Quality Improvement Coordinator Manual
A Guide to Continuous Quality Improvement
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Disclaimer

Some of the information contained in this guide was originally intended for the use by Nova Scotia pharmacists as a reference for their continuous quality improvement program, SafetyNET-Rx, as set forth by the Nova Scotia College of Pharmacists (NSCP). The authors of the original document were as follows:

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The information in this reference manual has been adapted for the use by Saskatchewan community pharmacy staff members as a reference for their continuous quality improvement (CQI) program, COMPASS (Community Pharmacists Advancing Safety in Saskatchewan) as set forth by the Saskatchewan College of Pharmacy Professionals (SCPP).
Introduction

Welcome to COMPASS (Community Pharmacists Advancing Safety in Saskatchewan) continuous quality improvement (CQI) program.

Participation in the program shows you value the importance of a safe medication system and are willing to take steps towards developing a culture of safety in Saskatchewan. The involvement of pharmacy teams in continuous quality improvement is so important.

Medication safety and safe medication practices are important issues throughout the health care spectrum. The Saskatchewan Ministry of Health has included patient safety and medication safety as part of their strategic plan. SCPP recognizes the importance of ensuring community pharmacies are not only recognizing, resolving, and learning from medication errors, but are also reviewing all their system processes to ensure patient safety.

Research from Nova Scotia through the SafetyNET-Rx program shows which components need to be included for a community pharmacy CQI program to be effective. The SafetyNET-Rx project identified that the CQI program needs to be both proactive and reactive to be effective. COMPASS, the Saskatchewan CQI program, was modeled after the SafetyNET-Rx project using the same tools and similar processes to be both proactive and reactive regarding medication incidents.

The COMPASS tools will be accessed through ISMP Canada and will include three online tools which meet the bylaw requirements for the CQI program. The online tools are the:

- Community Pharmacy Incident Reporting (CPhIR) tool
- Medication Safety Self-Assessment (MSSA) tool
- Quality Improvement tool

SCPP looks forward to working with community pharmacy teams as they implement and utilize the COMPASS tools and processes in order for residents to continue to receive quality pharmacy care in Saskatchewan.
CQI Bylaws/Program Requirements/ QI Coordinator Responsibilities

SCPP Regulatory Bylaws
Continuous Quality Improvement (CQI) Bylaw

Part I – Proprietary Pharmacies

Continuous Quality Improvement

12(1) In this section:

(a) ‘Continuous Quality Improvement’ means a structured process used within the pharmacy, which allows for the continual review and improvement of all aspects of the medication dispensing process, in order to ensure medication safety and a safe medication system. This includes but is not limited to utilizing specific tools for recording quality related events, proactively identifying any safety issues within the pharmacy, and documenting improvement plans to ensure medication safety within the pharmacy;

(b) ‘Quality Related Event’ means any preventable event that may cause or lead to inappropriate medication use or patient harm. Medication incidents may be related to professional practice, drug products, procedures, or systems, and include prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use, as per the Institute for Safe Medication Practices Canada Definition of Terms (2016); and

(c) 'Medication Safety Self-Assessment' means an Institute for Safe Medication Practices Canada quality improvement tool that allows pharmacy staff to assess themselves in different key areas, which encompass the characteristics of a safe medication system.

(2) Every pharmacy must have a Continuous Quality Improvement program that meets the following requirements:

(a) anonymous reporting of Quality Related Events to an independent, objective third party organization for the population of a national aggregate database, in which learnings can be communicated across the profession;

(b) completion of a Medication Safety Self-Assessment every two years by all pharmacy staff;

(c) development and monitoring of a Continuous Quality Improvement plan;

(d) documentation of all Continuous Quality Improvements; and

(e) participation in Continuous Quality Improvement meetings as follows:

   (i) the number of Continuous Quality Improvement meetings held per year will be determined by the Quality Improvement Coordinator and pharmacy manager in order to meet the requirements of clauses 12(2)(a), (b), (c), and (d) of Part I; and
(ii) there shall be no less than one Continuous Quality Improvement meeting held annually.

(3) Every pharmacy must have at least one designated Quality Improvement Coordinator.

(4) The pharmacy manager for each pharmacy shall designate a licensed pharmacist or pharmacy technician employed at that pharmacy as the Quality Improvement Coordinator for that pharmacy.

(5) The pharmacy manager for each pharmacy must report to the College:
   
   (a) the name of the designated Quality Improvement Coordinator for that pharmacy; any changes to the Quality Improvement Coordinator for that pharmacy; and
   
   (b) the initial approved Quality Improvement training undertaken by the designated Quality Improvement Coordinator for that pharmacy.

(6) Every Quality Improvement Coordinator shall undertake Quality Improvement training approved by the College within six months of his designation.

(7) The College shall record in the register for each pharmacy:
   
   (a) the designated Quality Improvement Coordinator, as identified by the pharmacy manager in accordance with clauses 12(5)(a) and (b) of Part I; and
   
   (b) the initial approved Quality Improvement training undertaken by the designated Quality Improvement Coordinator, as identified by the pharmacy manager in accordance with clause 12(5)(c) of Part I.

Program Requirements

1. Requires anonymous reporting of medication incidents to an independent, objective third party organization for population of a national aggregate database from which learnings arising from trends and patterns can be communicated across the profession.

2. Requires completion of a medication safety self-assessment biennially (every two years).

3. Requires development and monitoring of the progress of an improvement plan at CQI meetings.

4. Requires CQI meetings to be held for the purpose of providing staff education, discussing of medication incidents that have reached the patient regardless of harm, discussing near misses that had they not been caught could have caused patient harm, other near misses, completing of the MSSA, and developing and monitoring of the improvement plan. The number of CQI meetings held per year will be determined by the quality improvement coordinator and pharmacy manager in order to meet the above requirements. Recommended to meet no less than annually.

5. Requires documentation of quality improvements discussed at CQI meetings. Discussion and outcomes of the CQI meetings are to be documented using the quality improvement tool in CPhIR.
6. Requires each pharmacy to have designated at least one Quality Improvement (QI) Coordinator. The number of QI coordinators will depend upon the safety workload of the pharmacy.

**Other Components of the Program**

7. Manages known, alleged and suspected medication errors that reach the patient consistent with the best practices for this activity.

8. Encourages open dialogue on medication incidents between pharmacy staff and management through review of the pharmacy’s aggregate medication incident data (e.g. total number of incidents, type of incidents, etc.).

9. Achieves the purposes of an effective CQI program through ongoing education of pharmacy staff on the current best practices in medication incident management and adoption of these practices, with the goal of discouraging punitive identification or other approaches that is detrimental to reporting and learning.

**Quality Improvement Coordinator Responsibilities**

Each pharmacy must have at least one designated person within the pharmacy to be the Quality Improvement (QI) Coordinator. The pharmacy could designate an additional person to be a co–coordinator if the safety workload of the pharmacy warrants it. The QI Coordinator must be a pharmacist or pharmacy technician. While it is recommended that the quality improvement (QI) coordinator oversees the activities described below, it is still the responsibility of the pharmacy manager to ensure that the pharmacy complies with the program requirements.

Responsibilities of the QI Coordinator:

- participate in the in-person or online COMPASS training
- train other pharmacy staff members on the tools and processes of COMPASS
- ensure all pharmacy staff members identify, report, and discuss incidents, and are aware of all incidents that have occurred in the pharmacy.
- ensure that biennially, the medication safety self-assessment is completed and that there is a team of pharmacy staff members involved in the completion.
- ensure there are CQI meetings when appropriate e.g. to develop and monitor improvement plans, when a harm incident occurs, to complete the MSSA, when staff education is required.
- identify education needs of the pharmacy staff with respect to safe medication practice, medication safety and other safety related issues.
The Evidence Act

The following legislation enables an individual to apologize without it constituting an admission of fault. The following information is one section of *The Evidence Act*.

**Section 23 of *The Evidence Act***

**Effect of apology on liability**

23.1 (1) In this section, “apology” means an expression of sympathy or regret, a statement that one is sorry or any other words or acts indicating contrition or commiseration, whether or not the words or acts admit or imply an admission of fault in connection with the event or occurrence to which the words or acts relate.

(2) An apology made by or on behalf of a person in connection with any event or occurrence:

(a) does not constitute an express or implied admission of fault or liability by the person in connection with that event or occurrence;

(b) does not constitute an acknowledgment of the existence of a claim in relation to that event or occurrence for the purposes of section 11 of *The Limitations Act*;

(c) notwithstanding any wording to the contrary in any contract of insurance and notwithstanding any other Act or law, does not void, impair or otherwise affect any insurance coverage that is available to the person or would be available to the person in connection with that event or occurrence but for the apology; and

(d) must not be taken into account in any determination of fault or liability in connection with that event or occurrence.

(3) Notwithstanding any other Act or law, evidence of an apology made by or on behalf of a person in connection with any event or occurrence is not admissible in any action or matter in any court as evidence of the fault or liability of the person in connection with that event or occurrence.

2007, c.24, s.2.
Procedure When the Pharmacy Manager or QI Coordinator Changes

Pharmacy Manager Change

If there is a change to the pharmacy manager, please ensure the following:

- The new pharmacy manager is aware of and has access to the CPhIR username and password
- The pharmacy manager has designated an individual to be the Quality Improvement Coordinator (if the previous pharmacy manager was also the QI Coordinator)
- The new QI Coordinator must take the COMPASS training within 6 months of becoming the QI Coordinator.
- The link to the COMPASS - QI Coordinator training is [http://www.usask.ca/cpdpp/continuing-education-/Online%20Courses.php#QuickConnectWebinarSeries](http://www.usask.ca/cpdpp/continuing-education-/Online%20Courses.php#QuickConnectWebinarSeries)
- Email a copy of the signed Data Sharing Agreement, available from a link in the Pharmacy Manager Portal, to ISMP Canada at CPhIR@ismpcanada.ca (Attention: Ambika Sharma).

New Pharmacy Owner

When there is a new pharmacy owner, (name of proprietor changes), the manager must ensure that the Community Pharmacy Incident Reporting (CPhIR) system username and password are provided to the new owner. This allows for continuity of the incident reporting information, the medication safety self-assessment (MSSA) information and the quality improvement plan information.

Ensure a copy of the signed Data Sharing Agreement, available from a link in the Pharmacy Manager Portal, is emailed to ISMP Canada at CPhIR@ismpcanada.ca (Attention: Ambika Sharma)

In the event that the CPhIR username and password are not provided to the new owner, a new data-sharing agreement will need to be signed by the pharmacy manager and provided to ISMP Canada. All safety-related history with respect to medication incident reporting, medication safety self-assessment information and the quality improvement plan may be lost.

Note: In the event that a new data sharing agreement (DSA) needs to be signed, the DSA form can be accessed by the pharmacy manager by logging into the pharmacy manager portal from the SCPP website and printing off a new form. This form will have all the pharmacy and pharmacy manager specific information automatically imported.
No other DSA will be accepted by ISMP Canada except the form printed from the pharmacy manager portal.
Where can I find Contact Information for the COMPASS program?

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<tr>
<th>Inquiry Type</th>
<th>Contact</th>
<th>Contact Information</th>
</tr>
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<tbody>
<tr>
<td>Regulatory Issues</td>
<td>Jeannette Sandiford- Assistant Registrar-Field Operations and Quality Assurance – Saskatchewan College of Pharmacy Professionals (SCPP)</td>
<td><a href="mailto:jeannette.sandiford@saskpharm.ca">jeannette.sandiford@saskpharm.ca</a></td>
</tr>
<tr>
<td>Medication Safety Self-Assessment</td>
<td>Institute for Safe Medication Practices (ISMP) Canada</td>
<td><a href="mailto:mssa@ismp-canada.org">mssa@ismp-canada.org</a></td>
</tr>
<tr>
<td>Community Pharmacy Incident Reporting (CPhIR)</td>
<td>Institute for Safe Medication Practices (ISMP) Canada</td>
<td><a href="mailto:cphir@ismp-canada.org">cphir@ismp-canada.org</a></td>
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Resources Available on CPhIR

There are many resources available on the CPhIR website. Pharmacy staff members are encouraged to access as many of the resources as they require.

Pharmacy members can also sign up to receive newsletters automatically as they are made available. Newsletters available on the CPhIR website include:

- ISMP Canada Patient Safety Bulletin
- SafeMedicationUse.ca Newsletter and Alerts
- TransPhIR

There are also other resources available such as short video clips on specific topics with the CPhIR. For example, how to enter an incident and other videos that can be used for Continuing Education (CE) units.

The newsletters can be accessed through the [www.ismp.canada.ca](http://www.ismp.canada.ca) website or the [www.cphir.ca](http://www.cphir.ca) website.
COMPASS Program CQI Cycle

Below is the Continuous Quality Improvement (CQI) Cycle for Community Pharmacists. This provides a visual description of the process that will be used during the COMPASS program.

Abbreviations: CQI – Continuous quality improvement
Fig. 1 - Modified from SafetyNET-Rx CQI Cycle (Keeping the “continuous” in CQI)
Quick Reference: CPhIR & MSSA Electronic Links

The website link to CPhIR and MSSA is: https://secure.ismp-canada.org/CPHIR/Reporting/login.php

Using the pharmacy username and password provided by ISMP Canada, log into the CPhIR program.

For future reference, you may enter the pharmacy information below.

Username: _______________________________________
Password: _______________________________________

The MSSA electronic link can be accessed once the above CPhIR log in information is entered.
ISMP Community Pharmacy Incident Reporting (CPhIR) Program Instructional Guide

The following 9 pages are reprinted with permission directly from the ISMP Canada Community Pharmacy Incident Reporting (CPhIR) Program Instructional Guide.
Community Pharmacy Incident Reporting (CPhIR) Program
Instructional Guide

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Section 1  CPhIR Online Training Guide

Login the ISMP Canada Community Pharmacy Incident Reporting (CPhIR) Program at http://www.cphir.ca. You can access the CPhIR Online Training Guide by clicking “CE & Resources” from the menu located at the top of the CPhIR homepage. Select Training Video #2 and you can then view the narrated presentation of CPhIR Training Guide.

A Key Partner in the Canadian Medication Incident Reporting and Prevention System (CMIRPS)
Un partenaire clé du Système canadien de déclaration et de prévention des incidents médicamenteux (SCDPM)
Section 2  CPhIR Frequently Asked Questions

General Information

Who is ISMP Canada?
The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency committed to the advancement of medication safety in all healthcare settings. Our goal is the creation of safe and reliable systems for managing medications in all environments.

ISMP Canada works collaboratively with the healthcare community, regulatory agencies and policy makers, provincial, national and international patient safety organizations, the pharmaceutical industry and the public to promote safe medication practices.

ISMP Canada’s mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

Why should my pharmacy use CPhIR to report medication incidents?
The goal of ISMP Canada is to analyze medication incident reports and develop recommendations for enhancing patient safety in all healthcare settings. ISMP Canada created the CPhIR program with support from the Ontario Ministry of Health and Long-Term Care to specifically address incident reporting in community pharmacies. CPhIR contributes to the Canadian Medication Incident Reporting and Prevention System (CMIRPS) (Further information on CMIRPS is available at http://www.ismp-canada.org/cmirps.htm).

Medication incidents are often under-reported. CPhIR will provide you with the ability to document and analyze contributing factors (e.g. miscommunication, staffing, and education) that can cause errors in the medication-use system. From the data reported and through understanding of the contributing factors, your pharmacy team can develop and implement system-based strategies for quality improvement and prevent potential errors from occurring again in the future.

How long will it take to report a medication incident?
The amount of time depends on how much information is included in the report, but it probably will not take more than 10 minutes to complete a report.
Login

I forgot my username and/or password – how do I get a new one?
ISMP Canada will provide a username and password to login for the first time. If the
username and/or password is lost or forgotten, please contact ISMP Canada by clicking
“Contact ISMP Canada” on the login page. This will launch an e-mail window. Please
include your pharmacy name and the contact person in charge of CPhIR. You can
expect a response within two business days.

Is it possible to have more than one username per pharmacy?
No, each pharmacy location can only have access to one account. The key contact
person will provide the username and password to pharmacy staff to report medication
incidents. It is important to keep the password confidential.

Home

What is an Open Incident?
An Open Incident is an incident that has been entered into the system and is available
for editing within 90 days of the initial entry date.

All open incidents will automatically be closed after 90 days. Closed incidents can no
longer be edited. Once an incident is closed, it is available for search and analysis.

Can I access newsletters and publications about medication safety through
CPhIR?
The following are provided by ISMP Canada complimentary to all CPhIR users and are
accessible under the CPhIR home page:

- ISMP Canada Safety Bulletins
- SafeMedicationsUse.ca Consumer Newsletters and Alerts
- Medication Safety Alerts
- TransPhIR from CPhIR Newsletter

Report an Incident

Who can report a medication incident?
Any member of the pharmacy staff, including pharmacists, technicians, interns, and
students, can use CPhIR to report medication incidents. All pharmacy staff members
require the username and password to login to CPhIR.

What information is required to report an incident?
The following information is mandatory:
- Date Incident Occurred
- Type of Incident
- Incident Discovered By
- Medication System Stages Involved in this Incident
- Medication(s) Involved
- Degree of Harm to Patient due to Incident
- Incident Description/How the Incident was Discovered.

The following fields are optional: (i.e., not required to submit incident):
- Time Incident Occurred
- Patient’s Gender
- Patient’s Age
- Other Incident Information
- Contributing Factors to this Incident
- Actions at Store Level (Include action plan, person in charge, and target date for completion)
- Shared Learning for ISMP Canada to Disseminate (What has been done to prevent a similar occurrence in the future)

When you are ready to click “Submit Report to ISMP Canada”, a reminder will pop up to make sure that you do not supply identifying information (e.g., patient name or date of birth, pharmacy name, or healthcare provider names). Once you hit submit, the incident information is then stored into the ISMP Canada secured CPhI database.

Do I enter the date the medication incident occurred or the date it was discovered?
Please enter the date the incident occurred. For example, if an incorrect medication was dispensed Tuesday evening and the patient returns Wednesday morning, the incident happened Tuesday evening and this is the date entered.

If an incident or quality related event is identified and resolved prior to prescription order entry and dispensing, how can I capture this information in CPhI?
In this case, if applicable, check the “Prescribing” option next to the “Medication System Stages Involved in this Incident” field. Alternatively, you can document this information in the “Incident Description” field.

Can I enter more than two medications?
Yes, as you complete each medication field, a new medication field will appear.

When a medication is entered, the black medication box disappears before I can choose a medication – can it stay open longer?
To view the options in the black auto-finish box, place the cursor anywhere within the box and it will remain open until a selection is chosen.

Can I enter the DIN instead of the medication name in the medication field?
Yes, the black auto-finish box will also appear if a partial DIN is entered. If the DIN is chosen from the list, the medication name will automatically be entered.

If an incident occurs in which an incorrect medication has been dispensed, which medication should be identified in the Medication field?
The incorrectly dispensed medication should be specified in the “Medication” field, as this was the medication that was involved in the medication incident. Mention the intended medication that was to be dispensed in the “Incident Description” field.
For example, in the instance that Prevacid® was inadvertently dispensed instead of Percocet®, enter Prevacid® in the “Medication” field and mention Percocet® in the “Incident Description” field.

The expiry date and lot number of the medication dispensed were not properly recorded. Where can I document this in CPhIR?
You can document this in the “Incident Description” field.

Where can I document incidents that involve dispensing in blister packs?
Click on the “Expand All” button next to the “Other Incident Info” field. Under the “Rx Order Entry / Dispensing Label Generation” category, check the “Nursing Home/Blister Pack” option. Alternatively, you can document this information in the “Incident Description” field.

With respect to drug shortages, often we have to dispense a generic brand or an alternative brand of a medication. If an incident involves the use of different brands of a medication, where can I document this in CPhIR?
Click on the “Expand All” button next to the “Other Incident Info” field. Under the “Rx Supply / Ordering” category, check the option(s) that apply to the incident. Alternatively, you can document this information in the “Incident Description” field.

How about improper storage of medications? Where can I document this in CPhIR?
Click on the “Expand All” button next to the “Other Incident Info” field. Under the “Rx Preparation – Storage” category, check the option(s) that apply to the incident. Alternatively, you can document this information in the “Incident Description” field.

If one of the contributing factors to the incident is due to an incorrect address being entered for the patient, where can I document this in CPhIR?
You can document this in the “Incident Description” field.

How long do I have to edit an incident?
An incident can be edited within 90 days of the initial entry date.

What will happen after the incident is open for 90 days?
All open incidents will automatically be closed after 90 days. Closed incidents can no longer be edited. Once an incident is closed, it is available for search and analysis.

How do I edit or close an incident?
Only Open Incidents can be edited. Click on the “Home” tab, and under “Your Open Incidents,” find the incident to be edited (listed numerically by incident number, or date incident was first entered) and click on the “incident number-Open” (in blue). The incident reporting form for the selected incident will appear. Edit information as needed. Once the report is complete, scroll to the bottom of the form and click the checkbox to “Close record from future edits”. Then click “Submit Report to ISMP Canada” to close and submit the incident.

When I submit an incident, an error window pops-up, what does this mean?
Upon submission, if one of the mandatory fields is not complete, a pop-up window will appear as a reminder to fill in all mandatory fields. Click OK to return to the form and fill in the missing information.
It is taking quite a while to submit an incident after I press the “Submit Report to ISMP Canada” button. Why?
Depending on your Internet browser or connection, sometimes it may take longer to submit an incident. A pop-up message will alert you when submitting an incident takes longer than expected. This message will assure you that the incident is being submitted.

I entered information into the form and it logged out, is the information saved?
No. after 24 minutes of inactivity, CPhIR will automatically time out for confidentiality reasons. All unsaved information will be lost. To prevent lost information, submit data as an open incident. Open incidents can be edited within 90 days.

Search

How do I search for an open incident?
Open incidents cannot be searched. To find an open incident, click on the “Home” tab. All open incidents are sorted by incident number/date incident initially entered.

When I search for an incident, it does not display in the results, how do I find it?
Only closed incidents can be searched. All open incidents are displayed on the home page.

How do I export incident reports into PDF/Excel format?
Click the “Search” tab and enter the search criteria for the incidents to be exported. When the search results are displayed, scroll to the bottom of the page and click the “Export in PDF format” or “Export in Excel format.” All search results will be exported in the new file, which will appear in a new window.

Can I make customized graphs of my individual pharmacy data?
No. CPhIR does not graph individual pharmacy data. However the “Search” function allows you to find the selected data you wish to graph and export the incidents into Excel. Using Excel, you can then create customized charts and tables.

Stats

How do I view the graph with my pharmacy data and aggregate data?
Click the “Stats” tab. Select the “Type of Search Result” you would like to view and enter any of the specific search criteria. Scroll to the bottom of the form and click “Submit Search.” The results will display as a graph and tables with your pharmacy data and aggregate data.

I am using Internet Explorer and I can view my pharmacy data and aggregate data in tables but not in graphs. Why?
There is a security setting called “Binary and script behaviors” that has to be enabled for the graphs to render. To access the “Binary and script behaviors” setting, click on “Tools” and select “Internet Options”. Under the “Security” tab, click on the “custom level ...” button. You will then see a “Settings” menu. Scroll down the menu and under “ActiveX controls and plug-ins”, ensure that the “Binary and script behaviors” option is enabled.
Your Account

How do I change my password?
Click on the “Your Account” tab. Enter the old password and type in the new password. Do not use the same password that you use for other online accounts. All passwords must be 8 characters in length with letters, numbers, and punctuation. Passwords are also case-sensitive. Remember to check your CAPS lock key. Re-enter the new password and click “Update Password.”

CE & Resources

If there are members of my pharmacy staff who are new or not yet familiar with the CPhIR program, what is the best way to become familiarized with this tool?
Under the “CE & Resources” tab, there are multiple CE modules that are very useful for learning about fostering a reporting culture, how to navigate through CPhIR as well as some general information about medication safety and analysis. Each module is accompanied by a link to a set of presentation slides that the user can print or view in order to follow along during the module.

Quality Improvement

What is Continuous Quality Improvement (CQI) and why is it important?
CQI is an online environment for community pharmacies to document staff meetings and discussion in response to medication incidents (and incident analysis); as well as action plans to improve medication safety in the practice setting. Continuous quality improvement helps make the environment safer for practitioners and patients.

What is the difference between single and multi-incident analysis?
Single incident analysis allows you to analyze in detail of one reported incident (particularly those of high impact or resulting in severe patient harm) and identify potential contributing factors related to that incident.

Multi-incident analysis allows you to efficiently analyze a set of related incidents to identify potential system-based contributing factors. Either type of incident analysis will prompt you to develop system-based solutions to prevent similar incidents from recurring in your practice setting.

How do I import more than one incident into my Medication Incident Discussion?
Once you open the “Medication Incident Discussion” window, there are two methods to import medication incidents for discussion at the staff meeting and they are listed as follows:

A. You may import each incident by clicking “Add CPhIR Incident” and inputting the CPhIR incident number.
B. You may import a set of related incidents by clicking “Import CPhIR Incidents” and search the set of related incidents by the criteria desired. Then you can select all the desired incidents by marking the checkboxes listed under the
“Import” column. If you select the wrong incident, then you can simply unmark the checkbox or click the red-cross listed beside the CPhIR incident number. Once you complete your selection, click “Import Selected Incidents” to import all the desired incidents for your medication incident discussion with your staff members.

Why can’t I search or add a new medication incident in my Medication Incident Discussion?
Open incidents cannot be searched or added into the “Medication Incident Discussion” section. To find an open incident, click on the “Home” tab, which shows a list of all your open incidents and you may check all the incidents that you wish to close. All open incidents are sorted by incident number/date incident initially entered. Only closed incidents can be searched and added into the “Medication Incident Discussion” section.

Can I still edit my discussion after I finalize it?
Yes, you can click “edit” and revise or update any previous medication incident discussion prior to finalizing it. Once you confirm that you would like to finalize the discussion, you will no longer be able to update the medication incident discussion.

I accidentally closed my webpage during the discussion, was my information saved?
No, unfortunately the information will not be saved. Therefore, it is recommended to periodically save your work to prevent any unnecessary loss.

Will content from my CQI meeting discussion be reported to ISMP Canada?
The CQI module is intended for your pharmacy’s own documentation purposes. When you are ready to click “save and close”, a reminder will pop up to make sure that you do not supply identifying information (e.g. patient name or date of birth, pharmacy name, or healthcare provider names). Once you click “OK” (to submit), the meeting discussion is then stored into the ISMP Canada secured CPhIR database.

Can I print CQI discussion for my records?
Yes. At the end of the documentation page, you can click “Save & Print” and a nicely laid out PDF of your staff meeting discussion will be available for you to save electronically or print as a hard copy.

Confidentiality/Privacy Policy

How will data from CPhIR be used?
The goal of ISMP Canada is to analyze medication incident reports and develop recommendations for enhancing patient safety in all healthcare settings. Medication incidents submitted through CPhIR will be used only for the purposes of analysis, shared learning, and formulation of incident prevention strategies.

Who has access to the data entered into CPhIR?
ISMP Canada has a privacy policy stating that data are used by ISMP Canada only for the purposes of analysis, shared learning, and incident prevention strategy formulation. Only selected employees at ISMP Canada have access to the data submitted through CPhIR.
If you have any further questions, please contact ISMP Canada:

cphir@ismp-canada.org
(416) 733-3131 or (866) 544-7672
4711 Yonge Street, Suite 501
Toronto, Ontario
Canada M2N 6K8
www.ismp-canada.org
Medication Safety Self-Assessment (MSSA) Instructional Guide

The following 9 pages are reprinted with permission directly from the ISMP Canada Medication Safety Self-Assessment (MSSA) Instructional Guide.
Medication Safety Self-Assessment® (MSSA®)
Instructional Guide

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ISMP Canada is not a standard-setting organization. The Self-Assessment is a checklist of items, encompassing all aspects of safe medication usage. The self-assessment characteristics in the MSSA are not purported to represent a minimum standard of practice, and should not be considered as such. MSSA findings are intended for internal use and become more useful as repeat assessments are performed to see where improvements have been achieved over time. No pharmacy should expect to score high in all areas.
Section 1  Completing the MSSA Handbook

Assemble a team from your pharmacy staff members to complete the 89 Medication Safety Self-Assessment (MSSA) items. At a minimum, MSSA team members should include a pharmacist, a pharmacy technician, and the pharmacy manager. Because medication use and dispensing are complex processes that involve more than one person, the value and accuracy of the self-assessment will be enhanced if it is completed by a number of members of the pharmacy team.

The estimated time to complete the MSSA Handbook is about three hours. ISMP Canada recommends three team meetings of one hour each. The team and group discussions often lead to talk about possible changes in practice and how to make them. Hopefully the staff did not make ranking decisions too quickly, or fall into line with a manager's viewpoint or any one pharmacist's, before a discussion was possible. Such results tend to reflect one person's practice, rather than the pharmacy's activities in general. An alternative would be to get everyone's rankings off-line and summarize them, and then plan a meeting to discuss only those items that have received a range of rankings (i.e., items that are inconsistently ranked).

When a decision is made about the level of implementation for each self-assessment item, mark one of the following choices next to each item:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>There has been <strong>no activity</strong> to implement this item</td>
</tr>
<tr>
<td>B</td>
<td>This item has been <strong>discussed for possible implementation</strong> in the pharmacy but <strong>has not been implemented at this time</strong></td>
</tr>
<tr>
<td>C</td>
<td>This item <strong>has been partially implemented</strong> for some or all patients, prescriptions, drugs or staff</td>
</tr>
<tr>
<td>D</td>
<td>This item is <strong>fully implemented for some</strong> patients, prescriptions, drugs, or staff</td>
</tr>
<tr>
<td>E</td>
<td>This item is <strong>fully implemented for all</strong> patients, prescriptions, drugs, and staff</td>
</tr>
</tbody>
</table>

Please keep in mind that some of the MSSA items may refer to systems not currently in place at your store, yet these systems could be applicable to the scope of service provided and may reflect opportunities to enhance future medication safety. These items should be scored A or B, not E. That is, some of the self-assessment parameters may not yet be widely implemented, but they nonetheless reflect a level of practice to which all pharmacies should aspire. A rating of A indicates that the item is applicable to the store, but there has been no activity to implement it. An A rating identifies an opportunity for future quality and safety enhancements to the store systems.

Please refer to Page 5 to Page 9 of your MSSA Handbook for further details and instructions for conducting the self-assessment.
Section 2  Accessing your Online MSSA Account

Login to the ISMP Canada Community Pharmacy Incident Reporting (CPhIR) Program at http://www.cphir.ca. You can access your MSSA account by clicking “Your Account” from the menu located at the top of the CPhIR homepage.

You will be taken to the following page:

Click on the “Login to MSSA” button and you will automatically be directed to your MSSA account. If it is your first time accessing MSSA through CPhIR, you will be prompted to complete one of the two following options:
1. Link a current MSSA account, which has been used to enter online data, to your CPhIR account by entering your existing MSSA login details.

2. Automatically create a new MSSA account for your CPhIR account if you have not previously entered online MSSA data.
Section 3   Entering your MSSA Data Online

Before you start entering your MSSA question responses, you fill out your pharmacy’s demographics. After this, you can complete the Self-Assessment Items for each of the 10 Key Elements. Each Key Element and Core Distinguishing Characteristic will be scored separately. The following screenshot displays the web browser as seen when completing an online MSSA:

![Screenshot of MSSA web browser interface](image)

**Navigation Tab of the 10 Key Elements which each contain one or more Core Distinguishing Characteristics. Note that the tabs change when completed.**

**Identification of key elements**
- Allows you to save your current choices so that you can finish and/or change the assessment at a later time
- Click when complete, after which no more changes are allowed

Although it is possible to enter and save your results by section during several online visits, all data should preferably be entered at one time, as this will reduce the opportunity for entry errors.

Once you have completed all 10 Key Elements, click on the “Finalize Assessment” button at the bottom right-hand corner to tabulate scores. You are now ready to analyze your MSSA data (See Section 4 and Section 5 of this Instructional Guide). Please note that you cannot go back to make any changes to your entries once you “Finalize” your assessment.
Section 4   Navigating your MSSA Account

After you have entered all your answers online, there are several reports that are available for you to interpret your results. The database will produce weighted scores from your responses. Scores are weighted based on an item’s impact on patient safety and its ability to sustain improvement. You can view your results and print them in tabular or graphic form. This allows for a snapshot view of your current status, as well as comparison with aggregate data, from all pharmacies submitting data, when available. You can also compare against your own results to monitor your improvement over time. No other user of the MSSA is able to access or view your results. There is no link between the pharmacy identity and the aggregate self-assessment data.

The following screenshot displays the MSSA homepage and the navigation commands:
ISMP Canada protects the privacy, confidentiality and security of data submitted to the ISMP Canada server. (If more than one self-assessment has been completed, only the latest results are included in the aggregate, you can of course still view, print and compare against previous assessments.)

**Print Results:** Allows you to print the information you submitted in PDF form. Looking at the scores on the assessment item answers, you can identify which characteristics are most important and thus carry the highest values. Items are not equally weighted for scoring. Scores may range from 0 to 4, 0 to 8, 0 to 12, or 0 to 16. A question with a maximum weighted score of 16 obviously carries more importance with respect to medication safety than a question with a maximum score of 4.

**View Results:** Allows you to view your assessment results online. Information seen is the same as for “Print Results.”

**Compare Aggregate:** Allows you to compare your results against the aggregate scores of all users who have completed the MSSA online by region, province or Canada. You can compare Key Elements, Core Distinguishing Characteristics, and specific Self-Assessment Items. Separate graphs can be generated for each of the choices, as well as according to self-selected demographic criteria. The graph will indicate “n=“ for the number of users in the aggregate grouping. The graph represents your score (column) as a percent of the maximum weighted scores. The graph shows the average aggregate result (red dot) and the standard deviation (red I-bar) for the data for all the users represented by “n”.

For more information on interpreting the aggregate data, please refer to Section 5 of this Instructional Guide.

**Note:** Print all graphs with Landscape Orientation in order to print all the contents of a graph on one page.

**Compare Own Data:** Allows you to compare previous and current assessment scores for the Key Elements or the Core Distinguishing Characteristics as a percent of the maximum weighted scores. The graphs provide an easy-to-understand visual picture of the data in the Print Results option. When additional assessments have been completed, the graph will show all of your results.

For more information on comparing your MSSA data and trends over time, please refer to Section 5 of this Instructional Guide.

**Note:** Print all graphs with Landscape Orientation in order to print all the contents of a graph on one page.
Section 5 Analyzing your MSSA Data

Compare Aggregate

You can compare your aggregate scores by clicking the “Compare Aggregate” tab on the left panel of the MSSA homepage. This function allows you to compare your MSSA scores with other users nationally, provincially or regionally. After you click on the “Compare Aggregate” tab, you will see a screen which allows you to adjust the parameters you want to compare, such as Key Elements, Core Distinguishing Characteristics, etc. Once you have selected your parameters, click “submit.” The screenshot below illustrates the layout of an aggregate analysis graph:

![Aggregate Analysis Graph]

The red dot represents the average score for all the pharmacies in the aggregate. The red I-bar is the standard deviation.

The blue-purple bars denote user scores, while the bright blue bar shows the total.
Compare Own Data

Alternatively, you can compare your MSSA data and trends over time by clicking on the “Compare Own Data” tab on the left panel of the MSSA homepage. After selecting your parameters, you will get a screenshot similar to the one below:

For assistance with interpretation or use of your MSSA results, or for information on how other facilities have made use of their MSSAs, please feel free to contact ISMP Canada at mssa@ismp-canada.org.
Template Forms

ISMP Incident Form

This form can be used to record the details of an incident if the online CPhIR tool is not readily available. All information would then be entered into the online tool when it is available.

Date Incident Occurred (Mandatory): ______________ (YYYY-MM-DD)

Time Incident Occurred:

☐ Unknown
☐ Morning (06:00-12:00)
☐ Afternoon (12:00-18:00)
☐ Evening (18:00-00:00)
☐ Overnight (00:00-06:00)

Type of Incident (Mandatory):

☐ Incorrect patient
☐ Incorrect prescriber
☐ Incorrect drug
☐ Incorrect dose/frequency
☐ Incorrect strength/concentration
☐ Incorrect dosage form/formulation (include not splitting tablets as per patient's request)
☐ Incorrect route of administration
☐ Incorrect duration of treatment
☐ Incorrect quantity
☐ Incorrect storage
☐ Omitted Medication/Dose
☐ Expired medication
☐ Drug Therapy Problem - Contraindication
☐ Drug Therapy Problem - Adverse Drug Reaction
☐ Drug Therapy Problem - Documented allergy
☐ Drug Therapy Problem - Drug-drug/OTC/Natural Health Product interaction
☐ Drug Therapy Problem - Drug-food interaction
☐ Drug Therapy Problem - Drug-disease interaction
☐ Incorrect third-party billing

Incident Discovered By:

☐ Pharmacist
☐ Pharmacy Technician
☐ Pharmacy Student
☐ Patient
☐ Patient’s Family Member/Relative
☐ Patient's Caregiver/Home Aid/Assistant
- Patient's Friend/Visitor
- CCAC Home Care Coordinator
- Physician
- Medical Student
- Paramedic
- Nurse
- Nursing Student
- Social Worker
- Dentist
- Midwife
- Chiropodist/Podiatrist
- Respiratory Therapist
- Dietician
- Physiotherapist
- Occupational Therapist
- Veterinarian
- Other

**Medication System Stages Involved in this Incident (Mandatory):**

- Prescribing
- Rx Order Entry
- Prescription Preparation / Dispensing
- Administration
- Monitoring / Follow-up
- Not Applicable (Unable to determine one or more of the above medication system phases)

**Medications (Mandatory):**

<table>
<thead>
<tr>
<th>Medication name:</th>
<th>Medication 1</th>
<th>Medication 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIN:</td>
<td>--------------</td>
<td>--------------</td>
</tr>
</tbody>
</table>

**Gender**

- Unknown
- Male
- Female
- Unknown
- 0-28 days inclusive
- > 28 days to 18 years inclusive
- > 18 years to 65 years inclusive
- > 65 years
Degree of Harm to Patient due to Incident (Mandatory):

NO ERROR
- No Error (Medication Not Dispensed / Near Miss / Medication Discrepancy) - Circumstances or events that have the capacity to cause harm

NO HARM
- No Harm (Medication Dispensed) - No symptoms detected; no treatment required

HARM
- Mild Harm - Symptoms were mild, temporary and short term; no treatment or minor treatment was required
- Moderate Harm - Symptoms required additional treatment or an operation; the incident kept the patient in hospital longer than expected; or caused permanent harm or loss of function
- Severe Harm - Symptoms required major treatment to save the patient’s life; the incident shortened life expectancy; or caused major permanent or long term harm

DEATH
- Death - There is reason to believe that the incident caused the patient’s death or hastened the patient’s death

Incident Description / How Incident was Discovered:

Other Incident Info (Check all that apply):
- Rx is from:
  - Hospital
  - Medical Clinic / Prescriber's Office

- Rx is presented as a:
  - Hand-written Prescription
  - Computer-generated / Pre-printed Prescription
  - Verbal Prescription
  - Fax Prescription
  - e-Prescription

- Type of Rx
  - Regular
  - Narcotic / Controlled Drugs
  - Log

- Rx Order Entry / Dispensing Label Generation
  - New Rx
  - Repeat Rx
  - Balance Owing
  - Nursing Home/Blister Pack
**Rx Supply / Ordering**
- Interchangeable Brand Dispensed
- On-order / Back-order Item

**Rx Preparation - Dispensing**
- Patient/Patient Representative Waiting
- Patient/Patient Representative Coming Back to Pick Up
- Rx Delivery

**Rx Preparation - Checking**
- DUR Info Generated by Dispensing System

**Rx Preparation - Storage**
- Rx stored in pick-up drawers
- Rx stored in delivery basket or drawer
- Rx stored in on-order / balance-owing / back-order basket on dispensary counter
- Rx stored in fridge

**Administration**
- Medication was administered
- Medication was not administered

**Monitoring**
- Call-back / Follow-up Performed by Pharmacist

**Contributing Factors of this Incident**

**Critical patient information missing**
- Age
- Weight
- Height
- Allergies
- Body Surface Area
- Vital signs
- Lab values
- Pregnancy
- Renal/liver impairment
- Diagnosis / Medical Condition / Indication of Prescribed Medication
- Third Party Info

**Critical drug information missing**
- No medication history
- Inadequate medication reconciliation
- Outdated/absent references
- Inadequate computer screening
Miscommunication of drug order
- Illegible
- Ambiguous
- Incomplete
- Misheard orders
- Misunderstood orders (e.g. Intentional change of medication or dosage not indicated on Rx)
- Intimidation/faulty interaction

Drug name, label, packaging problem
- Look/sound-alike names
- Look-alike packaging
- Unclear/absent labelling
- Faulty drug identification

Drug storage or delivery problem
- Rx stored in wrong bag/pick-up drawer
- Rx given/delivered to incorrect patient

Drug delivery device problem
- Poor device design
- Misprogramming

Environmental, staffing, or workflow problem
- Noise
- Clutter
- Interruptions
- Change of shift
- Staffing deficiencies
- Workload
- Inefficient workflow

Staff education problem
- Competency validation
- New or unfamiliar drugs/devices
- Orientation process
- Feedback about errors/prevention

Patient education problem
- Lack of information
- Information provided to patient delegate
- Non-adherence
- Not encouraged to ask questions
- Lack of investigating patient inquiries

Lack of quality control or independent check systems
- Independent checks for high alert drugs/high risk patient population drugs
- Equipment quality control checks
Recommended actions at store level (include action plan, person in charge, and target date for completion):

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Shared Learning for ISMP Canada to disseminate:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
Documents

Documents included in this manual are for your reference and use, some of the documents included are also available in an electronic format on the CPhIR website under the Quality Improvement tab.

A copy of the SCPP Regulatory Bylaws – Part I – Proprietary Pharmacies, #12 Continuous Quality Improvement (CQI) has been included in this guide on page 6 for your review. These are the bylaws by which you and your pharmacy team will be inspected by the SCPP.

All Saskatchewan community pharmacies are required to have a CQI program that complies with these bylaws in place effective December 1, 2017.

A sample CQI Meeting Agenda has been included to help quality improvement coordinators and pharmacy managers conduct continuous quality improvement meetings. The agenda can be used in its entirety or just for those items that are going to be addressed during the CQI meeting. Time may be allocated for review of old business, review of new medication incidents, and announcements to staff. At the end of each meeting, a tentative date for the next meeting should be set by all in attendance. It is important that the improvement plan is reviewed and amended as needed at each meeting.

The CQI Documentation Form could be filled out for each CQI meeting. The form allows for documentation of the discussion and analysis of medication incidents and the creation of action plans to assist in the effort to reduce the likelihood of the medication incident reoccurring.

The CQI Meeting Report Form allows for documentation of any additional comment for the CQI meeting or items requiring follow-up. Additional documents included in this guide are intended as resources to aide pharmacies in topics related to the CQI.

Comprehensive Analysis (or Root Cause Analysis) Steps and Instructions provide pharmacies with directions on how to employ comprehensive analysis (root cause analysis) techniques when analyzing medication incidents during quarterly and staff meetings. A Constellation Diagram is also included to help staff visually discuss root causes and identify solutions.

The Suggested Protocol for Handling Medication Errors provides an easy-to- follow policy when a medication incident that has reached the patient has occurred or is suspected to have occurred in the dispensary. The protocol is generic enough to use in all instances where a medication incident has reached a patient and provides direct advice on how to proceed. This protocol should be placed on a shared notice space for all pharmacists, pharmacy techs and locum staff to view and reference.

The Canadian Disclosure Guidelines, compiled by the Canadian Patient Safety Institute (CPSI), provide guidance on how best to disclose medication incidents to patients who have been impacted. This document is meant as a guideline only, and pharmacies are encouraged to discuss the procedures in place in their pharmacy for disclosure to patients.
CQI Meeting Agenda

Date: ______________________________

1. Attendance

2. Old Business
   a. Quick review of medication incident statistics from last meeting
   b. Review of ongoing MSSA improvement strategies
   c. Review of action plans made
   d. Discuss Progress (continue/change action plans as needed)

3. New Business
   a. Presentation of medication incidents for consideration
   b. Discussion and analysis of medication incidents
      i. i.Summarization of issues
      ii. ii.Identify solutions
      iii. iii.Create action plan (use fishbone diagram if appropriate)
   c. Presentation of new MSSA improvement strategies

4. Announcements

5. Schedule date for next meeting

6. Adjourn

Continuous Quality Improvement (CQI) Documentation

Staff Attendance
- Pharmacists: Number: 
- Pharmacy Technicians: Number: 
- Pharmacy Students/Interns: Number: 
- Cashiers/Clerks/Other: Number: 

Medication Incident Discussion
New incidents discussed this meeting:

<table>
<thead>
<tr>
<th>Incident</th>
<th>CPhI IR Incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<table>
<thead>
<tr>
<th>Step 1</th>
<th>(Description)</th>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th>Step 2</th>
<th>(Incident Information)</th>
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<table>
<thead>
<tr>
<th>Step 3</th>
<th>(Contributing Factors)</th>
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<table>
<thead>
<tr>
<th>Step 4</th>
<th>(Contributing Factors)</th>
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</table>

<table>
<thead>
<tr>
<th>Steps 5 &amp; 6</th>
<th>(Prioritized Solutions)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ranking</td>
</tr>
<tr>
<td></td>
<td>1</td>
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<td></td>
<td>2</td>
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<td></td>
<td>3</td>
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<table>
<thead>
<tr>
<th>Step 7</th>
<th>(Action Plan)</th>
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</table>
MSSA Improvement Initiatives

New MSSA Improvement Initiatives discussed this meeting

<table>
<thead>
<tr>
<th>MSSA Improvement Initiative</th>
<th>Deficiency</th>
<th>Improvement Plan</th>
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<tbody>
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<table>
<thead>
<tr>
<th>MSSA Improvement Initiative</th>
<th>Deficiency</th>
<th>Improvement Plan</th>
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Staff Education Events

New Staff Education Events discussed this meeting

<table>
<thead>
<tr>
<th>Staff Education Event</th>
<th>Staff Education Needs</th>
<th>Implementation Plan</th>
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</table>

<table>
<thead>
<tr>
<th>Staff Education Event</th>
<th>Staff Education Needs</th>
<th>Implementation Plan</th>
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</table>

Meeting Attended By
CQI Meeting Report Form

Meeting #1 Comments: ____________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
Meeting #2 Comments: __________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
Meeting #3 Comments: __________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
Meeting #4 Comments: __________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
Comprehensive Analysis (or Root Cause Analysis) Steps and Instructions

Comprehensive Analysis or Root Cause Analysis is a method of problem solving techniques with a purpose of determining the “root cause” of a medication incident in order to prevent the medication incident from occurring again in the future. A Comprehensive Analysis or Root Cause Analysis views every medication incident as an opportunity to learn and improve a process by determining the “root cause” of a medication incident so that the issue can be addressed in order to take appropriate action in your community pharmacy to improve the overall process. When determining the “root cause” of a medication incident it can be helpful to use a constellation diagram with your pharmacy staff for brainstorming purposes. The constellation diagram will list various possibilities to where the “root cause” of the medication incident lies.

The steps to Comprehensive Analysis or Root Cause Analysis can be described as follows:

**What Happened?**

**Step 1:** Define and describe the medication incident that occurred in your community pharmacy.

When defining the medication incident that occurred in your pharmacy it is important to be specific about the incident that occurred (e.g. what drugs were involved). You may also want to categorize the medication incident that occurred in your pharmacy as well during this step (e.g. wrong dose; wrong drug).

**Step 2:** Detail as much information about the medication incident as possible.

Gather as much detail about the situation as possible on your own and from pharmacy staff who were working at the time of the medication incident. Asking questions such as “when did the medication incident happen?” and “what else was going on in the community pharmacy at the time?” are some examples. You may want experienced staff, who may be knowledgeable of why exactly the medication incident happened, to speak at your brainstorming session for determining the root cause of the problem.

**How and Why did it Happen?**

**Step 3:** Determine all possible causes of the medication incident using the Constellation Diagram and sort based on the categories of causes in the diagram.

During your brainstorming session with your pharmacy staff, start out by using the Constellation
Diagram on a white board or where everyone can see it and contribute. Fill in the medication incident defined in Step 1 in the center of the constellation where it says medication incident and the outcome. The constellation diagram contains categories where causes of the medication incident may lie. Brainstorm with your staff all the possible causes of the medication incident and document them under the appropriate categories. The categories listed in the diagram are only a suggestion so feel free to add any categories that you feel are appropriate for your pharmacy. Also, it is not important to fill all of the categories, it is only important for you and your staff to do a thorough brainstorming session here and to consider all of the categories on the Constellation Diagram so that no potential causes of the medication incident are missed.

**Step 4:** Define relationships between the potential causes of the medication incident identified in Step 3 by asking why repeatedly.

Now that your Constellation Diagram is filled out, look at each of the causes of the medication incident that you’ve listed under the categories individually. For each cause ask the team to brainstorm why it happened. For example, if you have determined that the medication incident was that the wrong medication was given out and one potential cause was that the staff member was not trained correctly, ask why. When you’ve determined the potential cause of the staff member not being trained correctly ask why again and keep going with this process until the question why cannot be answered. Continue this process for each of the potential causes that you have listed in your Constellation Diagram.

**What can be Done to Reduce the Likelihood of Recurrence?**

**Step 5:** Brainstorm which potential cause would eliminate the medication incident in the community pharmacy if it was fixed and identify potential solutions to eliminate the potential cause.

When brainstorming possible solutions to eliminate the cause of the medication incident the solution must meet three important criteria. First, the solution to eliminate the cause of the medication incident must eliminate the medication incident if it is implemented. Second, if eliminated, the root solution cannot result in more medication incidents within the pharmacy. Third, the solution must also be possible within the pharmacy. When conducting the brainstorming session there should be discussion among the pharmacy staff why a potential strategy for the removal of the cause of the medication incident does or does not meet the specified criteria. This process could leave you with only one possible solution or several.

**Step 6:** Rank solutions that will best eliminate the medication incident in the pharmacy

If Step 5 leaves you with only one possible solution than there is no need to determine the best solution as there is only one choice. If instead there are several possible solutions from Step 5 then the team should be asked to rank each solution based on effectiveness of eliminating the medication incident and feasibility of the solution. The averages of the two scores should be calculated and the solution with the best score should be chosen for implementation.

**Step 7:** Implement the solutions determined in Step 6 into your pharmacy’s process and monitor to ensure the solutions have been effective.
Upon implementation of the chosen solution it is important to monitor to ensure the solution has had the desired effectiveness. If the solution has not resulted in the desired effectiveness it could be because the “root cause” of the medication incident was incorrect or because the best possible solution to remove the “root cause” was not chosen.

**Step 8:** If the medication incident continues to occur repeat the Comprehensive Analysis or Root Cause Analysis process

If you determine that the solution implemented has not had the desired effectiveness it may be necessary to complete the Comprehensive Analysis or Root Cause Analysis again to determine a different “root cause” to the medication incident that may have been incorrectly defined previously, or to brainstorm a better solution to remove the “root cause” from the process. Because it may be necessary to repeat the process in your pharmacy for the same medication incident if the solution is not effective, it is important to keep all notes and information gathered about the medication incident until the solution has been deemed to be a success.
How to Create a Constellation Diagram

Constellation diagramming is an analysis and problem-solving tool developed in the Canadian Incident Analysis Framework. A constellation diagram offers a systematic way to analyze factors that contribute to medication incidents and near-misses at the system level. As a visual representation, constellation diagrams encourage teams to draw connections between contributing factors and bring clarity to problem-solving.

There are five steps to creating a constellation diagram:

- **Step 1:** Describe the incident or near-miss.
- **Step 2:** Identify potential contributing factors.
- **Step 3:** Define inter-relationships between and among potential contributing factors.
- **Step 4:** Identify the findings.
- **Step 5:** Confirm the findings with the team.

**Step 1: Describe the Incident**

Briefly summarize the incident and harm/potential harm in the centre of the diagram (typically less than ten words):

![Figure 1: Describe the Incident](image)

It is crucial for the team to clearly define the starting point for analysis. This can be a harmful outcome that the team wants to prevent (a near-miss event), or this can be a medication incident in which a medication error was made and the medication was dispensed to the patient (no-harm, mild-harm, severe-harm, or death).
Step 2: Identify Potential Contributing Factors

a. Add the contributing factors categories to the diagram (task, equipment, work environment, patient, care team, organization, etc.) (See Figure 2).

Figure 2: Add contributing factor categories

b. Identify the potential contributing factors to each category. Asking questions about each category can help your team brainstorm as many possible contributing factors that you can. Use sticky notes to add the factors (see Figure 3).
Identifying Contributing Factors

When identifying contributing factors, it is important to thoroughly interrogate the issue. Your team may want to consider the following questions to build your constellation diagram (this is not an exhaustive list, but rather, a starting-off-point for your brainstorming):

**TASK (care/work process):**
- Were there previous or predicted failures for this task?
- Were specialized skills required to perform the task?
- Was a fixed process or sequence of steps required (e.g. order sets, checklists)? Did it exist and was it followed?
- Was the information required to make care decisions available and up-to-date?
• Were there constraints or pressures (e.g. time, resources) when performing the task?

**EQUIPMENT (including information and communication systems):**

• Were the warning labels, reference guide and safety mechanisms functional and readily visible/accessible?

• Was the equipment standardized?

• Would the users describe this equipment as ‘easy to use’?

**WORK ENVIRONMENT:**

• Did noise levels interfere with communication?

• Was lighting adequate for the task?

• Was the work area adequate for the task(s) being performed (e.g. enough space, appropriate layout, accessible resource, etc)?

**PATIENT(S) CHARACTERISTICS:**

• Did the patient(s) have the information to assist avoiding the incident? If not, what would have supported the patient in assisting their care team?

• Did factors like age, sex, medications, allergies, diagnosis, other medical conditions, contribute to the incident? How did they contribute?

• Did any social or cultural factors contribute to the incident? What factors? In which way?

**CARE TEAM:**

• Was there a clear understanding of roles and responsibilities?

• Was the quality and quantity of communication (verbal/written) between team members appropriate (clear, accurate, free of jargon, relevant, complete, timely)?

• Were there regular team briefings/debriefings about important care issues?

• Was team morale good? Do team members support one another?

**ORGANIZATION:**

• Were relevant polices and procedure available, known, accessible, and did they meet the needs of users?

• Were there any workarounds to the documented policy/procedure?
• Was everyone (patients, clinicians, other staff) comfortable to speak-up about safety concerns?

• Was communication between staff and management supportive of day-to-day safe patient care?

• Did scheduling influence the staffing level, or cause stress or fatigue?

**Step 3: Define Inter-relationships between and among contributing factors**

Once your team has identified the potential contributing factors in Step 2, the second phase of analysis begins. Your team should be asking questions such as what was this influenced by? What else influenced the circumstances?

The team then expands the constellation diagram to include ‘relational chains’ of contributing factors (see Figure 4). This questioning process continues until there are no more questions, knowledge becomes limited, or until issues identified fall outside the scope of the analysis.

It is important to recognize that sometimes the relationships between the factors are a key part of the problem.
Step 4: Identify the Findings

The next step in the analysis is to identify the findings that are central to the incident (see Figure 5). The team can expect more than one key finding as there is seldom, if ever, only a single reason why an incident occurred.

Findings will be identified in three categories:

- Factors that, if corrected, would likely have prevented the incident or mitigated the harm — these will be the basis for developing recommended actions.
- Factors that, if corrected, would not have prevented the incident or mitigated the harm, but are important for patient/staff safety or safe patient care in general. These issues should be included in the team's findings and brought to the attention of appropriate individuals for follow-up and documents in the analysis report.
- Mitigating factors — factors that didn't allow the incident to have more serious consequences and represent solid safeguards that should be kept in place.
Step 5: Confirm the Findings with the Team

Ensure consensus and support for the development of recommended actions.

The team should agree on the findings before moving forward to develop recommended actions. If there is a lack of immediate agreement, it is important to discuss and work through any disagreements to strive for consensus before proceeding.

Figure 5: Completed Constellation Diagram
An Insulin Mix-up Incident

Incident Description: A patient with insulin-dependent diabetes had a prescription for Novolin®ge 30/70 Penfill® and was self-administering the drug every morning and every evening by insulin pen (Novolin-Pen®). The patient had recently obtained from the community pharmacy a refill of the cartridge prescription, receiving several boxes of 5 cartridges each. On the morning of the incident, the patient had inserted a new cartridge, taken from one of the new boxes, into the insulin pen.

A short time after self-injecting the prescribed morning dose, the patient was found in a diaphoretic state, with pupils dilated and with a decreased level of consciousness. Fortunately, the symptoms were recognized as signs of hypoglycemia, and the patient was given sugar followed by additional food. Shortly thereafter, the patient’s blood glucose level, measured with a glucometer, was approximately 2.5 mmol/L. Because of the unexplained hypoglycemia, the insulin supply was checked. It was discovered that one box of NovoRapid® insulin had been given to the patient, along with several boxes of the correct Novolin®ge 30/70.

Reference:
Causal Statement #1: Pharmaceutical “branding” through look-alike packaging increased the likelihood of incorrect product selection, dispensing and administration of the incorrect insulin, and the resulting acute hypoglycemia.

<table>
<thead>
<tr>
<th>Action #</th>
<th>Description</th>
<th>Hierarchy of effectivenss</th>
<th>Type of action</th>
<th>Timeframe for Implementatio n</th>
<th>Staff member(s) responsible for/ involved in implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>Apply warning labels to all look-alike insulin products in refrigerator</td>
<td>Simplification &amp; Standardization</td>
<td>Control</td>
<td>Immediate</td>
<td>Pharmacy manager – Oversee Pharmacy technician – Implement action</td>
</tr>
</tbody>
</table>
Segregate short, intermediate and long-acting insulins in the refrigerator

Simplification & Standardization

Control

Immediate

Pharmacy manager – Oversee and implement

**Causal Statement #2:** Repeated scanning of only one of the multiple items selected decreased the likelihood that an incorrect product selection would be detected, leading to the dispensing and administration of the incorrect insulin and the resulting acute hypoglycemia.

<table>
<thead>
<tr>
<th>Action #</th>
<th>Description</th>
<th>Hierarchy of effectiveness</th>
<th>Type of action</th>
<th>Timeframe for Implementation</th>
<th>Staff member(s) responsible for/in involved in implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2A</td>
<td>Require that each item be scanned during the dispensing process to maximize the value of the check process</td>
<td>Rules &amp; Policies</td>
<td>Control</td>
<td>Immediate</td>
<td>Pharmacy manager – Oversee Pharmacy technician, staff pharmacists – Implement action</td>
</tr>
</tbody>
</table>
Suggested Protocol for Handling Medication Errors

Error is discovered or patient alleges dispensing error

- Compare contents of medication container with drug name on prescription label

  DISCREPANCY IDENTIFIED
  - If patient is present, escort to a private area of pharmacy
  - Inform patient that a dispensing error has taken place. Offer a sincere apology
  - Establish if drug has been ingested

  DRUG INGESTED
  - Establish risk from ingestion to patient (# of doses ingested)
  - Contact Poison Control if necessary

  HIGH RISK
  - Refer to physician and/or hospital emergency department

  LOW RISK
  - Reassure patient (notify prescriber if necessary)
  - Advise patient that the incident will be investigated
  - Investigate cause of error using Root Cause Analysis
  - Develop action plan to prevent future errors and discuss with entire staff
  - Advise patient of action taken (verbally and/or in writing)

NO DISCREPANCY

- Compare original prescription with label for drug name, dosage form, strength, quantity and directions

  DISCREPANCY IDENTIFIED
  - NO DISCREPANCY

Reassure patient

- DRUG NOT INGESTED
Canadian Disclosure Guidelines

Checklist for Disclosure Process

The Canadian Patient Safety Institute (CPSI) developed the Canadian Disclosure Guidelines to help organizations be open and honest with patients and families about patient safety incidents. The objectives of the Guidelines are as follows:

Facilitate patient/healthcare provider communications that respect and address the needs of patients and strengthen relationships.

1. Promote a clear and consistent approach to disclosure
2. Promote interdisciplinary teamwork.
3. Support learning from patient safety incidents.

Ensure

☐ The immediate patient care needs are met
☐ Patient, staff and other patients are protected from immediate harm.

Disclosure Process Plan

☐ Gather existing facts.
☐ Establish who will present and who will lead the discussion.
☐ Set when the initial disclosure will occur.
☐ Formulate what will be said and how effective disclosure will be accomplished.
☐ Locate a private area to hold disclosure meeting, free of interruptions.
☐ Be aware of your emotions and seek support if necessary.
☐ Anticipate patient’s emotions and ensure support is available including who the patient chooses to be part of the discussion such as family, friends, etc.
☐ Contact your organization’s support services for disclosure if uncertain how to proceed.

Initial Disclosure

☐ Introduce the participants to the patient, functions and reasons for attending the meeting.
☐ Use language and terminology that is appropriate for the patient.
☐ Describe the facts of the adverse event and its outcome known at the time.
☐ Describe the steps that were and will be taken in the care of the patient (changes to care plan as applicable).
☐ Avoid speculation or blame.
☐ Express regret.
☐ Inform the patient of the process for analysis of the event and what the patient can expect to learn from the analysis, with appropriate timelines.
☐ Provide time for questions and clarify whether the information is understood.
☐ Be sensitive to cultural and language needs.
☐ Offer to arrange subsequent meeting along with sharing key contact information.
- Offer practical and emotional support such as spiritual care services, counselling and social work, as needed.
- Facilitate further investigation and treatment if required.

**Subsequent and Post-Analysis Disclosure**

- Continued practical and emotional support as required.
- Reinforcement or correction of information provided in previous meetings.
- Further factual information as it becomes available.
- A further expression of regret that may include an apology with acknowledgement of responsibility for what has happened as appropriate.
- Describe any actions that are taken as a result of internal analyses such as system improvements.

**Document the disclosure discussions as per organizational practices and include:**

- The time, place and date of disclosure.
- The names and relationships of all attendees.
- The facts presented.
- Offers of assistance and the response.
- Questions raised and the answers given.
- Plans for follow-up with key contact information for the organization.