Medication Safety Self-Assessment:

Focus on "Never Events" in Long-Term Care



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Introduction

The Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI) are excited to launch this new Medication Safety Self-Assessment (MSSA) program focusing on "never events".

"Never events are resident safety incidents that result in serious harm or death, and that can be prevented by using organizational checks and balances." 1

The Medication Safety Self-Assessment: Focus on "Never Events" (MSSA – Never Events) in Long-Term Care was designed to help Canadian healthcare practitioners in the long-term care sector to identify and address system vulnerabilities underlying critical incidents associated with high-alert medications, with a specific focus on never events.

Content has been derived from material developed through the Canadian Medication Incident Reporting and Prevention System (CMIRPS)², including ISMP Canada Safety Bulletins and MSSA programs for hospitals and long-term care and CPSI's Global Patient Safety Alerts³. Information from materials developed by ISMP in the US has also been incorporated, including from the ISMP Medication Safety Self-Assessment for High-Alert Medications.⁴ Selected supporting references for individual assessment items have been provided in Appendix 1.

This program is designed to support long-term care Homes in:

- Raising awareness of medication-related never events;
- Identifying high-leverage strategies to reduce the likelihood of never events and other critical incidents with high-alert medications;
- Creating a baseline measurement of the current implementation of recommended strategies to avoid never events; and
- Evaluating progress over time through periodic repeated measurement.

The value of ongoing evaluation with a self-assessment program in long-term care was highlighted in a 12-year review of responses to ISMP Canada's MSSA for Long-term Care, which showed that mean total self-assessment scores improved over time.⁵

The MSSA – Never Events assessment includes a total of 48 items, divided into 7 sections. Section I focuses on known never events and Section II on general strategies for safety. Sections II-VII focus on selected high-alert medication classes. Not all items will be applicable in all settings.

¹ Health Quality Ontario and Canadian Patient Safety Institute. Never Events for Hospital Care in Canada. Safer Care for Patients. September 2015. Available from:

 $[\]underline{\text{http://www.patientsafetyinstitute.ca/en/toolsResources/NeverEvents/Documents/Never%20Events%20for%20Hospital%20Care%20in%20Canada.pdf.}$

 $^{{}^2\} Canadian\ Medication\ Incident\ Reporting\ and\ Prevention\ System\ (CMIRPS);\ see:\ https://www.ismp-canada.org/cmirps/index.htm.}$

³ Canadian Patient Safety Institute. Global Patient Safety Alerts. Available from: http://www.patientsafetyinstitute.ca/en/NewsAlerts/Alerts/Pages/default.aspx.

⁴ Institute for Safe Medication Practices (United States). Medication Safety Self-Assessment for High-Alert Medications, 2017. Available from: https://www.ismp.org/assessments/high-alert-medications.

⁵ Medication Safety in Long-Term Care: Measuring Quality Improvement Over 12 Years. ISMP Canada Safety Bulletin, 2019; 19(3). Available from: https://www.ismp-canada.org/download/safetyBulletins/2019/ISMPCSB2019-i3-LTC-MSSA.pdf.

The assessment items are presented in an order that reflects the medication use process, beginning with resident/family engagement⁶ and then following the steps in the medication use process: prescribing, order processing/transcription, dispensing, administration and monitoring. Some sections also include "Supporting System Elements", such as Staff Competence and Education, and Quality Processes and Risk Management. Not all sections include items from each of these steps.

ISMP Canada and CPSI are not standard-setting organizations; the assessment items in this document are not intended to represent a minimum standard of practice and should not be considered as such. In fact, some of the items represent innovative practices that may not be widely implemented; however, their value in reducing errors is grounded in scientific research and expert analysis of medication errors and their causes.

This assessment is aligned with the World Health Organization Global Patient Safety Challenge: Medication Without Harm.⁷

The MSSA – Never Events and its components are copyrighted by ISMP Canada and may not be used in whole or in part for any other purpose or by any other entity except for self-assessment of medication systems as part of ongoing quality improvement activities.

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⁶ Patient Engagement Action Team. 2017. Engaging Patients in Patient Safety – a Canadian Guide. Canadian Patient Safety Institute. Last modified February 2018. Available at: www.patientsafetyinstitute.ca/engagingpatients.

⁷ World Health Organization. Medication Without Harm: WHO's Third Global Patient Safety Challenge. Available from: https://www.who.int/patientsafety/medication-safety/en/.

⁷ Institute for Safe Medication Practices (United States). Medication Safety Self-Assessment for High-Alert Medications, 2017. Available from: https://www.ismp.org/assessments/high-alert-medications.

Instructions for Completing the Self-Assessment

- 1. Establish an interdisciplinary team similar to the following:
 - Director of care
 - Resident/family representative/advocate
 - Resident safety/quality improvement and/or risk management professional
 - Physician
 - Pharmacist
 - · Pharmacy technician, if applicable
 - Registered Nurse
 - Registered Practical Nurse
- 2. Distribute the assessment document before the team meeting so that team members can review and consider the questions in advance.
- 3. Discuss each assessment item and evaluate the Home's current success in implementing the item. As necessary, investigate and verify the level of implementation for each item with other healthcare practitioners and staff outside the assessment team.

 Possible responses:
 - A There has been **no activity** to implement this item
 - B This item has been formally discussed and considered but not implemented
 - C This item has been **partially implemented** for some areas, residents, medications and/or staff in the Home.
 - D This item is **fully implemented for some** areas, residents, medications and/or staff in the Home
 - E This item is **fully implemented throughout** the Home
 - NA Not applicable use this option if the assessment criteria does not apply to your Home

Homes may want to consider assigning an individual to record any discussion generated around each assessment item and the rationale behind the selected choice. This information, meant for internal use only, can assist the team when reviewing scores for individual items or reassessing the Home at a later date.

Scoring Guidelines:

For all assessment items:

- All assessment items refer to medications prescribed, dispensed, and administered to all residents of the Home unless otherwise noted.
- Choice of E (full implementation) is appropriate only if all components are present in *all* areas of the Home, for *all* residents, *all* medications, and followed by *all* personnel. If only one or some of the components of the item have been fully implemented in only some or all areas of the Home, select C or D.

For assessment items that are not applicable to your Home:

Some assessment items may not be applicable to all long-term care Homes; for these times, criteria for a "not applicable" response have been provided. For example, some homes may not provide opioid infusions for end-of-life pain management and therefore there will be no associated risks.

5. Finalize your assessment.

You will be prompted to save your responses for each section before you proceed to the next section. When all responses have been entered, you will be prompted to "Check MSSA for errors" and then to submit your results.

Once you have submitted your results you cannot edit them. The web-based survey tool will immediately download the information into a secure database maintained solely by ISMP Canada. No data will be maintained on the Internet survey form after it has been submitted. Individual results can be viewed or accessed only by the Home submitting them. Confidentiality is assured.

6. Print/view your completed assessment.

Once your results have been submitted you will be able to print a report summarizing your results.

7. Compare your results to the aggregate.

Once your results have been submitted you will immediately be able to compare your results to the aggregate response. You can compare to the total aggregate or to demographically similar facilities using the filters provided.

8. Using aggregate data

Long-term care Homes can freely share their own results internally and externally to the organization as they deem appropriate; however, any comparisons to aggregate data can only be shared externally to the organization with written permission from ISMP Canada.

ISMP Canada and CPSI may use aggregate data for research and education purposes.

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⁸ To maintain confidentiality, a minimum of 3 responses are required before aggregate data can be viewed.

Frequently Asked Questions (FAQs)

These FAQs are related to the process for completing the self-assessment. FAQs related to content are provided within the document for selected assessment items.

How many team meetings should we schedule?

This self-assessment has been designed to be completed in one meeting of approximately 1-2 hours duration.

Do we need an interdisciplinary team to complete the self-assessment?

Because medication use is a complex, inter-disciplinary process, the value and accuracy of the assessment is significantly reduced if it is completed by a single individual or discipline involved in medication use.

Do we need senior leadership representation on our team?

Attendance by an individual from the Home's leadership team is valuable because the assessment contains many items that relate to your Home's overall commitment to resident safety. Furthermore, participation in the self-assessment provides senior leadership staff with insight into areas of risk in the medication use system.

What if an item doesn't apply to the services offered in my Home?

A "not applicable" response is available for selected assessment items.

May I make copies of the self-assessment document?

The copyright allows you to make copies of the self-assessment for internal use. You may not modify or alter the content in any way. Furthermore, you may not modify, transmit, post, or use the contents of this document for personal, public, or commercial purposes unless you have obtained written permission from ISMP Canada.

My organization has a number of sites. Do I need a password for each one?

It is recommended that each site within an organization complete the assessment independently.

How are individual items scored?

The assessment items are scored as follows:

- A=0 There has been <u>no activity</u> to implement this item.
- B=1 This item has been <u>formally discussed and considered</u>, but not implemented.
- C=2 This item has been <u>partially implemented</u> for some areas, residents, medications and/or staff.
- D=3 This item is <u>fully implemented for some</u> areas, residents, medications and/or staff.
- E=4 This item is fully implemented throughout the Home for all residents, medications and/or staff.
- NA=4 Not applicable items are scored as "fully implemented" since they should reflect items that do present any safety risks to the residents cared for by the Home.

How can we use our self-assessment results?

Once your data has been entered into the web-based program, there are several ways to examine the compiled information.

View/print options include:

- Summary of results ("report card" format)
- Graphs comparing your Home's results to the aggregate database for key elements and individual assessment items, including available filters based on demographic information submitted. (To ensure confidentiality, there must be at least 3 respondents in the aggregate to generate graphs.)

Can I share my data outside my organization?

Long-term care Homes can freely share their own results internally and externally to the organization as they deem appropriate; however, any comparisons to aggregate data can only be shared externally to the organization with written permission from ISMP Canada.

Demographic Information

1.	In which province or territory is your Home located:
2.	Which category best describes the size of the community served by your Home? Small population centre (1,000 - 29,999) Medium population centre (30,000 - 99,999) Large population centre (100,000 and over).
3.	Which category best describes your Home? Charitable Municipal Not-for-profit Private Other; please specify
4.	How many residents live in your Home? Less than 50 50-99 100-299 300-499 More than 500
5.	How are medications provided to residents? Internal pharmacy Received from an affiliated hospital or healthcare system Received from an outsourced provider not affiliated with the organization
5.	Is your Home part of a larger healthcare organization or corporate group with common governance? □ No □ Yes
	How many sites are there in your organization? 2-5 6-10 11-25 25-100 More than 100
7.	Has your Home previously completed the Medication Safety Self-Assessment for Long-Term Care? No Don't know Yes Most recent date(s) completed: 2018 2017 2016 2015 2014 or earlier Don't know

⁹ Statistics Canada Definitions (archived content); available from: https://www.statcan.gc.ca/eng/subjects/standard/sgc/notice/sgc-06.

Survey Tool

Scoring Your Self-Assessment

- A There has been <u>no activity</u> to implement this item
- B This item has been formally discussed and considered but not implemented
- C This item has been <u>partially implemented</u> for some areas, residents, medications and/ or staff in the Home
- **D** This item is <u>fully implemented for some</u> areas, residents, medications and/or staff in the Home
- E This item is <u>fully implemented throughout</u> the Home
- NA Not applicable Use this option if an assessment item does not apply to your Home

For self-assessment items with multiple components, full implementation (score of E) is appropriate only if all components are present. If only one or some of the components have been partially or fully implemented throughout the Home, self-assessment scores should not exceed "C" or "D".

I. NEVER EVENTS

Core Characteristic # 1: Strategies have been implemented to address known "never events". С D NA **Self-Assessment Items** 1.1 Medication orders are screened against validated allergies available on resident records (paper and electronic) and throughout the drug distribution system (computerized prescriber order entry [CPOE] systems, Pharmacy computers, automated dispensing cabinet [ADC] screens, etc.). ** Never event: resident harm or death associated with administration of a medication to which the resident was known to be allergic" ** 1.2 High dose/high concentration formats of opioids are not available unless prescribed for individual residents (i.e., not stocked in regular unit narcotic/controlled drug supplies or emergency drug boxes). Specific products not to be stocked: Fentanyl ampoules or vials with total dose greater than 100 mcg per container; HYDROmorphone ampoules or vials with total dose ii) greater than 2 mg; and Morphine ampoules or vials with total dose greater than iii) 15 mg in adult care areas and 2 mg in pediatric care areas. ** Never event: Overdose of hydromorphone (and other opioids) by administration of higher doses than intended due to complex calculations required with high dose/high concentration formats of these medications ** FAQ: How should situations requiring high dose/high concentration opioids be managed (e.g., end of life care)? If these medications are required, they should be labelled for individual residents and removed from the care area as soon as they

are no longer required for that resident.

II. GENERAL STRATEGIES FOR SAFETY

Core Characteristic # 2:									
Recognized high-leverage strategies for safety are implemented throughout the Home.									
Self-	Assessment Items	Α	В	С	D	E	NA		
Resid	lent/family engagement and education								
2.1	Residents and family caregivers are actively involved in shared decision-making about medication treatments and are encouraged to ask questions about the medications they are receiving.								
Presc	cribing								
2.2	Computerized prescriber order entry (CPOE) systems, which require prescribers to directly input medication orders into a computer system, are used throughout in the Home.								
	FAQ: Our Home uses the ePen to transmit orders to the pharmacy. Is this a CPOE system?								
	E-pens transmit an exact copy of the prescriber order to the pharmacy after the pen is placed in the docking station (similar to a fax). A CPOE system requires the prescriber to select the medication from a menu and enter the details of the order. The prescriber can view the resident's medication profile and there is often clinical decision support (e.g., medication allergies, access to current laboratory data).								
2.3	A list of prohibited dangerous abbreviations, symbols and dose designations, has been established for all communication of medication information and orders, including in handwritten or preprinted orders, medication administration records, medication labels, and in electronic systems. Examples include avoidance of "U" for "units" and abbreviated medication names; use of leading zeroes but not trailing zeros.								
Dispe	ensing								
2.4	Machine-readable coding (e.g., bar coding) is used in the pharmacy to verify medication selection prior to dispensing.								
	Select A or B if bar coding is not available.								
2.5	Machine-readable coding (e.g., bar coding) is used to verify products being loaded when filling automated dispensing cabinets (ADCs).								
	Select A or B if bar coding is not available. Select NA if automated dispensing cabinets are not in use in the Home.								

Core Characteristic # 2: Recognized high-leverage strategies for safety are implemented throughout the Home. В С NA D **Self-Assessment Items** 2.6 Opioid infusions (e.g., for end-of-life care) are prepared in the pharmacy and provided in a ready-to-use format that requires no further preparation or manipulation (i.e., infusions are not prepared by nurses in care areas). Select NA if opioid infusions are not provided in your Home. 2.7 TALLman lettering, when used to differentiate high-alert medications, follows the conventions recommended by ISMP Canada. Select A or B if TALLman lettering is not used in your Home. Administration 2.8 Electronic medication administration records (eMARs) are immediately accessible and used for reference during medication administration (i.e., at the bedside or medication administration location). Select A or B if paper medication records are used (handwritten or computer-generated). 2.9 Selected high-alert medications (as defined by the Home; e.g., opioids, insulin) are independently double-checked by another practitioner, and this check is documented in the health record, before administration. **OR** 2.9 Machine-readable coding (e.g., bar coding) is used prior to medication administration to identify both the resident and the medication/dose. Monitoring 2.10 All practitioners involved in the medication use process can easily and electronically access current laboratory values while working in their respective clinical locations. **Supporting System Elements Staff Competence and Education** 2.11 Practitioners who prescribe, dispense, and administer highalert medications receive ongoing information about associated risks, errors that have occurred in the Home or have been reported by external organizations, and strategies

to minimize these risks and errors.

Core Characteristic # 2:

Recognized high-leverage strategies for safety are implemented throughout the Home.

Self-A	Assessment Items	Α	В	С	D	E	NA
Qual	ity Processes and Risk Management						
2.12	One or more convened committees that include resident/family representatives and healthcare providers involved in the medication management process have been assigned responsibility for monitoring and evaluating the safety of the medication use system in the Home.						
2.13	The Home has identified a list of high-alert medications in use in the Home and established strategies to ensure the safe use of these medications (e.g., segregated storage, independent double check, auxiliary labelling).						
2.14	Internal reports of identified risks (including near misses), errors, and adverse reactions associated with high-alert medications are regularly reviewed and actions taken to address identified vulnerabilities.						
2.15	There is a standardized process to track the use of reversal agents and antidotes (e.g., glucagon, naloxone), and unexpected patterns of use of such medications are investigated to identify adverse drug events (preventable and non-preventable).						
2.16	Standardized processes are in place to review data and reports available through medication system technology (e.g., barcode scanning technology rates, automated dispensing cabinet [ADC] overrides), investigate identified problems, learn their causes, and recommend/facilitate action for improvement.						
	Select NA if no medication system technology is in use in the Home (i.e., no reports are available for review).						

Scoring Your Self-Assessment

- A There has been <u>no activity</u> to implement this item
- B This item has been formally discussed and considered but not implemented
- C This item has been <u>partially implemented</u> for some areas, residents, medications and/ or staff in the Home
- D This item is <u>fully implemented for some</u> areas, residents, medications and/or staff in the Home
- E This item is <u>fully implemented throughout</u> the Home
- **NA** Not applicable Use this option if an assessment item does not apply to your Home

III. ANTICOAGULANTS

Core Characteristic # 3:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of anticoagulants (blood thinners).

Scope: Unless otherwise stated, these items apply to oral agents (warfarin, direct oral anticoagulants [e.g., dabigatran, apixaban, rivaroxaban]), and those administered subcutaneously (unfractionated heparin, low molecular weight heparins [e.g., dalteparin, enoxaparin]).

Self-	Assessment Items	А	В	С	D	Ε	NA
Presc	cribing						
3.1	A standard, reliable process is in place to screen residents for recent anticoagulant use before invasive procedures, and, if therapy must be discontinued, protocols or guidelines define when anticoagulants should be stopped and restarted, and when alternative agents to bridge the resident should be considered.						
	FAQ; What does the term "bridge" mean in this item?						
	If a specific anticoagulant such as warfarin must be discontinued before an invasive procedure, the resident may require an alternative agent such as heparin or low molecular weight heparin in the interim. The alternative agent is often referred to as a "bridge" until the long-term anticoagulant can be resumed. The Home should develop protocols that define when bridge therapy will be prescribed. Often the decision is based on the resident's diagnosis or type of procedure that will be performed.						
3.2	Standardized protocols/order sets are used to direct the reversal of anticoagulation, when required (e.g., providing guidance for dosing of vitamin K for patients on warfarin with an elevated INR).						
Moni	toring			·			
3.3	When new residents (or residents returning from an inpatient stay) are receiving anticoagulant treatment, a practitioner verifies the indication for ongoing anticoagulation, reassessment date if applicable, and ensures laboratory testing is ordered if required.						

IV. INSULIN

Core Characteristic # 4:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of insulin.

Scope: Unless otherwise stated, these items apply to all concentrations of insulin prescribed, prepared, dispensed, and/or administered by the subcutaneous route, using a vial and syringe, pen, or continuous subcutaneous insulin infusion device (insulin pump).

Self-	Assessment Items	Α	В	С	D	Ε	NA
Presc	ribing						
4.1	The names for insulin products in computer order entry systems match order sets, protocols, medication administration records (paper and electronic), automated dispensing cabinet screens, infusion pump screens, medication labels, and any other format used to communicate medication information in the Home.						
4.2	Standard order sets that promote best practice (e.g., use of scheduled basal and bolus insulin doses, and appropriate correction doses) are used for all residents receiving subcutaneous insulin.						
4.3	Combination insulins are expressed using the full brand name and dose expression on the same line (e.g., NovoLOG Mix 70/30, not just NovoLOG Mix) in handwritten orders, computer order entry systems, order sets, protocols, medication administration records (paper and electronic), automated dispensing cabinet (ADC) screens, infusion pump screens, pharmacy labels, and any other format used to communicate medication information in the Home.						

Core Characteristic # 5 Strategies have been implemented to address risks associated with the use of concentrated insulins (e.g., U-200, U-300, U-500). **Self-Assessment Items** В С NA Prescribing Concentrated insulin products (e.g. U-200, U-300, U-500) are 5.1 clearly identified in computer order entry systems, order sets, protocols, guidelines, medication administration records (paper and electronic), automated dispensing cabinet (ADC) screens, infusion pump screens, drug storage bins, pharmacy labels, and any other format used to communicate medication information in the Home. Select NA if concentrated insulins are not used in your Home. Administration 5.2 Concentrated insulins (U-200, U-300, U-500) not given via a pen device, are administered with syringes specific to their strengths (i.e., U-100 insulin syringes and tuberculin syringes are not used). **Select NA** if concentrated insulins are not used in your Home.

Core Characteristic # 6									
Strategies have been implemented to address the risk associated with insulin pens.									
Self-Assessment Items A B C D E N							NA		
Dispensing									
6.1	Insulin pens are dispensed and labelled by the pharmacy for individual residents OR stocked in a profiled automated dispensing cabinet (ADC).								
Supp	orting System Elements								
Staff	Competency and Education								
6.2	During initial orientation and annually thereafter, all nurses and other health professionals who may administer insulin are educated about the proper use of insulin pens for a single resident and the dangers of sharing pens among multiple residents, even if the needle is changed in between residents.								

V. METHOTREXATE FOR NON-ONCOLOGIC USE

Core Characteristic # 7:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of methotrexate for non-oncologic indications.

Scope: Unless otherwise stated, these items apply to methotrexate administered by the oral, IM, or subcutaneous, route and used to treat non-oncologic conditions, such as rheumatoid arthritis, psoriasis, certain connective tissue or muscle inflammatory diseases, Crohn's disease, and multiple sclerosis. (Methotrexate used for an oncologic indication is excluded.)

Self-	Assessment Items	Α	В	С	D	E	NA
Preso	cribing and Dispensing						
7.1	Computer order entry systems (pharmacy and computerized prescriber order entry [CPOE]) have been programmed to default to a weekly rather than daily dosage regimen for oral, intramuscular and subcutaneous methotrexate.						

Scoring Your Self-Assessment

- A There has been <u>no activity</u> to implement this item
- B This item has been formally discussed and considered but not implemented
- C This item has been <u>partially implemented</u> for some areas, residents, medications and/ or staff in the Home
- D This item is <u>fully implemented for some</u> areas, residents, medications and/or staff in the Home
- E This item is <u>fully implemented throughout</u> the Home
- **NA** Not applicable Use this option if an assessment item

VI. OPIOIDS

Core Characteristic # 8:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of opioids.

Scope:

Unless otherwise stated, these items apply to opioids (including in combination with other analgesics that are administered by the following routes: oral, intramuscular, subcutaneous, transdermal, sublingual, nasal, and buccal/transmucosal.

Self-	Assessment Items	Α	В	С	D	E	NA
Presc	cribing						
8.1	Dosing guidelines are established that differentiate the management of opioid-naïve and opioid-tolerant residents (with criteria for determining opioid tolerance) and specify conditions that require dose adjustments.						
Dispe	ensing		•				
8.2	A process (e.g., alert requesting confirmation during order entry in computerized prescriber order entry [CPOE] and pharmacy systems) is in place to verify that the resident is opioid-tolerant before dispensing (or releasing from an automated dispensing cabinet [ADC]) long-acting opioids that are indicated only for such residents (e.g., fentanyl patches).						
8.3	Immediate-release and extended-release oral formulations of the same opioid are stored separately in the pharmacy.						
	Select NA if the Home is supplied by an external pharmacy that is not participating in the assessment.						
8.4	Immediate-release and extended-release oral formulations of the same opioid are stored separately in resident care areas where non-resident specific stock is available.						
	Select NA if opioids are only dispensed in resident-specific packaging.						
8.5	Morphine and HYDROmorphone are not stored right next to each other in the pharmacy.						
	Select NA if the Home is supplied by an external pharmacy that is not participating in the assessment.						

Core Characteristic # 8:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of opioids.

Scope:

Unless otherwise stated, these items apply to opioids (including in combination with other analgesics that are administered by the following routes: oral, intramuscular, subcutaneous, transdermal, sublingual, nasal, and buccal/transmucosal.

Self-	Assessment Items	А	В	С	D	E	NA	
8.6	Morphine and HYDROmorphone are not stored right next to each other in resident care areas where non-resident specific stock is available.							
	Select NA if opioids are only dispensed in resident-specific packaging.							
Administration								
8.7	The date, time, and anatomical location of an opioid transdermal patch applied to a resident is documented on the resident's medication administration record (MAR)/eMAR.							
8.8	Practitioners remove any previously applied transdermal opioid patches prior to the application of a new patch and document the patch removal on the resident's MAR/eMAR.							
8.9	A policy on the proper disposal of opioid patches exists and is followed (e.g., narcotic disposal system containers, containers that deactivate residual drug) and these items are not disposed with regular garbage.							
Moni	toring							
8.10	The Home uses a validated, standardized sedation scale (e.g., Richmond Agitation Sedation Scale, Pasero Opioid-Induced Sedation Scale ([POSS],) to guide the assessment and early detection of unintended advancing sedation during opioid therapy.							
8.11	Protocols for the use of naloxone include a requirement to monitor for signs of re-sedation and respiratory depression for at least 90 minutes after administration of the reversal agent.							

Core Characteristic # 9:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of continuous subcutaneous infusions of opioids (e.g., for end-of-life pain management).

Self-	Assessment Items	Α	В	С	D	E	NA
Resid	lent/family engagement and education						
9.1	When resident-controlled analgesia is used (e.g., continuous subcutaneous infusion of opioids with bolus dosing option), residents, family members, and visitors are educated about the dangers of any individual other than the resident activating the device to deliver a medication dose, and a warning label, "FOR RESIDENT USE ONLY," appears on the cord or activation button for the infusion pump.						
	Select NA if your Home does not provide resident controlled analgesia.						
Presc	cribing						
9.2	Standardized concentrations have been established for continuous subcutaneous infusions of opioids.						
	Select NA if your Home does not provide continuous subcutaneous infusions of opioids.						
9.3	Order sets for opioid infusions (e.g., for end-of-life care) express concentrations and hourly doses in a manner and sequence that matches the entries on medication administration records (paper/electronic), pharmacy labels and infusion pump programming requirements.						
	Select NA if your Home does not continuous subcutaneous infusions of opioids.						

Scoring Your Self-Assessment

- A There has been <u>no activity</u> to implement this item
- B This item has been formally discussed and considered but not implemented
- C This item has been <u>partially implemented</u> for some areas, residents, medications and/ or staff in the Home
- **D** This item is <u>fully implemented for some</u> areas, residents, medications and/or staff in the Home
- E This item is <u>fully implemented throughout</u> the Home
- NA Not applicable Use this option if an assessment item

VII. ORAL ANTI-CANCER DRUGS (CHEMOTHERAPY)

Core Characteristic # 10:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of **oral** anti-cancer drugs.

Scope: Unless otherwise stated, these items apply to oral medications used to treat cancer, including hormonal agents. The health risks associated with exposure to individual OACDs are typically assessed based on their potential for carcinogenicity, teratogenicity, genotoxicity, reproductive toxicity or organ toxicity.

Self-	Assessment Items	Α	В	С	D	E	NA
Prescribing							
10.1	Verbal/telephone orders are never accepted for oral anticancer drugs, except to hold or discontinue treatment.						
10.2	Orders for oral anti-cancer drugs to be taken or given on specific days are written explicitly including the specific dates medications are to be given (e.g., written as "Day 1, 2, 3," not "Days 1-3", noting the dates or indicating the start date and noting it as "Day 1").						
10.3	For intermittent treatment with oral anti-cancer drugs, the quantity prescribed and dispensed (e.g., number of tablets/capsules) for residents is the exact quantity required for a single cycle of treatment. For example, capecitabine is available in 500 mg tablets. If one cycle of treatment is ordered for capecitabine 1,250 mg/m2 [BSA = 1.6 m2] twice a day for 2 weeks, then the order would note 2,000 mg twice a day for 2 weeks with 112 tablets prescribed and dispensed to the Home.						
Dispensing							
10.4	Oral anti-cancer drugs are identified as such and handled in accordance with applicable guidelines and best practices, including segregated storage and use of personal protective equipment.						
10.5	All oral anti-cancer drugs are provided in a ready-to-use form that requires no further preparation or manipulation by the practitioner who will be administering it (i.e., provided in the exact dose required).						

Core Characteristic # 10:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of **oral** anti-cancer drugs.

Scope: Unless otherwise stated, these items apply to oral medications used to treat cancer, including hormonal agents. The health risks associated with exposure to individual OACDs are typically assessed based on their potential for carcinogenicity, teratogenicity, genotoxicity, reproductive toxicity or organ toxicity.

Self-A	Assessment Items	Α	В	С	D	Е	NA		
Adm	Administration								
10.6	Oral anti-cancer drugs are clearly identified as such and nurses are aware of and use appropriate handling practices, including use of personal protective equipment.								

Scoring Your Self-Assessment

- A There has been <u>no activity</u> to implement this item
- B This item has been formally discussed and considered but not implemented
- C This item has been <u>partially implemented</u> for some areas, residents, medications and/ or staff in the Home
- D This item is <u>fully implemented for some</u> areas, residents, medications and/or staff in the Home
- E This item is <u>fully implemented throughout</u> the Home
- NA Not applicable Use this option if an assessment item

VIII. EVALUATION

Core Characteristic # 11:

The following brief survey will assist ISMP Canada and CPSI to evaluate this self-assessment program.

After completion of the evaluation, you will be able to finalize and submit your results and compare them to the aggregate response.

Self-	Assessment Items	Α	В	С	D	E	NA
11.1	How many people were there in the team completing the assessment? A - 1 B - 2-4 C - 5-7 D - 8-10 E - more than 10						
11.2	Which disciplines/provider groups were involved in completing the assessment? A - Pharmacy only B - Nursing only C - Medicine only D - Nursing and Pharmacy E - Nursing, Pharmacy and Medicine						
11.3	How long did it take your team to complete the assessment? A – less than 1 hour B – 1-2 hours C – 2-3 hours D – 3-4 hours E – more than 4 hours						
11.4	Do you plan to take any action following completion of the assessment? A - No B - Maybe C - Yes						
11.5	Do you plan to incorporate this assessment into ongoing quality improvement activities for your practice setting? A - No B - Not sure C - Yes, at least every 3 years D - Yes, at least every 2 years E - Yes, every year						
11.6	Please rank the learning and insights gained from this program relative to the time invested: A - not worth it B - repeat of previous knowledge C - useful D - excellent E - invaluable						

Core Characteristic # 11:

The following brief survey will assist ISMP Canada and CPSI to evaluate this self-assessment program.

After completion of the evaluation, you will be able to finalize and submit your results and compare them to the aggregate response.

Self-	Assessment Items	Α	В	С	D	Ε	NA
11.7	Would you recommend this assessment program to a colleague in another organization? A - no B - unlikely C - maybe D - probably E - definitely						

Appendices

Appendix 1: Selected Supporting References

Appendix 2: Key Definitions

Appendix 1: Selected Supporting References

I: Never Events

Core Characteristic # 1

 Never Events for Hospital Care in Canada, September 2015. Canadian Patient Safety Institute and Health Quality Ontario. Available from:

 $\underline{http://www.patientsafetyinstitute.ca/en/toolsResources/NeverEvents/Documents/Never%20Events%20for%20Hospital%20Care%20in%20Canada.pdf.}$

Item 1.1

Allergy Never Events. ISMP Canada Safety Bulletin 2016; 16(10). Available from: https://www.ismp-canada.org/download/safetyBulletins/2016/ISMPCSB2016-10-AllergyNeverEvents.pdf

Item 1.2

Narcotics Safety. Accreditation Canada Required Organizational Practices 2018 Handbook: Qmentum; p. 44-45.

II: General Strategies for Safety

Core Characteristic # 2

Item 2.1

- Patient Engagement Action Team. 2017. Engaging Patients in Patient Safety a Canadian Guide. Canadian Patient Safety Institute. Last modified February 2018. Available from: www.patientsafetyinstitute.ca/engagingpatients.
- 5 Questions to Ask About Your Medications; see: https://www.ismp-canada.org/medrec/5questions.htm.

Item 2.4

Guidelines for Standard Order Sets, 2010. ISMP (US). Available from: https://www.ismp.org/guidelines/standard-order-sets.

Item 2.5

- Reaffirming the "Do Not Use: Dangerous Abbreviations, Symbols and Dose Designations" List. ISMP Canada Safety Bulletin, 2018; 18(4). Available from: https://www.ismpcanada.org/download/safetyBulletins/2018/ISMPCSB2018-05-DoNotUseList.pdf.
- The "Do Not Use" List of Abbreviations, Accreditation Canada Required Organizational Practices 2018 Handbook: Qmentum; p. 13-14.

Item 2.10

 Application of TALLman Lettering for Selected High-Alert Drugs in Canada, ISMP Canada Safety Bulletin 2015; 15(10). Available from: http://www.ismp-canada.org/download/safetyBulletins/2015/ISMPCSB2015-10_TALLman.pdf.

Item 2.15

Accreditation Canada Required Organizational Practices 2018 Handbook: Qmentum; p. 38-39.

III: Anticoagulants

Core Characteristic # 3

Item 3.3

• Death Associated with Inadequate Reassessment of Venous Thromboembolism Prophylaxis at and after Hospital Discharge. ISMP Canada Safety Bulletin, 2015; 15(6). Available from: https://www.ismp-canada.org/download/safetyBulletins/2015/ISMPCSB2015-06 VTE_ProphylaxisReassessment.pdf.

IV: Insulin

Core Characteristic # 4

Item 4.1

- ISMP Canada Guidelines for Subcutaneous Insulin Order Sets, 2013. Available from: https://www.ismp-canada.org/download/insulin/ISMP_Guidelines_SC_InsulinOrderSets.pdf
- ISMP Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults, 2017. Available at: https://forms.ismp.org/Tools/guidelines/Insulin-Guideline.pdf

Item 4.2

Knowledge Translation of Insulin Use Interventions / Safeguards; available from: https://www.ismp-canada.org/insulin/.

Core Characteristic # 5

Item 5.1

- ISMP Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults, 2017. Available at: https://forms.ismp.org/Tools/quidelines/Insulin-Guideline.pdf
- ISMP Canada Guidelines for Subcutaneous Insulin Order Sets, 2013. Available from: https://www.ismp-canada.org/download/insulin/ISMP Guidelines SC InsulinOrderSets.pdf
- Enhancing insulin-use safety in hospitals: Practical recommendations from an ASHP Foundation expert consensus panel. Am J Health-Syst Pharm—Vol 70 Aug 15, 2013. Available from: http://www.ajhp.org/content/ajhp/70/16/1404.full.pdf.

Core Characteristic 6

Item 6.2

- ISMP Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults, 2017. Available from: https://forms.ismp.org/Tools/quidelines/Insulin-Guideline.pdf
- ISMP: U-500 Insulin Safety: It's Time to Rethink Safe Use Practices. 2014. Available from: https://www.psqh.com/analysis/ismp-u-500-insulin-safety-it-s-time-to-rethink-safe-use-practices/.

V: Methotrexate for Non-Oncologic Use

Core Characteristic #7

Item 7.1

 Severe Harm and Deaths Associated with Incidents Involving Low-Dose Methotrexate. ISMP Canada Safety Bulletin, 2015; 15(9). Available from: http://www.ismp-canada.org/download/safetyBulletins/2015/ISMPCSB2015-09 Methotrexate.pdf.

VI: Opioids

Core Characteristic # 8

Item 8.1

- The 2017 Canadian Guideline for opioid therapy and chronic noncancer pain. CMAJ May 08, 2017. Available from: http://www.cmaj.ca/content/189/18/E659
- ISMP Canada. Safer Decisions Save Lives: Usability, Functionality, and Utility Testing of a Prototype Clinical Decision Support System to Enhance Opioid Prescribing. 2017. Available from: https://www.ismp-canada.org/download/OpioidStewardship/SDSL.PCI.UsabilityTesting.pdf

ISMP Canada. Pain Check In Prescriber Guidebook – EMR version. 2017. Available from: https://www.ismp-canada.org/download/OpioidStewardship/SDSL.PCIGuidebook.EMR.pdf

Items 8.5, 8.6, 8.7, 8.8

 HIGH ALERT Medication Feature: Reducing Patient Harm from Opiates. ISMP Medication Safety Alert! Feb 22, 2007. Available from: https://www.ismp.org/resources/high-alert-medication-feature-reducing-patient-harm-opiates

Item 8.10

- Richmond Agitation Sedation Scale; available from: http://www.acclaimhealth.ca/wp-content/uploads/2013/11/Agitation-Sedation-Scale-Richmond-RASS.pdf.
- Pasero C. Journal of PeriAnesthesia Nursing, Vol 24, No 3 (June), 2009: p. 186-190 [Cited 2018 Oct 9] Available from: http://www.mghpcs.org/eed_portal/Documents/Pain/Assessing_opioid-induced_sedation.pdf.

VII: Oral Anti-Cancer Drugs (Chemotherapy)

Core Characteristic # 10

 Analysis of Incidents Involving Oral Chemotherapy Agents. ISMP Canada Safety Bulletin, 2015; 15(4): https://www.ismp-canada.org/download/safetyBulletins/2015/ISMPCSB2015-04_OralChemotherapyAgents.pdf

Item 10.1

• ISMP International Medication Safety Self-Assessment for Oncology, 2012; item 44. Available from: https://mssa.ismp-canada.org/oncology/page/12.

Item 10.4

• Vu K, Emberly P, Brown E, et al. Recommendations for the safe use and handling of oral anticancer drugs in community pharmacy: A pan-Canadian consensus guideline. Canadian Pharmacists Journal / Revue des Pharmaciens du Canada, vol. 151, 4: pp. 240-253. First published May 16, 2018. Abstract available from: http://journals.sagepub.com/doi/abs/10.1177/1715163518767942.

Appendix 2: Key Definitions

(For the purpose of completing the assessment)

Adverse Drug Event

An injury from a medicine or lack of an intended medicine - includes adverse drug reactions and harm from medication incidents. 10

Automated Dispensing Cabinet

A drug storage device or cabinet that electronically dispenses medications in a controlled fashion and tracks medication use. ¹¹

Barcode scanning technology

The use of optical machine-readable representation of data found in barcodes on medication packages and resident identification bands to verify that the correct resident is receiving the correct medication, the correct solution or ingredient is selected prior to compounding a preparation, or the correct medication is retrieved from or stocked in the correct storage location. The process involves the use of a barcode scanner, an electrical device that can read and output printed barcodes to a computer.

Basal insulin

Insulin administered on a scheduled basis to maintain constant blood glucose levels during periods of fasting and between meals (e.g. long-acting insulin analogs, such as glargine or detemir).

Computer Order Entry System

Refers to any computer system into which medication orders are entered, including pharmacy computer systems and computerized prescriber order entry systems.

Computerized prescriber order entry

Refers to an electronic or computerized system into which an authorized prescriber directly enters medical orders, including medication orders. CPOE systems ideally also offer clinical decision support.

Concentrated insulin

Any insulin with a concentration greater than 100 units/mL, including U-200, U-300, and U-500 insulin.

¹⁰ Adapted from Bates DW, Spell N, Cullen DJ, Burdick E, Laird N, Petersen LA, Small SD, Sweitzer BJ and Leape LL, "The Costs of Adverse Drug Events in Hospitalized Patients. Adverse Drug Events Prevention Study Group," Journal of the American Medical Association 277, 4 (January 22, 1997): pp. 307–11.

¹¹ ISMP Medication Safety Self-Assessment for Automated Dispensing Cabinets. 2009. Available from: http://www.ismp.org/selfassessments/ADC/Login.asp.

Critical Incident

An incident resulting in serious harm (loss of life, limb, or vital organ) to the resident, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response. The investigation is designed to identify contributing factors and the response includes actions to reduce the likelihood of recurrence.¹²

Cycle

A dose of chemotherapy that is repeated at regular intervals. Several chemotherapy cycles may make up a total treatment protocol. For example, the CHOP chemotherapy protocol may consist of one cycle given every 3 weeks, resulting in six cycles for the course of therapy.

Dangerous Abbreviations, Symbols and Dose Designations

Abbreviations, symbols and dose designations that have been identified as easily misinterpreted or involved in medication incidents leading to harm and should be avoided in medication-related communications. ¹³ ISMP Canada's Do Not Use list of dangerous abbreviations, symbols and dose designations is available from:

http://www.ismp-canada.org/download/ISMPCanadaListOfDangerousAbbreviations.pdf

Family Caregiver

Defined as family members and other significant people (as identified by the care recipient) who provide care and assistance to individuals living with a debilitating physical, mental or cognitive condition.¹⁴ Similar terms: unpaid caregiver, informal caregiver

Harm

Harm is defined as a temporary or permanent impairment in body functions or structures. It includes mental, physical, sensory functions and pain.¹⁰

High-Alert Medications

High-alert medications are drugs that bear a heightened risk of causing significant resident harm when they are used in error.¹⁵

High-risk resident

Resident with risk factors that increase the likelihood of an adverse outcome.

Human Error

Inadvertently doing other than what was intended (e.g., a mental slip, lapse, or mistake). Human errors are unintentional acts, not behavioural choices.

¹² Davies J, Hebert P and Hoffman C, Canadian Patient Safety Dictionary (Ottawa: Royal College of Physicians and Surgeons of Canada, 2003).

¹³ ISMP Canada Definitions; available from: http://www.ismp-canada.org/definitions.htm

¹⁴ Family caregiver (definition). Canadian Caregiver Coalition website. http://www.ccc-ccan.ca/

¹⁵ ISMP's List of High-Alert Medications in Acute Care Settings; available from: http://www.ismp.org/Tools/institutionalhighAlert.asp

Independent Double Check

A process in which a second practitioner conducts a verification. Such verification can be performed in the presence or absence of the first practitioner. In either case, the most critical aspect is to maximize the independence of the double check by ensuring that the first practitioner does not communicate what he or she *expects* the second practitioner to see, which would create bias and reduce the visibility of an error. An automated check, e.g., bar coding is an acceptable independent double check; however, consideration must be given to the parameters that can be checked electronically before human checks are eliminated.¹⁰

Machine-Readable Coding

Any encoded identifying mark (e.g., bar code) representing data that can be read with a computerized reading device, such as a scanner or imager.¹⁴

Medication Device

Equipment such as infusion pumps, implantable pumps, syringes, pen devices that contain medication (e.g., epinephrine, insulin), tubing, resident-controlled analgesia pumps, automated compounding devices, robotics, and other related devices that are used for medication preparation, dispensing, and administration.

Medication Incident

Any preventable event that may cause or lead to inappropriate medication use or resident harm while the medication is in the control of a healthcare professional or resident. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/ packaging/ nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.⁸

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

Medication Safety

Freedom from preventable harm with medication use.¹⁰

Never Event

Never events are resident safety incidents that result in serious resident harm or death and are preventable using organizational checks and balances.¹⁶

Opioid-naïve resident

Residents who have not previously been taking opioids on a routine basis in a dose sufficient to produce tolerance (see "opioid-tolerant resident").

¹⁶ Never Events for Hospital Care in Canada. Health Quality Ontario and the Canadian Patient Safety Institute. September 2015. Available from:

 $[\]underline{\text{http://www.patientsafetyinstitute.ca/en/toolsResources/NeverEvents/Documents/Never%20Events\%20for\%20Hospital\%20Care\%20in\%20Canada.pdf}$

Opioid tolerant resident

Opioid tolerance is defined by the following markers: Residents receiving, for 1 week or longer, at least: 60 mg oral morphine/day; 25 mcg transdermal fentanyl/hour; 30 mg oral oxycodone/day; 8 mg oral hydromorphone/day; 25 mg oral oxymorphone/day; 60 mg oral hydrocodone/day; or an equianalgesic dose of another opioid, including heroin and/or non-prescribed opioids.

Oral Anti-Cancer Drug (OACD)

A drug that is used to treat cancer (or other indications) and includes some hormonal agents. The health risks associated with exposure to individual OACDs are typically assessed based on their potential for carcinogenicity, teratogenicity, genotoxicity, reproductive toxicity or organ toxicity.¹⁷

Professional Advisory Committee

An interdisciplinary committee that convenes on a scheduled basis, or when necessary, to review the safety, use, efficacy, and monitoring of medications that will be available for use in the Home. The committee also sets policies and procedures regarding the safety of the entire medication use process.

Practitioner

A licensed healthcare professional, who is authorized within the Home to prescribe, dispense, or administer medications (e.g., physician, pharmacist, pharmacy technician, nurse, nurse practitioner respiratory therapist).

Safety

Freedom from accidental injuries. 18

System

A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim. ¹⁹

TALLman Lettering

TALLman lettering is a method used to assist in the differentiation of look-alike/sound-alike drug names through the application of UPPER-CASE lettering to certain sections of drug names.²⁰

¹⁷ Vu K, Emberly P, Brown E, et al. Recommendations for the safe use and handling of oral anticancer drugs in community pharmacy: A pan-Canadian consensus guideline. Canadian Pharmacists Journal / Revue des Pharmaciens du Canada, vol. 151, 4: pp. 240-253. First published May 16, 2018. Abstract available from: http://journals.sagepub.com/doi/abs/10.1177/1715163518767942.

¹⁸ Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: Building a safer health system. Washington, DC, National Academy Press, 1999

¹⁹ World Alliance for Patient Safety. WHO draft guidelines for adverse event reporting and learning systems. Geneva (Switzerland): World Health Organization; 2005

²⁰ Application of TALLman Lettering for Selected High-Alert Drugs in Canada. ISMP Can Saf Bull; 15(10), p. 1-3. Available from: http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2010-08-TALLmanforOncology.pdf