



CONTINUOUS QUALITY ASSURANCE

A Guide for Community Pharmacies



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DISCLAIMER

The information contained in this guide is intended to serve as a reference for informational purposes only. It is not intended as a complete guide to continuous quality assurance as set forth by the Nova Scotia College of Pharmacists (NSCP). This information is intended for use by pharmacy staff within the scope and standards of their professional practice. Having this information does not ensure that you comply with the *Continuous Quality Assurance Standards for Community Pharmacies*; staff must be actively engaged in the quality assurance process to be in compliance.

The authors cannot be held responsible for the continued currency of the information or for any errors or omissions in the guide for any consequences in the form of liability, loss or direct/indirect damage.

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Canadian Foundation
for Pharmacy

HOW TO USE THIS GUIDE

It is recommended that you thoroughly acquaint yourself with the contents of this assessment guide. The documents included in this guide have been selected to help you better understand the Continuous Quality Assurance (CQA) standards as set forth by the Nova Scotia College of Pharmacists (NSCP). Once you have read through the guide, we encourage you to sit down with staff members to review the documents and to discuss how best to implement the CQA standards in your store.

Below is the Continuous Quality Improvement (CQI) Cycle for Community Pharmacists (Figure 1). This provides a visual description of the process by which the standards and their associated practices should be integrated into your pharmacy practice. Its purpose is to help you better understand when and how to use the forms included in this guide.

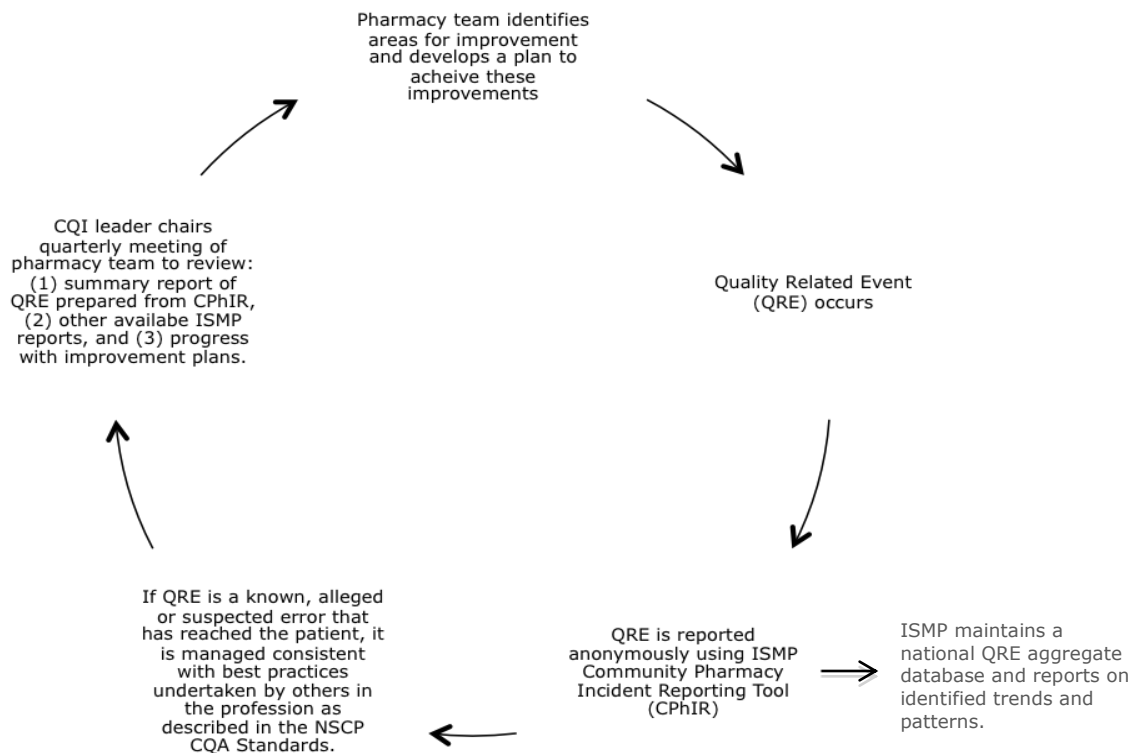


Figure 1. CQI Cycle for Community Pharmacies

Documents included in this binder are for your reference and use include:

A copy of the *Continuous Quality Assurance Standards in Community Pharmacies* has been included in this guide for your review. These are the standards by which you and your pharmacy will be inspected by the NSCP. All Nova Scotia community pharmacies were required to have a CQA program that complies with these standards, in place effective November 1, 2010. Institute for Safe Medication Practices (ISMP) Canada resources which provide assistance in helping to meet the standards have also been included.

A sample *QRE Quarterly Meeting Agenda* has been included to help CQA coordinators and pharmacy managers conduct quarterly staff meetings. By following a standard agenda, quarterly meetings should address the same content and provide staff members with a predictable, structured flow. Time is allocated for review of old business, review of new quality related events (QREs), 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 *QRE Quarterly Meeting Report Form* should be filled out for each quarterly meeting. The form encourages discussion and analysis of QREs based on a number of dimensions, including workflow, staffing and environment issues. The creation of action plans in each of these areas assist in the effort to reduce the likelihood of the QRE reoccurring. These forms also aide in the discussion of “old business” during quarterly QRE meetings to ensure follow through on the action plans.

The *CQA Summarization Document* will be used by the inspectors to help assure the pharmacy has achieved the standards of practice. The document is also useful to provide a “self-audit” for pharmacies nearing their inspection date. Please ensure that this document is filled out completely and accurately. It can be useful to fill this document out monthly to help keep track of the number of QREs reported and when quarterly meetings take place.

FAQs have been provided as a quick reference on a number of topics related to the CQA standards. Additional documents included in this guide are intended as resources to aide pharmacies in topics related to the CQA standards.

Root Cause Analysis Instructions provide pharmacies with directions on how to employ root cause analysis techniques when analyzing QREs during quarterly

and staff meetings. A *Fishbone Diagram* is also included to help staff visually discuss root causes and identify solutions.

A sample *Confidentiality Agreement* has been included to aide in adhering to confidentiality provisions as stated in Standard #7.

The *Suggested Protocol for Handling Medication Errors* provides an easy-to-follow policy when a QRE 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 QRE 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 QREs 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. Finally, the *Nova Scotia Apology Act* is to serve as a reference when preparing for disclosure.



Standards of Practice

Continuous Quality Assurance Programs in Community Pharmacies

Introduction

Given community pharmacy's key role in the medication management segment of the health care process, an effective continuous quality improvement (CQI) process for community pharmacies that is both proactive and responsive, and that enables enhancement of the safety culture of the pharmacy as well as its practices, can be expected to have a substantial impact on patient safety.

Recognizing the importance of continuous quality improvement (CQI) in enabling pharmacies to provide optimal patient care, the Practice Regulations to the Pharmacy Act includes a requirement for pharmacies in Nova Scotia to establish and maintain a continuing, documented quality assurance program.

In consideration of the existing evidence on best practice in the area of CQI, including the results from the SafetyNET project, the NSCP has identified the required components of an effective quality assurance program, and community pharmacies in Nova Scotia will be assessed for compliance with the Practice Regulations against this standard. While it is recommended that each pharmacy identifies a staff member who will act as a quality assurance (QA) coordinator and oversee the undertaking of the activities described in these standards, it is the responsibility of the pharmacy manager to ensure that the pharmacy develops, maintains and enforces policies and procedures to comply with these standards of practice.

Purpose

To provide a standard for an effective CQI process for community pharmacies that ensures pharmacies engage in active enhancement of the safety and quality of their professional services and practices both on a regular, ongoing basis as well as in response to quality related events (QREs). QREs include known, alleged or suspected medication errors that reach the patient as well as those that are intercepted prior to dispensing.

Standard

A CQI process that fulfills a pharmacy's legislated requirements as set out in the Practice Regulations achieves the following:

- 1) Monitors staff performance, equipment, facilities and adherence to standards of practice.
- 2) Manages known, alleged and suspected medication errors that reach the patient consistent with the best practices for this activity undertaken by others in the profession, including:
 - i. Taking appropriate and necessary action to optimize patient care, including prompt consultation with the patient's other health care provider(s) for determination of appropriate action to minimize negative impact on the patient.
 - ii. Ensuring the management of error process is appropriately communicated to the patient.
 - iii. Ensuring the management of error minimizes undue stress and frustration for the patient.

- iv. Ensuring the management of error should include an apology (as enabled by the *Apology Act*) in which the pharmacist acknowledges the negative impact to the patient, and commits to taking the steps appropriate to minimize the likelihood of recurrence of the incident.
 - v. Promptly analyzing the error for causal factors.
 - vi. Communicating to the patient the causal factors of the error when appropriate, and actions taken to reduce the likelihood of recurrence.
 - vii. Documenting the details of the known, alleged or suspected error or discrepancy promptly and thoroughly, including statements from all pharmacy staff involved and the steps taken to resolve the problem.
 - viii. Communicating to all pharmacy staff the appropriate details of the error, including the causal factors of the error and actions taken to reduce the likelihood of recurrence.
- 3) Enables and requires anonymous reporting of quality related events (QREs) 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.

(NOTE: QREs include errors that reach the patient as well as those that are intercepted prior to dispensing. The extent to which intercepted errors are reported will be a professional judgment decision of the pharmacy manager in consideration of the nature of the intercepted error, its implication for patient safety and the extent to which it is recurring).

- 4) Encourages open dialogue on QREs between pharmacy staff and management through quarterly review of the pharmacy's aggregate QRE data (e.g. total number of incidents, type of incidents, etc.).
- 5) Documents quality improvements made as a result of the quarterly CQI meetings of staff.
- 6) Requires completion of a medication safety self-assessment annually, and monitoring the progress of the resulting enhancement plan at quarterly CQI meetings.
- 7) Includes provisions to protect the confidentiality of information relating to specific patients.
- 8) Achieves the purposes of an effective CQI program as described at the beginning of this document through ongoing education of pharmacy staff on the current best practices in QRE management and adoption of these practices, with the goal of discouraging punitive identification or other approaches that are detrimental to reporting and learning.

References

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- Taylor JA, Brownstein D, Klein EJ, Strandjord TP. Evaluation of an Anonymous System to Report Medical Errors in Pediatric Inpatients. *Journal of Hospital Medicine.* 2007; Vol 2 / No 4: 226-233
- Wiederholt JB, Schommer1 JC, Mount JK, McGregor TD, Braatz PD. The Wisconsin Pharmacy Self-Inspection Project: An Application of Berwick's Theory of Continuous Improvement. *American Journal of Pharmaceutical Education.* 2002; 66:27 – 35
- Zed PJ. Drug-Related Visits to the Emergency Department. *Journal of Pharmacy Practice.* 2005; 18; 329 – 335

Adopted: January 19th 2010

Resources

The information about the following *Institute for Safe Medication Practices Canada* (ISMP) tools is being provided as a reference for pharmacists and pharmacies desiring assistance in identifying resources to assist them in achieving compliance with the NSCP *Standards of Practice for Continuous Quality Assurance Programs in Community Pharmacies*, specifically standards # 3 and # 6.

Standard # 3:

Community Pharmacy Incident Reporting (CPhIR) Program

Medication incidents are often under-reported. CPhIR will provide community pharmacies with the ability to document, anonymously report 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, the pharmacy team can develop and implement system-based strategies for quality improvement and prevent potential errors from occurring again in the future.

Link: <http://www.cphir.ca>

Cost: <http://www.ismp-canada.org/products/>

- \$325 (annual rate)

(Pharmacies can test using CPhIR by accessing the CPhIR Training Site at <http://www.cphir.ca/training>. Login with the username = testuser and password = testuser. There is also a Training Centre (see top menu bar after login) with a self-directed video clip on how to use CPhIR)

Standard # 6

Medication Safety Self-Assessment® for Community/Ambulatory Pharmacy (MSSA-CAP)

The Institute for Safe Medication Practices Canada (ISMP Canada) MSSA-CAP is designed to:

- Heighten awareness of the distinguishing characteristics of a safe medication system in community pharmacy practice;
- Act as a quality improvement tool;
- Create a baseline of a pharmacy's efforts to enhance the safety of medication use and evaluate these efforts over time.

The self-assessment tool is divided into 10 key elements that most significantly influence safe medication use. Each key element is defined by one or more core distinguishing characteristics of a safe medication system. Representative self-assessment items are provided to help pharmacies evaluate the degree to which their practice meets each of the core distinguishing characteristics. For example, under the Key Element of Patient Information, there is one core distinguishing characteristic followed by 6 self-assessment items that represent practices that enhance medication system safety in that area. The pharmacy team completing this tool rates the level of implementation in the pharmacy for each self-assessment item.

Link: <http://www.ismp-canada.org/amssa/>

Cost: <http://www.ismp-canada.org/products/>

- \$35 for the document
- \$325 for the program (annual rate)

CQA FREQUENTLY ASKED QUESTIONS (FAQS)

What is a Quality Related Event (QRE)?

As defined in the NSCP Standards of Practice for Quality Assurance in Community Pharmacies, "QREs include errors that reach the patient as well as those that are intercepted prior to dispensing. Do all QREs need to be reported?"

As stated in the NSCP Standards of Practice for Quality Assurance in Community Pharmacies, "The extent to which intercepted errors are reported will be a professional judgment decision of the pharmacy manager in consideration of the nature of the intercepted error, its implication for patient safety, and the extent to which it is reoccurring." However, as per Standard #2, all medication errors that reach a patient must be recorded both anonymously online, as well as fully and identifiably within readily retrievable records in the pharmacy.

What is a coordinator?

As part of SafetyNET-Rx, each store will ideally select at least two in-store coordinators, preferably one pharmacist and one pharmacy technician. These coordinators will be responsible for training their staff by creating an open dialogue on QREs and introducing the SafetyNET-Rx program. These individuals are responsible to bring the pharmacy team together annually to complete the Medication Safety Self-Assessment (MSSA) survey, train staff to use the Canadian Pharmacy Incident Reporting (CPhIR) tool and to schedule and facilitate quarterly QRE review meetings.

Is it mandatory to have a CQA binder?

No, but it will help to ensure that your pharmacy carries out an effective CQA process and will make your pharmacy inspection easier and less time consuming for both you and your inspector.

What is the Medication Safety Self-Assessment (MSSA) survey?

The MSSA survey assists pharmacies by allowing them to self-rate on a variety of safe practice characteristics across the spectrum of pharmacy activities. This assessment requires the pharmacy team to answer 89 questions on ten key elements. The tool will be completed by each participating pharmacy annually. For year two and onward, each pharmacy will receive a report identifying their improvement, including where they are in comparison to national aggregate results of participating pharmacies, at the end of the study. Completing the MSSA annually will fulfill standard #6 of the CQA standards.

Is there a fee for the use of ISMP Canada’s MSSA and the CPhIR tool?

Yes. For Nova Scotia pharmacies there is a fee of \$325 for the MSSA and \$325 for CPhIR. Additional information on these tools can be found at <http://www.ismp-canada.org/>.

Why do pharmacies have to annually complete the MSSA?

Annual completion of the MSSA will provide pharmacies with the ability to assess their pharmacy services with the goal of working towards ongoing improvement, independent of any QREs. This is considered a proactive CQA activity. By completing the MSSA each year, a pharmacy can produce reports to monitor their progress in improvement. By entering this data online, individual pharmacies can compare their self-assessment to aggregate data of all pharmacies involved in SafetyNET-Rx.

What is the Canadian Pharmacy Incident Reporting (CPhIR) tool?

Developed in collaboration with the ISMP Canada, the Ontario Ministry of Health and Long-term Care (OMHLTC), and the participating pharmacies of initial SafetyNET-Rx pilot, CPhIR is an online reporting program that allows pharmacies to anonymously and easily report a QRE directly from their own computer terminals to an independent organization for population of a national aggregate database. Graphs can be generated instantaneously in order to assist Coordinators and managers in presenting QRE information to their staff for discussion at quarterly meetings and to identify trends over time.

Having access to CPhIR has many advantages, including ISMP Canada’s established policies and processes that enable anonymous reporting and that rigorously protect privacy, participants have comfort with using the program to submit sensitive information. By submitting to a nation database, pharmacies enable the identification of safety-related trends and patterns that can be communicated across the profession, not just in their own pharmacy.

I’m new, can I explore the CPhIR tool before I start submitting QREs?

Pharmacy staff who are new can explore CPhIR at www.cphir.ca/training. Please enter “testuser” as both the username and password. Logging in will allow you to explore all the capabilities of the live tool but any data entered will not be recorded or saved. To submit QREs to ISMP Canada, you must be registered with a username and password to access the live CPhIR, found at www.cphir.ca.

Is there a paper form that can be used in place of the online form?

Participants can choose to use paper forms to collect error reports if they prefer. These forms can be found on your CPhIR account under the "Report an Incident" tab. On the right hand side of the page, there is an option to "Print Blank Page." This can assist in having all members of the pharmacy participate in the SafetyNET-Rx program when computer terminals may not be readily available to enter an online error report. Paper forms can be collected from staff and entered manually into the online reporting system at set time intervals to ensure that all information is captured for the production of QRE reports.

Is the information that is submitted to ISMP Canada confidential?

Yes, the information submitted to ISMP Canada does not include identifiers for either the individual entering the data or the patient affected by the QRE. This ensures anonymity of all individuals involved in the incident. The specific information submitted by individual pharmacies can only be viewed by that particular pharmacy by logging in using their username and password.

*Please remember to submit data as an open incident to prevent lost information as CPhIR will automatically timeout after 24 minutes for confidentiality reasons.

What are quarterly QRE reviews?

At least once every quarter, teams within each pharmacy including pharmacy managers, staff pharmacists and technicians should meet to discuss the previous quarter's QREs and to formulate strategies to reduce the likelihood of them occurring in the future. To provide a discussion framework for the meeting, using CPhIR, Coordinators can generate an Internal QRE Report detailing the reported QREs, as well as analysis and summary reports of the submitted QREs. Depending on the frequency and severity of the QREs occurring at the pharmacy, the pharmacy manager may decide that such meetings may take place more frequently.

Why are pharmacy inspections important to community pharmacies?

The *Standard of Practice for Quality Assurance Programs in Community Pharmacies* was approved by the Council of the Nova Scotia College of Pharmacists (NSCP) on March 10th, 2010. As such, NSCP inspectors are now assessing pharmacies for compliance with this standard upon the imminent distribution of the document to pharmacy managers. All pharmacies in Nova Scotia are being assessed against this standard as part of their routine inspection.

Where can I find contact information for those involved in SafetyNET-Rx?

Inquiry Type	Contact	Contact Information
Standards of Practice	Bev Zwicker- Deputy Registrar, Nova Scotia College of Pharmacists (NSCP)	bzwicker@nspharmacists.ca
Medication Safety Self-Assessment	Institute for Safe Medication Practices (ISMP) Canada	mssa@ismp-canada.org
Canadian Pharmacy Incident Reporting (CPhIR)	Institute for Safe Medication Practices (ISMP) Canada	cphir@ismp-canada.org

SCHEDULE OF AUDITS

Process	Jan	Feb	Mar	April	May	June	July	Aug	Sept	Oct	Nov	Dec
1. Staff Performance (Annually)												
2. Drug Inventory (3 months)												
i. Check & Removal of outdated stock												
ii. Documentation of notices to pharmacies of drug recalls, drug warnings and adverse drug reactions (ADRs)												
iii. Documentation of reporting of ADRs by pharmacists to Health Canada												
iv. Narcotic Reconciliation (monthly)												
3. Equipment and Facilities (annually)												
i. Valid certification of equipment (e.g. fridge, automated tablet counter, sterile hood, compound equipment, blood pressure monitor, scale, etc.)												
4. Adherence to Standards of Practice (record at quarterly staff meetings)												
i. Ensuring ongoing adherence to any and all of NSCP deficiency correction action plan(s) of pharmacies												
ii. Monitoring process of documented CQI plan(s)												
iii. Documentation of Quarterly staff meetings (quarterly: standard)												
iv. Signed confidentiality agreements on file for all dispensary staff (annually)												
v. Completion of medication safety self-assessments (annual: standard)												
5. An audit of Quality Related Events												
i. Documentation of the reporting of QREs to an independent, third party organization (quarterly)												
ii. Documentation of medication incidents (quarterly)												

QUARTERLY MEETING AGENDA

Date: _____

1. Attendance
2. Old Business
 - a. Quick review of QRE statistics from last meeting
 - b. Review of action plans made
 - c. Discuss Progress (continue/change action plans as needed)
3. New Business
 - a. Presentation of QREs for consideration
 - b. Discussion and analysis of QREs
 - i. Summarization of issues
 - ii. Identify solutions
 - iii. Create action plan (use fishbone diagram if appropriate)
4. Announcements
5. Schedule date for next meeting in 3 months
6. Adjourn

Adapted from Florida Pharmacy Continuous Quality Improvement (CQI) Manual, 2002.

QRE Quarterly Meeting Report Form

	Quarterly Meeting #1	Quarterly Meeting #2	Quarterly Meeting #3	Quarterly Meeting #4
Date				
Number of pharmacists present				
Number of technicians present				
Pharmacy manager present (Y/N)				
Pharmacy Owner present (Y/N)				
Number of QREs reviewed				

QRE QUARTERLY MEETING REPORT FORM

Meeting #1 Comments: _____

Meeting #2 Comments: _____

Meeting #3 Comments: _____

Meeting #4 Comments: _____

QRE QUARTERLY MEETING ACTION PLAN FORM

Planned Action	QRE Meeting #1 (Date & Discussion)	Follow-Up		
		QRE Meeting #2 (Date & Discussion)	QRE Meeting #3 (Date & Discussion)	QRE Meeting #4 (Date & Discussion)
Ex. Place Rx's to be picked up in red basket	May 19, 2011 Confusion surrounding which Rx's to be picked up vs. waited for. Will use colour-coded baskets.	August 19, 2011 Not adopted by all staff. Discussed again to ensure everyone is on same page.	November 19, 2011 Working well. Less confusion and reduced near misses.	February 19, 2012 Trained new staff on procedure. Still working well.

ANNUAL MSSA IMPROVEMENT PLAN FORM

MSSA Element					
	I	II	III	IV	V
Deficiency	<p>Ex. Complete OTC drug information is not always taken upon new patient intake</p>				
Improvement Plan	<p>Ex. Put a reminder sticky on computer terminal to ask patients to name complete list of OTC drugs at intake and upon refills</p>				

ANNUAL MSSA IMPROVEMENT PLAN

MSSA Element						
		VI	VII	VIII	IX	X
Deficiency						
Improvement Plan						

CQA SUMMARIZATION DOCUMENT

General Information	
Pharmacy Trade Name:	License No.:
Address:	Phone/Fax No.:
Email:	
Time period of report (mm/yyyy – mm/yyyy):	

Medication Safety Self-Assessment
--

Date of last completed self-assessment: (dd/mm/yyyy) _____
How many individuals participated in the completion of the self-assessment? _____
Dates of follow-up discussions with staff: _____
Was an analysis of the self-assessment results completed? (Y/N) ____ If Yes, when? _____

QRE Reporting

Number of QREs reported each month:
Jan _____ Feb _____ Mar _____ Apr _____ May _____ Jun _____ Jul _____
Aug _____ Sep _____ Oct _____ Nov _____ Dec _____
Who primarily enters QRE data?
<input type="checkbox"/> Person who discovers QRE <input type="checkbox"/> Pharmacist <input type="checkbox"/> Technician <input type="checkbox"/> Student

QRE Quarterly Meetings					
-------------------------------	--	--	--	--	--

	Q1	Q2	Q3	Q4	
Date of meeting (dd/mm/yyyy)					

Number of participants				
	Q1	Q2	Q3	Q4
Length of meeting				
Number of QREs reviewed (individually or as part of a summary review of the total)				
Number of improvement plans made				
Number of previous improvement plans reviewed				

Staff Education

Have staff CQI education activities taken place? (Y/N) ____ (these can include independent study lessons, etc.)

If yes, when? (dd/mm/yyyy) _____

Please provide a short description of what was covered:

Pharmacist's signature: _____ Date: _____

Inspector's signature: _____ Date: _____

Adapted from National Association of Boards of Pharmacy (NABP) Model Act, 2010. (16 July, 2010)



ROOT CAUSE ANALYSIS STEPS AND INSTRUCTIONS

Root Cause Analysis is a method of problem solving techniques with a purpose of determining the “root cause” of a QRE in order to prevent the QRE from occurring again in the future. Root Cause Analysis views every QRE as an opportunity to learn and improve a process by determining the “root cause” of a QRE 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 QRE it can be helpful to use a fishbone diagram with your pharmacy staff for brainstorming purposes. The fishbone diagram will list various possibilities to where the “root cause” of the QRE lies.

The steps to SafetyNET-Rx Root Cause Analysis can be described as follows¹:

Step 1: Define and describe the QRE that occurred in your community pharmacy.

When defining the QRE 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 QRE that occurred in your pharmacy as well during this step (e.g. wrong dose; wrong drug).

Step 2: Detail as much information about the QRE 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 QRE. Asking questions such as “when did the QRE 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 QRE happened, to speak at your brainstorming session for determining the root cause of the problem.

Step 3: Determine all possible causes of the QRE using the SafetyNET-Rx Fishbone 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 SafetyNET-Rx Fishbone Diagram on a white board or where everyone can see it and contribute. Fill in the QRE defined in Step 1 in the head of the fishbone where it says QRE. The back of the fishbone diagram contains categories where causes of the QRE may lie. Brainstorm with your staff all the possible causes of the QRE and fill them into the lines 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 SafetyNET-Rx Fishbone Diagram so that no potential causes of the QRE are missed.

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

Now that your SafetyNET-Rx Fishbone Diagram is filled out, look at each of the causes of the QREs that you've listed under the categories individually. For each cause ask the team to brainstorm why it happened. For example, if you've determined that the QRE 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 SafetyNET-Rx Fishbone Diagram.

Step 5: Brainstorm which potential cause would eliminate the QRE 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 QRE the solution must meet three important criteria. First, the solution to eliminate the cause of the QRE must eliminate the QRE if it is implemented. Second, if eliminated, the root solution cannot result in more QREs 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 QRE 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 QRE 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 QRE 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 QRE was

incorrect or because the best possible solution to remove the “root cause” was not chosen.

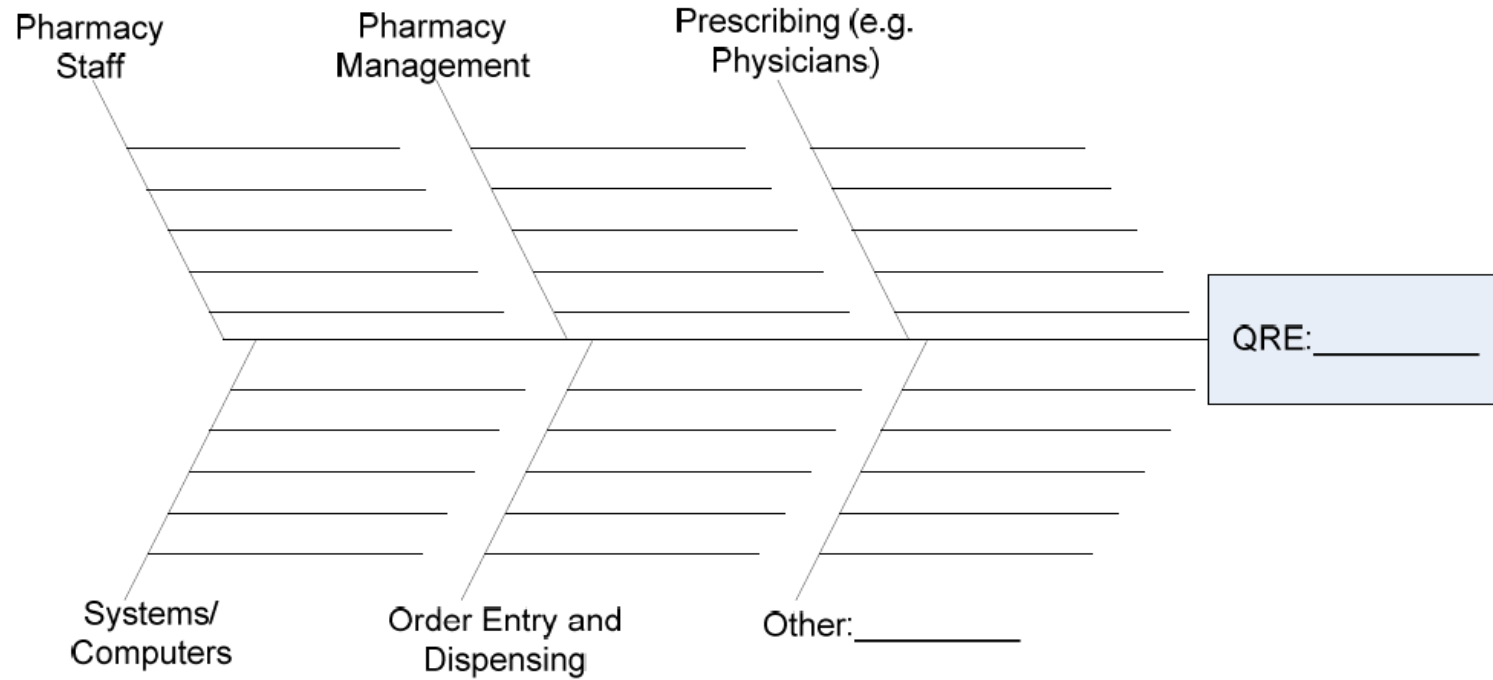
Step 8: If the QRE continues to occur repeat the SafetyNET-Rx Root Cause Analysis process

If you determine that the solution implemented has not had the desired effectiveness it may be necessary to complete the SafetyNET-Rx Root Cause Analysis again to determine a different “root cause” to the QRE 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 SafetyNET-Rx Root Cause Analysis in your pharmacy for the same QRE if the solution is not effective it is important to keep all notes and information gathered about the QRE until the solution has been deemed to be a success.

Meeting Date: _____

Version: _____

QRE Fishbone Diagram



CONFIDENTIALITY AGREEMENT

Patient/client health records and personal information (including demographic information) are privileged and confidential.

I understand that I may become aware of patient information in the course of performing my duties at _____ and I am prohibited from divulging or communicating this information both during and after my employment.

I agree to respect the patient's right to confidentiality and privacy.

I agree to access patient's personal health information only as permitted in the performance of my duties.

I agree to preserve the confidentiality of all clinical or patient information and to not divulge this information in any form, except where authorized by the patient or required by law. Any breach, on or off duty, of this Agreement will be taken seriously. Any violation can or may result in legal or disciplinary action including dismissal.

I acknowledge that I have read this Confidentiality Agreement and understand my responsibilities as they pertain to confidentiality of personal information. I agree to be bound by the provisions of this Agreement both during and after my employment.

Signature of Employee	Date	Position
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Signature of Employee	Date	Position
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Signature of Employee	Date	Position
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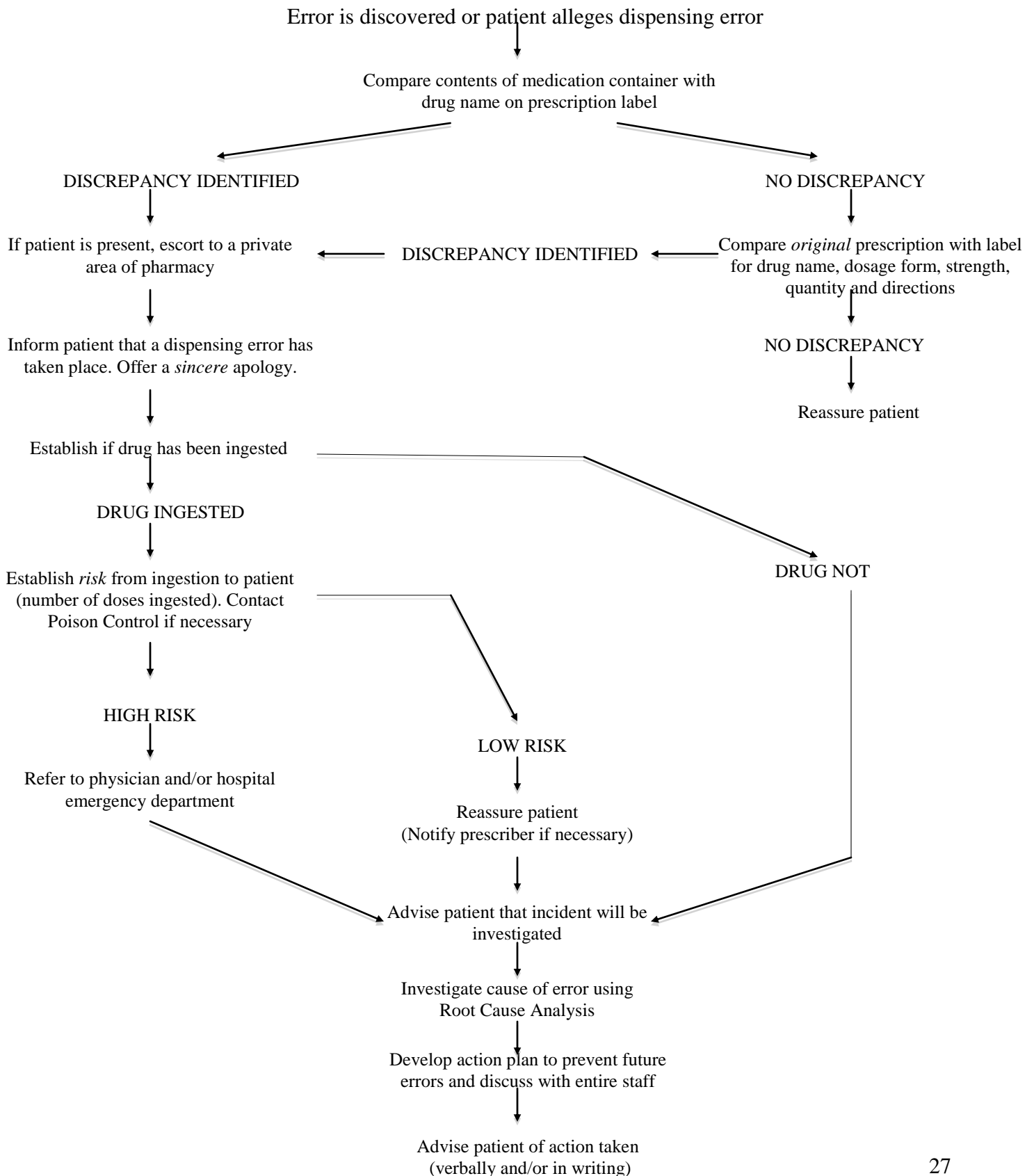
Signature of Employee	Date	Position
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Signature of Employee	Date	Position
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Signature of Employee	Date	Position
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* This Agreement should be signed by all staff members having access to patient information, including demographic information (patient/client addresses, etc.)

SUGGESTED PROTOCOL FOR HANDLING MEDICATION ERRORS



CANADIAN DISCLOSURE GUIDELINES

CHECKLIST FOR DISCLOSURE PROCESS

- The immediate patient care needs are met
- Ensure 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.

Source: Canadian Patient Safety Institute (CPSI). *Canadian Disclosure Guidelines*. 2008. Available: www.patientsafetyinstitute.ca

AN ACT RESPECTING THE EFFECT OF AN APOLOGY AND TO PROHIBIT ITS USE AS EVIDENCE OF FAULT OR LIABILITY

Be it enacted by the Governor and Assembly as follows:

1 This Act may be cited as the Apology Act.

2 In this Act,

(a) "apology" means an expression of sympathy or regret, a statement that one is sorry or any other words or actions indicating contrition or commiseration, whether or not the words or actions admit or imply an admission of fault in connection with the matter to which the words or actions relate;

(b) "court" includes a tribunal, an arbitrator and any other person who is acting in a judicial or quasi-judicial capacity.

3 (1) An apology made by or on behalf of a person in connection with any matter (a) does not constitute an express or implied admission of fault or liability by the person in connection with that matter;

(b) does not constitute a confirmation of a cause of action or acknowledgment of a claim in relation to that matter for the purpose of the Limitations of Actions Act;

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

(d) may not be taken into account in any determination of fault or liability in connection with that matter.

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

4 Nothing in this Act affects a prosecution for a contravention of an enactment.

5 (1) The Governor in Council may make regulations

(a) defining any word or expression used but not defined in this Act;

(b) deemed necessary or advisable by the Governor in Council to carry out effectively the intent and purpose of this Act.

(2) The exercise by the Governor in Council of the authority contained in subsection (1) is regulations within the meaning of the Regulations Act.

6 This Act comes into force on such day as the Governor in Council orders and declares by proclamation.

Source: Apology Act, Bill No. 233 C-34 (2008). Retrieved from http://nslegislature.ca/legc/bills/60th_2nd/3rd_read/b233.htm