onset and length of action; insulin is available in short, intermediate and long-acting formulations. Most treatment regimens attempt to mimic normal insulin release in the body by combining short-acting insulin with intermediate or long-acting insulin. Short-acting insulin is typically used around mealtimes, or to manage unexpectedly high blood glucose levels, and intermediate and long-acting insulins provide an ongoing level of circulating insulin in the body. Doses are measured in “units” and are tailored to individual patient need, which can vary considerably from person to person; some people may require as little as 4 units of insulin per day, while others may require over 300 units per day. Lack of standard dosing for insulin means that dosage forms must be able to be manipulated easily to deliver any dose. Dose frequency also varies from patient to patient, with some residents requiring insulin only once daily, while others require 4 or more injections per day. Some people with diabetes utilize an insulin pump that delivers insulin continuously during the day.

For many years, insulin was provided in vials, and nurses (and patients at home) would ‘draw up’ each dose using a needle and syringe. In hospitals, it was common for insulin to be supplied as “floor stock” and the same vial would be used to administer insulin to several patients. It would also have been common for LTC homes to keep a vial of short-acting insulin in the medication room fridge to manage unexpected high blood glucose levels (e.g., as part of the emergency drug box medication supply). The use of insulin in vials is now mostly reserved for people who require large doses of insulin, as insulin manufacturers have moved to provision of insulin in “pen” devices. These devices are portable and simplify insulin administration because the syringe and needle are integrated into the design of the pen. The pens include a dial to measure the dose of insulin; making it easy to correctly measure the desired dose, and also to verify the dose prepared. The ability to verify the dose to be administered also makes insulin pens popular in institutional settings. Examples of insulin pens are shown in Figures 3and 4 below.

Figure 3: Examples of insulin pens

Figure 4: Insulin pen dialed to 10 units

Some insulin pens require replacement of the insulin cartridge when empty; examples of the packaging of insulin cartridges is shown in Figure 5.

Figure 5: Boxes of insulin cartridges and internal packaging[16]

In the interview with EW[17], she described accessing extra cartridges from the medication room refrigerator, placing the cartridge into a spare insulin pen, and then disposing of the empty cartridge with the other used medication supplies.

[16] Patient Report of Insulin Mix-Up Shared. ISMP Canada Safety Bulletin,2007; 7(6). Available from: https://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2007-06InsulinMixUp.pdf.

[17] EW Interview, Vol 1, Feb 14, 2018, p. 60-69.

Some newer insulins are available in disposable pens that cannot be taken apart. The Ontario Drug Benefit Formulary[18] covers insulin in vials, cartridges, and disposable pens, allowing prescribers to select the formulation they feel best meets the needs of a particular resident.

Dispensing of insulin pens

Insulin pens are dispensed individually for each resident. They cannot be shared from one resident to another, because, even when the needle is changed on a pen, there is a risk of blood-borne contamination from the insulin cartridge.[19]

It would be common for a LTC Home to have several insulin-dependent residents on a unit, necessitating the availability of several insulin pens at any one time, with the current pens in use stored in the medication cart and back-up supplies stored in the refrigerator in the medication room. (Insulin is recommended to be used within 28 days of opening if stored at room temperature, therefore it is usually refrigerated until opening.) Insulin pens contain 3 mL of insulin, usually 300 units of 100 units/mL concentration. As individual needs vary widely, the rate of use of a single pen would also vary widely among residents.

Insulin pens are generally dispensed in packages of 3 (Figure 6) at a time and insulin cartridges in packages of 5. If there are 5 residents on a unit receiving insulin, each of whom is on 2 types of insulin, it would be possible to have 20 extra insulin pens (2 each x 5), or 10 partial boxes of cartridges (up to 40 extra cartridges) in the fridge at any one time.

Figure 6: Box of 3 insulin pens

ii) Narcotics and controlled drugs

Narcotics and controlled drugs are medications that are defined under federal legislation as requiring additional controls. These controls have been implemented in an attempt to prevent diversion and

[18] Ontario Drug Benefit Formulary; available from: https://www.formulary.health.gov.on.ca/formulary/.
[19] Alert! Use of One Insulin Pen for Multiple Patients is a High-Risk Practice. ISMP Canada Safety Bulletin; 2013;13(4); available from: http://www.ismp-canada.org/download/safetyBulletins/2013/ISMPCSB2013-04_ALERT_InsulinPenHighRiskPractice.pdf.

misuse. Many drugs in this group, opioid medications in particular, are considered to be high alert medications because of the risk of respiratory depression, possibly leading to death.

Additional considerations related to storage of narcotics and controlled drugs are discussed under question 1c.

iii) Anticoagulants

Anticoagulants, also called "blood thinners" are commonly prescribed for LTC residents to manage conditions such as atrial fibrillation and for the prevention or treatment of serious blood clots (venous thromboembolism, or pulmonary emboli). Anticoagulants are considered to be high-alert medications because overdose can lead to severe bleeding, including the associated risk of stroke.

Warfarin is a widely known anticoagulant that has been commonly used for many years. Warfarin requires regular blood tests to ensure that the prescribed dose remains in the safe range and is generally dispensed for a specific time period as determined by the next scheduled blood test. Warfarin is generally dispensed as part of the medication strip described earlier; some pharmacies program the automated dispensing machine so that warfarin is the only medication in a pouch, to facilitate undistracted dose verification.

Medication Administration

Medication administration records (MARs) are used to guide medication administration in LTC Homes. These may be electronic MARs (eMARs), which provide real-time recording of medication administration or paper MARs generated from the pharmacy computer system (cMARs).

Homes with eMAR systems usually have mobile computers on top of the medication cart to guide medication administration. The eMAR system uses different colours to alert nurses of medications pending. LTC homes without eMAR systems generally use computer-generated paper MARs (cMARs) provided by the pharmacy service provider. The cMARs are stored in a binder on top of the medication cart. Both eMARs and cMARs include a recent photograph of each resident to support correct identification for medication administration. Most homes have processes in place to update photos annually or when there is a significant change in a resident's appearance.

During medication administration passes, each medication is checked against the MAR. The identity of the intended recipient is expected to be confirmed using two identifiers (e.g., photograph and birthdate confirmation, or staff member knowledge of resident identity for residents who cannot confirm their identity). Medications not administered are recorded as such.

Nurses are expected to exercise clinical judgement when administering medications and should not administer a medication they are unfamiliar with.

Narcotics and controlled drugs must be recorded on the MAR as well as the individual narcotic record sheet. To my knowledge, such additional documentation is not in place for other high-alert medications in LTC Homes. Separate diabetic and anticoagulant record sheets were popular in hospitals a number of years ago and were discontinued to eliminate the requirement to document medication administration in more than one location.

A 2014 report from the Canadian Institute for Health Information (CIHI) identified that seniors living in LTC Homes take more prescription medications, and more potentially dangerous medications, than seniors living at home.[20] Nearly two-thirds (60.9%) of Canadians aged 65 and older who live in LTC Homes take 10 or more different prescription drugs. Not surprisingly, medication administration takes up a significant portion of a typical nursing shift. Administering medication to 30 residents can take 2.5-3 hours and this process must be repeated up to four times every day.

Monitoring

Prescribers have overall responsibilities for therapeutic outcomes. Nurses are responsible for immediate monitoring of therapeutic outcomes and potential adverse reactions to medications. Pharmacists provide clinical support (e.g., medication review and consultation) to support achievement of pharmacotherapy goals. Clinical pharmacy support is limited, with many Homes having a pharmacist on-site one day per week.

1. b) Are there variations in medication management systems from facility to facility?

All LTC homes are required to comply with the minimum standards for medication management as set forth in the regulations and as monitored by compliance evaluators. There may be variability in the detailed mechanisms of provision of medication to LTC residents, subject to local culture, resources, and capabilities. Across the LTC industry, there is a high level of consistency in approach; for example, medications dispensed with a high degree of accuracy through the use of automation (strip packages) and availability of electronic MAR systems. The level of consistency in medication management systems is much higher in LTC Homes than in acute care hospitals.

[20] Vogel L. Two-thirds of seniors in long-term care take 10 or more drugs: CIHI. CMAJ June 10, 2014 186 (9) E309; DOI: https://doi.org/10.1503/cmaj.109-4797

Medication Safety Self-Assessment program for LTC

ISMP Canada's Medication Safety Self-Assessment (MSSA) program for LTC Homes provides some insight into areas of consistency and variability in medication management processes in this setting. The MSSA program is a comprehensive online survey that includes the ability for participating facilities to compare their responses to the aggregate dataset. The program was developed and made available through ISMP Canada collaborative initiatives with the Ontario Ministry of Health and Long-Term Care and Health Quality Ontario as well as Health Canada. The *Long-Term Homes Care Act* requires LTC homes to annually complete an evaluation of the medication management system using an assessment instrument specifically designed for this purpose[21] and the MSSA program supports Homes to comply with this requirement.

The MSSA for Long Term Care is directed toward interdisciplinary teams in LTC Homes. The program is intended to complement a facility's ongoing medication safety-related activities, such as review of medication incident and near-miss reports. The MSSA process aims to heighten awareness of the characteristics of a safe medication system, assist in the identification of opportunities for system improvements, and support the identification of priorities for enhancing medication system safeguards.

The MSSA for LTC was first introduced in 2006. As of June 1, 2018, a total of 1942 assessments had been completed by 542 Ontario facilities; many participating homes have completed the self assessment at least 3 times since 2006. Table 1 shows the number of Homes completing an assessment by year.

Table 1: Ontario LTC Homes Completing the MSSA for LTC, by year

Year	LTC Homes Completing
2006	18
2007	14
2008	266
2009	85
2010	43
2011	190
2012	169
2013	155
2014	212
2015	204
2016	250
2017	194
2018 (to June 1)	95

[21] Long Term Care Homes Act, 2007; available from: https://www.ontario.ca/laws/statute/07l08, s. 116.

The MSSA for Long Term Care consists of 132 items assessing the safety of the medication use system. The self-assessment items were developed on the basis of best practice expectations, analysis of medication incidents, and expert opinion.

The MSSA assessment items are grouped into 10 categories, considered to represent the key elements of safe medication use:

I. RESIDENT INFORMATION
II. DRUG INFORMATION
III. COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION
IV. DRUG LABELLING, PACKAGING, AND NOMENCLATURE
V. DRUG STANDARDIZATION, STORAGE, AND DISTRIBUTION
VI. MEDICATION DELIVERY DEVICE ACQUISITION, USE AND MONITORING
VII. ENVIRONMENTAL FACTORS
VIII. STAFF COMPETENCE AND EDUCATION
IX. RESIDENT EDUCATION
X. QUALITY PROCESSES AND RISK MANAGEMENT

Each participating home enters their response data into ISMP Canada's secure website using a unique password. Each facility can generate site-specific reports and graphs of their own results, as well as comparative graphs, based on aggregate results from similar facilities and aggregate provincial or national results. An individual Home can also use their MSSA results to generate a baseline status report on the safety of its medication system, and evaluate progress over time. Figure 7 shows the overall results by key element for participating Ontario LTC Homes compared with the total Canadian aggregate response.

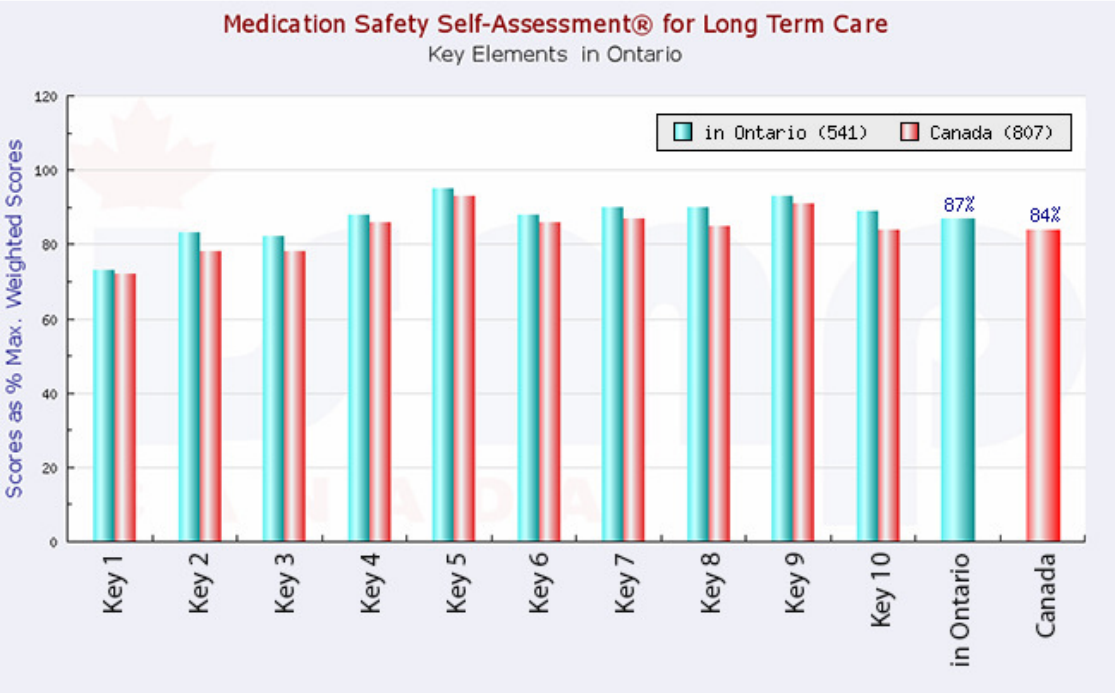

Figure 7: Key Elements: Ontario LTC Homes compared to Canadian aggregate data

There is a high degree of consistency in responses of LTC Homes in Ontario. The range of total scores (lowest to highest) for Ontario LTC Homes completing the MSSA in calendar 2017 (total 194 Homes completing) is shown in Figure 8.

Figure 8: Range of scores (lowest to highest) for Ontario LTC Homes completing the MSSA in 2017

The information submitted to date by participating LTC Homes suggests many areas of strength. Selected examples of practices and strategies that have been widely implemented include:

- Dispensing of medications to care units in labelled, ready-to-use single doses or in resident-specific unit-of-use containers. Of interest, the MSSA data suggest a higher level of provision of unit dose drug distribution systems in LTC Homes than in acute care facilities.
- Completion of a best possible medication history and medication reconciliation, using a standardized process, on admission
- Prescribers are available to assess the needs of residents to prescribe and review medications as required
- A limited after hours/emergency stock has been established
- A pharmacist is on call to respond to questions and come into the Home if needed
- High-alert medications have been defined and identified for the Home
- Allergy screening by pharmacy information systems and listing of medication allergies on every page of a resident's medication administration record
- The laboratory has a critical notification system so that prescribers will be notified of test results requiring immediate attention
- Standard medication administration times have been established and are consistently used, including dosing windows to adjust dosing when the first dose is given at a non-standard time.
- A process for conflict resolution is available when there are expressed concerns about the safety of a prescriber's order for a resident

1. c) How are medications in both categories (controlled and non controlled) stored, tracked and disposed of?

Storage

Medications must be stored securely in designated areas that are used exclusively for this purpose. Most LTC homes have a medication room on each unit, with access restricted to individuals involved in medication management (i.e., registered nurses [RNs] and registered practical nurses [RPNs]).

Many homes have electronic access systems such as swipe cards for restricted areas. Some carts have electronic access via individual codes or fingerprints. Electronic access systems provide the ability to track individual access into the secured area.

Medications for administration to residents are placed in individual bins in medication carts, which are expected to be locked when not in use. Non-oral medications (e.g., creams, eyedrops, inhalers) are placed in a separate designated area in the medication cart for each resident.

Refrigerated items

Certain medications require refrigeration (e.g., insulins, injectable drugs, vaccinations, eyedrops) and a refrigerator is typically located in this secured area, however, it is not itself secured. These items are kept in the refrigerator in the medication room; if the medication is stable at room temperature (e.g., insulin can be stored at room temperature for 28 days) the container in use is stored in the medication cart and unopened containers are stored in the fridge.

Narcotics and controlled drugs

Narcotics and controlled drugs are stored in a separate double-locked stationary cupboard in the medication room or in a separate locked area within the medication cart to comply with federal regulations.

In LTC homes, these medications are dispensed as individual prescriptions. Unlike in hospitals, LTC homes do not have a central supply of narcotics and controlled drugs – for billing reasons, each of these medications must be individually dispensed for the resident for whom it is ordered. Narcotics and controlled drugs, including targeted substances such as benzodiazepines, are commonly dispensed in 30-day blister cards, rather than traditional prescription vials, to facilitate compliance with federal requirements to track these drugs.

Narcotics and controlled drugs must be counted each shift; the shift count is a transfer of responsibility from the outgoing nurse to the incoming nurse. Discrepancies in the narcotic count are expected to be immediately reported to the manager or manager on call and are resolved prior to nurses leaving the

premises at the end of their shift. It is often challenging to ensure that shift counts are actually completed by 2 nurses together; a key barrier is lack of overlap at shift change.

Many acute care hospitals are moving towards the use of automated dispensing cabinets (ADCs) to manage narcotics and controlled drugs. Such cabinets facilitate tracking of use of these medications and reduce the likelihood of selection errors by limiting access to specific compartments in the cabinet. I am not aware of literature describing the use of ADCs in Ontario LTC Homes; however, there is emerging literature describing their use in LTC Homes in the US. [22, 23]

Tracking

Medications are delivered by a driver employed or contracted by the pharmacy service provider on a regular schedule. There is generally a written record of each medication delivery and the record is returned to the sending pharmacy.

When medications are delivered to a LTC Home, items received are confirmed against the resident list and distributed to care areas where nurses check new medications received against the original written order and the MAR before placing in each resident's designated bin or compartment in the medication cart. Completing these checks can be time-consuming; depending on the number of regular medications and narcotics/controlled drugs, it can take 1-2 hours to check and store the weekly order for each unit.

Under legislation, LTC Homes are required to establish and maintain a detailed list of all medications ordered and received by the home; this record must be maintained for 2 years. There may be opportunity to develop standard audit processes to check the drug record book for unusual patterns of use. The 2009 Report of the Auditor General identified that periodic reconciliation of controlled substances administered to residents with records of drugs received from pharmacy and those on hand had not been completed in the three homes visited.[24]

Medication Disposal

Non-controlled medications that are not administered for any reason must be safely disposed. It is common for LTC Homes to have a large plastic bucket in the medication room for this purpose (Figure 9).

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[22] Hilborn, H. Using Automated Dispensing Systems in Illinois Long-Term Care Facilities. Muchshelist. 2016 Mar. Available from: https://www.muchshelist.com/insights/article/using-automated-dispensing-systems-illinois-long-term-care-facilities

[23] Spears, J. A new age for long-term care pharmacies. McKnight's Long-Term Care News. Oct 4, 2010. Available from: https://www.mcknights.com/guest-columns/a-new-age-for-long-term-care-pharmacies/article/180350/.

[24] 2009 Report of the Office of the Auditor General of Ontario, Chapter 4. Available from: http://www.auditor.on.ca/en/content/annualreports/arreports/en09/410en09.pdf.

Figure 9: 20 litre pails for medication disposal

When the bucket is full, it is sealed, and arrangements are made for environmentally safe disposal. Although access to medications intended for disposal did not appear to be a factor in the cases under review, these buckets represent a potential source of a variety of medications that could be improperly used as they are typically "open", without a "one-way" drop that deter access once items are placed into the container.

Narcotics and controlled drugs must be disposed of by two registered healthcare providers, one of whom is a member of the registered nursing staff of the Home and the second is a physician or pharmacist. Narcotics and controlled drugs to be destroyed must be stored in a secure area, separately from any medications available for administration to residents. The following information must be documented for each item to be destroyed[25]:

- Date of removal from the medication storage area
- Name of the resident for whom the medication was prescribed
- Prescription number, where applicable
- Name, strength and quantity of the medication
- Reason for destruction
- Date of destruction
- Names of the individuals completing the destruction
- Manner of destruction

The manner of destruction must ensure that the medication is altered to such an extent that it cannot be consumed. Often, soap and water are added to form a slurry in a container, which is then sealed and arrangements made for environmentally safe disposal.

There is a significant amount of wasted medication in LTC Homes. One Home contacted estimated that each unit of 20-30 residents collects approximately one 20 litre (5 gallon) pail monthly. Provision of

[25] Ontario Pharmacists Association. OPA Best Practice Guidelines for Long-Term Care Inspections of the Medication Management System; available from: https://www.opatoday.com/Media/Default/Tools%20and%20forms%20-%20LTC/2016-06-20%20LTC-TableUpdate_Complete.pdf

medications on a weekly basis (instead of monthly) has reduced wastage. Identifying further opportunities to reduce wastage can minimize diversion opportunities as well as costs to the system.

Preventing intentional harm in the LTC setting

1. **What steps are in place/could have been in place that would have prevented the misuse of insulin by a registered nurse?**

Before proposing possible strategies to reduce the likelihood of misuse of insulin, it may be helpful to understand the problem of diversion in general.

Prescription drug diversion, whereby a legally prescribed substance or a substance under control of a regulated person or facility is transferred from the intended individual recipient or organization to another person for any illicit use, is a recognized contributor to harm. There is a great deal of literature related to mechanisms of diversion.[26] Examples that I have come across over my career have been related to various strategies for self-use, such as theft from hospital supplies, replacing a syringe content with saline, or removal of medications from a disposal unit.

Attention to diversion of medications has increased recently in response to the national opioid crisis. Most literature on diversion arises out of acute health care facilities and pertains to opioids and other controlled substances; however, there are lessons from acute care that inform the LTC setting. The most commonly diverted drug class is opioids, owing to their high abuse potential and the value of these drugs on the illegal street market.[26,27] Other medications commonly targeted for diversion include benzodiazepines, stimulants, and performance enhancing drugs (steroids); however, it should be noted that other prescription drugs such as blood pressure medication might also be diverted.

There is no doubt that harm occurs from diversion. Harm can occur to the practitioner or staff member through misuse and addiction. Harm also occurs both directly to the resident if a practitioner is impaired and is incapable of performing the health care duties, and indirectly, if a resident does not receive their medicines and suffers a worsening condition or quality of life. Harm occurs at an institutional level with increased costs, reduced morale, eroded trust in the institution, and impacted resident care.[26]

Certain factors can increase the likelihood of diversion of medications in a LTC Home. The listed factors also apply to other healthcare areas and facilities, and this is not a complete list:

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[26] Berge KH, Dillon KR, Kikkink KM et al. Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention. Mayo Clin Proc. 2012 Jul; 87(7): 674–682. doi: 10.1016/j.mayocp.2012.03.013

[27] Wood D. Drug Diversion. Aust Presc 2015; 38: 164-6. doi:10.18773/austprescr.2015.058.

i) *Medication volume:*

Most residents in long term care are on multiple medications. Moreover, most patients receive additional medications on an "as-needed" basis, necessitating a certain amount of accessible supply being stored in patient care areas.

ii) Medication distribution:

Medication in a facility must move from a delivery area to a care area and then to a patient. Within these steps there may be a number of people handling the medications, and the medications may need to travel from unit to unit.

iii) Medication format:

Medications can come in a number of formats such as oral, injectable and topical (e.g., applied on the skin). Oral pills or tablets can be counted and differentiated by size, shape and colour, making it easy to count the number remaining in a container. Injectable medications however, are generally a clear liquid in a vial, and as such, the identity cannot be determined by appearance alone. Furthermore, it may be impossible for the eye to perceive small volume changes in a vial, e.g., the difference between 2 mL and 1.5 mL in an opioid vial. Opioid and other types of patches are applied on the skin as a convenient means to deliver a consistent amount of drug over time. In order to function properly, these patches have significantly more active medication than is actually delivered. After the removal of the patch, a significant amount of drug remains, so even "used" patches have notable amounts of active drug still available for diversion.

iv) Storage of medications:

Medication storage mechanisms vary from facility to facility. Narcotics and controlled drugs are subject to stricter procedures than non-controlled drugs, although both must remain accessible within reasonable effort and time. Vulnerabilities to diversion are common: medication room doors may be left open (newer facilities have fingerprint access which only allows door to be open for short period of time), drug carts may be left unlocked and unattended while staff are at a bedside, and, depending on the design and features of a medication storage area, access to one medication may provide access to many medications.

v) Staffing:

Staffing levels and oversight vary during the time of day. Nurses are registered healthcare providers who practice independently, and with the exception of independent checks for high-alert medications, it is uncommon for more than one nurse to be involved in the administration of most medications. Individual nurses have their own medication carts to administer medications to the group of residents they are responsible for.

In LTC Homes it is not uncommon for a single RN to be "in-charge" of the entire LTC home on evenings and nights, with a resident care load as well as a requirement to help the RPN staff if a problem arises.

In this instance, EW was an RN, but an RPN would have had similar access to medications and this risk also exists in hospitals.

vii) Resident population:

The high number of individuals with cognitive impairment means that they are less aware and less able to express concern if they are not getting expected medications.

viii) Waste:

Medications, especially injectables and some topical medications are packaged in titratable amounts; i.e., the entire amount of medication in the container may not be used in the dose. For example, morphine may be supplied as 10 mg/1 mL, but only 1 mg may be needed. This results in a 9 mg oversupply that is called waste. There are procedures in place to manage waste (e.g., disposing in a secure container with a double check for narcotics and controlled drugs); however, these procedures may not always be followed, and they are generally different for controlled drugs versus non-controlled drugs. The manipulation of waste, or the theft of wasted products, is a recognized route of diversion. Furthermore, the death of a resident or transfer of an individual to hospital, may leave behind significant amounts of unused medications that must be wasted or otherwise disposed. This is also discussed under question 1c under *Medication Disposal.*

Mechanisms of diversion

Although there are a number of ways to classify mechanisms of diversion, it may be useful to consider that diversion occurs generally under three overlapping categories: simple theft, fraud, or deception.

- Medications can be stolen from bulk containers by taking pills, or drinking from a cough syrup bottle, or taking a resident's oral medication for oneself. This can also occur by stealing residual pharmaceutical products from waste. This simplest mechanism relies upon lax security and lack of oversight or control of medications. In the case of EW, she used insulin dispensed for the intended resident as well as other residents, which was stored in the medication room fridge and not counted.
- Medications can be ordered in excess from the pharmacy without obvious need (e.g., reordering a patient's insulin pen despite having sufficient quantities on hand). Orders for patients can be forged, for example, by falsely writing a verbal order in a chart and processing that order, while diverting the medications for oneself. This can also take the form of falsely documenting a wasted drug and keeping the supply for oneself.
- Deception involves the appearance of proper practice to others, while diverting a medication. This can occur when a diverting practitioner replaces an active drug in a syringe with another drug or other clear fluid, making it seem like there is a syringe containing the proper amount of drug. Deception can also involve a colleague witnessing what appears to be proper wastage of a drug, but that drug has, unknown to them, already been replaced by a diverting worker; what appears to be, and is documented as a proper wastage procedure, is actually not. The act of recording a medicine as administered to a resident, but in reality taken for oneself, is also a form of deception as it would appear to a reviewing individual that the medication was delivered to the resident at the appropriate date and time. One similar method of diversion would be to withdraw two tablets of a drug from the storage area, document two tablets as given to the patient, but only give one to the patient and take the other oneself, or give another drug similar in appearance to the patient and keep the desired drug for oneself

(e.g., replacing Tylenol #3 with plain Tylenol, which are very similar in appearance). In this manner, the resident would confirm the fact they had received medication and this makes the diversion much more difficult to detect.

In any health care setting, the variety and quantity of medications required for healthcare make prevention of intentional misuse of any drug difficult. There is an ill-defined balance between efficient access for therapeutic purposes and restrictions on use to prevent harm. Despite regular review of narcotic and controlled drug inventories through shift counts, diversion still occurs, and it can go undetected for extended periods of time. It is also important to point out that there are many medications that can cause harm or death when used inappropriately, either by mistake or with intent, and it will not be possible to predict or prevent all possible avenues of intentional harm. However, the ready availability of insulin in the LTC Homes where EW worked was cited as a significant factor in her selection of insulin as a means of causing harm[28] and any available mechanisms to enhance oversight of insulin should be explored.

The ubiquitous use of, and requirement for, insulin in a variety of dosage forms constrains opportunities within existing medication distribution systems in both LTC Homes and hospitals to mitigate the potential for intentional harm from insulin misuse. There may be opportunity to enhance oversight of insulin supplies; for example:

- Limit the supply of insulin per resident to a current pen and a spare pen, or a maximum 10-day supply based on usage.
- Implement a central supply process for replacement insulin pens in LTC homes. This could be accomplished through a controlled manual inventory in each unit, similar to narcotic storage, or electronically controlled, for example using an automated dispensing cabinet (ADC). Several acute care hospitals using ADCs contacted during preparation of this report have implemented systems whereby new insulin pens are obtained from the ADC and then placed in a patient-specific location. See additional discussion of ADCs below.
- Under legislation, LTC Homes are required to establish and maintain a detailed list of all medications ordered and received by the home; this record must be maintained for 2 years. There may be opportunity to develop standard audit processes to check the drug record book for unusual patterns of use (e.g., monthly or quarterly, if not already established).
- ISMP Canada has advocated for independent double checks (reflective verification of the medication prepared against the prescriber order) for insulin due to the risk of harm if insulin is administered in the incorrect dose or to the incorrect person.[29] Such checks can help to identify an inadvertent error and EW describes the use of such checks in her practice setting; however she also notes that following the check there was nothing to prevent her from changing the dose dialed up on the insulin pen.

It must be acknowledged that the non-prescription status of insulin means that restrictions imposed in one practice setting may be circumvented through access elsewhere. Increased awareness of the high-

[28] EW Interview, Vol 1, Feb 14, 2018, p. 60-69.
[29] Insulin Errors. ISMP Canada Safety Bulletin, 2003; 3(4); available from: http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2003-04Insulin.pdf

alert nature of insulin and potential harm associated with misuse may suggest an opportunity to review the ongoing need for non-prescription public access or other mechanisms to add safeguards. Of interest, exposures called through to the Ontario, Manitoba and Nunavut poison centres indicates there has been a yearly increase in the number of calls associated with insulin (from 131 calls in 2013 to 224 calls in 2017).[30] These numbers reflect both inadvertent overdoses and intentional use of insulin for self-harm.

Automated dispensing cabinets (ADCs)

One strategy that is increasingly being used in acute care hospitals to manage access to medications and support correct medication selection is the implementation of ADCs. The use of these devices in patient care areas is increasingly being recognized as a way to improve the safety and efficiency of hospital medication systems. When implemented in concert with unit-dose packaging, pharmacist review of medication orders, and an interface with a pharmacy information system, these devices can improve the safety of the medication system while making required medications readily accessible in care areas. ADC technology can include refrigerated units, making it possible to store replacement insulin pens in a monitored way. They could also potentially be used to manage medications currently stored in the emergency drug box as well as narcotics and controlled drugs. ADCs provide some useful tools for enhancing the safety of administration of high-alert medications.

A key learning with ADCs is that unless they are used appropriately, the risks associated with placing high-alert medications in these devices can be similar to those associated with manual ward stock systems. Additionally these units carry a high capital cost that would need to be balanced against potential gains.

Pharmacy technician support for medication management in LTC

There may be opportunity for LTC homes to engage pharmacy technicians to assist in medication management activities, including medication ordering, receiving and inventory management.

Presently, all activities associated with receiving medications, stocking medication carts, storing medications in medication rooms, preparing medications, and disposing of unneeded non-controlled medications are the responsibility of nursing staff. This is a significant burden of activity to healthcare workers not formally trained in these tasks. Pharmacy technicians are registered healthcare professionals regulated by the Ontario College of Pharmacists, have specific training in medication distribution and could provide cost-effective support to enhance system safety, providing an additional “check” in the system as well as allowing nursing staff to spend more time in direct resident care.

[30] Personal communication with Dr. Margaret Thompson, Medical Director, Ontario, Manitoba and Nunavut Poison Centres, 31May2018.

Pharmacy technicians can also support other medication-related processes in LTC, including completion of the best possible medication history at admission.

Enhanced on-site pharmacist support

Enhanced on-site pharmacist involvement could support optimization of medication management to improve health outcomes for LTC residents, as well as additional oversight of medication management within LTC Homes. As noted in the *Medication Management* section under *Monitoring,* while most LTC Homes have a consultant pharmacist, this support is limited, with many Homes having a pharmacist on-site only one day per week. Consultant pharmacists must focus on priority client needs, rather than overall optimization of care, and they have little involvement in medication distribution or oversight, beyond assisting with destruction of narcotics and controlled drugs. A resident with a sudden change in blood sugar control is an example of a situation where a pharmacist might be able to play a role in determining underlying factors that may have contributed, such as an adverse drug event.

The CIHI finding that seniors in LTC Homes take more prescription medications, and more potentially dangerous medications, than seniors living at home[31] suggests there is an opportunity to increase the role of pharmacists in LTC. There are studies in hospitals demonstrating the cost-effectiveness of pharmacists in terms of salary cost versus dollars saved through decreased or optimized medication use[32,33] and drug costs could potentially be reduced through the use of increased pharmacist resources in this sector. Pharmacists are integrally involved in current deprescribing initiatives in Canada (see https://deprescribing.org).[34] One area where pharmacists have had a positive impact in LTC Homes is assisting in rebalancing medication passes to help manage nursing workload through increased use of long-acting medications, where appropriate, and shifting of medication administration times, particularly for once-daily medications, to a lighter medication pass time (e.g., noon).

Of interest, in the current medication management model, consultant pharmacists are employed by the pharmacy service provider, while all of the other allied health personnel (dietitians, physiotherapists, social workers, etc.) are employed by the LTC Home.

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[31] Vogel L. Two-thirds of seniors in long-term care take 10 or more drugs: CIHI. CMAJ June 10, 2014 186 (9) E309; DOI: https://doi.org/10.1503/cmaj.109-4797.

[32] De Rijdt T, Willems L, Simoens S. Economic effects of clinical pharmacy interventions: a literature review. Am J Health Syst Pharm. 2008;14(12):1161–1172. doi: 10.2146/ajhp070506.

[33] Gallagher J, Byrne S, Woods N, Lynch D, McCarthy S. Cost-outcome description of clinical pharmacist interventions in a university teaching hospital. BMC Health Serv Res. 2014; 14: 177. Published online 2014 Apr 17. doi: 10.1186/1472-6963-14-177

Cost-outcome description of clinical pharmacist interventions in a university teaching hospital

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Detecting intentional harm in the LTC setting

1. **Do you recommend any measures as part of a medication management system that would be able to detect whether an ill or unresponsive patient was intentionally harmed by the misuse of medication?**

There are potential opportunities to detect whether an ill or unresponsive resident was intentionally harmed by the misuse of medication:

i) Evaluation of sudden changes in resident condition, specifically hypoglycemia

A sudden change in resident condition should prompt an evaluation of possible causes, including administration of an unprescribed medication either via medication error or intentional misuse. A defined set of intervention responses to the unexpectedly decompensated patient, including vital signs and finger glucose determination, can provide an opportunity to mitigate harm.

An ISMP Canada Safety Bulletin published in 2007described the importance of *considering medication error as part of the differential diagnosis for unexpected hypoglycemia.*[35] (Appendix 5) Learning shared in this bulletin is also relevant for situations of intentional harm. A focused review was conducted of a cluster of voluntarily submitted medication incident reports in which use of insulin or an oral hypoglycemic agent led to harm, including death, in nondiabetic patients. The review included 811 incidents involving insulin of which 88 (10.9%) were categorized as harmful, and 149 incidents involving oral hypoglycemic agents of which 10 (6.7%) were categorized as harmful. Although all of the incidents reviewed involved the inadvertent administration of a hypoglycemic agent to nondiabetic patients, hypoglycemia is well-known to present a risk of harm in diabetic patients as well. A significant finding from the review was the missed opportunities to reduce the degree of harm (or the recurrence of harm) associated with medication incidents involving hypoglycemic agents. Early identification of an error involving insulin or an oral hypoglycemic agent can provide a window of opportunity to mitigate harm and also identify and eliminate the underlying cause(s) of the error to prevent recurrence. This also applies to the intentional use of insulin; regardless of whether insulin was given inadvertently or intentionally, protocols to routinely check blood sugar when a resident is found with a decreased level of consciousness or other signs of hypoglycemia could provide an opportunity for rescue before permanent harm occurs.

ii) Review of the use of rescue medications, specifically glucagon

Review of the use of rescue or symptom management medications from the emergency drug box provides an opportunity to identify a potential adverse drug event – regardless of etiology (i.e., pharmacologic incompatibility, medication error or intentional harm). The US Institute for Healthcare Improvement[36] recommends auditing health records for specific medications, laboratory data and

[35] Unexpected Hypoglycemia – Consider Medication Error in the Differential Diagnosis. ISMP Canada Safety Bulletin; 2007; 7(1); available from: https://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2007-01Hypoglycemia.pdf.
[36] Institute for Healthcare Improvement; see: www.ihi.org

prescriber orders as a means of measuring iatrogenic harm. Their "trigger tools" assist healthcare organizations to focus on specific criteria that suggest the possibility of an adverse event. The IHI Trigger Tool for Measuring Adverse Drug Events[37] includes diphenhydramine, vitamin K, naloxone, and blood glucose less than 50 mg/dl (2.8 mmol/L)[38]. ISMP in the US also recommends tracking the use of glucagon specifically.[39]

In particular, situations in which individuals fail to recover as expected when glucagon is administered necessitate investigation. In other words, if the usual treatment is not working, then something unusual may be happening. In three of the cases where EW administered insulin intentionally, glucagon was used; two of these cases required transfer to hospital to manage continued low blood sugars.

Glucagon acts in the body to stimulate the liver to produce glucose. It is administered by injection; blood glucose peaks in 5-20 minutes if injected intravenously, 30 minutes if injected intramuscularly and 30-45 minutes if given subcutaneously.[40] Glucagon 1 mg administered SC or IM produces an increase in blood glucose from 3-12 mmol/L in 60 minutes.[41] Hypoglycemia can recur if an individual has low glycogen stores (the body's glucose storage system) or if they haven't eaten. Glucagon has a duration of effect of about 60-90 minutes (shorter if given intravenously). Typically, people recover well with food intake; dosing can be repeated in 20 minutes if needed.

Detailed evaluation of the clinical record following the administration of glucagon can potentially identify an adverse drug event, leading to further investigation of whether an incorrect dose of insulin was administered (either by accident or intentionally). This is aligned with a recommendation from the 2009 Auditor General's Report that LTC Homes should "develop and implement policies to ensure consistent identification and documentation of adverse drug reactions, so that action can be taken to prevent future occurrences".[42]

If a LTC Home is considering the implementation of ADCs, inclusion of rescue medications in the ADC provides an automated mechanism for tracking the use of rescue agents for individual residents.

Medical directives for glucagon and other rescue agents are determined locally by each LTC Home in Ontario. There is opportunity to develop a province-wide approach to these orders and mechanisms of supplying the medications, including notification and investigation requirements. For example, the Director of Care, and the consultant pharmacist should be notified when these agents are used; it is

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[37] Institute for Healthcare Improvement. IHI Trigger Tool for Measuring Adverse Drug Events; available from: http://www.ihi.org/resources/Pages/Tools/TriggerToolMeasuringADEsinMentalHealthSetting.aspx

[38] Joslin Diabetes Center. Conversion Table for Blood Glucose Monitoring; available from: http://www.joslin.org/info/conversion_table_for_blood_glucose_monitoring.html.

[39] Measuring up to medication safety. ISMP Medication Safety Alert! March 10, 2005; Volume 10, Issue 5. Available from: http://www.ismp.org/resources/measuring-medication-safety

[40] Glucagon monograph in Lexicomp Drug Information, 23rd ed, 2014. Lexicomp, Hudson, Ohio,p. 977-978.

[41] Diabetes Canada. Clinical Practice Guidelines, Chapter 14: Hypoglycemia. Available from: http://guidelines.diabetes.ca/cpg/chapter14.

[42] 2009 Report of the Office of the Auditor General of Ontario, Chapter 4. Available from: http://www.auditor.on.ca/en/content/annualreports/arreports/en09/410en09.pdf.

assumed that the attending physician and the resident's substitute decision maker would routinely be notified of use of these agents in the current structure.

2. Are there any steps that a long-term care facility can take to analyze a medication incident that would help detect whether a patient was intentionally harmed by the misuse of medication?

Creation of a positive safety culture in an organization is foundational to engaging all staff, as well as residents and family members, in actively identifying and addressing potential safety concerns on an ongoing basis. In such a culture, team members openly discuss errors and strategies for safety with a system focus, rather than using errors in assessment of personnel competence. Medication incident[43] reporting and review of incidents by an interdisciplinary committee is required under Ontario legislation. Such review should include near miss incidents as well as incidents that reach a resident. If a near miss report suggests the potential for a serious event, a comprehensive incident analysis may produce significant learning.[44]

To provide a standardized approach to the analysis of critical incidents and near-miss events in health care, the Canadian Patient Safety Institute, ISMP Canada, Saskatchewan Health, Patients for Patient Safety Canada, and other individuals, worked together to develop the Canadian Incident Analysis Framework (CIAF).[45] The Framework is an analytic tool for performing a system-based review of incidents, including but not limited to medication incidents. It utilizes well established methods for analysis designed to help determine the contributing factors to an event and to identify strategies for implementing system improvements. The goals of incident analysis are to determine (i) what happened, (ii) why it happened, (iii) what can be done to reduce the likelihood of a recurrence; and iv) what has been learned and can be shared to broadly enhance safety. Effective incident analysis can prevent healthcare organizations from undertaking cursory reviews that focus too heavily on the performance of individuals at the "sharp end" of the health care system (the point where care is delivered). The use of incident reporting and learning systems at local, provincial and national levels, with mechanisms for shared learning, is key to overall system safety.

The CIAF was designed to support healthcare organizations to analyze incidents with a quality improvement focus; however, the foundational principles are applicable in a situation of intentional harm. Prior to undertaking an incident review, the team is asked to consider the following questions:

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[43] The term "medication incident" is widely used to represent the preventable subset of potential and actual adverse drug events. It is also recognized as an alternative term for "medication error".

[44] Near Miss Identification and Reporting. ISMP Canada Safety Bulletin, 2007; 7(7). Available from: https://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2007-07NearMiss.pdf

[45] Incident Analysis Collaborating Parties. Canadian Incident Analysis Framework. Edmonton, AB: Canadian Patient Safety Institute; 2012. Incident Analysis Collaborating Parties are Canadian Patient Safety Institute (CPSI), Institute for Safe Medication Practices Canada, Saskatchewan Health, Patients for Patient Safety Canada (a patient-led program of CPSI), Paula Beard, Carolyn E. Hoffman and Micheline Ste-Marie. Available from: http://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF

1. Is the event thought to be the result of a criminal act?
2. Is the event a purposefully unsafe act (an act where care providers intend to cause harm by their actions)?
3. Is the event related to substance abuse by the provider/staff member?
4. Does the event involve suspected patient abuse of any kind?

The CIAF references an *Incident Decision Tree,* a management tool developed by the National Patient Safety Agency/National Health System in the United Kingdom and based on the work of James Reason, a noted psychologist who specializes in the study of human error.[46] The *Incident Decision Tree* (Figure 10) was designed to assist healthcare managers to differentiate between intentional and unintentional harm and to determine appropriate actions following a patient safety incident.[47]

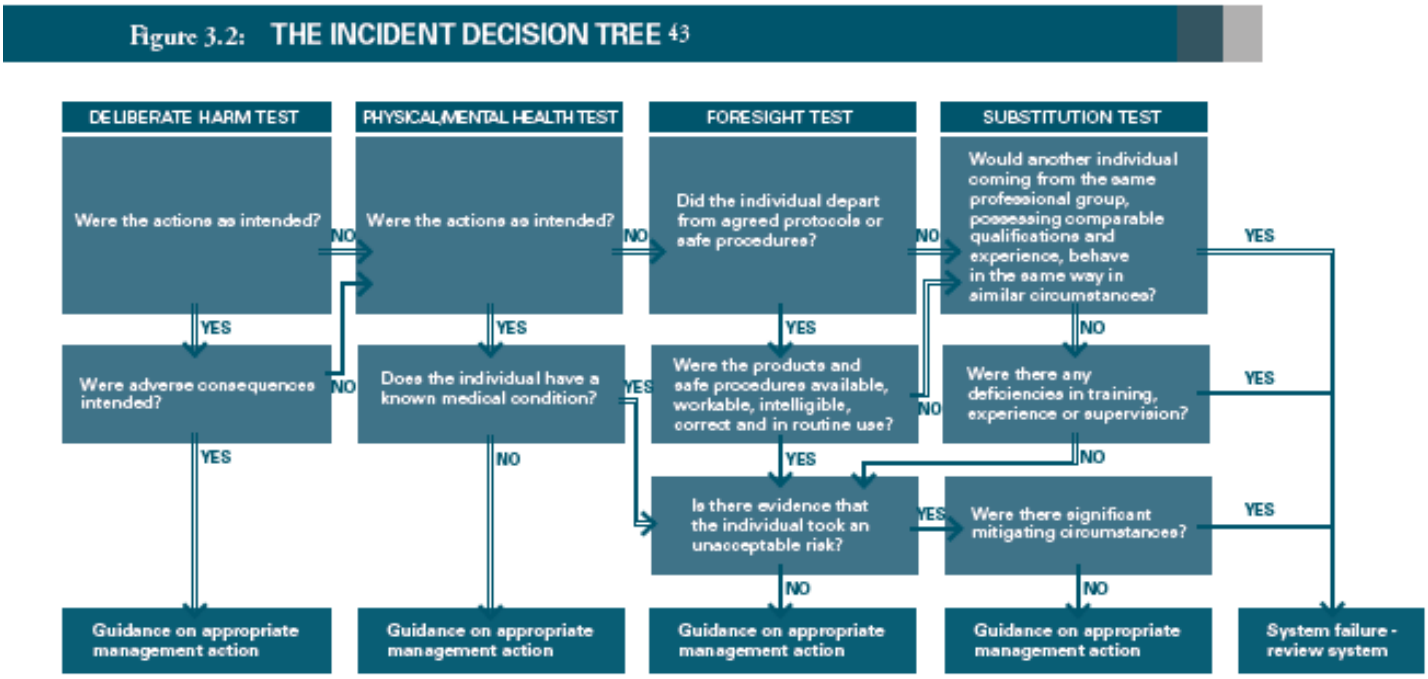


Figure 10: Incident Decision Tree[48]
(An alternate representation is provided in Appendix 6)

The use of the Incident Decision Tree is aligned with David Marx's work on "just culture"[49], which is premised on the idea that healthcare providers should be held accountable for their behavioural

[46] Reason J. Human Error: Models and Management. BMJ 2000; 320; 768. Available from: https://www.bmj.com/content/320/7237/768
[47] NHS Just Culture Guide; available from: https://improvement.nhs.uk/documents/2490/NHSi_just_culture_guide_A3.pdf
[48] Canadian Incident Analysis Framework; available from: http://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF, p. 28.
[49] David Marx. Patient Safety and the "Just Culture": A primer for healthcare executives, April 2001. Available from: https://psnet.ahrq.gov/resources/resource/1582/patient-safety-and-the-just-culture-a-primer-for-health-care-executives.

choices within a system, and for flagging safety concerns within the system, but not for "human errors" which should be an anticipated part of system design.

Building capacity among LTC leadership personnel in systematic incident analysis using the CIAF or similar methodology, along with sufficient resources to conduct such analyses, can help to support a systematic and consistent approach to review of resident safety incidents.

B/ Medication Management in Home Care

1. **a) Please describe whether and how medication is overseen and managed in the home care setting.**
   b) What safeguards are in place in the home care setting with respect to both controlled and non-controlled drugs and high-alert medications in both of these categories?

Increasingly, the provision of health-related services in a person's own home forms an important part of medical care. Home Care services may be provided by RNs, RPNs, and PSWs or care aides, depending on the type of service required. Other allied health providers, including pharmacists, may also be involved. Oral medications may be provided by the patient's usual pharmacy; however intravenous and other injectable medications are commonly provided by a specialty pharmacy contracted to provide medication preparation services for a particular geographic region.

Injectable medications commonly administered or managed for patients at home include intravenous antibiotics and intravenous or subcutaneous opioid infusions for pain management. Nurses may come to the patient's home to administer the medications or to check the infusion site and adjust pump programming. Medication supplies are delivered directly to the patient's home by the pharmacy so that all supplies required for the patient's care are at the home when the nurse arrives.

The most frequently provided controlled medications in the Home Care environment are opioids for pain management; these might be infusion cassettes or ampoules/vials for management of breakthrough pain. These medications require tracking systems to ensure delivery to the Home and programming of the infusion device can only be performed by nursing staff. Once medications are received in the home, there are no controls or limited controls (e.g., symptom relief kits) on who can access the medications and diversion can occur.

With the movement of healthcare activities previously conducted in hospitals into the home comes associated complexity and an increased potential for medication incidents. Healthcare professionals providing Home Care work alone and have to be able to self-identify high risk situations and connect with colleagues remotely to obtain additional support. If high-alert drugs must be administered in the home, another healthcare provider is not available to provide an independent double check; some organizations encourage a double check between the caregiver and patient (or a family member).

Technology is increasingly playing a role in supporting Home Care Nurses (e.g., access to online drug information and ability to connect with colleagues for independent double checks of high-alert medications and pump programming).

Storage and Disposal of Medications

Healthcare personnel have little ability to control environmental factors in a patient's home, such as medication storage set up and location, other than ensuring that refrigerated medications are stored appropriately. Other family members and visitors to the home can readily access medications and this presents a risk for misuse and diversion. Large supplies of unused medications left in the home after a patient dies can be particularly problematic – processes for ensuring return of these medications to a community pharmacy or other safe means of disposal are not consistently available or followed. Most rely on family members to return unused medications, rather than scheduled pick-ups.

Knowledge deficit related to signs and symptoms of toxicity due to medications.

In 2014, ISMP Canada published a review of deaths associated with medication incidents occurring outside regulated healthcare facilities.[50] Completed investigations of 122 deaths associated with medication incidents from four provincial Offices of the Chief Coroner or Chief Medical Examiner spanning a 6-year period (January 1, 2007, to December 31, 2012) were reviewed. 45 incidents were identified that occurred in an individual's home, a group home, or other residential setting. In all cases, medications were administered by the patient, family members or unregulated providers. A key theme identified was 'Knowledge deficit related to signs and symptoms of toxicity'. Unfortunately, in many of the incidents, caregivers or family members did not recognize warning symptoms of toxicity, which resulted in missed opportunities for rescue measures.

Preventing intentional harm in the Home Care Setting

1. **What steps are in place/could have been in place that would have prevented the misuse of insulin by a registered nurse?**

Ensuring adequate supplies of medications - without excessive amounts in the Home - can limit diversion and misuse. Attention to safe storage and disposal of unused or expired medications is also important.

The MedsCheck at Home program provides an opportunity for medication reviews by a community pharmacist in the home. This can include a review of how medications are stored and the program

[50] Deaths Associated with Medication Incidents Occurring Outside Regulated Healthcare Facilities. ISMP Canada Safety Bulletin, 2014; 14(2). Available from: https://www.ismp-canada.org/download/safetyBulletins/2014/ISMPCSB2014-2_DeathsAssociatedwithMedicationIncidents.pdf.

notes that the pharmacist can remove expired or unused medications for disposal. http://www.health.gov.on.ca/en/pro/programs/drugs/medscheck/docs/home.pdf

For palliative care and end of life care, some home care service providers (including pharmacies) arrange for unused medications to be removed (e.g. with the pick-up of *symptom relief kits*) and this is a preferred practice.

ISMP Canada's Medication Safety Self-Assessment program for Home Care Organizations[51] includes several assessment items related to safe storage and disposal of medications in the home (Figure 11). Completion of this self assessment by Home Care organizations can assist in identifying current medication system vulnerabilities and opportunities for improvement.

5. MEDICATION STANDARDIZATION, STORAGE, DISTRIBUTION AND DISPOSAL

	Self-Assessment Items	A	B	C	D	E
5.1	For organizations supporting clients residing within a RESIDENTIAL PROGRAM, a STANDARDIZED PROCESS to ensure consistent dispensing and packaging by all pharmacy provider(s) is in place to minimize confusion for the PSWs. **FAQ 5.1**	Not Applicable ☐				
5.2	The organization has a STANDARDIZED PROCESS in place, to ensure medication changes are processed, dispensed and communicated in a consistent manner by all pharmacy partners for clients receiving medication-related services to minimize confusion.					
5.3	The organization has developed a STANDARDIZED PROCESS to ensure safe medication storage by clients (e.g., child safe lock box required for client with dementia).					
5.4	The organization has developed a STANDARDIZED PROCESS to assist clients with removal and safe disposal of all discontinued or expired medications.					
5.5	The organization has a STANDARDIZED PROCESS to ensure narcotics and controlled medications are prioritized for timely safe disposal to prevent accidental use in the home or theft.					
5.6	The organization has a STANDARDIZED PROCESS to ensure the proper disposal of sharps.					
5.7	The organization has a STANDARDIZED PROCESS to ensure the safe and proper disposal of transdermal patches.					

Figure 11: Assessment items related to safe storage and disposal of medications in Home Care

[51] Medication Safety Self-Assessment Program for Home Care Organizations; information available from: https://mssa.ismp-canada.org/homecareorg1.

Detecting intentional harm in the Home Care setting

1. **Do you recommend any measures as part of a medication management system that would be able to detect whether an ill or unresponsive patient was intentionally harmed by the misuse of medication?**
2. **Are there any steps that a long-term care facility or a home care service provider can take to analyze a medication incident that would help detect whether a patient was intentionally harmed by the misuse of medication?**

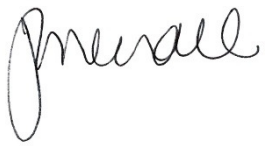
Awareness of the signs and symptoms of toxicity is critical for patients and family caregivers in the Home setting as they can potentially intervene or call for help if they are informed of what to look for and when to seek help.

Regardless of the setting, severe and unexpected hypoglycemia is a flag to determine the cause, once rescue steps have been taken. If glucagon is needed, the previous 24-48 hours of medication administration (insulin and oral agents), and nutritional intake should be considered, and medications adjusted if applicable.

As discussed in the LTC section, if investigation determines that a patient safety incident has occurred, the Canadian Incident Analysis Framework (CIAF) can be used – this analysis framework is applicable to any healthcare setting.

Thank you for the opportunity to submit this report to the Public Inquiry into the Safety and Security of Residents in the Long-Term Care Homes System.

Respectfully submitted,



Julie Greenall
Director of Projects and Education, ISMP Canada

List of Appendices

Appendix 1: Letter of engagement and questions to be answered

Public Inquiry into the Safety and Security of Residents in the Long-Term Care Homes System

The Honourable Eileen E. Gillese
Commissioner

Ontario

Commission d'enquête publique sur la sécurité des résidents des foyers de soins de longue durée

L'honorable Eileen E. Gillese
Commissaire

`May 14, 2018,

Dear Ms. Greenall:

It was a pleasure meeting with you and Ms. Hyland last Friday. We look forward to working with you.

As agreed, you are to prepare a report and to participate as an expert witness in the Inquiry's public hearings. We anticipate at this point that you will be required to attend at the hearing for a maximum of two days in mid-September. We hope to be able to provide you with a more precise date shortly.

Set out below are the questions which we would like you to address in your report:

Medication Management

1. Please describe the medication management system in long term care homes in Ontario in respect of both controlled and non-controlled drugs and high-alert medications in both of those categories.
    a. What are the minimum requirements for medication management systems both in terms of infrastructure and oversight as the medication flows from pharmacy to patient?
    b. Are there variations in medication management systems from facility to facility?
    c. How are medications in both categories stored, tracked and disposed of?
2. Please describe whether and how medication is overseen and managed in the home care setting.
3. What safeguards are in place in the home care setting with respect to both controlled and non-controlled drugs and high-alert medications in both of those categories?

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Preventing Intentional Harm

1. What steps are in place/could have been in place that would have prevented the misuse of insulin by Elizabeth Wettlaufer?

Detecting Intentional Harm

1. Do you recommend any measures as part of a medication management system that would be able to detect whether an ill or unresponsive patient was intentionally harmed by the misuse of medication?

2. Are there any steps that a long term care facility or a home care service provider can take to analyze a medication incident that would help detect whether a patient was intentionally harmed by the misuse of medication?

We would appreciate receiving a report by not later than May 25th but wish to discuss the contents of the report with you prior to its delivery.

Thank you again for agreeing to act as an expert for the LTCI. If you have any questions or with di discuss this matter further, please do not hesitate to contact me.

Yours very truly,

Mark Zigler
Co-Lead Commission Counsel

Appendix 2: Curriculum Vitae: Julie Greenall

Curriculum Vitae
Julie Greenall, RPh, BScPhm, MHSc (Bioethics), ACPR, FISMPC
Director of Projects and Education, ISMP Canada
julie.greenall@ismpcanada.ca; 416-733-3131 ext 223

Profile:

Julie has more than 35 years of clinical and management experience in pharmacy practice in community hospitals, long-term care and community pharmacy. Julie received her BScPhm degree in 1981 and an MHSc in Bioethics in 2006, both from the University of Toronto.

Julie joined ISMP Canada in 2004 to complete the first Canadian Fellowship in Safe Medication Management and became a staff member in 2005. In her current position as Director of Projects and Education, she is responsible for ISMP Canada's consultation and education programs.

Julie has participated in numerous medication system reviews, root cause analyses of critical medication incidents and proactive risk assessment projects. Associated with these reviews, Julie has been an expert witness for coroner inquests.

Julie has been an author and reviewer of medication safety-related articles and is actively involved in the development of ISMP Canada Safety Bulletins. Julie is a co-author of the 2006 Canadian Root Cause Analysis Framework and the revised Canadian Incident Analysis Framework released in 2012. In 2015-16, she led the revision of ISMP Canada's Failure Mode and Effects Analysis Framework and Hospital Medication Safety Self Assessment program.

Julie has provided educational presentations and workshops on a variety of medication safety topics across Canada and internationally and is a media spokesperson for ISMP Canada.

Education:

2006	**Masters of Health Science in Bioethics,** University of Toronto, Toronto, ON
2005	**Fellowship in Safe Medication Management,** ISMP Canada, Toronto, ON This one-year program provided a comprehensive curriculum covering a variety of safety-related topics, including the relationship of human factors engineering principles to error opportunity and design of systems for patient safety, root cause analysis and failure mode and effects analysis.
1997	**Teaching and Training Adults Certificate Program,** Georgian College, Barrie, Ontario (75 contact hours).
1982	**Accredited Canadian Pharmacy Residency,** Toronto General Hospital, Toronto, ON This one-year post-graduate specialty program provided practical experience in areas such as clinical pharmacy, drug information, and sterile manufacturing.
1981	**Bachelor of Science in Pharmacy,** University of Toronto, Toronto, ON

Professional Experience

January 2012 – present
Director of Projects and Education, ISMP Canada, Toronto, ON
(New job title January 2014; evolving responsibilities since 2012)

Key responsibilities:

- Oversight of ISMP Canada's consultation and education programs
- Strategic and operational planning and day to day organizational management activities
- Coordinating, supervising and conducting consultation projects (e.g., incident analysis, proactive risk assessment, medication system safety reviews)

Selected highlights:

- Project lead and key content expert for development of an online learning program: *Medication Safety Considerations for Compliance Packaging,* 2016-2017
- Project lead and key content expert for update of ISMP Canada's *Canadian Failure Mode And Effects Analysis Framework: Proactively Assessing Risk in Healthcare,* 2015-2016, 2018
- Project lead and key content expert for update of ISMP Canada's *Hospital Medication Safety Self Assessment,* 2015-2016
- Project lead and key content expert for community pharmacy on-site assessments, 2014-present
- Development and implementation of framework for community pharmacy on-site assessments on referral from the Ontario College of Pharmacists, 2013-2014
- Expert witness, coroner's inquest into a multi-drug toxicity death in a small hospital, June 2014
- Expert witness, coroner's inquest into a multi-drug toxicity death in a detention centre, March 2014
- Leadership of collaborative project with 4 Provincial Offices of the Chief Coroner/Chief Medical Examiner 2012-14
    - Abstraction, review and analysis of deaths investigated by coroners and medical examiners that were associated with a medication incident, including publication of associated ISMP Canada Safety Bulletins (http://www.ismp-canada.org/download/safetyBulletins/2014/ISMPCSB2014-2_DeathsAssociatedwithMedicationIncidents.pdf; http://www.ismp-canada.org/download/safetyBulletins/2013/ISMPCSB2013-08_DeathsAssociatedWithMedicationIncidents.pdf)
    - Sub-component: HYDROmorphone Demonstration Project (http://www.ismp-canada.org/download/safetyBulletins/2013/ISMPCSB2013-10_HYDROmorphone.pdf)
- Expert witness, coroner's inquest into an opioid-related death in a long-term care home, March 2012
- ISMP Canada lead for the development of the *2012 International Medication Safety Self Assessment for Oncology* (joint project with ISMP (US) and the International Society of Oncology Pharmacy Practitioners)
- Member, Accreditation Canada working groups on Managing Medication Standards and Required Organizational Practices, 2011-2012
- Customization of ISMP Canada's *Canadian Failure Mode and Effects Analysis Framework: Proactively Assessing Risk in Healthcare* for a provincial pharmacy regulatory body, 2011-2012
- Customization of the *Canadian Root Cause Analysis Framework* for a provincial pharmacy regulatory body, 2010-2011.
- Committee member, Patient Safety Review Committee of the Office of the Chief Coroner for Ontario, 2011-present

2005 - 2011
Project Leader, ISMP Canada, Toronto, ON

Key responsibilities:

- Coordinating, supervising and conducting medication system safety reviews, analyses of sentinel events, prospective risk assessments and other consultation projects in various healthcare settings including acute care, long term care and community living, including proposal development and report writing.
- Developing customized workshops and educational presentations for practitioners of all disciplines in a variety of settings
- Coordinating and writing safety bulletins and articles for publication
- Participating in strategic and operational planning activities as part of the ISMP Canada leadership team

Selected accomplishments:

- Co-chair, revision of Medication Safety Self-Assessment® for Hospitals, 2006
- Co-author, Canadian Root Cause Analysis Framework, 2006 and revised version, the Canadian Incident Analysis Framework released 2012

2005 – 2015
Staff Pharmacist, Georgian Bay General Hospital, Midland/Penetanguishene, Ontario
(Casual; approximately one shift per month)

Key responsibilities:

- Provision of clinical and distributive medication services for inpatients

1996 – 2004
Manager, Pharmacy, North Simcoe Hospital Alliance, Midland/Penetanguishene, Ontario
(formerly Huronia District Hospital and Penetanguishene General Hospital; now Georgian Bay General Hospital)

Key responsibilities:

- Administrative and clinical oversight of the pharmacy department, including supervision of professional and technical staff, policy and procedure development and implementation, budget management, workload measurement
- Clinical and distributive functions i.e., pharmacotherapy monitoring and intervention, interdisciplinary rounds, dispensing, sterile and non-sterile compounding.

Selected accomplishments:

- Developed and enhanced the medication safety management system, and associated educational activities
- Implemented centralized IV admixture of selected medications, 2001
- Implemented Meditech Pharmacy Information System module, 1998
- Implemented a parenteral nutrition program, 1995

1991 – 1996
Director of Pharmacy, Penetanguishene General Hospital, Penetanguishene, Ontario

1987 – 1989
Director of Pharmacy, Huronia District Hospital, Midland, Ontario

1985 – 1986
Chief Pharmacist, Southwestern Regional Centre, Blenheim, Ontario
(600 bed residential care facility for individuals with intellectual disabilities)

Staff Pharmacist Experience:

1994 – 1996	Huronia District Hospital, Midland, Ontario
1990 – 1994	Shoppers Drug Mart, Midland, Ontario
1990 – 1991	Penetanguishene General Hospital, Penetanguishene, Ontario
1989 – 1990	Shoppers Drug Mart, Wasaga Beach, Ontario
1987	Dostal IDA, Caledonia, Ontario
1986	Hamilton Psychiatric Hospital, Hamilton, Ontario
1985	Super X Drugs, Chatham, Ontario
1982 – 1984	Queensway-Carleton Hospital, Nepean, Ontario
1982	Boots Drug Stores, Ottawa, Ontario

Professional Registration, Memberships and Other Activities

Registrations:
- Pharmacy Examining Board of Canada Registration 1981
- Licensed with Ontario College of Pharmacists 1982

Memberships:
- Canadian Society of Hospital Pharmacists
- Ontario Pharmacists Association
- Canadian Pharmacists Association
- Canadian Bioethics Society (approx. 2006-2010)

Other Activities:
2003 – 2004 Member, Product Advisory Committee, HealthPro buying group
2001 – 2002 Member, Standards of Practice working group, Ontario College of Pharmacists

Publications

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Appendix 3: Ontario Government Pharmacy Medication Order Form

Ontario

Ministry of Health and Long-Term Care

Supply Chain and Facilities Branch
Tel. 416 327-0837
Fax 416 327-0818

Requisition for ODB Approved Non-Prescription Drugs

Instructions

- Complete the client header information and the columns to indicate the "**Quantity Ordered**" and the "**Quantity on Hand**".
  Note: The products marked with an "*" under the "Units" column are issued in shelf packs.
  Therefore, a quantity of one (1) must be entered under the "Qty. ordered (units)" column to receive six (6) tubes of 100g.
- Fax **both** pages of your order to OGPMSS in Toronto.
  Note: Please refer to the transport schedule for order deadlines to meet the next scheduled delivery for your zone.

Ship to Address

Home Name					Client No.
Unit No.	Street No.	Street Name			Telephone No.
City			Province ON	Postal Code	Fax No.
Home Licence No.		Qualified Residents	Ordered By		
Home Administrator's Name (Please print)			Home Administrator's Signature		Date (yyyy/mm/dd)

Product Number	Quantity Ordered (units)	Units *shelf packs	Description	Quantity on hand
Analgesics				
6528-1002-1	X	100	Acetylsalicylic Acid 325 mg Ent Tab	
6528-1008-1	X	100	Acetylsalicylic Acid 650 mg Ent Tab	
6528-1010-2	X	1000	Acetaminophen 325 mg Tab	
6528-1011-2	X	1000	Acetaminophen 500 mg Tab	
6572-1717-2	X	100g	Analgesic Rub	
Antacids				
6554-1503-0	X	425mL	Aluminum Hydroxide 64 mg/mL O/L	
6554-1505-0	X	500mL	Magnesium Hydroxide 80 mg/mL O/L	
6554-1507-0	X	350mL	Aluminum Hydroxide & Magnesium Hydroxide 40 mg & 40 mg/mL O/L	
6554-1509-0	X	350mL	Aluminum Hydroxide & Magnesium Hydroxide & Dimethylpolysiloxane 40 mg & 40 mg & 5 mg/mL O/L	
Antihistamines				
6501-1006-0	X	100	Cyproheptadine HCl 4 mg Tab	
6501-1008-2	X	100	Chlorpheniramine Maleate 4 mg Tab	
6501-1101-1	X	250	Diphenhydramine HCl 25 mg capsule or caplet	
6501-1102-0	X	100	Diphenhydramine HCl 50 mg capsule or caplet	
Anti-infectives				
6502-1501-0	X	500mL	Hydrogen Peroxide 3% Solution	
6572-1509-0	X	500mL	Povidone-Iodine 10% Top Solution	
Anti-nauseants				
6557-1001-1	X	100	Dimenhydrinate 50 mg Tab	
6557-1401-0	X	10	Dimenhydrinate 100 mg Sup	
6557-1402-0	X	10	Dimenhydrinate 50 mg Sup	
6557-1501-2	X	75mL	Dimenhydrinate 3 mg/mL O/L	
Cathartics				
6556-1006-0	X	100	Bisacodyl 5 mg Ent Tab	
6556-1401-0	X	100	Bisacodyl 10 mg Sup	
6556-1402-0	X	24	Glycerin 2.34 g Sup Adult	
6556-1901-3	X	*24x133mL	Sodium Biphosphate & Sodium Phosphate 160 mg & 60 mg/mL Enema	
6556-1004-1	X	1000	Sennosides A and B 8.6 mg Tab	
6556-1605-0	X	336g	Psyllium Mucilloid Oral Pd	

Home Name	Client No.

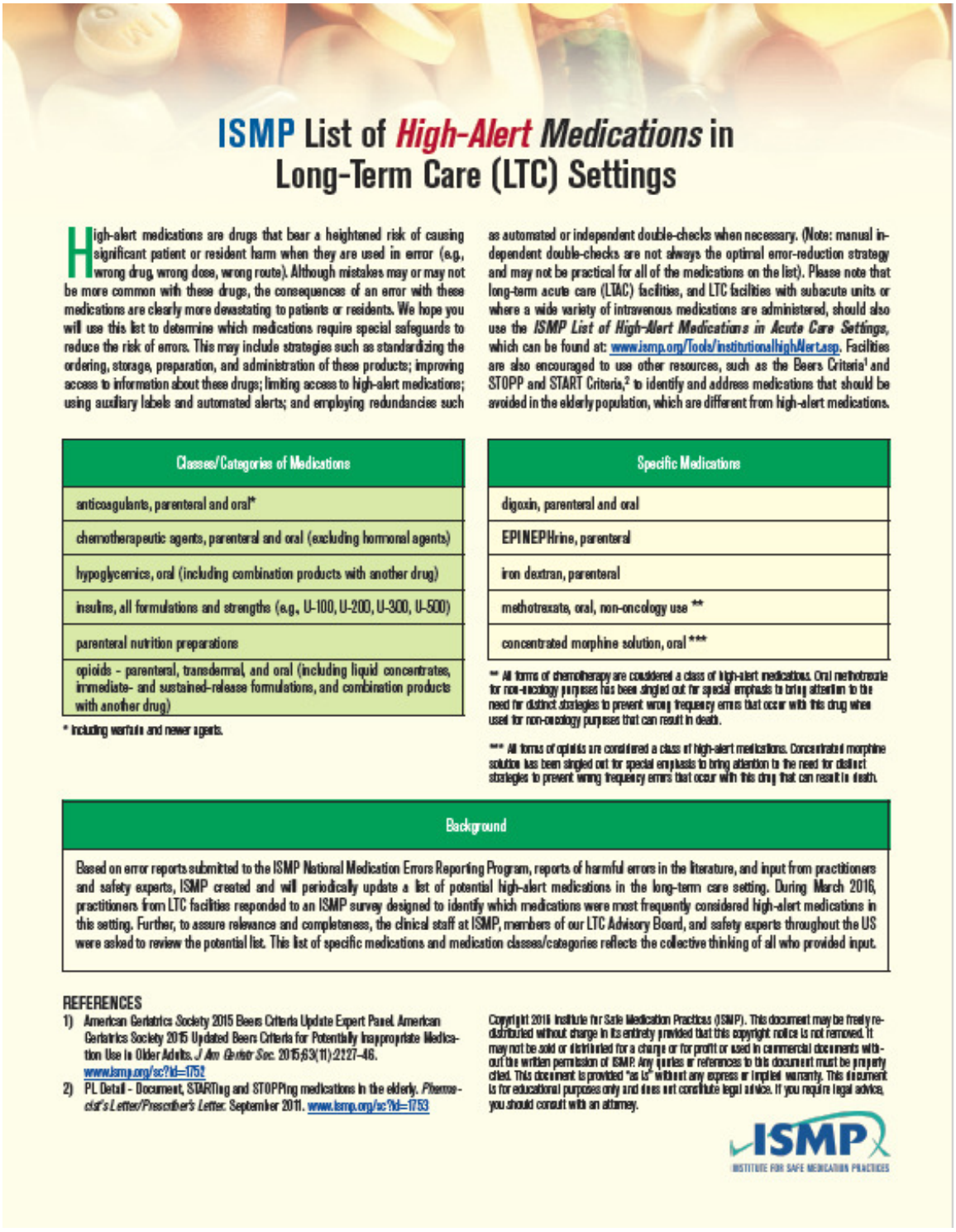
3060-97E (2018/01) Disponible en français 7530-5038-E Page 1 of 2

Product Number	Quantity Ordered (units)	Units *shelf packs	Description	Quantity on hand
Cathartics				
6556-1104-0	X	100	Docusate Sodium 100 mg Cap	
6556-1503-0	X	500mL	Cascara Sagrada O/L	
Cough Preparations				
6544-1508-1	X	250mL	Dextromethorphan Hydrobromide 3 mg/mL O/L	
6544-1504-1	X	250mL	Guaifenesin 20 mg/mL O/L	
Dermatologicals				
6572-1751-4	X	650mL	Body Lotion	
6572-1715-0	X	500mL	Calamine Lotion	
6572-1730-0	X	100g	Silicone 20% Cream	
6572-0502-0	X	*12x500mL	Isopropyl Rubbing Alcohol	
6572-1713-1	X	100g	White Petroleum Ointment	
6572-1710-2	X	100g	Zinc Oxide 15% Ointment	
Electrolytic, Caloric & Water Balance				
6537-1102-0	X	100	Potassium Chloride 600 mg LA Cap (8 mEq)	
6537-1004-0	X	100	Potassium Chloride 600 mg LA Tab (8 mEq)	
6537-1505-0	X	500mL	Potassium Chloride 1.33 mEq/mL O/L	
6542-4501-0	X	1000mL	Sterile Water for Irrigation	
6542-4507-1	X	500mL	Sodium Chloride 0.9% Sol for Irrigation	
6590-1201-2	X	*25x10mL	Water for Injection	
Hemorrhoidal Preparations				
6572-1752-0	X	30g	Zinc Sulphate 0.5% Ointment	
Iron Preparations				
6518-1002-1	X	100	Ferrous Gluconate 300 mg Tab	
6518-1004-0	X	100	Ferrous Sulfate 300 mg Tab	
Opthalmic Preparations				
6552-1804-0	X	15mL	Methylcellulose 1% Oph Sol	
6552-1803-0	X	15mL	Methylcellulose 0.5% Oph Sol	
Vasodilators				
6523-1001-0	X	100	Nitroglycerin 0.6 mg SL Tab	
Vitamins				
6578-1007-2	X	100	Multivitamin Tab	
6578-1102-1	X	90	Vitamin B Cpd & C Cap or Tab	
6578-1501-0	X	50mL	Vitamins A & C & D& B Complex Ped O/L	
6578-2203-1	X	10mL	Cyanocobalamin 1 mg/mL Inj Sol	
6578-4012-2	X	250	Ascorbic Acid 500 mg Tab	
Forms				
7530-5038-E	Requisition for ODB Approved Non-Prescription Drugs (Form No. 3060-97E). Form available online at: http://www.forms.ssb.gov.on.ca/mbs/ssb/forms/ssbforms.nsf/GetFileAttach/014-3060-97E~17/$File/3060-97E.pdf			

Print Form

Clear Form

Appendix 4: List of High-Alert Medications in Long-Term Care Settings[52]



ISMP List of *High-Alert Medications* in Long-Term Care (LTC) Settings

High-alert medications are drugs that bear a heightened risk of causing significant patient or resident harm when they are used in error (e.g., wrong drug, wrong dose, wrong route). Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients or residents. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies such as standardizing the ordering, storage, preparation, and administration of these products; improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels and automated alerts; and employing redundancies such as automated or independent double-checks when necessary. (Note: manual independent double-checks are not always the optimal error-reduction strategy and may not be practical for all of the medications on the list). Please note that long-term acute care (LTAC) facilities, and LTC facilities with subacute units or where a wide variety of intravenous medications are administered, should also use the *ISMP List of High-Alert Medications in Acute Care Settings*, which can be found at: www.ismp.org/Tools/institutionalhighAlert.asp. Facilities are also encouraged to use other resources, such as the Beers Criteria[1] and STOPP and START Criteria,[2] to identify and address medications that should be avoided in the elderly population, which are different from high-alert medications.

Classes/Categories of Medications
anticoagulants, parenteral and oral*
chemotherapeutic agents, parenteral and oral (excluding hormonal agents)
hypoglycemics, oral (including combination products with another drug)
insulins, all formulations and strengths (e.g., U-100, U-200, U-300, U-500)
parenteral nutrition preparations
opioids - parenteral, transdermal, and oral (including liquid concentrates, immediate- and sustained-release formulations, and combination products with another drug)

* Including warfarin and newer agents.

Specific Medications
digoxin, parenteral and oral
EPINEPHrine, parenteral
iron dextran, parenteral
methotrexate, oral, non-oncology use **
concentrated morphine solution, oral ***

** All forms of chemotherapy are considered a class of high-alert medications. Oral methotrexate for non-oncology purposes has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent wrong frequency errors that occur with this drug when used for non-oncology purposes that can result in death.

*** All forms of opioids are considered a class of high-alert medications. Concentrated morphine solution has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent wrong frequency errors that occur with this drug that can result in death.

Background

Based on error reports submitted to the ISMP National Medication Errors Reporting Program, reports of harmful errors in the literature, and input from practitioners and safety experts, ISMP created and will periodically update a list of potential high-alert medications in the long-term care setting. During March 2016, practitioners from LTC facilities responded to an ISMP survey designed to identify which medications were most frequently considered high-alert medications in this setting. Further, to assure relevance and completeness, the clinical staff at ISMP, members of our LTC Advisory Board, and safety experts throughout the US were asked to review the potential list. This list of specific medications and medication classes/categories reflects the collective thinking of all who provided input.

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2) PL Detail - Document, STARTing and STOPPing medications in the elderly. *Pharmacist's Letter/Prescriber's Letter.* September 2011. www.ismp.org/sc?id=1753

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

[52] ISMP List of High-Alert Medications in LTC Settings; available from: https://www.ismp.org/sites/default/files/attachments/2017-11/LTC-High-Alert-List.pdf.

Appendix 5: ISMP Canada Safety Bulletin: Unexpected Hypoglycemia

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national nonprofit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

ISMP CANADA

HIROC

The Healthcare Insurance Reciprocal of Canada (HIROC) is a member-owned expert provider of professional and general liability coverage and risk management support.

Volume 7, Issue 1 **ISMP Canada Safety Bulletin** March 30, 2007

Unexpected Hypoglycemia: Consider Medication Error in the Differential Diagnosis

A recent cluster of voluntarily submitted medication incident reports in which use of insulin or an oral hypoglycemic agent led to harm in nondiabetic patients has prompted a focused review. The term "medication incident" is widely used to represent the preventable subset of potential and actual adverse drug events. It is also recognized as an alternative term for "medication error".[1] Ten drugs accounted for 43% of all harmful medication incidents reported to ISMP Canada. Of these, insulin was second only to opioids as a leading cause of harm.[2] Oral hypoglycemic agents have been identified as high-alert medications, but an ISMP US survey indicated that only 23% of healthcare practitioners (nurses, pharmacists) considered them as high-alert medications.[3] The purpose of this bulletin is to heighten awareness of medication incidents involving insulin and oral hypoglycemic agents.

The risk of drug-induced severe hypoglycemia (e.g., blood glucose less than 2.8 mmol/L) exists with both insulin and oral hypoglycemic agents such as those that stimulate the body's release of insulin (sulfonylureas [e.g., glyburide, gliclazide, glimepiride, chlorpropamide, tolbutamide] and metiglinides [e.g., repaglinide and nateglinide]).[4] The incidents reported to ISMP Canada involving these medications are summarized in Table 1. Although it is impossible to infer or project the absolute occurrence rate of specific incidents on the basis of voluntary reports, these data are useful to indicate trends and areas of concern.

Table 1. Reported medication incidents* involving insulin and oral hypoglycemic agents that stimulate insulin release

Category of medication	Total no. of reports	No. of reports categorized as harmful,† including death
All insulins	811	88 (10.9%)
Oral hypoglycemic agents that stimulate insulin release (sulfonylureas and metiglinides)	149	10 (6.7%)

* ISMP Canada's voluntary reporting program has been in place since 2001. A total of 19,508 incident reports (including reports of near misses) have been collected since the program's inception. Of these, 886 (4.5%) were reported to have resulted in harm to patients, including death.

† As defined by the Canadian Medication Incident Reporting and Prevention System (CMIRPS).[5]

The following examples of voluntary reports involving harm are shared:

- A nondiabetic patient received 50 units of insulin subcutaneously (0.5 mL) instead of the intended heparin 5,000 units (0.5 mL); this incident led to serious harm.
- A nondiabetic adult patient being treated for dementia was experiencing recurrent hypoglycemia. An endocrinologist was consulted who ordered blood tests to rule out the presence of hypoglycemic medications; the results came back positive. Follow-up investigations by the pharmacy led to the conclusion that the sulfonylurea glimepiride had been dispensed instead of galantamine.
- An elderly nondiabetic nursing home resident suddenly became tremulous. She was transferred to hospital after becoming unresponsive. In hospital, she was treated for hypoglycemia and admitted. Blood tests confirmed therapeutic levels of glyburide, a drug that had not been prescribed for her. This information was communicated to the nursing home. A few days after returning to the nursing home, the patient was again found unresponsive and was readmitted to the hospital for treatment of hypoglycemia. Although her hypoglycemia was treated, she died several days later. Follow-up autopsy identified a therapeutic level of glyburide in her blood and concluded that a medication error had probably occurred repeatedly.
- In two unrelated case reports, patients received glyburide instead of prednisone from their community pharmacies. Both patients took the glyburide for several days, which led to severe hypoglycemia. In one case, the error was recognized when the patient presented to a local hospital emergency department and a pharmacist conducted a medication review. The patient required treatment and monitoring, and

the community pharmacy was notified of the error. In the other case, the error was not recognized until after admission. Despite intravenous administration of dextrose 50% and admission to the intensive care unit, the patient died. In both cases, the containers were labelled as prednisone, and the medication errors were discovered only after inspection of the tablets.

These cases illustrate the importance of considering the possibility of a medication error when hypoglycemia occurs unexpectedly. Numerous medications can cause hypoglycemia; "however the predominant causes of drug-induced hypoglycemia, even in nondiabetic patients, are the drugs used to treat diabetes."[6] Cases of unexpected hypoglycemia due to the inadvertent administration of insulin or an oral hypoglycemic agent to nondiabetic patients have been reported in literature.[6-12] It has also been highlighted that patients who were admitted to hospital for treatment of hypoglycemia and who denied any use of a hypoglycemic agent had received such medication inadvertently.[11,12] Although all of the case reports highlighted here involved the inadvertent administration of a hypoglycemic agent to nondiabetic patients, medication errors can lead to hypoglycemia in diabetic patients as well.[7,14,15]

The cases described suggest preventative strategies for error-induced harm from insulin and oral hypoglycaemic agents. In the first case, insulin was substituted for heparin. Underlying factors contributing to mix-ups between insulin and heparin include the fact that both of these medications are dosed in units, they are available in similar formats (e.g., 10 mL multidose vials), and both may be stored in patient care areas and may be placed in close proximity to one another (e.g., atop a medication cart).[6,7] In the glimepiride and galantamine mix-up, the intended drug (glimepiride) was stored beside the galantamine in the pharmacy. In one of the mix-ups between glyburide (Diabeta) and prednisone (Deltasone), the drugs were also stored side by side in the pharmacy. Other reported substitution errors have included glyburide for oxybutynin (Ditropan), glyburide for lorazepam, and chlorpropamide for chlorpromazine.[7,9,10,12] Preventative strategies include:

- Segregate insulin in storage areas. Specifically, do not store insulin vials on top of medication carts or on counters in medication rooms.
- Consider use of 5,000 unit single-dose ampoules of heparin or prefilled syringes for subcutaneous administration whenever possible.
- Manage oral hypoglycemic agents as high-alert medications. For example:
  1. Review how oral hypoglycemic agents are stored in the pharmacy and ensure they are optimally stored for differentiation.
  2. Dispense patient-specific unit doses of these agents whenever possible.

An overview of submitted medication incident reports involving insulin, the underlying causes of these incidents, and the resulting recommendations were highlighted in a previous ISMP Canada bulletin.[14]

Although prevention strategies are paramount, a significant finding from this review is the identification of missed opportunities to reduce the degree of harm (or the recurrence of harm) associated with medication incidents involving hypoglycemic agents. Early identification of an error involving insulin or an oral hypoglycemic agent can provide a window of opportunity to mitigate harm and also identify and eliminate the underlying cause(s) of the error to prevent recurrence. It is essential to **consider the possibility of a medication error, in the differential diagnosis, whenever unexpected hypoglycemia occurs**.

ISMP Canada gratefully acknowledges the input provided by (in alphabetical order): Bill Cornish, RPh, BScPhm, ACPR, Drug Information Services, Sunnybrook Health Sciences Centre; Patti Cornish, RPh, BScPhm, Patient Safety Service, Sunnybrook Health Sciences Centre; Edward Etchells, MD, FRCP, Director, Patient Safety Service, and Staff Physician, Division of Internal Medicine, Sunnybrook Health Sciences Centre, and Associate Professor, University of Toronto; Sandra Nicholson, RPh, BScPhm, Sunnybrook Health Sciences Centre and John Senders, PhD, Professor Emeritus, Faculty of Applied Sciences, University of Toronto.

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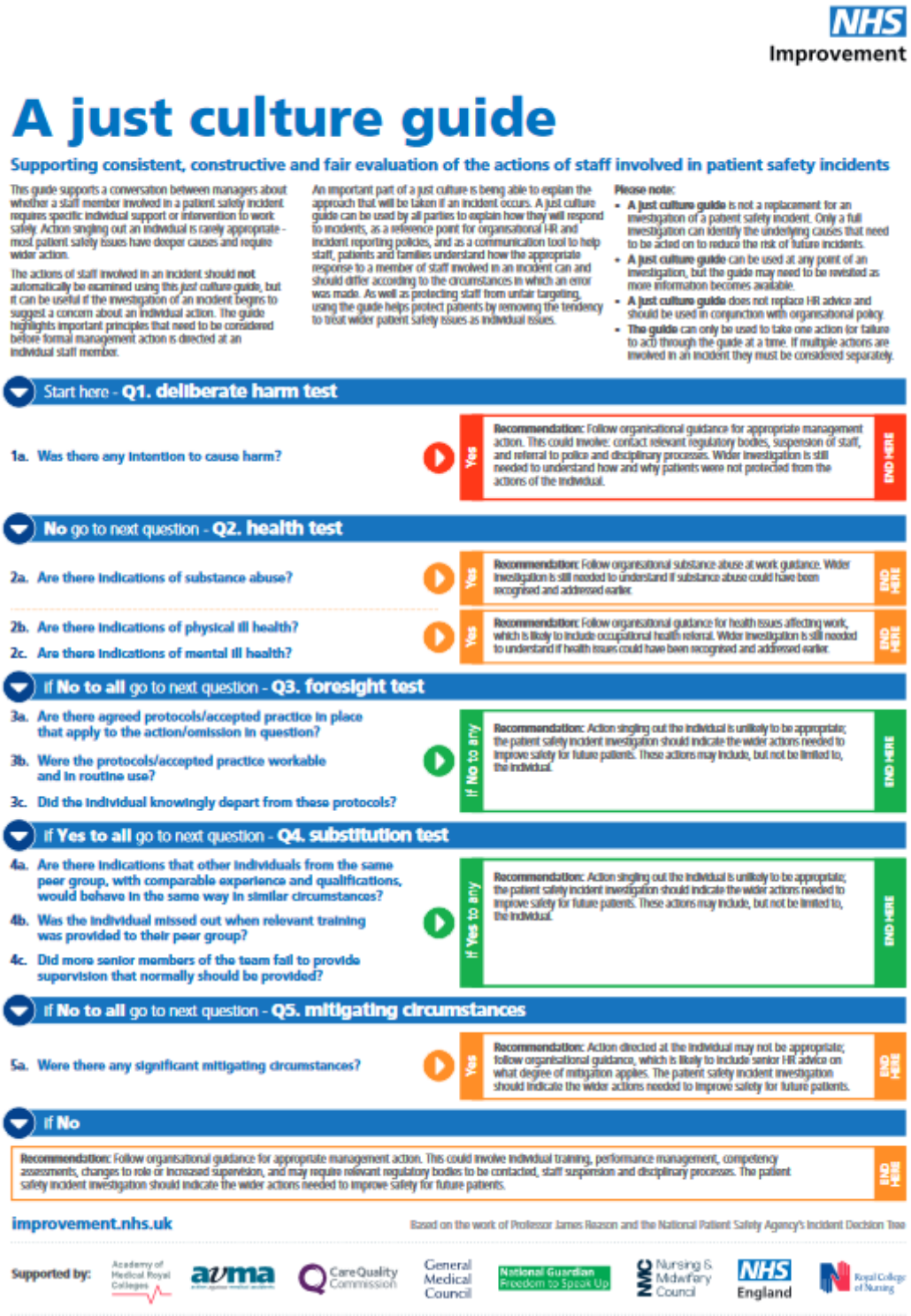
ALERT: Zytram XL Name Looks and Sounds Like Zyban

ISMP Canada has received a report of concern about a newly marketed product with the brand name Zytram XL. Zytram XL is the brand name for tramadol hydrochloride controlled release tablet. Zytram XL looks and sounds like a brand name for buproprion hydrochloride, Zyban. Zytram XL is an opioid analgesic, whereas Zyban is a smoking cessation aid. With both products available in 150 mg tablets (Zytram XL is also available in 200 mg, 300 mg, and 400 mg controlled release tablets), the reporter expressed concerns about the possibility of an inadvertent mix-up. Subsequently, ISMP Canada received a second report in which a prescription for "Zytram XL 150 mg po once daily" was processed as "Zyban 150 mg po once daily". ISMP Canada has notified Health Canada and Purdue Pharma, and both organizations are following up on these reports.

The following strategies are suggested as interim measures to reduce the risk of a mix-up: use the generic name (in addition to the brand name where applicable), clarify the indication of the drug with the patient and the prescriber if necessary, clearly distinguish the two drugs in the product selection screen of pharmacy order entry systems, and avoid stocking these items in close proximity in the pharmacy.

Appendix 6: NHS Just Culture Guide[53]



NHS Improvement

A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this *just culture guide*, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- **A just culture guide** is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- **A just culture guide** can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- **A just culture guide** does not replace HR advice and should be used in conjunction with organisational policy
- **The guide** can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - Q1. deliberate harm test

1a. Was there any intention to cause harm?

Yes → **Recommendation:** Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual. END HERE

No go to next question - **Q2. health test**

2a. Are there indications of substance abuse?

Yes → **Recommendation:** Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier. END HERE

2b. Are there indications of physical ill health?

2c. Are there indications of mental ill health?

Yes → **Recommendation:** Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier. END HERE

If **No to all** go to next question - **Q3. foresight test**

3a. Are there agreed protocols/accepted practice in place that apply to the action/omission in question?

3b. Were the protocols/accepted practice workable and in routine use?

3c. Did the individual knowingly depart from these protocols?

If No to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. END HERE

If **Yes to all** go to next question - **Q4. substitution test**

4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?

4b. Was the individual missed out when relevant training was provided to their peer group?

4c. Did more senior members of the team fail to provide supervision that normally should be provided?

If Yes to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. END HERE

If **No to all** go to next question - **Q5. mitigating circumstances**

5a. Were there any significant mitigating circumstances?

Yes → **Recommendation:** Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. END HERE

If No

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. END HERE

improvement.nhs.uk

Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

Supported by: Academy of Medical Royal Colleges; avma; CareQuality Commission; General Medical Council; National Guardian Freedom to Speak Up; NMC Nursing & Midwifery Council; NHS England; Royal College of Nursing

[53] NHS Just Culture Guide; available from: https://improvement.nhs.uk/documents/2490/NHSi_just_culture_guide_A3.pdf