Medication Safety Self-Assessment:
Focus on "Never Events" in Hospitals and Ambulatory Care Centres

2019

ISMP Canada
Institute for Safe Medication Practices Canada
Institut pour la sécurité des médicaments aux patients du Canada

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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 patient 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" in Hospitals and Ambulatory Care Centres (MSSA – Never Events) was designed to help Canadian healthcare practitioners in hospitals and ambulatory care centres 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 Alerts[3]. 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 hospitals and ambulatory care centres 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 assessment includes a total of 108 items, divided into 13 sections. Section I focuses on known never events and Section II on general strategies for safety. Sections II-XIII focus on selected high-alert medication classes. Not all items will be applicable in all settings.

Within each section, the assessment items are presented in an order that reflects the medication use process, beginning with patient engagement[5] and then following the steps in the medication use process: prescribing, order processing/transcription, dispensing, administration and monitoring. Some

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

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. Healthcare practitioners in hospitals and ambulatory care centres may choose to use this assessment as an important resource for informing and prioritizing their actions for quality improvement.

This assessment is also aligned with the World Health Organization Global Patient Safety Challenge: Medication Without Harm.[6]

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

[6] 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:
   - Senior leadership representative
   - Patient or patient representative/advocate
   - Patient safety/quality improvement and/or risk management professional
   - Nursing director/manager
   - Pharmacy director/manager
   - Physician leader (e.g., chief of service)
   - Frontline staff (at least one of each of the following):
     - Registered nurse
     - Registered practical nurse
     - Pharmacist
     - Pharmacy technician
     - Pharmacy assistant, if applicable
     - Physician

   Include representation from different services within the facility.

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 facility'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, patients, medications and/ or staff in the facility.
   D This item is **fully implemented for some** areas, patients, medications and/or staff in the facility
   E This item is **fully implemented throughout** the facility
   NA Not applicable – use this option if the assessment criteria does not apply to your facility

   Facilities 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 facility at a later date.

   Scoring Guidelines:
   For all assessment items:
   - All assessment items refer to medications prescribed, dispensed, and administered to *all* patients or clients of the facility unless otherwise noted.

- Choice of E (full implementation) is appropriate only if all components are present in *all* areas of the facility, for *all* patients, *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 facility, select C or D.

For assessment items that are not applicable to your facility:
Some assessment items may not be applicable to all facilities; for these items, criteria for a "not applicable" response have been provided. For example, facilities that do not treat pediatric patients will have 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 facility submitting them. **Confidentiality is assured.**

6. View/print your completed assessment.

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

7. Compare your results to the aggregate.

Once your results have been submitted you will immediately[7] 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

Facilities can freely share their own results internally and externally to the organization as they deem appropriate; however, any comparison to the de-identified aggregate can only be shared externally to the organization with the written permission of ISMP Canada.

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

[7] To maintain confidentiality, a minimum of 3 responses is required in the ISMP Canada database 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.

Are there situations where the MSSA - Never Events is not appropriate for a facility?
This MSSA version is intended for use by hospitals and ambulatory care centres. Not all items will apply in all contexts (e.g., specialty care settings); this can be addressed through use of the "not applicable" response.

How many team meetings should we schedule?
This self-assessment has been designed to be completed in one meeting of approximately 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 facility's leadership team is valuable because the assessment contains many items that relate to your facility's overall commitment to patient 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 facility?
Some assessment items may not be applicable to all facilities; for these items, criteria for a "not applicable" response have been provided. For example, facilities that do not treat pediatric patients will have no associated risks.

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 no activity to implement this item.

B=1 This item has been formally discussed and considered, but not implemented.

C=2 This item has been partially implemented for some areas, patients, medications and/or staff.

D=3 This item is fully implemented for some areas, patients, medications and/or staff.

E=4 This item is fully implemented throughout the facility for all patients, medications and/or staff.

NA Not applicable items are scored as "fully implemented" since they should reflect items that do present any safety risks to the patients served by the organization.

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 facility's results to the aggregate database for key elements, core characteristics 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 we share our results?

Facilities can freely share their own results internally and externally to the organization as they deem appropriate; however, any comparison to the de-identified aggregate can only be shared externally to the organization with the written permission of ISMP Canada.

Demographic Information

1. In which province or territory is your facility located: _____

2. Which category best describes the size of the community[8] served by your facility?
   - ☐ 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 facility?
   - ☐ Hospital
   - ☐ Ambulatory care centre
   - ☐ Other; please specify _____

4. Please indicate your facility type:
   - ☐ Teaching hospital (university affiliation/medical students)
   - ☐ Community hospital
   - ☐ Specialty hospital: pediatrics
   - ☐ Specialty hospital: mental health
   - ☐ Ambulatory care centre: general medical
   - ☐ Ambulatory care centre: emergency/urgent care
   - ☐ Ambulatory care centre: dialysis
   - ☐ Ambulatory care centre: endoscopy
   - ☐ Ambulatory care centre: oncology
   - ☐ Ambulatory care centre: surgical
   - ☐ Other (please specify): _____

5. For hospitals:
   Size:
   - ☐ Less than 50 beds
   - ☐ 50-99 beds
   - ☐ 100-299 beds
   - ☐ 300-499 beds
   - ☐ More than 500 beds

6. For ambulatory care centres
   Average number of outpatient visits per month
   - ☐ Less than 500
   - ☐ 500-2499
   - ☐ 2500-4999
   - ☐ More than 5000

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

7. Pharmacy services
   - ☐ Inpatient pharmacy
   - ☐ Medications received from an affiliated hospital or healthcare system
   - ☐ Medications received from an outsourced provider not affiliated with the organization
   - ☐ Other; please specify _____

5. Is your facility part of a larger healthcare organization with common governance?
   - ☐ No
   - ☐ Yes

     How many sites are there in your organization?
     - ☐ 2-5
     - ☐ 6-10
     - ☐ 11-30
     - ☐ More than 30

5. Has your facility previously completed a Medication Safety Self-Assessment (MSSA)?
   - ☐ No
   - ☐ Yes

   If yes, which of the MSSAs have you completed? (Check all that apply.)
   - ☐ MSSA for Hospitals, Canadian Version I, II or III
   - ☐ Anticoagulant Safety
   - ☐ Epidural Label Safety Checklist
   - ☐ HYDROmorphone Safety Self-Assessment
   - ☐ ISMP International Medication Safety Self-Assessment for Oncology
   - ☐ Operating Room Medication Safety Checklist

Survey Tool

Scoring Your Self-Assessment

- **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, patients, medications and/ or staff in the facility
- **D** This item is fully implemented for some areas, patients, medications and/or staff in the facility
- **E** This item is fully implemented throughout the facility
- **NA** Not applicable – Use this option if an assessment item does not apply to your facility

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 facility, self-assessment scores should not exceed "C" or "D".

I. NEVER EVENTS

Core Characteristic # 1:

Strategies have been implemented to address known "never events".

Self-Assessment Items		A	B	C	D	E	NA
1.1	Medication orders are screened against validated allergies available on patient records (paper and electronic) and throughout the drug distribution system (computerized prescriber order entry [CPOE], Pharmacy computers, automated dispensing cabinet [ADC] screens, etc.). ** Never event: patient harm or death associated with administration of a medication to which the patient was known to be allergic" **						
1.2	Medications intended for topical use (e.g., concentrated epinephrine, chlorhexidine) are ***never*** placed in a parenteral syringe and open containers are not used to hold medications intended for injection (e.g., local anesthetic with diluted epinephrine combination products.) ** Never event: inadvertent injection of medications intended for topical use **						
1.3	Vincristine (and other vinca alkaloids as applicable) is **always** dispensed in a minibag and labelled with a prominent warning label that reads "**For intravenous use only – fatal if given by other routes"**, in accordance with World Health Organization recommendations (i.e., syringes are never used). ** Never Event: wrong route administration of chemotherapy agents** ***Select NA*** *if vincristine and other vinca alkaloids are not administered in your facility.*						
1.4	Confirmation is required (e.g., by sequential sign off) that the administration of any prescribed intrathecal medications has been completed before dispensing any medication that is known to be fatal if inadvertently given by this route (e.g., vinca alkaloid or bortezomib). ** Never Event: wrong route administration of chemotherapy agents** ***Select NA*** *if intrathecal medications are not administered in your facility.*						

Core Characteristic # 1:

Strategies have been implemented to address known "never events".

Self-Assessment Items		A	B	C	D	E	NA
1.5	Vials of concentrated forms of electrolytes (e.g., potassium chloride, potassium phosphate, sodium chloride) are not available in **any** care areas. ** Never event: intravenous administration of a concentrated electrolyte solution ** ***Select NA** if concentrated forms of electrolyte solutions are **never** used in your facility.*						
1.6	High dose/high concentration formats of opioids are not available as regular unit stock in care areas. Specific products not to be stocked: i) Fentanyl ampoules or vials with total dose greater than 100 mcg per container; ii) HYDROmorphone ampoules or vials with total dose greater than 2 mg; and iii) Morphine ampoules or vials with total dose greater than 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 patients and removed from the care area as soon as they are no longer required for that patient.*						
1.7	Paralyzing agents (neuromuscular blocking agents) are only available in critical care areas and are segregated from other stock medications. ** Never event: Neuromuscular blockade without sedation, airway control and ventilation capability ** ***Select NA** if paralyzing agents are not used for any procedures in your facility.*						

II. GENERAL STRATEGIES FOR SAFETY

Core Characteristic # 2:

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

Self-Assessment Items		A	B	C	D	E	NA
Patient engagement and education							
2.1	Patients and family caregivers are **actively involved in shared decision-making** about medication treatment and are encouraged to ask questions about the medications they are receiving.						
2.2	Patients and family caregivers are actively involved in conversations about medication history, medication discharge planning and medical conditions being treated to reduce the likelihood of omission of a medication needed to manage a chronic condition (e.g., omission of a chronic corticosteroid).						
2.3	Patients prescribed high-alert medications are provided with information about common types of errors known to be problematic with these drugs, and how to prevent and detect these errors at home (e.g., methotrexate inadvertently prescribed daily for arthritis, wrong dose errors due to frequently changing warfarin orders, mix-ups between rapid-acting and basal insulins).						
Prescribing							
2.4	Computerized prescriber order entry (CPOE) systems are used to transmit orders for medications throughout the facility.						
2.5	Standardized protocols/order sets have been developed for high-alert medications (e.g., chemotherapy, anticoagulants, opioids, insulin, concentrated electrolytes), and are used whenever these medications are prescribed, dispensed, and administered.						
2.6	Concentrations of infusions of high-alert medications are standardized to limit the number of choices available, and the majority of infusions are standardized to a single concentration only.						
2.7	Standard infusion concentrations are selected based on commercially available premixed solutions of high-alert medications.						

Core Characteristic # 2: Recognized high-leverage strategies for safety are implemented throughout the facility.							
Self-Assessment Items		**A**	**B**	**C**	**D**	**E**	**NA**
2.8	Standard protocols and order sets express high-alert medication infusion doses in a manner (e.g., mg, mmol, mg/kg, mcg/kg/min) and sequence that matches the entries on medication administration records (paper/electronic), medication labels and medication administration and preparation devices (e.g., infusion pumps, automated compounders).						
2.9	A list of prohibited dangerous abbreviations, symbols and dose designations has been established for 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.)						
Dispensing							
2.10	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.*						
2.11	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 ADCs are not in use in the facility.*						
2.12	Commercially prepared, premixed IV solutions of high-alert medications are used whenever they are available from the manufacturer. ***Select NA*** *if IV infusions of high-alert medications are not administered in your facility.*						
2.13	Infusions of high-alert medications, when not available commercially, are prepared in the pharmacy in a form that requires no further preparation or manipulation by the practitioner who will be administering it (i.e., these items are not prepared in care areas). ***Select NA*** *if IV infusions of high-alert medications are not administered in your facility.*						

Core Characteristic # 2:

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

Self-Assessment Items		A	B	C	D	E	NA
2.14	TALLman lettering, when used for high-alert medications, follows the conventions recommended by ISMP Canada.						
2.15	Strategies are undertaken to minimize the possibility of errors with medication products that have look-alike/sound-alike names or similar or confusing manufacturer labelling and packaging.						
Administration							
2.16	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).*						
2.17	Selected high-alert medications. as defined by the facility, (e.g., anticoagulants, chemotherapy, insulin, etc) are independently double-checked by another practitioner, and this check is documented in the health record, before administration.						
	****OR****						
2.17	Machine-readable coding (e.g., bar coding) is used prior to medication administration to identify **both** the patient and the medication/dose.						
2.18	Infusion pumps with activated dose error-reduction software (DERS), are used to administer infusions of high-alert medications via the intravenous and epidural routes. ***Select A or B*** *if infusion pumps with DERS are not available.*						
Monitoring							
2.19	All practitioners involved in the medication use process can easily and electronically access current laboratory values while working in their respective clinical locations.						
2.20	In hospitals, a standardized process is consistently used to verify and reconcile medications on admission, internal transitions and discharge. The medication history is considered in the context of known medical conditions to avoid omission of chronic medications.						

Core Characteristic # 2:

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

Self-Assessment Items		A	B	C	D	E	NA
	Select NA *if your facility is an ambulatory care centre.*						
2.21	In ambulatory care centres, a standardized process is consistently used to verify and reconcile medications on initial and repeat encounters. The medication history is considered in the context of known medical conditions to avoid omission of chronic medications. ***Select NA*** *if your facility is a hospital.*						
Supporting System Elements							
Staff Competence and Education							
2.22	Practitioners who prescribe, dispense, and administer high-alert medications receive ongoing information about associated risks, errors that have occurred in the facility or have been reported by external organizations, and strategies to minimize these risks and errors.						
Quality Processes and Risk Management							
2.23	One or more convened committees, that include patient(s) and representatives from disciplines involved in the medication management process, have been assigned responsibility for monitoring and evaluating the safety of the medication use system in the facility.						
2.24	The facility has identified a list of high-alert medications in use in the facility and established strategies to ensure the safe use of these medications.						
2.25	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.						
2.26	There is a standardized process to track the use of reversal agents and antidotes (e.g., flumazenil, naloxone, glucagon), and unexpected patterns of use of such medications are investigated to identify adverse drug events (preventable and non-preventable).						

Core Characteristic # 2:

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

Self-Assessment Items		A	B	C	D	E	NA
2.27	Standardized processes are in place to review data and reports available through medication system technology (e.g., barcode scanning technology rates, activation of smart infusion pump dose error-reduction software (DERS), 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 Hospital (i.e., no reports are available for review).*						

Core Characteristic # 3:

Recognized high-leverage strategies for safe care of pediatric patients are implemented wherever they are cared for in the facility.

Self-Assessment Items		A	B	C	D	E	NA
Prescribing							
3.1	Prescribers include the mg/kg dose for pediatric patients (under 40 kg) along with the patient-specific dose when prescribing medications that have published pediatric mg/kg dosing guidelines. ***Select NA** if your facility does not provide care to pediatric patients.*						
Dispensing							
3.2	A pharmacist verifies the prescriber's calculated dose (based on mg/kg dosing guidelines) for pediatric medication orders and confirms the appropriateness of the dose before the medication is prepared and dispensed. ***Select NA** if your facility does not provide care to pediatric patients.*						

III. ANTICOAGULANTS

Core Characteristic # 4:

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 injectable agents (unfractionated heparin, low molecular weight heparins [e.g., dalteparin, enoxaparin]).

Self-Assessment Items		A	B	C	D	E	NA
Prescribing							
4.1	A standard, reliable process is in place to screen patients 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 patient 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 patient 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 facility should develop protocols that define when bridge therapy will be prescribed. Often the decision is based on the patient's diagnosis or type of procedure that will be performed.*						
4.2	Infusions of unfractionated heparin for therapeutic indications are standardized to a single concentration.						
4.3	Protocols and order sets direct the reversal of anticoagulation.						
Dispensing							
4.4	High-dose unfractionated heparin products (greater than or equal to 10,000 total units per container) are not stocked in care areas.						
Monitoring							
4.5	When patients taking an anticoagulant are discharged from a hospital or ambulatory care centre a practitioner verifies that appointments have been scheduled for clinician reassessment of anticoagulation and laboratory testing if required.						

IV. CONCENTRATED ELECTROLYTES

Core Characteristic # 5:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of intravenous infusions of concentrated electrolytes.

Scope: Unless otherwise stated, these items apply to the following injectable concentrated electrolytes: potassium chloride, hypertonic sodium chloride for injection (greater than 0.9% concentration), potassium phosphate, sodium phosphate, and potassium acetate.

Self-Assessment Items		A	B	C	D	E	NA
Prescribing							
5.1	Practitioners use mmol as the standard, facility-defined dosing unit of measure to prescribe, label, dispense, administer, and document doses of potassium for all adult and pediatric patients (i.e., mEq is not used). ***Select NA*** *if potassium (oral or intravenous) is not administered in the facility.*						
5.2	Small volume single or intermittent IV infusions of potassium chloride, potassium phosphate, sodium phosphate, sodium chloride in concentrations greater than 0.9%, are never referred to as "bolus" doses in computer order entry systems, order sets, protocols, pharmacy labels or medication administration records (paper or electronic), automated dispensing cabinet (ADC) screens, or infusion pump screens. ***Select NA*** *if small volume IV infusions of potassium chloride, potassium phosphate, sodium phosphate, sodium chloride in concentrations greater than 0.9% are not used in your facility.* ***FAQ: Why should the term "bolus" not be used in reference to concentrated electrolyte infusions?*** *"Bolus" doses might be misinterpreted as direct, undiluted, and/or rapid IV administration.*						
Dispensing							
5.3	In the pharmacy, containers of concentrated electrolytes are stored separately from other medications. ***Select NA*** *if your facility does not have an inpatient pharmacy and your pharmacy service provider is not participating in this assessment.*						

Core Characteristic # 5:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of intravenous infusions of concentrated electrolytes.

Scope: Unless otherwise stated, these items apply to the following injectable concentrated electrolytes: potassium chloride, hypertonic sodium chloride for injection (greater than 0.9% concentration), potassium phosphate, sodium phosphate, and potassium acetate.

Self-Assessment Items		A	B	C	D	E	NA
5.4	Sodium phosphate injection is used in place of potassium phosphate to treat hypophosphatemia. ***Select NA*** *if neither sodium phosphate or potassium phosphate injection are used in your facility.*						
5.5	To prevent mix-ups with 5% dextrose solutions, IV containers of **5% sodium chloride** are not procured, ordered, or stocked in the facility. ***Select NA*** *if sodium chloride is not administered in concentrations higher than 0.9% (i.e., normal saline) in your facility.*						
5.6	Containers of 3% sodium chloride are restricted to the pharmacy and/or approved critical care or emergency/urgent care units, stocked in limited quantities, labelled with appropriate warnings (e.g., CONCENTRATED sodium chloride, administer via central line only), and segregated from other medications. ***Select NA*** *if sodium chloride is not administered in concentrations higher than 0.9% (i.e., normal saline) in your facility.*						
5.7	Magnesium sulfate is provided in a ready-to-use, standard concentration (e.g., 20 g/500 mL) for IV bolus doses and maintenance infusions in obstetrical patients. ***Select NA*** *if magnesium sulfate is not administered by IV infusion in your facility.*						
Administration							
5.8	Loading doses of magnesium sulfate are administered from a maintenance infusion bag, using only infusion pumps with dose error-reduction software and a "loading dose" (sometimes called a "bolus dose") feature that automatically starts/ resumes the maintenance infusion at the prescribed rate of infusion once the loading dose has infused. Loading doses are never administered via a basic infusion mode. ***Select NA*** *if magnesium sulfate is not administered via IV infusion in your facility.*						

V. EPIDURAL AND SPINAL (NEURAXIAL) ANESTHESIA

Core Characteristic # 6:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of epidural and spinal (neuraxial) anesthesia.

Scope: Unless otherwise stated, these items apply to both single drug and combinations of opioids and local anesthetics administered to adults, neonates, and pediatric patients. This includes continuous infusions of epidural analgesia/anesthesia with opioids or local anesthetics (including epidural PCA), single injections of epidural or intrathecal opioids or local anesthetics, and combination intrathecal injection and epidural continuous infusion.

Examples of medications administered via these routes include opioids (e.g., morphine, HYDROmorphone, fentanyl, and SUFentanil) and local anesthetics (e.g., bupivacaine, ropivacaine, lidocaine).

Self-Assessment Items		A	B	C	D	E	NA
Patient Engagement and Education							
6.1	Patients receive verbal and written information about the signs and symptoms of an epidural abscess or post-dural puncture headache and what to do if it occurs, since patients may be discharged before the onset of symptoms. ***Select NA*** *if epidural and spinal anesthesia are not administered in your facility.*						
Prescribing							
6.2	The facility has established a limited number of standard mixtures, concentrations, and safe maximum doses for epidural and spinal opioids and local anesthetics that reflect the needs of the population(s) served. ***Select NA*** *if epidural and spinal anesthesia are not administered in your facility.*						
6.3	Order sets include instructions on when to discontinue and restart anticoagulants and antiplatelet medications when inserting or removing epidural and spinal catheters (to prevent spinal hematoma). ***Select NA*** *if epidural and spinal anesthesia are not administered in your facility.*						
Dispensing							
6.4	For epidural products containing both a local anesthetic and an opioid, the anesthetic agent is listed first on the label followed by the opioid (e.g., bupivacaine 0.1% and fentanyl 2 mcg/mL). ***Select NA*** *if epidural and spinal anesthesia are not administered in your facility.*						

Core Characteristic # 6:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of epidural and spinal (neuraxial) anesthesia.

Scope: Unless otherwise stated, these items apply to both single drug and combinations of opioids and local anesthetics administered to adults, neonates, and pediatric patients. This includes continuous infusions of epidural analgesia/anesthesia with opioids or local anesthetics (including epidural PCA), single injections of epidural or intrathecal opioids or local anesthetics, and combination intrathecal injection and epidural continuous infusion.

Examples of medications administered via these routes include opioids (e.g., morphine, HYDROmorphone, fentanyl, and SUFentanil) and local anesthetics (e.g., bupivacaine, ropivacaine, lidocaine).

Self-Assessment Items		A	B	C	D	E	NA
6.5	All bags and syringes of epidural/spinal opioids and local anesthetics, and their overwraps, if applicable, are labelled with a prominent auxiliary warning (e.g., on a brightly coloured label) indicating "Epidural Use Only". ***Select NA*** *if epidural and spinal (neuraxial) anesthesia are not administered in your facility.*						
Administration							
6.6	Epidural medications are administered using dedicated infusion pumps, specifically configured for the epidural route, that are clearly differentiated from all other medication administration devices and are placed on separate poles from those used for other medications. ***Select NA*** *if epidural and spinal anesthesia are not administered in your facility.*						
6.7	The administration set used for epidural infusion pumps does not contain any access ports (Y-connectors), can be distinguished from all other administration sets and medical tubing (e.g., a yellow stripe running the length of the tubing), and is not used for anything other than epidural infusions. ***Select NA*** *if epidural and spinal anesthesia are not administered in your facility.*						
6.8	Medications for epidural and spinal administration are obtained from the unit supply by the person who will be administering the medication and brought to the patient's bedside immediately before use. ***Select NA*** *if epidural and spinal anesthesia are not administered in your facility.*						

Core Characteristic # 6:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of epidural and spinal (neuraxial) anesthesia.

Scope: Unless otherwise stated, these items apply to both single drug and combinations of opioids and local anesthetics administered to adults, neonates, and pediatric patients. This includes continuous infusions of epidural analgesia/anesthesia with opioids or local anesthetics (including epidural PCA), single injections of epidural or intrathecal opioids or local anesthetics, and combination intrathecal injection and epidural continuous infusion.

Examples of medications administered via these routes include opioids (e.g., morphine, HYDROmorphone, fentanyl, and SUFentanil) and local anesthetics (e.g., bupivacaine, ropivacaine, lidocaine).

Self-Assessment Items		A	B	C	D	E	NA
6.9	Epidural infusion lines and central venous access lines are secured on opposite sides of the patient's back or chest. ***Select NA*** *if epidural and spinal anesthesia are not administered in your facility.*						

Scoring Your Self-Assessment

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, patients, medications and/ or staff in the facility

D This item is fully implemented for some areas, patients, medications and/or staff in the facility

E This item is fully implemented throughout the facility

NA Not applicable – Use this option if an assessment item does not apply to your facility

VI. INSULIN, SUBCUTANEOUS AND INTRAVENOUS

Core Characteristic # 7:

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

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

Self-Assessment Items		A	B	C	D	E	NA
Prescribing							
7.1	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, pharmacy labels, and any other format used to communicate medication information in the facility. ***Select NA*** *if insulin is not prescribed, dispensed or administered in your facility.*						
7.2	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 facility. ***Select NA*** *if insulin is not prescribed, dispensed or administered in your facility.*						
7.3	Standard order sets that promote best practice (e.g., use of scheduled basal insulin doses and correction doses) are used for all patients prescribed subcutaneous insulin. ***Select NA*** *if insulin is not prescribed or administered in your facility.*						

Core Characteristic # 8:

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		A	B	C	D	E	NA
Patient engagement and education							
8.1	Patients who will be taking a concentrated insulin at home receive verbal and written instructions explaining how to administer the specific insulin dose(s) and the importance of using the correct measuring device. ***Select NA*** *if your facility does not prescribe or dispense concentrated insulin for self-administration at home.*						
Prescribing							
8.2	Concentrated insulin products (e.g. U-200, U-300, U-500) are 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 facility. ***Select NA*** *if concentrated insulins are not used in your facility.*						
Administration							
8.3	Concentrated insulins (U-200, U-300, U-500) are administered using a commercially supplied pen device or a syringe specifically designed to administer the required concentration (i.e., U-100 insulin syringes and tuberculin syringes are not used). ***Select NA*** *if concentrated insulins are not used in your facility.*						

Core Characteristic # 9

Strategies have been implemented to address risks associated with the use of insulin pens.

Self-Assessment Items		A	B	C	D	E	NA
Dispensing							
9.1	Insulin pens are dispensed from the pharmacy for individual patients OR stocked in a profiled ADC. ***Select NA*** *if insulin pens are not used in your facility.*						
Supporting System Elements							
Staff Competency and Education							
9.2	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 patient only** and the dangers of sharing pens among multiple patients, even if the needle is changed in between patients. ***Select NA*** *if insulin pens are not used in your facility.*						

Core Characteristic # 10

Strategies have been implemented to address risks associated with intravenous infusion of insulin.

Self-Assessment Items		A	B	C	D	E	NA
Prescribing							
10.1	Concentrations for continuous IV infusions of insulin are standardized for the patient groups served by the facility (i.e., neonates, pediatric patients and adults) and ideally there is one concentration used for each group (e.g., 1 unit/mL for adults). ***Select NA*** *if insulin is not administered by IV infusion in your facility.*						

VII. LIPID-BASED MEDICATIONS vs. CONVENTIONAL FORMULATIONS

Core Characteristic # 11

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of lipid-based medications.

Scope: Unless otherwise stated, these items apply only to drugs available in both lipid-based and conventional formulations, including amphotericin B, bupivacaine, cytarabine, DOXOrubicin, irinotecan, and vinCRIStine.

Self-Assessment Items		A	B	C	D	E	NA
Prescribing and dispensing							
11.1	Only one formulation (either lipid-based or conventional) is available on formulary, or used in the facility, for medications in this category to reduce the risk of dosing errors with these products. ***Select NA*** *if medications in this category are not used in your facility.*						
Supporting System Elements							
Staff Competence and Education							
11.2	Practitioners who may prescribe, dispense, or administer lipid-based medications or their conventional formulations have been educated about the differences between products and the risk of patient harm if these products are confused with each other. ***Select NA*** *if medications in this category are not used in your facility.*						

Scoring Your Self-Assessment

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, patients, medications and/ or staff in the facility

D This item is fully implemented for some areas, patients, medications and/or staff in the facility

E This item is fully implemented throughout the facility

NA Not applicable – Use this option if an assessment item does not apply to your facility

VIII. METHOTREXATE FOR NON-ONCOLOGIC USE

Core Characteristic # 12:

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 any route (i.e., oral, intramuscular, intravenous, subcutaneous) 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		A	B	C	D	E	NA
Patient engagement and education							
12.1	Patients who are discharged on methotrexate receive clear verbal and written instructions that specify the **weekly dosing** schedule, emphasize the danger of taking extra doses, and warn patients to avoid taking extra doses for symptom control. ***Select NA*** *if methotrexate for non-oncologic indications, such as rheumatoid arthritis (i.e., weekly dosing) is not prescribed, dispensed or administered in your facility.*						
Prescribing and Dispensing							
12.2	Computer order entry systems have been programmed to default to a *weekly* rather than *daily* dosage regimen for subcutaneous, intramuscular, and oral methotrexate. ***Select NA*** *if methotrexate for non-oncologic indications, such as rheumatoid arthritis (i.e., weekly dosing) is not prescribed, dispensed or administered in your facility.*						
12.3	Prescriptions for non-oncologic use of methotrexate provided to patients upon discharge only include the number of tablets or other dosage forms needed for weekly dosing, not to exceed a 4-week supply. ***Select NA*** *if methotrexate for non-oncologic indications, such as rheumatoid arthritis (i.e., weekly dosing) is not prescribed, dispensed or administered in your facility.*						

IX. OPIOIDS

Core Characteristic # 13:

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) used for any indication except moderate sedation, that are administered by the following routes: oral, IV, IM, subcutaneous, transdermal, sublingual, buccal/transmucosal, and intranasal.

For opioids used in moderate sedation, see Section XIII; for opioids used for epidural or spinal anesthesia (neuraxial administration), see Section V.

Self-Assessment Items		A	B	C	D	E	NA
Patient Engagement and Education							
13.1	Patients discharged on opioids are provided with verbal and written information about pain management and safe use of opioid medications. ***Select NA*** *if your facility does not prescribe opioids for self-administration at home.*						
Prescribing							
13.2	Protocols and order sets include dosing guidelines that differentiate the management of opioid-naïve, opioid-tolerant, and high-risk patients (with criteria for determining opioid tolerance) and specify conditions that require dose adjustments.						
Dispensing							
13.3	A process (e.g., alert requesting confirmation during order entry) is in place to verify that the patient is **opioid-tolerant** before dispensing (or releasing from an automated dispensing cabinet [ADC]) long-acting opioids that are indicated only for such patients (e.g., fentanyl patches). ***Select NA*** *if long-acting opioids are not prescribed, dispensed or administered in your facility.*						
13.4	Immediate-release and long-acting oral formulations of the same opioid are stored separately in the pharmacy. ***Select NA*** *if long-acting opioids are not prescribed, dispensed or administered in your facility, or if your facility is supplied by an external pharmacy that is not participating in this assessment.*						

Core Characteristic # 13:

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) used for any indication except moderate sedation, that are administered by the following routes: oral, IV, IM, subcutaneous, transdermal, sublingual, buccal/transmucosal, and intranasal.

For opioids used in moderate sedation, see Section XIII; for opioids used for epidural or spinal anesthesia (neuraxial administration), see Section V.

Self-Assessment Items		A	B	C	D	E	NA
13.5	Immediate-release and long-acting oral formulations of the same opioid are stored separately in care area stock. ***Select NA*** *if long-acting opioids are not prescribed, dispensed or administered in your facility.*						
13.6	Morphine and HYDROmorphone are not stored right next to each other in the pharmacy. ***Select NA*** *if your facility is supplied by an external pharmacy that is not participating in this assessment.*						
13.7	Morphine and HYDROmorphone are not stored right next to each other in care areas.						
13.8	Morphine and HYDROmorphone are stocked in different strengths in the lowest possible strength or concentration in care areas (e.g., HYDROmorphone 2 mg/mL; morphine 10 mg/mL).						
Administration							
13.9	IV push doses of opioids are never prepared by drawing up the contents into a commercially labelled, prefilled flush syringe of 0.9% sodium chloride.						
13.10	The date, time, and anatomical location of an opioid transdermal patch applied to a patient is documented on the patient's medication administration record (MAR)/eMAR. ***Select NA*** *if transdermal opioid patches are not administered in your facility.*						
13.11	Practitioners remove any previously applied transdermal opioid patches prior to the application of a new patch and document the patch removal on the patient's medication administration record (MAR)/eMAR. ***Select NA*** *if transdermal opioid patches are not administered in your facility.*						

Core Characteristic # 13:

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) used for any indication except moderate sedation, that are administered by the following routes: oral, IV, IM, subcutaneous, transdermal, sublingual, buccal/transmucosal, and intranasal.

For opioids used in moderate sedation, see Section XIII; for opioids used for epidural or spinal anesthesia (neuraxial administration), see Section V.

Self-Assessment Items		A	B	C	D	E	NA
13.12	A policy on the proper disposal of transdermal opioid patches exists and is followed (e.g., narcotic disposal system containers, containers that deactivate residual drug). Used patches are never disposed with regular garbage. ***Select NA*** *if transdermal opioid patches are not administered in your facility.*						
Monitoring							
13.13	The organization/facility uses a validated, standardized sedation scale (e.g., Pasero Opioid-Induced Sedation Scale ([POSS], Richmond Agitation Sedation Scale) to guide the assessment and early detection of unintended advancing sedation during opioid therapy.						
13.14	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 # 14:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of continuous infusions of opioids (e.g., post-operative pain management, palliative care).

Self-Assessment Items		A	B	C	D	E	NA
Patient engagement and education							
14.1	Patients, family members, and visitors are educated about the dangers of any individual other than the patient activating the PCA button to deliver a medication dose (i.e., PCA by proxy); and a warning label, "FOR PATIENT USE ONLY," appears on the cord or activation button for PCA. ***Select NA*** *if your facility does not provide patient-controlled analgesia.*						
Prescribing							
14.2	Standardized concentrations have been established for continuous intravenous/subcutaneous opioid infusions for the populations served by the facility (i.e., for neonates, pediatric patients and adults). ***Select NA*** *if continuous opioid infusions are not provided for any populations served by your facility.*						

Scoring Your Self-Assessment

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, patients, medications and/ or staff in the facility

D This item is fully implemented for some areas, patients, medications and/or staff in the facility

E This item is fully implemented throughout the facility

NA Not applicable – Use this option if an assessment item does not apply to your facility

X. ORAL ANTI-CANCER DRUGS (CHEMOTHERAPY)

Core Characteristic # 15:

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.

For a more detailed assessment of oncology-related medication safety strategies, refer to the 2012 ISMP Medication Safety Self-Assessment for Oncology; available from: https://mssa.ismp-canada.org/oncology.

Self-Assessment Items		A	B	C	D	E	NA
Prescribing							
15.1	Verbal/telephone orders are never accepted for oral anticancer drugs, except to hold or discontinue treatment. ***Select NA*** *if oral anticancer drugs are not prescribed, dispensed or administered in your facility.*						
15.2	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"). ***Select NA*** *if oral anticancer drugs are not prescribed, dispensed or administered in your facility.*						
15.3	For intermittent treatment with oral anti-cancer drugs, the quantity prescribed and dispensed (e.g., number of tablets/capsules) for ambulatory patients 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 to be dispensed. ***Select NA*** *if oral anticancer drugs are not prescribed or dispensed at your facility.*						

Core Characteristic # 15:

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.

For a more detailed assessment of oncology-related medication safety strategies, refer to the 2012 ISMP Medication Safety Self-Assessment for Oncology; available from: https://mssa.ismp-canada.org/oncology.

Self-Assessment Items		A	B	C	D	E	NA
Dispensing							
15.4	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). ***Select NA*** *if oral anticancer drugs are not prescribed, dispensed or administered in your facility.*						
15.5	Oral anti-cancer drugs are handled in accordance with applicable guidelines and best practices, including use of personal protective equipment in pharmacy as well as in care areas. ***Select NA*** *if oral anticancer drugs are not prescribed, dispensed or administered in your facility.*						

Scoring Your Self-Assessment

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, patients, medications and/ or staff in the facility

D This item is fully implemented for some areas, patients, medications and/or staff in the facility

E This item is fully implemented throughout the facility

NA Not applicable – Use this option if an assessment item does not apply to your facility

XI. OXYGEN

Core Characteristic # 16:

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

Rationale: Oxygen, a medical gas, can be a crucial part of medical treatment and may be overlooked in terms of standardized safety strategies to assure correct administration.

Self-Assessment Items		A	B	C	D	E	NA
Administration							
16.1	Protocols for transporting patients requiring oxygen therapy include an independent double check of the oxygen level in portable oxygen equipment prior to transfer, and this check is documented in the health record.						

Scoring Your Self-Assessment

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, patients, medications and/ or staff in the facility

D This item is fully implemented for some areas, patients, medications and/or staff in the facility

E This item is fully implemented throughout the facility

NA Not applicable - Use this option if an assessment item does not apply to your facility

XII. PARALYZING AGENTS (NEUROMUSCULAR BLOCKING AGENTS)

Core Characteristic # 17:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of paralyzing agents (neuromuscular blocking agents).

Scope: Unless otherwise stated, these items apply to all paralyzing agents used in any inpatient and outpatient locations within the facility.

	Self-Assessment Items	A	B	C	D	E	NA
Prescribing							
17.1	A standard protocol or order set is used when paralyzing agents are prescribed for ventilated patients outside of the operating room (OR) and post-anesthesia care unit (PACU). ***Select NA*** *if paralyzing agents are not used in your facility.*						
Dispensing							
17.2	Paralyzing agents are only available in rapid sequence intubation kits, surgical suites, post-anesthesia care unit/anesthesia stock, the emergency department and critical care units, where patients can be ventilated and monitored by practitioners with demonstrated competencies. ***Select NA*** *if paralyzing agents are not used in your facility.*						
17.3	Storage bins and ADC pockets or drawers containing paralyzing agents include an auxiliary label to clearly communicate that respiratory paralysis will occur and ventilation is required when administering these agents (e.g., WARNING: PARALYZING AGENT—CAUSES RESPIRATORY ARREST; WARNING: CAUSES RESPIRATORY PARALYSIS—PATIENT MUST BE VENTILATED). ***Select NA*** *if paralyzing agents are not used in your facility.*						
Administration							
17.4	A standardized process is in place to confirm that patients have been intubated before a paralyzing agent is prepared and administered. ***Select NA*** *if paralyzing agents are not used in your facility.*						

XIII. PROCEDURAL SEDATION

Core Characteristic # 18:

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

Scope for Moderate Sedation: Unless otherwise stated, these items apply to all moderate sedation agents (e.g., ketamine, propofol, midazolam, etomidate, fentanyl in combination with another agent(s) [e.g., midazolam, propofol, nitrous oxide in oxygen) administered to adults, neonates, and pediatric patients undergoing a procedure in any inpatient or outpatient setting.

Scope for Minimal Sedation: Unless otherwise stated, these items apply to all minimal sedation agents (e.g., midazolam, diazepam, ketamine, nitrous oxide in oxygen) administered to neonates or pediatric patients undergoing a procedure in any inpatient or outpatient setting.

Exclusions: Sedation of patients undergoing mechanical ventilation in a critical care environment, or sedation used to provide analgesia to patients postoperatively or to patients with chronic painful conditions or receiving hospice/end-of-life care.

Self-Assessment Items		A	B	C	D	E	NA
Prescribing							
18.1	The facility has conducted a thorough assessment to identify all locations where moderate sedation of patients occurs to standardize care, monitor these practice sites, and provide oversight to promote safety. ***Select NA*** *if procedural sedation is not provided in your facility.*						
18.2	The medications, routes, and dosage ranges used for moderate sedation have been selected based on known drug properties that impact their onset, duration, synergistic effects, and adverse effects; and they have been reviewed by, at minimum, an anesthesiologist and a pharmacist (ideally the Pharmacy And Therapeutics Committee or similar medical staff committee) to ensure they are supported by current literature, expert opinion, or national guidelines. ***Select NA*** *if procedural sedation is not provided in your facility.*						
18.3	Only a credentialled professional trained in the use of drugs causing deep sedation, and who is not simultaneously involved in a procedure, is permitted to administer medications that could lead to deep sedation of non-ventilated patients (e.g., propofol, ketamine, etomidate), even if moderate sedation is intended. (PALS or ACLS certification alone is **not sufficient**.) ***Select NA*** *if procedural sedation is not provided in your facility.*						
18.4	In *ambulatory care centres*, a protocol for the immediate activation of emergency medical services (EMS) for life-threatening complications has been established, with clear understanding that this does not replace the practitioner's responsibility to provide initial rescue. ***Select NA*** *if your facility is a hospital.*						

Core Characteristic # 18:

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

Scope for Moderate Sedation: Unless otherwise stated, these items apply to all moderate sedation agents (e.g., ketamine, propofol, midazolam, etomidate, fentanyl in combination with another agent(s) [e.g., midazolam, propofol, nitrous oxide in oxygen) administered to adults, neonates, and pediatric patients undergoing a procedure in any inpatient or outpatient setting.

Scope for Minimal Sedation: Unless otherwise stated, these items apply to all minimal sedation agents (e.g., midazolam, diazepam, ketamine, nitrous oxide in oxygen) administered to neonates or pediatric patients undergoing a procedure in any inpatient or outpatient setting.

Exclusions: Sedation of patients undergoing mechanical ventilation in a critical care environment, or sedation used to provide analgesia to patients postoperatively or to patients with chronic painful conditions or receiving hospice/end-of-life care.

Self-Assessment Items		A	B	C	D	E	NA
Dispensing							
18.5	Only a 1 mg/mL strength of midazolam injection is provided to procedural areas to prevent dosing confusion and to facilitate slow titration of the medication. ***Select NA*** *if procedural sedation is not provided in your facility.*						
Monitoring							
18.6	Protocols exist that permit emergency administration of appropriate reversal agents and include a minimum requirement for monitoring for re-sedation. ***Select NA*** *if procedural sedation is not provided in your facility.*						

Scoring Your Self-Assessment

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, patients, medications and/ or staff in the facility

D This item is fully implemented for some areas, patients, medications and/or staff in the facility

E This item is fully implemented throughout the facility

NA Not applicable – Use this option if an assessment item does not apply to your facility

Core Characteristic # 19:

Strategies have been implemented to address risks associated with prescribing, dispensing, administering and monitoring of procedural sedation in *pediatric patients*.

Self-Assessment Items		A	B	C	D	E	NA
Dispensing							
19.1	Pharmacy dispenses all prescribed doses of oral liquid medications for minimal sedation for pediatric patients in **ready-to-use, unit-dose containers that contain the exact prescribed amount.** ***Select NA*** *if your facility does not provide procedural sedation for pediatric patients.*						
Administration							
19.2	Oral sedatives are only administered to children in preparation for a procedure (e.g., MRI) by trained healthcare professionals, or family caregivers under supervision, *after* the child has arrived at the facility to ensure proper monitoring of neurological and respiratory status; in addition, resuscitation equipment is readily available in the event of respiratory depression. ***Select NA*** *if your facility does not provide procedural sedation for pediatric patients.*						
Monitoring							
19.3	For pediatric patients, at least one practitioner skilled in obtaining vascular access in children is available during the procedure and the recovery period. ***Select NA*** *if your facility does not provide procedural sedation for pediatric patients.*						

XIV. EVALUATION

Core Characteristic # 20:

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		A	B	C	D	E	NA
20.1	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						
20.2	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						
20.3	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						
20.4	Do you plan to take any action following completion of the assessment? A – No B – Maybe C - Yes						
20.5	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						
20.6	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 # 20:

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		A	B	C	D	E	NA
20.7	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

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III: Anticoagulants

Core Characteristic 4

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Core Characteristic 5

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Core Characteristic 11

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Core Characteristic 12

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Core Characteristic 13

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Core Characteristic 14

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X: Oral Anti-Cancer Drugs

Core Characteristic 15

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Item 15.1

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XI: Oxygen

Core Characteristic 16

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Core Characteristic 18

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Core Characteristic 19

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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.[9]

Automated Dispensing Cabinet

A drug storage device or cabinet that electronically dispenses medications in a controlled fashion and tracks medication use. [10]

Barcode scanning technology

The use of optical machine-readable representation of data found in barcodes on medication packages and patient identification bands to verify that the correct patient 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 inpatient and/or outpatient electronic or computer system into which an authorized prescriber enters medical orders.

Concentrated insulin

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

Critical Incident

An incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and

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[9] 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.

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

response. The investigation is designed to identify contributing factors and the response includes actions to reduce the likelihood of recurrence.[11]

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.[12] 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

Dose error-reduction software (DERS)
Refers to the integral computer software in smart infusion pumps intended to warm users of potential over or under delivery of a drug, electrolyte, or other fluid by checking programmed doses against pre-set limits specific to a drug (e.g. morphine) and to a clinical application (e.g. epidural administration) or location (e.g. neonatal intensive care unit, medical/surgical unit).

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.[13]
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 patient harm when they are used in error.[14]

High-risk patient
Patient with risk factors that increase the likelihood of an adverse outcome.

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

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

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

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

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.

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, patient-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 patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/ packaging/ nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.[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 patient safety incidents that result in serious patient harm or death and are preventable using organizational checks and balances.[15]

[15] Never Events for Hospital Care in Canada. Health Quality Ontario and the Canadian Patient Safety Institute. September 2015. Available from: http://www.patientsafetyinstitute.ca/en/toolsResources/NeverEvents/Documents/Never%20Events%20for%20Hospital%20Care%20in%20Canada.pdf

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

Opioid-tolerant patient
Opioid tolerance is defined by the following markers: Patients 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
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.[16]

Parenteral
Administration via the subcutaneous, intramuscular, intravenous, epidural or spinal route.

Pharmacy and Therapeutics 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 facility. The committee also sets policies and procedures regarding the safety of the entire medication use process, on behalf of the medical staff and facility administration.

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

Procedural Sedation
A technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function. Procedural sedation and analgesia (PSA) is intended to result in a depressed level of consciousness that allows the patient to maintain oxygenation and airway control independently. [17]

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[16] 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.

[17] Procedural sedation definition. American College of Emergency Physicians. Available at https://emedicine.medscape.com/article/109695-overview

Rescue
An intervention (usually provided urgently) used to reverse an adverse drug effect (e.g. to correct adverse physiologic consequences of a deeper-than-intended level of sedation), or to reverse a pathophysiologic condition (e.g. use of a hypertonic saline rescue to treat severe hypovolemia).

Safety
Freedom from accidental injuries.[18]

Sedation, Deep
A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

Sedation, Moderate
An induced state characterized by a minimally depressed consciousness such that the patient is able to continuously and independently maintain a patent airway and respiratory rate, retain protective reflexes, and remain responsive to verbal commands and physical stimulation.[6] (See also Deep Sedation.)

Smart Pump Technology
An infusion pump with dose error reduction software (DERS) that is capable of alerting the user to unsafe dose limits and programming errors if standard concentrations and dose limits have been programmed into the pump's library.

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. TALLman lettering has typically been applied to syllables or groups of letters within drug names to bring attention to the points of dissimilarity between confusable names.[20]

[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