Medication Safety Support Service

Identification of Medication Safety Indicators for Public Reporting

March 2010

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A Key Partner in the Canadian Medication Incident Reporting and Prevention System
Un partenaire clé du Système canadien de déclaration et de prévention des incidents médicamenteux

Acknowledgements

ISMP Canada would like to acknowledge the support from the Ontario Ministry of Health and Long-Term Care for this project. The feedback from experts across the healthcare fields in Ontario who participated in the focus group has also been extremely helpful and is very much appreciated.

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Executive Summary

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent, national, not-for-profit agency dedicated to advancing medication safety in all healthcare settings. Since 2002, ISMP Canada has participated in a joint initiative with the Ontario Ministry of Health and Long-Term Care (MOHLTC), titled the Medication Safety Support Service (MSSS). As part of its MSSS responsibilities, in 2009 ISMP Canada undertook to identify three medication safety indicators that are feasible and suitable for public reporting in Ontario.

To address this project, ISMP Canada developed a multi-phase process that included a systematic literature review, compilation and evaluation of possible indicators, and a consensus generation process involving a focus group with Ontario healthcare experts from various disciplines.

From a list of more than 300 potential medication safety indicators, two analysts at ISMP Canada, working independently and using a defined set of selection criteria, narrowed the focus to 49 and subsequently 12 candidate indicators. The selection criteria used in the evaluation of indicators focused upon a) aligning with current patient safety initiatives in Ontario and/or Canada, b) composed of data which are feasible or readily available, c) of acceptable validity and quality, d) actionable, e) understandable by the target audience, and f) evidence-based.

The 12 candidate indicators for hospital reporting were organized into three categories: structure indicators (measure of the environment), process indicators (measure of compliance with medication safety-associated processes of care), and outcome indicators (reflecting outcomes of care).

A focus group of leading experts across the healthcare fields in Ontario was convened and, through a modified nominal group technique, reached consensus on the three most promising or important medication safety indicators for public reporting. The three indicators chosen by the group through its reiterative voting and discussion process were:

- **Venous thromboembolism prevention:** The number of eligible patients who received appropriate venous thromboembolism prophylaxis as a proportion of the number of eligible patients.
- **Acute myocardial infarction discharge medications:** Number of patients with acute myocardial infarction who were prescribed appropriate

medications at discharge as a proportion of the number of patients with acute myocardial infarction.

- **Medication reconciliation:** The number of patients with medication reconciliation performed on admission as a proportion of the number of patients (or patients eligible for medication reconciliation) admitted.

In addition, there was a minority opinion for a fourth indicator: proportion of total deaths in Ontario associated with medication incidents. This outcome indicator would be based upon data from the office of Ontario's chief coroner.

Background: The MOHLTC-ISMP Canada medication safety indicator project

The Institute for Safe Medication Practises Canada (ISMP Canada) is an independent, national, not-for-profit agency committed to the advancement of medication safety in all health care settings. ISMP Canada is a key partner in the Canadian Medication Incident Reporting and Prevention System, working with members of the healthcare community, regulatory agencies and policy makers, patient safety organizations, the pharmaceutical industry, and the public.

In 2002, a joint initiative was struck between the Ontario Ministry of Health and Long-Term Care and ISMP Canada, titled the Medication Safety Support Service (MSSS). Spearheaded by ISMP Canada, the MSSS is supported by a provincial multidisciplinary advisory committee of representatives from the provincial professional colleges and associations of medicine, nursing and pharmacy, as well as the Ontario Hospital Association. The MSSS has led to a number of important medication safety projects, including recommendations in systems-based enhancements in the handling of concentrated electrolytes (potassium chloride), opioids (narcotics) and anticoagulants.

One of the deliverables of the MSSS for the MOHLTC in 2009 was the recommendation of three medication safety indicators for public reporting in the acute care setting.

What are indicators?

In healthcare settings, indicators are used as tools to quantitatively assess processes and outcomes of care (New South Wales Therapeutic Advisory Group, 2007). Indicators can be used to monitor the quality and appropriateness of care being provided, as well as suggest aspects or issues that may require further attention. Nationally and internationally, indicators have been implemented in hospitals to improve healthcare delivery by monitoring performance, identifying issues that require further investigation, providing feedback, and evaluating interventions through audits (MacKinnon & McCaffrey, 2004). Moreover, when indicators are used to report to the public, they ensure greater transparency for our healthcare system. As former Ontario Minister of Health, George Smitherman, once said: “Transparency may not always provide us with the news we want to hear but it leads to the actions we all need to take.”

What are medication safety indicators?

Indicators of medication safety are an important sub-set of healthcare indicators. In the context of this project, medication safety refers to two aspects. The first aspect is to ensure the patients are ordered the most appropriate pharmacological treatment plan based on the best available evidence. The second aspect is to ensure that the treatment plan is carried out as ordered. This is consistent with the position that "achieving safer care has three agendas, all of which are necessary for success: identifying what works (efficacy), ensuring that the patient receives it (appropriate use), and delivering it flawlessly (no errors)" (Leape, 2002). Indeed, deficiencies in the first aspect of medication safety, such as the low rate of venous thromboembolism prophylaxis, had been the focus of both national and international patient safety initiatives and reports (Safer Healthcare Now!, 2008; Shojania, 2001). Likewise, deficiencies of the second aspect of medication safety, such as administration of a medication to the incorrect patient, are commonly known as medication errors and considered a key aspect of medication safety. The medication safety indicators selected in this report cover both aspects of medication safety. They may be used to monitor and evaluate management, clinical and support functions that affect how safely and effectively medications are being used in our healthcare system (MacKinnon & McCaffrey, 2004).

Types of medication safety indicators

Similar to other aspects of health care, the medication system can be considered in terms of structure, process and outcomes (New South Wales Therapeutic Advisory Group, 2007). Monitoring these different aspects of the medication use system requires different types of indicators:

1. **Structure indicators:** measures of the environment, such as the hospital infrastructure or systems. Determining whether a healthcare institution has a policy and process for reporting and analyzing medication incidents would be an example of a structure indicator. Such outcomes are not directly linked to outcomes, but can be helpful in guiding system improvements. Such indicators typically require yes/no

answers and provide a snapshot of the organizational structure. (New South Wales Therapeutic Advisory Group, 2007)

2. **Process indicators:** measures of compliance with processes of care that have been shown to improve health outcomes. An example of a process indicator would be the percentage of appropriate or eligible patients who receive a specific treatment (e.g., antithrombotic medication for patients at risk of venous thromboembolism). Process indicators may be directly linked to outcomes and can be helpful in guiding system-based improvements.
3. **Outcome indicators:** these provide data related to the outcomes of care or health system performance. An example may be the number of medication incidents that occur that result in harm or death, per patient day of care. Outcome indicators may be easy for the general public to understand. At the same time, however, they may not provide specific information to guide system-based improvement.

Recommendation of medication safety indicators for public reporting in acute care setting

In Ontario, the Patient Safety program of the MOHLTC has established eight hospital-based indicators: numbers of cases of clostridium difficile, Methicillin Resistant Staphylococcus Aureus [MRSA], Vancomycin Resistant Enterococcus [VRE], central-line primary blood stream infection [CLI], and ventilator-associated pneumonia [VAP]; hospital standardized mortality ratio [HSMR]; and compliance with surgical site infection prevention and hand hygiene guidelines (Ministry of Health and Long-Term Care, 2009). Only one of these indicators (surgical site infection prevention) is directly related to medication safety. Thus it appears that there is an important opportunity for publicly reported patient safety indicators: currently, there are very few that focus on medication safety. Given the importance of medication safety, it is appropriate and important that this be considered.

Purpose

Through literature review and a consensus generating process, identify three medication safety indicators that are feasible and suitable for public reporting in Ontario.

Methodology

ISMP Canada met with key stakeholders, including MOHLTC and OHQC, and developed a multi-phase process which included:

- a systematic literature review;
- development of selection criteria for indicators;
- extraction of medication safety indicators from the literature and development of medication safety indicators based on the literature;
- using the set of selection criteria and through two screening rounds, narrowing down the list to 12 candidate indicators;
- focus group session with a panel of experts, in which consensus was reached on the three most appropriate indicators to recommend to the MOHLTC for consideration;
- production of a final report.

This multi-phase methodology is consistent with indicator development processes described by both Canadian and international bodies (Agency for Healthcare Research and Quality, 2006; Canadian Institute for Health Information, 2003; New South Wales Therapeutic Advisory Group, 2007).

Systematic literature review

A review of the literature was conducted to identify national and international work on the subject of medication safety indicators. Databases that were searched included Medline, Embase and Google; the following table shows the search terms.

Table 1: Search terms used for literature review

Search Index/Database	Search terms
MedLine	"Quality Indicators, Health Care"[Mesh] "Medication Errors"[Mesh] “medication errors”[Mesh] AND “indicators” “medication safety” “patient safety” “indicators” “Medication Safety indicators” “errors, medication safety indicator” “medication” AND “indicators” “medication safety” and “indicators”
Embase	“drug safety” (subject heading) “medication error” (subject heading) “patient safety” (subject heading) “medication safety” “indicators” “Medication Safety indicators” “errors, medication safety indicator” “medication” AND “indicators” “medication safety” AND “indicators” “medication errors” AND “indicators” “inappropriate medication” AND “elderly” “Beer’s list” AND “medication” AND “elderly” “medication safety” AND “children” “patient education” AND “medication adherence” AND “outcomes”
Google	“selection criteria, medication safety indicators” “Medication safety indicators” “evaluation criteria medication indicators” “Indicators for Drug & Therapeutics Committees” “indicators, performance, medications, Canada”

In addition to the above literature search, the “references” section of the articles identified was also manually searched to identify further articles regarding the subject of medication safety indicator.

Furthermore, a number of specific healthcare and patient safety organizations were consulted for reports and grey literature, such as the Institute for Health Improvement, Accreditation Canada, Canadian Institute for Health Information (CIHI), and the Canadian Patient Safety Institute. Indicator manuals from other institutions were

also included in literature review, such as those from the (Australian) New South Wales Therapeutic Advisory Group.

The literature retrieved included more than 100 domestic and international journal articles, studies and reports (see Appendix). All articles identified were printed and compiled for extraction of medication safety indicators.

Development of selection criteria

The following sources were consulted on the selection criteria previously used in the development of medication safety indicators:

- MOHLTC Health System Information Management (HSIM) Division Patient Safety Indicators Working Group (criteria for indicator evaluation) (Ministry of Health and Long-Term Care, 2009);
- New South Wales Therapeutic Advisory Group's *Indicators for Quality Use of Medicines in Australian Hospitals* (New South Wales Therapeutic Advisory Group, 2007)
- Agency for Healthcare Research and Quality's *Guide to Patient Safety Indicators* (Agency for Healthcare Research and Quality, 2006)
- CIHI's *Hospital Report 2003: Acute Care* (Canadian Institute for Health Information, 2003)

Of these sources, the primary one for the evaluation of the raw list of indicators was the MOHLTC Working Group Criteria, as it aligns with provincial objectives.

The six selection criteria used in the evaluation of indicators were:

1. **Alignment with current acute care patient safety initiatives in Ontario and/or Canada:** Alignment with current or emerging medication safety programs or projects in Canada (e.g., the work of Safer Healthcare Now!, Accreditation Canada, etc.)
2. **Burden of data collection and feasibility:** The data required for the indicator are readily available for the areas and the time periods required. There are no unreasonable obstacles or constraints on access, and the information can be used without restrictions.

3. **Validity and data quality:** The indicator appears to measure what is intended and is accepted by the healthcare community. The indicator covers relevant content or domains, and the indicator has predictive power.
4. **Actionable:** The information being collected can be used to inform and influence policy or funding or alter behaviour of health services providers.
5. **Understandable:** The indicator can be readily interpreted and the intended audience can generally understand the changes in values. In this case, since the ultimate objective is to produce public reports, the indicator must be meaningful to the general public.
6. **Evidence-based:** There was evidence that the highlighted practice would result in improved outcomes.

Extraction and development of indicators

Each analyst independently extracted medication safety indicators from the articles identified in the systematic literature search. As well, a small number of indicators were created by the analysts, reflecting important aspects of medication safety. This process resulted in the identification of more than 300 potential indicators, which were then entered into an Excel spreadsheet.

Using a set of defined and specific selection criteria, the list of over 300 indicators were submitted to two rounds of analysis and screening. The goal was to reduce the list to 12 indicators.

Screening round one

The main objective of this round of screening is to reduce the initial list of indicators to a more manageable number by quickly excluding indicators which clearly did not meet the selection criteria. The two analysts continued to work independently through this process. At the end, the results of the two analysts were compared, and discrepancies were discussed and resolved. Through this process, the initial list of indicators was reduced to 49.

Screening round two

These 49 indicators were then subjected to a second round of evaluation by the analysts. Guided by the selection criteria, after further discussion and deliberation, the number of indicators was reduced to 12: four each of structure, process and outcome indicators. These were the indicators presented to the expert focus group during the consensus generation process.

Consensus generation

An expert focus group was created and charged with the task of selecting three indicators from the preliminary list of 12 candidates through a reiterative, consensus-generating process, using a modified nominal group technique (Moore, 1994). Invitations to the focus group were sent to experts and stakeholders from the Ontario Ministry of Health and Long-Term Care, hospitals, long-term care home and health quality organizations. Invitees included health policy analysts, research analysts, measurement and evaluation specialists, physicians, pharmacists, nurses, risk management staff, and other healthcare professionals.

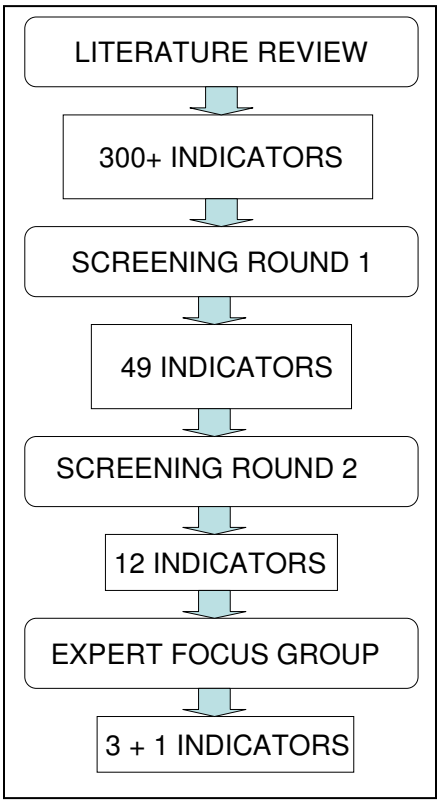
The 12 candidate indicators were presented within the three categories (structure, process and outcome). Information given on each indicator included:

- **detailed description:** what the indicator measures and how it may be measured (including how the numerator and denominator would be defined or counted)
- **rationale:** why this comprises an appropriate medication safety indicator, including how it is described in the literature and its importance for patient safety
- **alignment with other indicators or measures:** the use of the same or similar indicator or measure by other organizations
- **limitations:** weaknesses or limitations in the literature concerning this indicator or concerning the indicator itself (e.g., whether it is appropriate for some settings but not others).

After discussion of the 12 candidate indicators, participants broke into small groups and, after more discussion, used stickers to "vote" on their choice of indicators. Participants then described the rationale of their selections, generating further discussion and debate. Then a second round of voting was held to generate consensus on the three final indicator selections.

Results

As described, two screening rounds were utilized to reduce the list of potential indicators from over 300 to 49 and then to 12. These 12 indicators were then reviewed by the expert focus group and discussed until consensus was reached.



a) Screening round one

As described, working independently, analysts applied the selection criteria to the over 300 potential indicators identified through the literature review. Results were then compared and 49 indicators were selected. These 49 indicators are shown in table 2, divided into their three categories (structure, process and outcome). Please note that in some cases, what is shown below represents areas for indicator development rather than an actual indicator. Sample indicator definitions are shown only when available from the literature.

Table 2: 49 Candidate Medication Safety Indicators (Results of Screening Round 1)

Subject Area	Sample Indicator Definition (if available)	*Source of Indicator*
Structure Indicators		
Remove concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride > 0.9%) from client service areas	Yes/No response or incorporation into a questionnaire	*(Accreditation Canada, 2009)*
Patient Safety Culture	Suitable indicator may be developed based on the modified Stanford instrument (MSI) Patient Safety Culture in Healthcare Organization utilized by Accreditation Canada	*(Accreditation Canada, 2009) (Ginsburg et al, 2009)*
Access to current protocols, guidelines, dosing recommendations, checklists, and/or pre-printed order forms for high risk/high alert drugs	Yes/No response or incorporation into a questionnaire	*(Accreditation Canada, 2009)*
Service providers seek an independent double check before administering high-alert/high-risk medications medication	Yes/No response or incorporation into a questionnaire	*(Accreditation Canada, 2009)*
Establish a reporting system for sentinel events, adverse events, and near misses, including appropriate follow-up	Yes/No response or incorporation into a questionnaire	*(Accreditation Canada, 2009)*
Carry out one client safety-related prospective analysis per year, and implement appropriate improvements	Yes/No response or incorporation into a questionnaire	*(Accreditation Canada, 2009)*
The team uses at least two client identifiers before administering medications	Yes/No response or incorporation into a questionnaire	*(Accreditation Canada, 2009)*
Monitoring and reducing adverse drug events by assigning pharmacists on rounds	Number of beds with daily pharmacist participation in interdisciplinary direct patient care as a percentage of all beds	*(Nigram et al., 2008; Shojania, Duncan, McDonald, & eds, 2001; Canadian Society of Hospital Pharmacists 2008)*
The organization has removed the following products from patient care areas: hydromorphone ampoules or vials with concentration greater than 2 mg/mL (exceptions include palliative care); and morphine ampoules or vials with concentrations greater than 15 mg/mL	Yes/No response or incorporation into a questionnaire	*(Accreditation Canada, 2009)*

The organization standardizes and limits the number of medication concentrations available	Yes/No response or incorporation into a questionnaire	*(Accreditation Canada, 2009)*
Policy and process to administer pneumonococcal vaccine	Yes/No response or incorporation into a questionnaire	*(Accreditation Canada, 2009; National Quality Forum, 2009) (Canadian Society of Hospital Pharmacists, 2008)*
Policy and process to administer the influenza vaccine	Yes/No response or incorporation into a questionnaire	*(Accreditation Canada, 2009; National Quality Forum, 2009) (Canadian Society of Hospital Pharmacists, 2008)*
There is a formal process to review and approve pre-printed physician orders	Yes/No response or incorporation into a questionnaire	*(Hospital Pharmacy in Canada Editorial Board, 2008)*
Is there a forum for regular multidisciplinary consideration of the therapeutic management of individual patients?	Yes/No response or incorporation into a questionnaire	*(NSW Therapeutic Assessment Group Inc, 1998)*
Machine-readable coding systems (bar codes) for administration	Yes/No response or incorporation into a questionnaire	*(Canadian Society of Hospital Pharmacists, 2008; Nigram et al., 2008; Shojania et al., 2001)*
Unit dose drug distribution systems	Yes/No response or incorporation into a questionnaire	*(Canadian Society of Hospital Pharmacists, 2008; Hospital Pharmacy in Canada Editorial Board, 2008; Shojania et al., 2001)*
Computerized physician order entry systems that include clinical decision support	Yes/No response or incorporation into a questionnaire	*(Canadian Society of Hospital Pharmacists, 2008; Kaushal, Shojania, & Bates, 2003; Shojania et al., 2001)*

Process Indicators		
Percentage of patients with atrial fibrillation that are discharged on warfarin	Numerator: Number of patients with atrial fibrillation that are discharged on warfarin Denominator: Number of patients discharged with atrial fibrillation in sample	*(New South Wales Therapeutic Advisory Group, 2007)*
Documentation of allergy status	Number of patient profiles in which allergy status is documented before dispensing the first prescription / medication order to the patient as a percentage of all patient profile	*(Nigram et al., 2008)*
Acute Myocardial Infarction (AMI) Discharge Medications	Numerator: Number of patients with AMI who were prescribed appropriate medications (defined as aspirin, beta blocker, angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) and statin at discharge Denominator: Number of patients with AMI	*(Canadian Society of Hospital Pharmacists, 2008; New South Wales Therapeutic Advisory Group, 2007; Safer Healthcare Now!, 2007a)*
Community Acquired Pneumonia Antibiotic Selection	Numerator: Number of patients presenting with community acquired pneumonia that are prescribed guideline concordant antibiotic therapy Denominator: Number of patients presenting with community acquired pneumonia in sample	*(New South Wales Therapeutic Advisory Group, 2007)*
Prevalence of depression without antidepressant therapy	Numerator: Number of long term care (LTC) residents with depression but without antidepressant therapy Denominator: Number of LTC residents with depression	*(Ministry of Health and Long-Term Care)* *(interRAI, 2006)*
Prevalence of antipsychotic drug use in absence of psychotic and related conditions	Suitable indicator may be developed	*(Ministry of Health and Long-Term Care) (interRAI, 2006)*
Potentially Inappropriate Medications for Elderly (Beer's Criteria)	Numerator: Number of LTC residents taking a medication in the Beer's list Denominator: Number of LTC residents	*(Saskatchewan Health, 2002)* *(Ontario Health Quality Council, 2009)* *(Lau, Kasper, Potter, Lyles, & Bennett, 2005)*
Drug-Drug Interactions	Numerator: Number of residents taking a predefined interacting drug combination Denominator: Total number of residents Predefined interacting drug combinations include: Cotrimoxazole and glyburide Clarithromycin and digoxin	*(Juurlink, Mamdani, Kopp, Laupacis, & Redelmeier, 2003)*

Use of Appropriate Medications for People with Asthma	Percentage of patients 5 to 56 years of age during the measurement year who were identified as having persistent asthma and who were appropriately prescribed medication during the measurement year	*(National Committee for Quality Assurance, 2009; National Quality Forum, 2009)*
Percentage of patients with chronic heart failure that are prescribed appropriate medications at discharge	Numerator: Number of patients with chronic heart failure that are prescribed appropriate medications at discharge Denominator: Number of patients with chronic heart failure in sample	*(Canadian Society of Hospital Pharmacists, 2008; New South Wales Therapeutic Advisory Group, 2007)*
Percentage of patients receiving sedatives at discharge that were not taking them at admission	Numerator: Number of patients receiving sedatives at discharge that were not taking them at admission Denominator: Number patients receiving sedatives at discharge in sample	*(New South Wales Therapeutic Advisory Group, 2007)*
Medication reconciliation rate upon admission	Numerator: Number of patients with medication reconciliation performed on admission Denominator: Number of patients (or patients eligible for medication reconciliation) admitted Adjust the denominator accordingly in hospitals using predefined criteria to select patients eligible for medication reconciliation (e.g. patient taking more than five medications)	*(Canadian Patient Safety Institute, 2009; Nigram et al., 2008; Safer Healthcare Now!, 2007b)*
Medication reconciliation rate upon discharge	Number of patients whose medication profiles are reconciled within 24 hours before hospital discharge as a percentage of discharged patients	*(Nigram et al., 2008; Safer Healthcare Now!, 2007b)*
Tissue Plasminogen Activator (t-PA) Considered for stroke	Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke whose time from symptom onset to arrival is less than 3 hours who were considered for t-PA administration	*(National Quality Forum, 2009)*
Patients with ischemic stroke discharged on antiplatelet therapy	Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack who were prescribed antiplatelet therapy at discharge	*(National Quality Forum, 2009)*
Surgical Safety: Anaesthesia medication check prior to induction of anaesthesia	Suitable indicator may be developed based on the Surgical Safety Checklist criteria	*(World Health Organization, 2009)*
Surgical Safety: Allergy check prior to induction of anaesthesia	Suitable indicator may be developed based on the Surgical Safety Checklist criteria	*(World Health Organization, 2009)*
Antibiotic prophylaxis for surgery	Numerator – number of selected surgical patients whose prophylactic antibiotics were initiated within 60 minutes prior to surgical incision Denominator – number of selected surgical patients.	*(Safer Healthcare Now!, 2007c)*

	"Selected surgical patients" defined as patients undergoing coronary artery bypass graft, cardiac surgery, hip arthroplasty, knee arthroplasty, hysterectomy, and vascular surgery	
Venous thromboembolism prevention (VTE)	Numerator: Number of eligible patients who received appropriate VTE prophylaxis Denominator: Number of eligible patients Eligible patients: Patients undergoing Major General surgery and Hip Fracture Surgery (Refer to SHN getting started kit for details)	*(Safer Healthcare Now!, 2008)*
Patient with a history of falls is not taking psychotropic medications	Suitable indicator may be developed	*(Basger, Chen, & Moles, 2008)*

Outcome Indicators		
Percentage of recorded INRs > 5	Numerator: the number of INRs >5 Denominator: the number of doses reviewed	*(Patient Safety First, 2008)*
Narcotic (opioid) overdoses	Number of patients who received opiates who receive subsequent treatment with naloxone	*(Patient Safety First, 2008)*
Insulin induced hypoglycemia	Number of patients who received 25%/50% glucose to correct insulin induced hypoglycemia	*(Patient Safety First, 2008)*
Frequency of medication incidents by severity	Frequency of medication incidents categorized according to severity (e.g., no error, no harm, harm, death)	*(Ontario Health Quality Council, 2009)*
Frequency of harm or death medication incidents by stages	Frequency of harm or death medication incidents categorized according to medication system stages (e.g., prescribing, dispensing, administration…etc.)	*(Leape et al., 1995)*
Frequency of harm or death medication incidents by incident types	Frequency of harm or death medication incidents categorized according to medication incident type (e.g., incorrect dose, incorrect medication, etc.)	*(Ontario Health Quality Council, 2009)*
Top 10 medication with harm/death incidents	Top 10 medications associated with harm or death medication incidents	*(ISMP Canada, 2006; Ontario Health Quality Council, 2009)*
Medication incidents per 1000 days	Number of medication incidents per 1000 days	*Derived from (Institute for Healthcare Improvement, nd)*
Medication Incident Rate (Harm or Death incidents)	Numerator: Number of medication incidents with an outcome of harm or death Denominator: Number of patient days	*Derived from(Institute for Healthcare Improvement, nd)*
Death Associated With Medication Incident each year	Numerator: Number of deaths associated with medication incidents in Ontario health care institutions Denominator: Total number of deaths in Ontario	
Death and complications from medication error	Number of patient deaths or serious complications (central nervous system damage with sequelae, myocardial infarction, pulmonary embolism, blood disorders) likely to be caused by medication errors	(Millar, Mattke, & Members of the OECD Patient Safety Panel, 2004)

b) Screening round two

The 12 indicators presented to the expert panel for analysis were as described in Table 3. As shown they comprised:

- four structural indicators
  - Concentrated electrolytes
  - Narcotic safety
  - Medication incident reporting and analysis
  - Prospective analysis
- four process indicators
  - Acute myocardial infarction (AMI) discharge medications
  - Medication reconciliation
  - Antibiotic prophylaxis for surgery
  - Venous thromboembolism (VTE) prophylaxis
- four outcome indicators
  - Top ten medications associated with medication incidents
  - Medication incident types
  - Medication incident rate
  - Deaths associated with medication errors.

Table 3: 12 Candidate Medication Safety Indicators (Results of Screening Round 2)

Category/ Type	Indicator	Description	Rationale	Alignment with	Limitations
Structure	Concentrated electrolytes	Concentrated electrolytes are removed from patient care areas (yes/no) (percentage of patient care areas where concentrated potassium vials are available) NB: concentrated electrolytes include concentrated potassium chloride, potassium phosphate and sodium chloride > 0.9%	Worldwide, there have been numerous case reports of patient deaths from accidental intravenous administration of concentrated potassium chloride (Joint Commission, 1998)	• Accreditation Canada required organizational practice (ROP) • World Health Organization (WHO) • Joint Commission • NSW Therapeutic Advisory Group	Evidence from case reports only
Structure	Narcotic safety	Three criteria: a) removal of hydromorphone ampoules or vials with concentration > 2 mg/mL (excepting palliative care) (yes/no) b) removal of morphone ampoules or vials with concentrations > 15 mg/mL (yes/no) c) standardization and limitation of the number of parenteral narcotic (opioid) concentrations available (yes/no)	Case reports of patient harm and death from narcotic (opioid) medication mix-ups (ISMP Canada, 2006)	• Accreditation Canada ROP	Evidence from case reports only
Structure	Incident reporting and analysis	The organization has a policy and process for reporting and analyzing medication incidents (yes/no) NB: medication incidents include near misses as well as errors that reach the patient; an example of an appropriate analysis methodology is Root Cause Analysis	Growing realization that most healthcare errors reflect systemic weaknesses and often have root causes which can be generalized and corrected (World Alliance for Patient Safety, 2005); learning from other high performance industries such as aviation	• Accreditation Canada • WHO	Does not measure the quality of the reporting and analysis process

Category/ Type	Indicator	Description	Rationale	Alignment with	Limitations
Structure	Prospective analysis	The organization conducts at least one medication safety-related analysis per year (yes/no) NB: examples of prospective analysis include fault tree analysis, worst-case analysis, hazard analysis and critical control point (HACCP) and failure mode and effects analysis (FMEA)	Prospective analysis helps to create a culture of safety by ensuring proactive reviews and improvements to prevent the occurrence of an adverse event (Accreditation Canada, 2009)	• Accreditation Canada ROP	Does not measure the quality of an analysis
Process	Acute Myocardial Infarction (AMI) discharge medications	Proportion of AMI patients who are discharged with appropriate medications NB: appropriate medications are defined as aspirin, beta blockers, ACE inhibitors or ARBs, and statins. Requires defining both the: *numerator* -- number of patients with AMI who were prescribed appropriate medication at discharge *denominator* -- number of patients with AMI	Multiple randomized controlled trials have established the efficacy of aspirin, beta blockers, ACE inhibitors or ARBs, and statins for secondary prevention of AMI; yet, many AMI patients are not discharged on appropriate medications (Safer Healthcare Now!, 2007a)	• Safer Healthcare Now! • Institute for Healthcare Improvement • NSW Therapeutic Advisory Group	Only appropriate for acute care hospitals; does not apply to long-term care
Process	Medication reconciliation	Proportion of patients with medication reconciliation performed on admission NB: requires definition of both the: *numerator* – number of patients with medication reconciliation performed on admission *denominator* – number of patients (or patients eligible for medication reconciliation) admitted The denominator may need to be adjusted in hospitals using predefined	Errors at patient transition points have been identified as a significant source of medication incidents. Multiple studies have shown that medication reconciliation reduces unintended medication discrepancies with potential for harm (Kwan et al., 2007; Nigram et al., 2008; Safer Healthcare Now!, 2007b)	• Safer Healthcare Now! • Institute for Healthcare Improvement • NSW Therapeutic Advisory Group • WHO • Joint Commission	Does not provide information regarding the quality of the best possible medication history and medication reconciliation

Category/ Type	Indicator	Description	Rationale	Alignment with	Limitations
		criteria to select patients eligible for medication reconciliation (e.g., patients taking more than five medications)		• Canadian Safety Indicators for Medication Use	
Process	Antibiotic prophylaxis for surgery	Proportion of surgical patients who receive prophylactic antibiotics NB: requires definition of both the *numerator* – number of selected surgical patients whose prophylactic antibiotics were initiated within 60 minutes prior to surgical incision *denominator* – number of selected surgical patients. "Selected surgical patients" defined as patients undergoing coronary artery bypass graft, cardiac surgery, hip arthroplasty, knee arthroplasty, hysterectomy, and vascular surgery	Surgical site infections are the second most common type of adverse events occurring among hospitalized patients in the U.S. There is extensive clinical evidence supporting the use of antibiotic prophylaxis administered in a timely manner for the prevention of surgical site infections (Safer Healthcare Now!, 2007c).	• Safer Healthcare Now! • Institute for Healthcare Improvement • NSW Therapeutic Advisory Group • WHO Surgical Safety Checklist	Does not measure the appropriateness of the antibiotic selected. Is not applicable to long-term care settings.
Process	Venous thrombo-embolism (VTE) prevention	Proportion of at-risk or eligible patients who receive thromboprophylaxis NB: requires definition of both the *numerator* – number of eligible patients who received appropriate VTE prophylaxis *denominator* – number of eligible patients. "Eligible patients" typically defined as patients undergoing major general surgery and hip fracture surgery (Safer Healthcare Now!, 2008)	Thromboprophylaxis has been shown to reduce symptomatic and fatal VTE, as well as reducing all-cause mortality, while at the same time decreasing healthcare costs. For example, a comprehensive analysis of patient safety practices by the Agency for Health Research and Quality considered the appropriate use of thromboprophylaxis the highest-ranked patient safety practice for hospitals (Shojania et al., 2001).	• Safer Healthcare Now! • Institute for Healthcare Improvement • NSW Therapeutic Advisory Group • ISMP Canada Anticoagulant project	Not applicable to long-term care settings

Category/ Type	Indicator	Description	Rationale	Alignment with	Limitations
Outcome	Top ten medications	List of top ten medications associated with harm or death medication incidents NB: potential data sources is ISMP Canada's Ontario Medication Incident Database (OMID)	Informs the public about the medications most frequently associated with reported medication incidents with harm or death (ISMP Canada, 2006)	• Ontario Health Quality Council (Ontario Health Quality Council, 2009) • Reports from major patient safety organizations in the UK and US (Medmarx, 2010; National Patient Safety Agency, 2008)	Quantitative data based on voluntary reporting, so cannot establish data reliability or validity. The frequency of medication incidents may be related to how often or commonly a medication is used.
Outcome	Medication incident *types* – harm or death incidents	Frequency of medication incidents resulting in harm or death, categorized according to the type of incident (e.g., incorrect dose, incorrect medication, incorrect patient, etc.) NB: potential data source is ISMP Canada's OMID	Informs the public about the types of medication incidents most frequently associated with harm or death.	• Ontario Health Quality Council (Ontario Health Quality Council, 2009) • Reports from patient safety organizations such as National Patient Safety Agency (NPSA) and Medmarx (Medmarx, 2010; National Patient Safety Agency, 2008)	Quantitative data based on voluntary reporting so cannot establish data reliability or validity. Frequency of incident types may be related to different reporting practices among different healthcare disciplines.
Outcome	Medication incident *rates* – harm or death incidents	Proportion of medication incidents that result in harm or death per days of patient care	A direct medication safety outcome measure and one that is easy for the public to understand.	• Institute for Healthcare Improvement (Institute for	May lead to comparison of voluntary reporting incident

Category/ Type	Indicator	Description	Rationale	Alignment with	Limitations
		NB: requires definition of both the *numerator* – number of medication incidents with an outcome of harm or death *denominator* – number of patient days		Healthcare Improvement, nd)	rates, a step that is not supported by ISMP Canada because of data quality issues inherent to voluntary systems. The definition of harm may differ between hospitals and it is very difficult to ensure reliability or validity of quantitative data. Such an indicator may be more feasible if there were a province-wide, standardized mandatory medication incident reporting system.
Outcome	Deaths associated with medication incidents	Proportion of total deaths in Ontario that are associated with medication incidents. NB: a potential data source could be the Ontario's Coroner's office. Requires definition of both the: *numerator* – number of deaths associated with medication incidents in	Derived from reliable quantitative data, as opposed to voluntary reporting, and is independent of hospital safety culture and incident reporting systems. Informs the public about the number of deaths associated with medication incidents in relation to common	• Institute of Medicine	Does not provide information about medication incidents of lesser severity (e.g., harm or near misses). Implementation requires

Category/ Type	Indicator	Description	Rationale	Alignment with	Limitations
		Ontario healthcare institutions *denominator* – total number of deaths in Ontario	causes of death. This can be easy for the public to understand: a landmark Institute of Medicine report compared the estimated annual deaths due to preventable medical mistakes to other common causes of death (breast cancer, car accidents, HIV infections) (Kohn, Corrigan, & Donaldson, 1999).		coordination with the Ontario coroner's office.

c) Expert focus group

The expert focus group session took place on December 2, 2009 where 17 participants were asked to select 3 indicators from the 12 candidate indicators (see table 3). The participants were divided into 7 small groups, with 2 to 3 participants per group. Each small group was then provided with 3 "voting" stickers, of which only 1 vote can be applied to an indicator. Of the 21 votes available,

- Six votes were for the process indicator of VTE prophylaxis
- Five votes each for the process indicators of AMI discharge medication and medication reconciliation
- Two votes for the outcome indicator of deaths associated with medication errors
- One vote each for the process indicator of antibiotic prophylaxis for surgery and the outcome indicator of medication incident type
- One vote proposing a composite indicator including the structure indicators of concentrated electrolytes and narcotic safety.

All participants discussed the rationale of their choices. After considerable discussion and debate, a second round of voting was held. Results were:

- Seven votes each for the process indicators of AMI discharge medication and VTE prophylaxis (unanimous selection by the 7 small groups of participants)
- Five votes for medication reconciliation (a process indicator)
- Two votes for the outcome indicator of deaths associated with medication incidents.

The expert panel therefore agreed on three process indicators: AMI discharge medication, VTE prophylaxis and medication reconciliation. Results suggest that the panel also supports, although to a lesser extent, an outcome indicator of deaths associated with medication incidents.

d) Themes from the focus group discussion

During the focus group session, each participant contributed their expertise and unique perspectives throughout the various phases of the consensus generation process, resulting in a rich and fruitful discussion. Thematic analysis of the focus group discussion notes revealed a number of themes that provide important insights into the underlying rationale of the group's selections. All except one of the identified themes were specific to individual indicators. The following is a summary of these themes.

i) Indicators as an accountability tool versus increasing public awareness

It was evident early in the group discussion that there was a need to clarify whether the focus of the process should be on identifying indicators suitable for use as an accountability tool, or choosing those appropriate for increasing public awareness of medication safety issues. The following comment demonstrates the differences and tensions between the two functions.

> *"There is a need to distinguish between 'public reporting', and the Ministry's performance measurement system for accountability purposes - of which some indicators are shared with the public.."*

As a result of the group discussion, the purpose of the session was clarified to be identifying indicators that support accountability, with consideration given to their suitability for sharing with the public, or public reporting.

ii) Challenges of structure indicators

The four structure indicators (removal of concentrated electrolytes, narcotic safety, incident reporting system and prospective analysis) were discussed primarily as a group rather than separately. While there was a general consensus that these were important indicators, some participants were not sure whether structure indicators would be of interest from a public perspective:

"From the public perspective I believe the interest would be related more to outcome than structure."

Another participant observed that dichotomous indicators may not be conducive to tracking improvement over time:

"Where there is a yes or no response for the indicator, I am not sure as to the usefulness of continued reporting [each year] for measuring improvement over time'?"

To overcome this limitation, a participant suggested that a "composite" indicator could be developed by grouping multiple structure indicators together. In this manner, the progress of individual hospitals could be tracked over time:

"An indicator could be created to show the number of structure indicators that have been implemented."

iii) Debates on Process Indicators

Considerable discussion was held concerning the four candidate process indicators: acute myocardial infarction (AMI) discharge medications, antibiotic prophylaxis for surgery, medication reconciliation, and venous thromboembolism (VTE) prophylaxis. Comments suggested that the power and importance of these indicators stemmed from their strong evidence base and their impact upon clinical outcomes.

- ***AMI discharge medications***

There was general agreement of its importance. This was confirmed by the fact that this indicator received unanimous votes as one of the three final indicators. The following comment also spoke to the importance of this indicator:

"We know there are clear mortality benefits from use of ACE inhibitors, beta blockers in AMI."

- ***Antibiotic prophylaxis for surgery***

This indicator is already one of the eight patient safety indicators for public reporting in Ontario and some members of the expert focus group viewed its inclusion as an opportunity to widen its scope:

> *"Because teams are already reporting for specific types of surgeries, there would be an easier implementation to expand the scope of the current indicator.."*

Others opinioned that since this indicator is already implemented the focus should be on other indicators:

> *"We agreed that it was very important but decided that that this area was already addressed."*

- ***Medication Reconciliation***

There was considerable discussion concerning this indicator, with most focusing upon three issues: a) the relative priority of system integration versus direct patient impact; b) the importance of the indicator balanced against the difficulties in implementing it; and c) the difference between collecting a quantitative measure instead of a perhaps more important qualitative measure.

Compared to other indicators, medication reconciliation relates to the issue of overall system integration and for some participants, this was an important strength:

> *"I am interested in medication reconciliation because it captures many parts of the system.."*

> *"Integration within the healthcare system is important and this indicator can provide a measure of system integration."*

For other participants, however, medication reconciliation (med rec) is a less desirable indicator because it is not closely linked to patient outcomes or impact. As one participant said:

> *"We all agree that med rec is very important. However, the other indicators are directly linked to patient outcomes such as AMI discharge indicators and VTE prophylaxis indicators. Med rec is valuable, however, many factors affect the process quality and therefore the results can be variable and direct patient impact may or may not be there."*

A key issue in discussing medication reconciliation is the balance between its importance and how difficult it may be to develop clear definitions and measures. Although all focus group participants agreed that medication reconciliation is important, they also acknowledged there are methodological or practical limitations. For instance, ensuring comparability in medication reconciliation rates between hospitals may be difficult, as different institutions may have varying criteria in determining which patients are candidates:

> *"There is a huge concern regarding how to measure an indicator related to med rec. Even the suggested denominator leaves it open to the organization as to who they are focusing medication reconciliation on. Unless there is a very clear guideline with regards to the defined denominator, a hospital may choose to aim to provide med rec to patients taking 15 medications or more, for example. They will be able to achieve a hundred percent medication reconciliation for eligible patients. It doesn't reflect quality. For example, with the Accreditation Surveys, not everyone is clear on the measures. Because of the lack of clarity and also variability, we should be very hesitant to use it for reporting, at this time."*

Other participants, while acknowledging the current difficulties, nonetheless felt indicator development should proceed because of its importance for medication safety:

> *"Since we agree that med rec is important we need to attempt to find the optimal measure that can be agreed upon."*

> *"The indicators that are being publicly reported now involved extensive stakeholder consultations to arrive at a definition. This could be considered for med rec."*

Facing this dilemma, participants proposed a variety of possible approaches to facilitate both medication reconciliation and its measurement. These included:

- approaching the measurement of medication reconciliation as a "stretch goal" (*"there is homework here, it's not something you could just go out and do, maybe it is a stretch goal."*
- involving the public, as suggested by one participant:

  > *"I like the term stretch goal and I also see this as an opportunity to communicate the importance of med rec to the public. If we could clarify the definitions and engage the public in*

the discussions, perhaps the patient can have increased awareness of, and facilitate med rec by carrying medication history information and bringing it to the hospital."

- ***VTE prophylaxis***

Like the AMI discharge medication indicator, there was unanimous support for this indicator. The general acceptance of the importance of this indicator was summarized well by the comment:

If I only had one to vote, the VTE prophylaxis wins and the reason is the hundreds of randomized clinical trials behind it."

iv) Limitations of Outcome Indicators

Discussion was also held regarding the outcome indicators: top ten medications, medication incident types, medication incident rates, and deaths associated with medication incidents

- ***Top ten medications***

The discussion regarding assembling and publishing a list of the top ten medications associated with medication incidents focused primarily on its actionability. Some claimed that the top 10 medication as an indicator is not actionable (*"The top 10 medication is not actionable, it is happening")* whereas others suggested that it may be helpful by pointing to areas of concern and helping to focus quality improvement efforts (*"[it] might inform us as to where we want to go together and fix something."*).

- ***Medication Incident types and medication incident rates***

The group acknowledged that these two indicators are valuable since they communicate information highly relevant to the public in an understandable manner. However, the group expressed concerns about data quality, as currently the only data source is voluntary hospital medication incident reporting systems. This issue could be addressed if the MOHLTC were to make medication incident reporting systems or critical incident reporting systems mandatory; however, such a move would require a level of readiness and could be met with resistance by hospitals.

- ***Death associated with medication error***

This indicator generated considerable interest since it is one that the public would be interested in and would probably be able to easily understand. As one participant said:

> *"The reason why we put our vote on this indicator is because we thought the public would be interested in that simple number."*

Unlike medication incident type and rates, this indicator would not be dependent upon voluntarily-reporting data. This was seen as a strength:

> *"This indicator may be an opportunity or chance for consistent reporting. Although the coroner report may not necessarily capture everything, in comparison to voluntary data, this may be a good source."*

While some participants acknowledged the value of this information to the public, others urged caution. An indicator regarding death may be sensitive information for communicating with the public. Comments included:

> *"The HSMR [Hospital standardized mortality ratio] has been deleted from all the score cards and accountability agreements. And the reason it was deleted was the inappropriate use of the indicator i.e. comparing hospitals based on the indicator."*

> *"When you start publicly reporting this information, like the number of deaths associated with medication error, we have to be able to act on that data quickly. I am not sure what that indicator would be able to tell you."*

Conclusions

This report describes a systematic process undertaken by ISMP Canada to identify and describe a small number of practical indicators of medication safety for Ontario. In identifying these indicators, ISMP Canada focused on ensuring those developed and selected would align with current patient safety initiatives and be feasible, of acceptable quality (valid and reliable), actionable, understandable by the intended audience, including the public, and evidence-based.

In the process of reaching consensus on the identified indicators, a panel of leading healthcare professionals discussed a number of issues regarding the nature and use of medication safety indicators. For example, it was evident early in the process that those developing indicators must be clear as to whether they are to be used primarily as tools for accountability processes or as means of increasing public awareness of medication safety issues. The group decided the indicators should first and foremost enhance healthcare accountability and protect patient health and well-being.

Data quality is another important issue that influenced the group's decisions. Medication reconciliation, medication incident types and medication incident rates all concern important areas of medical care (particularly medication reconciliation, which is a reflection of systems integration) but are limited by methodological or data weaknesses (such as the lack of standardized definitions).

The three indicators selected (AMI discharge medication, VTE prophylaxis and medication reconciliation) reflect their importance in enhancing accountability in medication safety in Ontario hospitals. Moreover, if clearly defined and communicated with appropriate explanations they should be understandable by the public. These indicators point to important areas in the healthcare system at which deficiencies can result in significant patient harm. There is potential for the indicators to provide hospitals and healthcare providers with tangible and realistic mechanisms for measuring performance and, ultimately, improving quality of care.

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