The Systems Approach to Quality Assurance for Community Pharmacies

acp Alberta College of Pharmacy
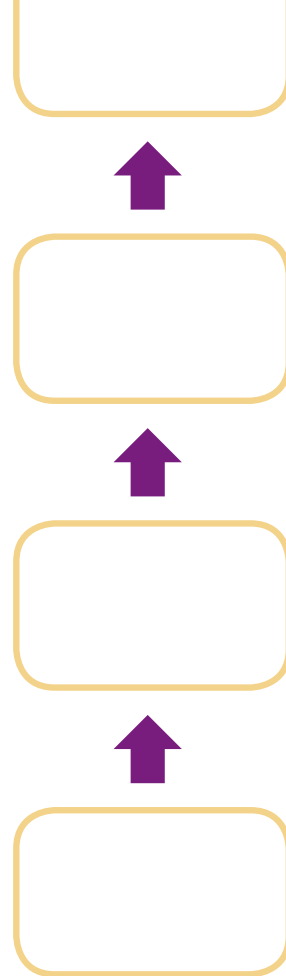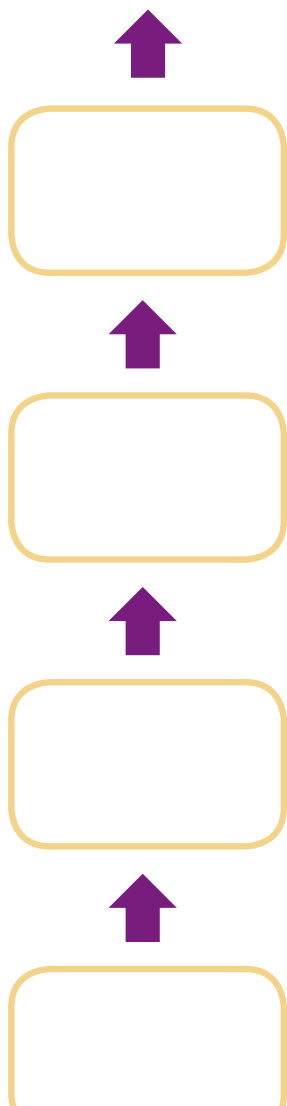
ISMP CANADA

Acknowledgements

This adaptation of the Canadian Root Cause Analysis Framework[1] for the community pharmacy setting has been completed by the Alberta College of Pharmacy with assistance from ISMP Canada and permission from the Canadian Patient Safety Institute. The Canadian Root Cause Analysis Framework was developed collaboratively by the Canadian Patient Safety Institute, ISMP Canada and Saskatchewan Health in 2005/06 to provide a standardized approach to the analysis of critical incidents and near miss events in healthcare.

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. 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.

More information about ISMP Canada is available at **www.ismp-canada.org**.

The Alberta College of Pharmacy governs pharmacists, pharmacy technicians, and pharmacies in Alberta to support and protect the public's health and well-being. The College takes responsibility for pharmacy practice by setting and enforcing high standards of competence and ethical conduct. Major activities include ensuring that only qualified pharmacists and pharmacy technicians are licensed in the province, and that they maintain their knowledge and skills at the highest level possible. The College also ensures that pharmacies provide a practice environment for their employees that supports quality practice and the safety of their clients.

More information about the Alberta College of Pharmacy is available at **abpharmacy.ca**.

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1 "Canadian Root Cause Analysis Framework: A Tool for Identifying and Addressing the Root Causes of Critical Incidents in Healthcare." *Canadian Patient Safety Institute, Institute for Safe Medication Practices Canada* and *Saskatchewan Health.* 2006. Available from **www.patientsafetyinstitute.ca**.

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Introduction

As healthcare providers, we strive to provide the very best care for our patients. Despite our best efforts, sometimes things go wrong and errors happen – in some cases resulting in harm to patients. A great deal of attention has been paid in recent years to how we can make healthcare safer for patients, recognizing that other industries that manage serious risks in their day-to-day operations, such as aviation, have done a much better job than healthcare. While providing healthcare is very different from flying an airplane, there are things we can learn from other industries about how they have managed to reduce risk in their systems. One such opportunity is thoroughly analyzing incidents that have occurred. This is often referred to as *root cause analysis* (RCA) or incident analysis and is defined in the Canadian Root Cause Analysis Framework[2] as:

an analytic tool that can be used to perform a comprehensive, system-based review of critical incidents. It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans.

At its most basic level, incident analysis is intended to answer three questions:

1. What happened?
2. Why did it happen?
3. What can be done to reduce the likelihood of recurrence?

With this in mind, incident analysis is a useful tool to help pharmacy teams meet the quality assurance objectives of the Standards for the Operation of Licensed Pharmacies (SOLP). Both the licensee of a pharmacy and all pharmacy staff have a duty to:

- minimize the risk of drug incidents,
- report drug incidents,
- respond to drug incidents in a manner that ensures the care and safety of the patient, and
- follow up on drug incidents to evaluate whether practice changes or preventive measures are required to prevent future drug incidents.

The use of incident analysis helps teams identify root and contributory factors surrounding a drug incident; understanding these factors helps teams develop action plans to minimize risk of further incidents.

The incident analysis process is based on the premise that individual practitioners are acting with positive intent and do not knowingly work to cause harm to patients. The following sections describe work by James Reason on the *systems approach,*[3] David Marx's work on *just culture,*[4] and application of human factors engineering principles, which support this premise.

Systems approach

Historically in healthcare, we have expected practitioners to maintain professional competence and exercise due care in day-to-day practice. When errors happened, we focused on the actions of the individual(s) involved, rather than taking a broader system perspective. The *systems approach* recognizes that, as humans, we are not capable of performing perfectly, and supports the perspective that accidents are caused by flaws in the working environment, or system, and that human errors should be an expected part of any working environment. To prevent accidents, we need to identify the potential human errors that can occur in a particular system and rebuild it to mitigate these expected errors.

Just culture

David Marx's work on *just culture* differentiates between aspects of daily practice that are within and outside the control of individual practitioners. As individuals, we choose how we practice within an environment but have less control over the environment itself. For example, in a community pharmacy, it is common for all the staff to multi-task – entering prescriptions into the computer system or checking prescriptions while talking on the phone or waiting "on hold," or while chatting with other staff. Marx would consider these to be "at risk" behaviours – and we should recognize that they increase the risk of error. However, the community pharmacy environment is highly distracting – phones and fax machines are ringing, interruptions are frequent as customers come and go, and workload is not predictable – and these things are not within the control of the staff in the pharmacy. The concept of a just culture recognizes that in incident analysis, the individual and system factors must be balanced. There are things that can be done from a system design perspective to reduce the likelihood of error, but individual practitioners also need to take responsibility for safe behavioural choices within the system.

2 "Canadian Root Cause Analysis Framework: A Tool for Identifying and Addressing the Root Causes of Critical Incidents in Healthcare." *Canadian Patient Safety Institute, Institute for Safe Medication Practices Canada* and *Saskatchewan Health*. 2006. <**www.patientsafetyinstitute.ca**>

3 Reason, J. "Human Error: Models and Management." *BMJ* 320.7237 (2000): 768–770.

4 Marx, D. "Patient Safety and the 'Just Culture': A Primer for Health Care Executives." New York: Prepared for Columbia University under a grant provided by the National Heart, Lung, and Blood Institute. 17 Apr. 2001. PDF. Available at **www.mers-tm.net/support/marx_primer.pdf.**

Impact of human factors engineering principles

Human factors engineering (HFE) is a branch of engineering science that is related to how we interact with the world around us. HFE combines biomechanics, kinesiology, physiology and cognitive science to design processes to improve efficiency, reliability and safety through understanding of human capabilities and limitations. A basic understanding of HFE is key to the incident analysis process as these principles impact both the potential for errors to happen and the development of strategies for improvement that are likely to result in sustained change.

As pharmacists or pharmacy technicians must perform a final check on each and every prescription, our culture has supported the focus on individual care and vigilance to prevent errors. As a result, approaches to error prevention have commonly relied on education and policy development. While these are important supports, HFE principles tell us that when used alone, they are unlikely to be effective over the long term. The following *hierarchy of effectiveness* illustrates the importance of considering alternative strategies.

↑ Forcing functions and constraints

Technology and automation

Standardization and simplification

Reminders, checklists and double-checks

Policies and procedures

Education, training and communication

The last two items on this hierarchy are considered to be *low leverage* strategies because they must be followed consistently by individual practitioners in order to be effective. The remaining items on the list require physical process changes, which then help, and in some cases *force*, practitioners to work in a particular way. If the pharmacy computer system will not allow processing of a prescription if allergy information has not been entered, this is an example of a forcing function. If correctly designed, process changes based on these higher leverage strategies are more likely to result in sustained positive system impact than those that rely on individual care and vigilance.

Sharp vs. blunt

The healthcare system is often described as having both a *sharp* and *blunt* end. The sharp end is where the interaction between the patient and provider takes place. Incorrect actions on the part of the provider can cause direct and immediate harm to the patient, similar to unexpectedly coming in contact with something sharp.

However, we have learned that many of the factors that lead to incidents are beyond the control of the individual practitioner and are a result of decisions made far from the patient/provider interface. As this is considered to be the opposite of the sharp end, it is referred to as the *blunt* end of the system.

The purpose of an incident analysis is to look for the underlying blunt end factors that may have contributed to the incident. This is in keeping with SOLP 6.4(d), which indicates that drug incident documentation must include a description of factors contributing to the drug error. These blunt end factors may include things like management and regulatory factors, physical environment issues and organizational culture.

The US Department of Veterans Affairs "Getting at Patient Safety" (GAPS) Center describes the sharp end/blunt end concept as follows:[5]

> *Sharp end:* people use time, procedures, tools, knowledge about the patient, expectancies, coordination between healthcare providers, and information to create safety. The sharp end experiences pressures that conflict with those of blunt end people.

> *Blunt end:* The organization decides what is available (tools, people, access to expertise) and the rules of the game (policies and procedures). For example, there is no point in asking for something if you know the answer will be "no." The blunt end experiences pressures which conflict with those of sharp end people.

In a community pharmacy, sharp end factors might include failure to identify an incorrect product dispensed from a look-alike package or the misinterpretation of a handwritten prescription. These factors would appear to rest with the practice or competence of the individual practitioner until we identify contributing blunt end factors such as sub-optimal lighting, look-alike packaging and labelling, reliance on handwritten prescriptions (rather than computer-generated), staffing ratios that do not reflect workplace needs, all of which are beyond the control of pharmacists, pharmacy technicians and pharmacy employees (i.e., assistants and clerks).

Responding to incidents

Whenever an incident occurs, any necessary emergency measures must be initiated in the interest of patient safety. This is addressed by SOLP 6.5:

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5 "Sharp End – Blunt End Concept." *US Department of Veterans Affairs – Getting at Patient Safety (GAPS) Centre.* Internet. 4 March 2011. <**www.gapscenter.va.gov/stories/SharpBluntWhatIs.asp**>

If a drug error is discovered, or if there is a reasonable suspicion that a drug error has occurred or will occur, the licensee must ensure that the following steps are taken:

a. initiate immediately any emergency measures required to protect the health and safety of the patient;

b. contact the patient immediately and disclose the drug error and its implications;

c. immediately advise all other regulated health professionals and caregivers whose care for the patient may be affected by the drug error and notify them of the drug error and its implications;

d. take appropriate steps to promptly remedy the error by ensuring that the patient receives the correct drug;

e. take reasonable steps when necessary to ensure that the incorrect drug is returned to the licensed pharmacy for safekeeping to avoid risk of harm or further harm; and

f. implement changes in practices, procedures or staffing in the licensed pharmacy to prevent a recurrence of the drug error, if required.

Duty to report

Remember that pharmacy staff have an ethical and legal duty to disclose drug incidents to the affected patient(s). There is an obligation to be honest about adverse events, to act in the patient's best interests (beneficence), and to "do no harm" (nonmaleficence). Patients have a right to know about a drug error that may adversely affect their health and well-being and to make informed choices. As per SOLP 6.5(b), contact the patient immediately and disclose the drug error and its potential health implications.

While the impact on involved staff cannot be compared to that experienced by the patient and their family, it is important to consider the need for critical incident stress debriefing and employee assistance program intervention. Practitioners are well recognized as the "second victims" when preventable adverse events occur.[6]

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6 Wu, A. "Medical Error: The Second Victim." *BMJ* 320.7237 (2000): 726-727.

When should you consider an incident analysis?

You can apply the overall process concepts for incident analysis to any incident, regardless of severity, but a detailed analysis of an incident is typically undertaken when harm has occurred or significant potential for harm has been identified. This document describes the use of this framework for the analysis of a medication or *drug incident*.[7] However, you can also use this methodology to conduct a system-based analysis of nearly any situation where the outcome was not as anticipated. Note that an incident analysis is usually undertaken for events that are considered to be *preventable*.

As per SOLP 6.3, a licensee must ensure that a quality assurance process is implemented and maintained in a licensed pharmacy. The quality assurance process should:

a.   provide for reporting, investigating, documenting and evaluating drug incidents that occur in the pharmacy;
b.   include regular review and feedback mechanisms to prevent drug incidents; and
c.   include a process or procedure for responding to complaints or concerns.

Incident analysis is always conducted *after* an incident occurs; prospective analysis tools, such as Failure Mode and Effects Analysis (FMEA), can be used to identify system vulnerabilities before an incident occurs so that proactive process and workflow changes can be implemented.[8] Pharmacy teams can also undertake other prospective risk assessment activities, such as regularly evaluating how drugs are stored in the pharmacy. A pharmacy technician might be assigned to identify any products with look-alike packaging that are stored adjacent to one another and move them to reduce the chance of selecting the incorrect product, thus minimizing the risk for a selection error to occur.

Before conducting an incident analysis, it is important to ensure the incident is appropriate for this type of analysis. Incident analysis is based on the premise that practitioners do not knowingly cause harm to patients. If there is any suggestion that the actions of a practitioner were deliberate (e.g., a criminal or other purposely unsafe act, alcohol or substance abuse, or involved alleged or suspected patient abuse) the incident should be managed through the usual administrative/performance management process.

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7 According to SOLP 6, a "drug incident means any preventable event that may cause or lead to inappropriate drug use or patient harm. Drug incidents may be related to the practice of pharmacists or the practice of pharmacy technicians, drugs, health care products, aids and devices, procedures or systems, and include: i. prescribing; ii. order communications; iii. product labeling, packaging, nomenclature; iv. compounding; v. dispensing; vi. distribution; vii. administration; viii. education; ix. monitoring; and x. use." An "adverse drug event means an unexpected and undesired incident related to drug therapy that results in patient injury or death or an adverse outcome for a patient, including injury or complication."
A "drug error means an adverse drug event or a drug incident where the drug has been released to the patient."

8 Failure Mode and Effects Analysis (FMEA) is a team-based, structured process that can be used to identify how and where a process might fail and what steps can be taken to address the identified failures. It includes mapping the steps in a process, identifying the potential failure points and consequences of each and ultimately what steps can be taken to reduce the potential for the identified failures to occur. For example, a pharmacy team might choose to undertake an FMEA of the process for patient prescription pick-up to identify gaps that could lead to incorrect patient identification and dispensing of a prescription to the wrong patient.

Components of incident analysis

An incident analysis will always include the following components:
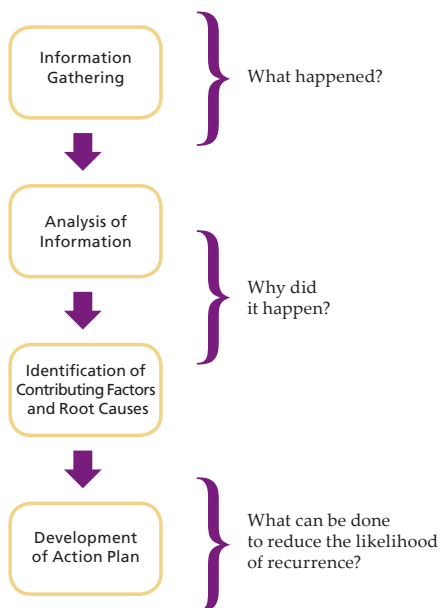
Figure 1: Components of incident analysis

The analysis team

> Incident analysis is intended to be conducted by a team that includes front-line practitioners who are involved in the day-to-day work.

Why it is important to involve the whole team

All individuals who were directly or indirectly involved in the incident need to take part in the analysis. According to the Standards of Practice for Pharmacists and Pharmacy Technicians 1.9, "…each pharmacist and pharmacy technician must participate in the quality assurance processes required by the Standards for the Operation of Licensed Pharmacies or another workplace quality assurance program applicable to the pharmacists' or the pharmacy technicians' practice." These individuals may participate as part of the analysis team or may provide information through interviews.

Involving direct care providers in the incident analysis has two important benefits:

1. When all members of the team contribute to a detailed examination of the events leading up to the incident they may, and often do, discover new information not previously known by all team members.
2. Detailed analysis of an incident provides an opportunity for those involved in the incident to help find ways to reduce the likelihood of similar incidents in the future. This allows them to have a direct impact on the system in which they work and to take ownership of changes.

A relatively new concept in incident analysis is the inclusion of patient/family representatives as part of the analysis team.[9, 10, 11] In some organizations where patients have participated in incident analysis, the patient or family member involved in the incident is part of the analysis team and in others, it is another client of the service provider.

Pharmacy licensees have a key responsibility for the blunt end of the system and their involvement in the incident analysis helps to demonstrate a commitment to change. Additionally, they are responsible for overseeing the development and implementation of recommendations for system change;

they need to fully understand the rationale and level of urgency for recommendations made by the team. This responsibility is described in SOLP 6.1:

> A licensee must ensure that:
> a. the licensed pharmacy has appropriate systems, policies and procedures in place to minimize the risk of a drug incident or an adverse drug event; and
> b. regulated members and employees of the licensed pharmacy:
>   i. are trained; and
>   ii. are required as a term of their employment to comply with those systems, policies and procedures.

Further, in SOLP 6.7, the licensee has a duty "to make changes or take preventative measures promptly in response to a drug error if the protection of the public requires it."

Sometimes teams invite external experts/consultants with specialized knowledge to assist with specific aspects of the analysis or development of recommended actions. For example, a community pharmacy incident analysis team might ask a representative from their computer software company to come to the pharmacy to discuss potential enhancements to the computer system screen display that the team has identified as problematic.

Who should be on the team?

In a small community pharmacy, it is likely that the full dispensary staff will be involved in an incident analysis. In a pharmacy with a larger team, only selected staff members may be asked to participate. Regardless of the size of the team, it is important that as many perspectives as possible are represented (e.g., licensee, staff pharmacist, pharmacy technician, pharmacy student, pharmacy employees). In an

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9 "Benefits and Risks of Including Patients on RCA Teams." *Institute for Safe Medication Practices (ISMP)*. Web. 5 Jan. 2011. <**www.ismp.org/Newsletters/acutecare/articles/20080605_2.asp**>

10 Munch, D. "Patients and Families Can Offer Key Insights in Root Cause Analysis." *Focus on Patient Safety* 7.4 (2004): 6-7. Web.

11 Zimmerman, Theresa M., and Geraldine Amori. "Including Patients in Root Cause and System Failure Analysis: Legal and Psychological Implications." *Journal of Healthcare Risk Management* 27.2 (2004): 27-34. Print.

incident that involves practitioners outside the pharmacy, it is helpful to invite the other practitioner(s) involved in the incident, or others with similar expertise, to assist the team to work through the incident and identify potential solutions to reduce the likelihood of recurrence. It is also helpful to invite people to participate who are naïve to the day-to-day dispensing processes; for example, staff or management from the pharmacy front shop.

An incident analysis meeting is intended to be a confidential meeting where the team can openly discuss an incident.

To be effective, discussion about the incident should not be shared with other staff members who are not part of the analysis meeting. Some organizations require team members to sign a confidentiality agreement (see Appendix 1 for an example) at the outset of the process. This agreement reinforces that information and opinions shared within the discussion are not to be transmitted or disclosed outside of the communication mechanisms stipulated by applicable organizational policies and/or provincial legislation.

Conducting an incident analysis

To work through the incident analysis process, it is necessary to break down each component of the process into more detailed sub-components, as shown in Figure 2. We will explain in detail each of these sub-component processes in the following sections, using an example of a dispensing error that occurred in a community pharmacy. The example has been adapted from an incident published in an ISMP Canada Safety Bulletin in which a patient was inadvertently dispensed one box of Novo-Rapid® with several boxes of the intended Novolin GE 30/70®.[12]

The team cannot proceed to analyze the incident if they do not have a clear understanding of the circumstances surrounding the event. It is helpful to develop a standardized approach (e.g., a template or checklist, such as the one provided in Appendix 2), to assist the team leader to prepare information for review by the team. A systematic process for assessing information needs and gathering information will help to ensure that the analysis is thorough and credible.

Initial understanding

Information available to the team at the outset of the review is considered to be the initial understanding of the incident and is based on the facts known at the time.

In many cases the *initial understanding* is the information provided in an incident report. Review of the initial understanding often identifies information gaps that require additional follow-up by the team. It also provides a "bird's eye view" of the incident and helps the team to begin to understand how the incident unfolded.

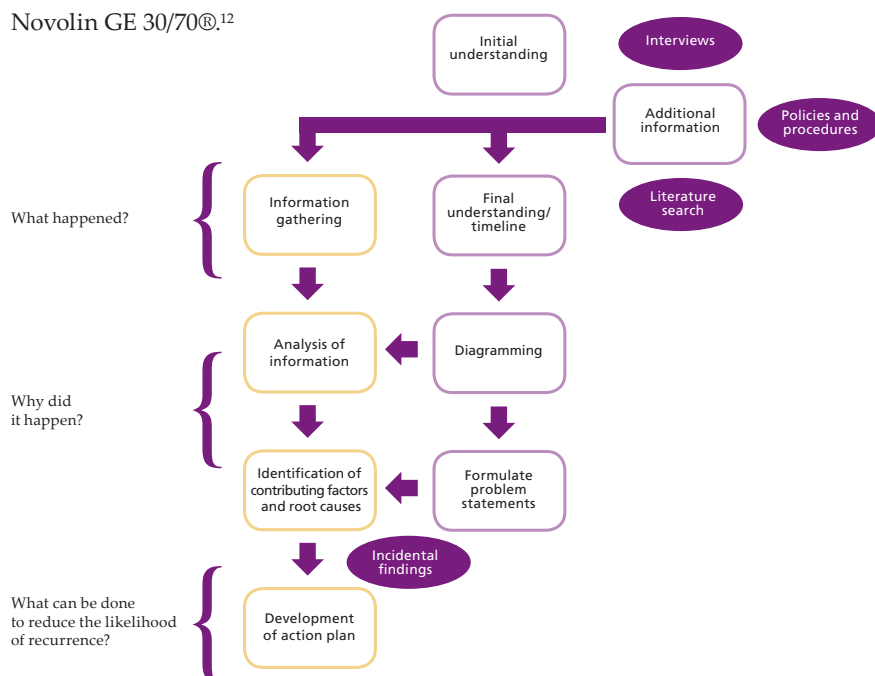A sample initial understanding is shown in Figure 3 below.

Figure 2: Incident analysis process

Information gathering

The information gathering stage of the process is intended to answer the "What happened?" question.
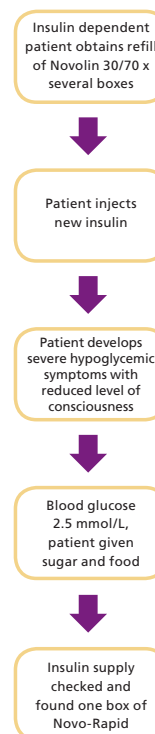

Figure 3: Example initial understanding

This information may also be communicated through an incident report. SOLP 6.4 indicates that the quality assurance process must

provide for reporting, investigating, and evaluating drug errors, and must comply with the following:

a. within 24 hours of initial discovery, the licensee must ensure that any suspected drug error is investigated and, if verified, is documented;

b. the regulated member involved in the drug error must document an account of the error as soon as possible after the discovery. If the regulated member involved is not on duty at the time of discovery, the regulated member or employee who discovers the drug error must initiate the documentation;

c. drug error documentation must:
   i. be in a format that can be easily audited and reviewed, and
   ii. be retained for at least 10 years after the error is discovered;

d. the documentation must include a description of factors contributing to the drug error and actions taken to prevent recurrence; and

e. the report must clearly identify whether it relates to a drug incident or an adverse drug event.

An example of an incident report that might have been completed at the community pharmacy where this incident occurred is shown in Appendix 3. Refer to Appendix 4 for a full incident report template, which includes notifications and follow-up actions.

With respect to notifications, SOLP 6.5 indicates that if a drug error is discovered, or if there is a reasonable suspicion that a drug error has occurred or will occur, the licensee must:

b. contact the patient immediately and disclose the drug error and its implications,

c. immediately advise all other regulated health professionals and caregivers whose care for the patient may be affected by the drug error and notify them of the drug error and its implications.

Additional information

To fully analyze how and why an incident occurred, the analysis team needs to be able to put themselves in the shoes of the practitioners involved in the event. A simulation or cognitive "walk-through" of an event can be very helpful to understanding how the circumstances unfolded. It is also important for the team to look at the packaging and labelling of the medications involved to assess the potential for the drug name or appearance to have contributed to the incident. The boxes and internal packaging of the two insulins involved in the example case are shown in Figure 4 below.

Figure 4: Novolin® GE 30/70 and Novo-Rapid®
(Photographs used with permission from ISMP Canada)

Make any organizational policies and procedures that are relevant to the incident available during the incident review. They help establish the expectations related to the standard of care. An incident analysis is also an opportunity to review existing policies and procedures to ensure they are aligned with current best practice expectations; changes in practice expectations may form the basis for recommended actions arising from the analysis. For example, in this case, bar-coding technology was in place and it would be expected that a written procedure would be available to guide staff in how to use this technology.

Practice/literature review

When an incident occurs, it presents an opportunity to review current pharmacy practices. While this review does not contribute to the final understanding of an incident, it helps determine if there are leading practices or evidence-based guidelines relevant to the event.

The occurrence of a serious or potentially serious incident should also trigger a review of internally reported incidents or close calls to assess whether similar problems have been previously identified and what strategies have been implemented to resolve them. SOLP 6.6 requires quarterly review of drug incidents, thus a mechanism should already be in place to facilitate review of previously reported incidents. This is discussed in more detail in the action plan section of this paper.

Review of safety bulletins, such as those published by ISMP Canada (**www.ismp-canada.org/ISMPCSafetyBulletins.htm**) and ISMP [US] (**www.ismp.org/Newsletters/default.asp**), can help the team plan and develop corrective interventions. Sometimes, unique safety events have no literature citations available. Consultation with colleagues may also help determine if the issue in question has been previously observed in everyday practice, but not published.

Final understanding

When all the information is gathered, the team will be able to fill in the gaps identified in the initial understanding of the event to create a *final understanding*. This final understanding will then help them determine underlying problems that may have contributed to the incident.

Care of the patient after the incident was discovered may be relevant to mitigation of harm from the incident; therefore, it is appropriate to include details related to management once the incident was discovered. In terms of actions taken after the incident was discovered, in the final understanding the team should focus on actions taken that are relevant to care of the patient, rather than creating a detailed timeline describing the internal incident notification process.

The team will use information provided in the final understanding or timeline as a starting point for identifying system-based factors underlying the event. Therefore, it is crucial that the *actual* acts or processes as they occurred are recorded, rather than what was *supposed* to happen.

In almost all cases, the final understanding of the event is different from the initial understanding, reinforcing the importance of fully investigating the event circumstances.

A sample narrative timeline is provided in Table 1, and a blank template is available in Appendix 5.

Table 1: Sample narrative timeline adapted from insulin incident (*final understanding*)

Time	Information item	Information source
4:30 p.m., 3 days prior to event	Patient calls for refill of insulin prescription from usual community pharmacy - will pick up in the evening.	Prescription record
5:00 p.m.	Technician processes refill in the computer and leaves the label in a basket for filling by the dispensary (high school) student.	Technician interview
5:30 p.m.	Student obtains 5 boxes of insulin from fridge and scans the top box 5 times, labels the top box, then tapes all 5 boxes together. The prescription is left in the basket for the pharmacist to check.	Technician and student interviews
5:50 p.m.	Pharmacist sees that insulin boxes look the same, checks DIN on top box against prescription hard copy, and signs off. Insulin placed in refrigerator for pick-up; bag and receipt placed in pick-up bin with note, "medication in fridge."	Pharmacist interview
8:40 p.m.	Patient's wife comes in to pick up insulin. Student retrieves from refrigerator, bags and gives to patient's wife.	Student and patient/family interviews
9:00 p.m.	Patient's wife places in home refrigerator.	Patient/family interview
7:30 a.m., day of event	Patient reloads cartridge into insulin pen and administers as usual.	Patient/family interview
7:45 a.m.	Patient found with decreased level of consciousness, sweating with dilated pupils by family member.	Patient/family interview
7:50 a.m.	Patient given sugar, followed by food by family member.	Patient/family interview
8:00 a.m.	Glucometer reading 2.5 mmol/L.	Patient/family interview
8:15 a.m.	Patient's wife calls the local hospital and is advised to come to the Emergency Dept. and bring all medications.	Patient/family interview
9:20 a.m.	IV Dextrose administered; kept for observation x 4 hours.	Patient/family interview
12:45 p.m.	Emergency physician reviews medications prior to discharge and notices one insulin box is Novo-Rapid®.	Patient/family interview
3:00 p.m.	Patient's wife contacts pharmacy to advise of dispensing error.	Patient/family interview

Analysis of information

Once the team has a clear understanding of the circumstances surrounding the event, as outlined in the final understanding, they can begin to analyze the information to answer the "Why did it happen?" question.

In this part of the analysis, the focus is on recognizing the system and human factors issues that may have contributed to the incident.

It is human nature to focus on the actions of the practitioners at the intersection between the patient and provider (i.e., the sharp end). However, the goal of the incident analysis process is to push the team to move away from the sharp end towards the blunt end (underlying system factors that contributed to the event but were not under the direct control of the practitioners involved).

During this phase of the analysis, the team will need to ask questions such as "Why did this happen?" and "What was this caused by?" The team will use the final understanding of the event as well as other information such as environmental factors (e.g., lighting, staffing levels, noise level and interruptions in the workplace) to answer the "why" and "caused by" questions to identify the underlying factors to the precipitating incident, and patient outcome if harm resulted. An incident analysis checklist and sample questions adapted from the US Joint Commission Root Cause Analysis Matrix[13] and the Veterans Affairs Triage and Triggering Questions[14] (provided in Appendices 6 and 7) may help teams to ensure they have completed a thorough analysis.

Analysis teams are generally highly successful at determining the sequence of events and identifying contributing factors close to the event, but often find it difficult to identify the deeper issues. A key aspect of the incident analysis process is working to understand how the various contributing factors relate to each other and ensuring that the analysis has progressed far enough into the blunt end of the system.

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13 "Joint Commission Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events in Sentinel Event Guidelines for Ambulatory Care, January 2011." 23 Feb. 2011. <**www.jointcommission.org/assets/1/6/2011_CAMAC_SE.pdf**>

14 "Triage and Triggering Questions." *United States Department of Veterans Affairs National Center for Patient Safety*. 14 Feb. 2011. <**www.patientsafety.gov/CogAids/Triage/index.html#page=page-1**>

Identification of contributing factors and root causes

Diagramming

One method that can help the team to delve deeper into the analysis is the use of diagramming. Creation of "cause and effect" diagrams can help teams better understand inter-relationships and ensure a thorough review of the incident.

Visualization through diagramming helps clarify team understanding and shifts the focus away from individual performance towards system performance and underlying factors. It also helps the team avoid the trap of hindsight bias.[15]

While other types of diagrams can be used, "tree" diagrams work well for this type of analysis. Causal chains or "branches" are developed as the team asks "why" and "caused by" questions until there are no more questions or no more information is available. A sample tree diagram is shown in Figure 5, and a blank template is provided in Appendix 8.

There are four steps involved in developing a tree diagram of an incident:

Step 1: Identify the outcome to be prevented (typically the harm that could have or did occur)
Step 2: Develop causal chains/branches
Step 3: Complete the diagram
Step 4: Identify root causes

Before beginning the analysis, the team needs to decide on the starting point. This is usually the harmful outcome that the team wishes to prevent, which is often, but not always, the actual outcome. In the case of an incident that was recognized before the patient was involved (e.g., a near miss or close call), or where an incident occurred, but action was taken before harm resulted, the starting point for analysis would be the potential harm, as no harm actually occurred. Remember, the team should focus on actions taken that are relevant to care of the patient.

Step 1: Identify the problem
Once the team has determined the starting point for analysis, they can then begin to work away from the sharp end of the event toward the underlying problems at the blunt end.

Figure 5: Sample tree diagram

Asking "why" and "caused by" questions will help the team to develop causal "chains" of contributing factors.

Contributing factors may be actions or conditions. Actions are momentary and short-lived (e.g., checking a prescription while on the phone), while conditions exist over time (e.g., multiple demands on attention). The team should try to complete the causal chains one at a time, although the organization of ideas is usually very fluid at this point in the analysis. This part of the process can also be assisted by the use of "sticky" notes.

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15 "Hindsight bias is the inclination to see events that have already occurred as being more predictable than they were before they took place." Hoffrage, U. and R. Pohl. *Hindsight Bias: A Special Issue of Memory*. Champlain, NY: Psychology Press as quoted by Wikipedia. 15 Apr. 2011.
<en.wikipedia.org/wiki/Hindsight_bias#cite_note-0>

Step 2: Develop causal chains

Teams continue to ask "why" at each level of cause and effect until there are no more questions, knowledge becomes limited, or until the issues identified fall outside the scope of the analysis.
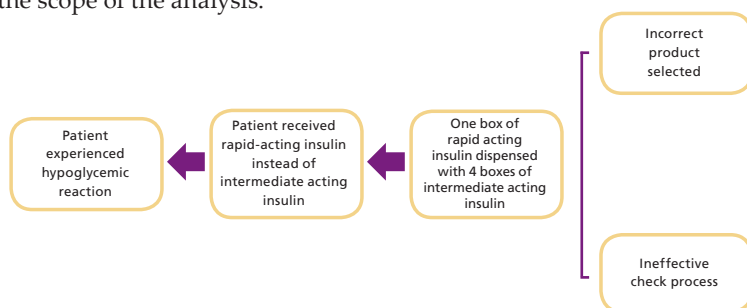
Step 3: Complete the diagram

The final step in the analysis process is to identify the significant underlying factors.
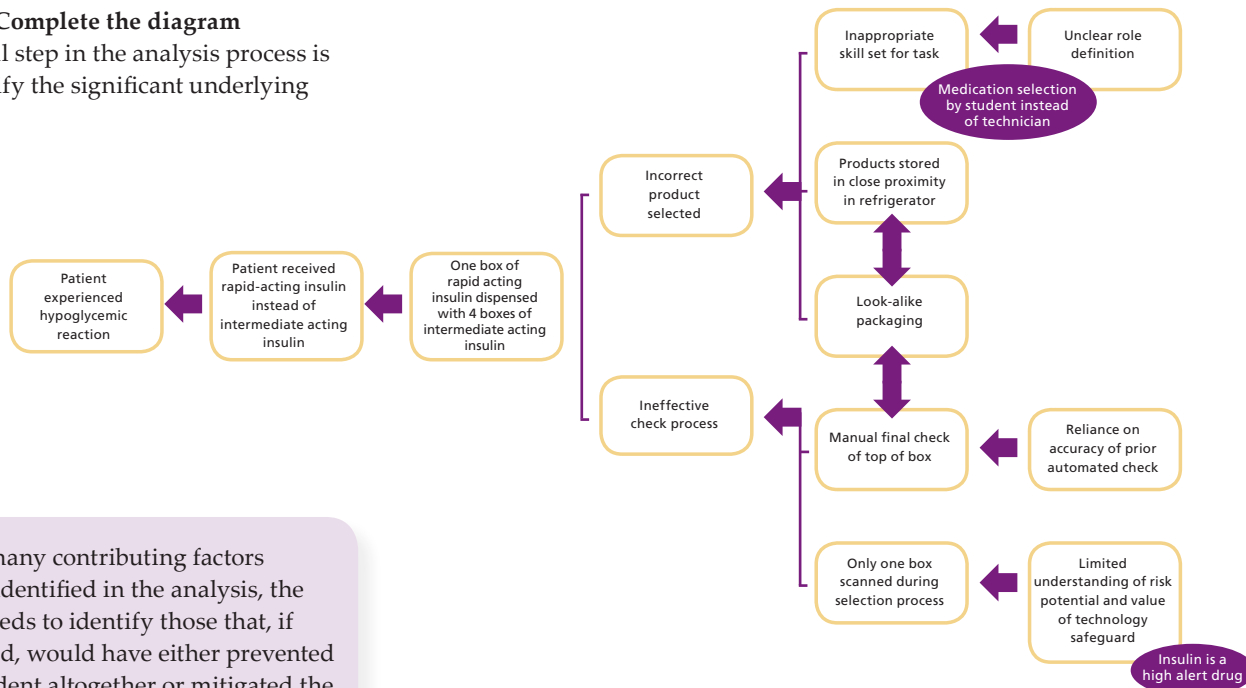
While many contributing factors will be identified in the analysis, the team needs to identify those that, if corrected, would have either prevented the incident altogether or mitigated the patient harm from the incident. These factors are the **root causes**.

Tree diagrams, if done correctly, will help to lead the team to the root causes. These factors are also typically things that are "actionable," i.e., concrete steps can be taken to correct them. The team should expect to identify a number of underlying contributing factors or problems and a few root causes. Incidents can be very complex with many inter-related factors. The example used here was selected to support a basic understanding of the process; many incidents will require more complex and non-linear diagramming.

Another consideration in diagramming is the need to assess whether appropriate action was taken to prevent or mitigate the harm resulting from the incident. In our example, had the patient not proactively sought medical help, or had the hospital not recommended assessment in the emergency department, the patient's condition could have worsened and might not have been so readily resolved.

Incidental findings

During an incident analysis, it is common for teams to uncover other issues, which may not be direct causes of the event, but are relevant to patient safety or to patient care in general. Teams should bring these issues to the attention of the appropriate individuals for follow-up. An example of an incidental finding related to the insulin incident example used might be that the refrigeration space was found to not be sufficient for the number of medications requiring refrigerated storage. If a written report is being completed, it should include the incidental findings and any related recommendations.

Causal statements

Problem statements, also called causal statements, are a useful way to clearly articulate the underlying problems that contributed to an event. These statements are intended to target system-based issues, not individual performance or behaviour.

The team goes back through the work they have already completed to ask: if this factor were eliminated or corrected, would it have prevented the outcome?

If we ask this question for each of the causal factors identified in our example:

- unclear role definition,
- products stored in close proximity in refrigerator,
- look-alike packaging,
- reliance on accuracy of prior automated check, and
- limited understanding of risk potential and value of safeguard,

we can see that had they not been present or had they been corrected, there is a high probability that the incident could have been prevented or the harm mitigated (meaning that, in this case, the selection error would have been detected before the medication left the pharmacy).
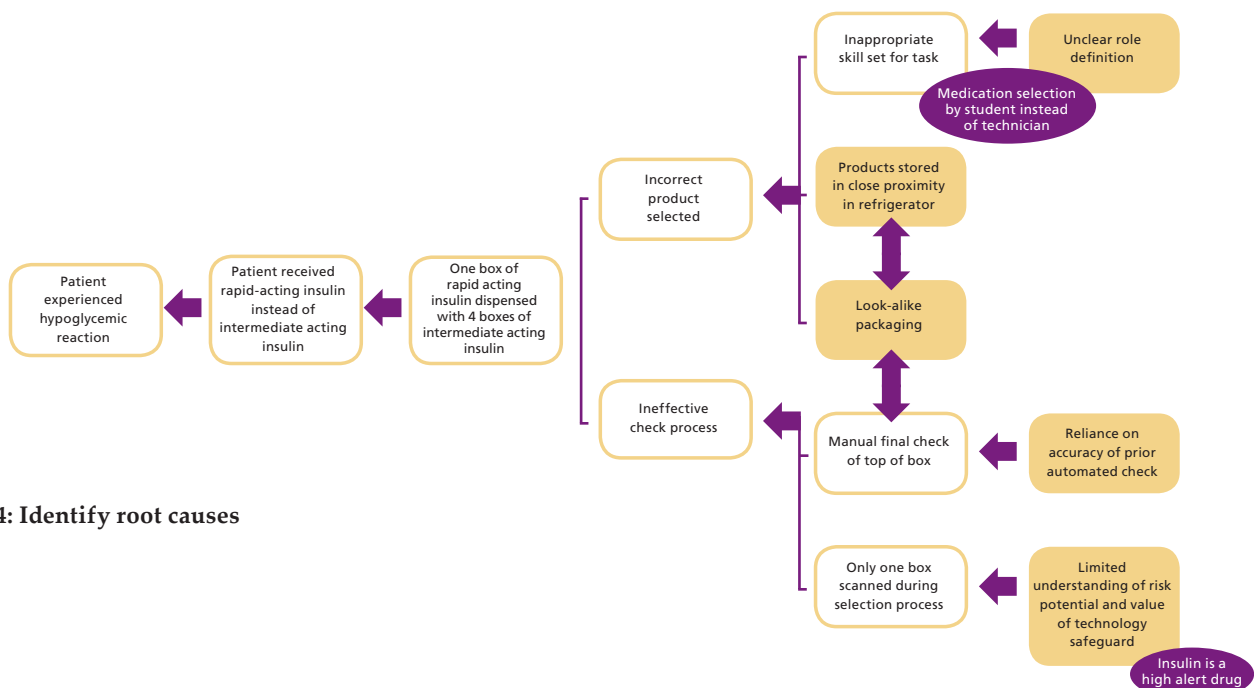
Step 4: Identify root causes

Having confirmed that these factors were significant contributors to the incident, they can now be translated into causal statements.

Causal statements are intended to specifically focus on the underlying factors. An A, B, C format is used, where:

A = Antecedent (this is usually the causal factor)
B = Bridging or behavioural language
C = Consequences

Thus a problem statement would read as follows:

(A) This set of circumstances
(B) increased/decreased the likelihood
(C) that this set of consequences would/would not occur.

Using this statement format to address the insulin incident we have been working through, two of the causal statements related to these factors might read:

Unclear role definition increased the likelihood that a student would work outside his/her skill set, in this case selecting the incorrect form of insulin, leading to the dispensing and administration of the incorrect insulin and the resulting acute hypoglycemia.

A B C

Pharmaceutical "branding" through look-alike packaging increased the likelihood of incorrect product selection and dispensing of the incorrect insulin, leading to administration by the patient and the resulting acute hypoglycemia.

Development of action plan

The ultimate purpose of an incident analysis is the development of actions to reduce the potential for recurrence of a similar event.

As stated in SOLP 6.7, a licensee must make changes or take preventative measures promptly in response to a drug error if the protection of the public requires it. The team will need to identify measures to address the underlying factors they have uncovered. The initial focus is on correction of the causal factors that allowed the outcome. If there are no actions that can be implemented to eliminate the identified problems, the team should look for controls to reduce the possibility of recurrence. Note that applying a control means that although checks will be in place, there still is a chance of reproducing the same or related circumstances that led to the original incident.
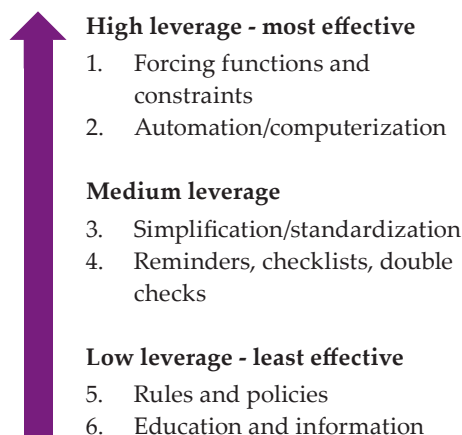
Occasionally a team may choose to accept one or more identified contributing factors without further intervention. For example, the frequency and/or severity of the incidents may not be significant. The team may determine that one of the identified problems cannot be altered, and must be accepted; however, this determination needs to be considered very carefully. Some opportunities for change may be beyond the control of the local team, but could be addressed externally. In our case example, the packaging and labelling of the two products contributed to the potential for mix-up; this concern is beyond the control of an individual pharmacy but could be forwarded to the manufacturer, Health Canada and ISMP Canada.

As discussed in the section on application of human factors engineering principles, when developing action plans, many possible categories of options with varying degrees of effectiveness are available.

The team should be educated about this range (see below, listed in order from most to least effective) and encouraged to recommend the most effective solution that is reasonable and/or possible given the circumstances. As noted earlier, items such as training and policy development are necessary components, but when used alone, do not change the underlying conditions that lead to error.

Options for change

Remember the *hierarchy of effectiveness:*

High leverage - most effective
1. Forcing functions and constraints
2. Automation/computerization

Medium leverage
3. Simplification/standardization
4. Reminders, checklists, double checks

Low leverage - least effective
5. Rules and policies
6. Education and information

Actions should:

- target the identified underlying problems;
- offer a long-term solution to the problem;
- have a greater positive than negative impact on other processes, resources and schedules;
- be objective and measurable; and
- be achievable and reasonable.

From a human factors standpoint, the strongest interventions are those that involve physical or architectural changes or forcing functions. In a community pharmacy, this might mean renovating the dispensary to improve workflow. Other human factors interventions include reduction of distractions and strategies to reduce reliance on memory and vigilance, such as building in redundant cues and using warning labels.
When discussing potential actions,

encourage the team to consider innovative ideas; just because things have always been done in a particular way doesn't mean that is the only way the work can be accomplished. Some forward-thinking healthcare organizations are beginning to hire human factors and industrial engineers to help them with process redesign. For the causal statements described earlier, the following actions could be considered for implementation:

1. *Unclear role definition increased the likelihood that a student would work outside his/her skill set, in this case selecting the incorrect form of insulin, leading to the dispensing and administration of the incorrect insulin and the resulting acute hypoglycemia.*

   a. Develop standard job descriptions for all dispensary staff with clearly defined role expectations and review expectations during orientation. (Low leverage – policies and procedures.)

   b. Provide a copy of the job description and review expectations during orientation of new staff members. (Low leverage – education and information.)

2. *Storage of both intermediate and rapid-acting insulins in close proximity in the refrigerator increased the likelihood of incorrect product selection and dispensing of the incorrect insulin, leading to administration by the patient and the resulting acute hypoglycemia.*

   a. Segregate short-, intermediate- and long-acting insulins in the refrigerator. (Medium leverage – simplification and standardization.)

At the conclusion of the incident analysis, the team should provide a summary of all the actions they consider reasonable to correct the identified underlying problems related

to the incident to the owner/manager and other senior leaders who may not have been involved in the analysis. The senior leadership will then make decisions about prioritization and implementation of recommendations and actions, and will determine the allocation of required resources; this is not the responsibility of the analysis team. For best success, assign one or two individuals to implement the actions. It is also important to establish a specific time frame for completion of the implementation, as it is easy to move on to other projects once the incident analysis has been completed.

Measurement

When developing an action plan, it is important to consider how you will know you have been successful.

The final step is ensuring that the changes have been implemented, that improvements have been sustained and that the desired outcomes have been achieved. One way to measure the success of an intervention is to monitor for repeated similar errors. SOLP 6.6 requires licensees to, at least quarterly:

a.   review the drug-error reports for the licensed pharmacy to evaluate whether practice changes or preventative measures are required to prevent future drug errors, and
b.   assess whether any changes implemented as a result of a drug error were successful in advancing patient safety.

Additionally, the licensee must communicate the results of the licensee's drug error review to all employees who work in the prescription department, along with any other information required to assist in ensuring that the risk of a drug error is reduced, as per SOLP 6.8.

Appendix 9 shows an example of a drug incident quarterly review report that might have been completed at the community pharmacy where our example incident occurred. Refer to Appendix 10 for the quarterly review report template.

Since the circumstances that led to an incident on a particular day may not recur in the same way within a measurable time frame, monitoring for recurrence may not be sufficient to ensure the changes implemented have been effective. In other words, since safety is often described as "what doesn't happen," it can be difficult to assess the effectiveness of changes implemented. As a result, we must often consider what are called "proxy" measures, meaning that we assume that if certain things are in place, the likelihood of an error has been reduced.

A full sample action plan, including measurement strategies for our example case, is provided in Appendix 12. A blank action plan template is provided in Appendix 11.

Conclusion

The incident analysis process is intended to provide a structured and consistent methodology to help teams understand how incidents occur so that they can take steps at the system level to reduce the likelihood of recurrence. A quick reference summary of the incident analysis process is provided in Appendix 13.

The incident analysis goals and process are aligned with the Standards for the Operation of Licensed Pharmacies in Alberta; undertaking this type of analysis when incidents occur will help pharmacy teams meet the quality assurance objectives of the Standards.

In addition to resolving problems in one pharmacy, it is also important to find ways to share de-identified information with others so that the impact of an incident analysis is felt system-wide – in other words, we are not just protecting our own patients, but all patients. ISMP Canada and the Alberta College of Pharmacy encourage practitioners to report medication incidents for the purpose of shared learning. You can report incidents through the secure web portal at **www.ismp-canada.org/err_index.htm** or by telephone at 1-866-54-ISMPC. A consumer website is also available: **www.safemedicationuse.ca**.

Appendices

Appendix 1: Confidentiality agreement for incident analysis

Appendix 2: Incident analysis meeting checklist

Appendix 3: Drug incident - sample completed patient safety report

Appendix 4: Drug incident - patient safety report

Appendix 5: Incident analysis - narrative timeline template

Appendix 6: Minimum scope of incident analysis for a medication incident

Appendix 7: Triage and triggering questions for incident analysis

Appendix 8: Incident analysis diagram template

Appendix 9: Drug incident - sample completed quarterly review report

Appendix 10: Drug incident - quarterly review report

Appendix 11: Incident analysis action and measurement plan template

Appendix 12: Sample completed incident analysis action and measurement plan template

Appendix 13: Incident analysis process summary and quick reference guide

Confidentiality agreement for incident analysis[16]

Name: _____

<p align="right">please print</p>

Position: _____

1. I understand that this incident analysis is a confidential process that is being conducted for the purpose of quality improvement. This document represents my commitment to treat any information with which I am entrusted through this analysis in a manner that respects the privacy of patients, practitioners and involved organizations, including information that does not specifically identify individual healthcare practitioners, institutions or patients. This includes information held in any format, such as fax, email, discussions and other records. This obligation does not apply to information in the public domain.

2. I agree to respect the following rules regarding the treatment of information with which my organization is entrusted.
    a. I will not access information related to the incident unless it is needed to perform my current job duties or to fulfill my responsibilities as part of this incident analysis.
    b. I will not disclose information related to the incident except as permitted by the *Health Information Act* to perform my job or meet my responsibilities as part of this incident analysis.
    c. I will not engage in discussions about information arising from this analysis in public or in any area where it is likely to come to the attention of others who are not entitled to receive such information, such as hallways, elevators, washrooms, cafeteria, locker rooms, lounges, public reception areas, etc.
    d. I will not allow another person to use my authorized access (e.g., security pass or username and password) to gain access to information related to the incident or analysis.
    e. I will only access, process, and transmit information using authorized hardware, software and other equipment.
    f. I understand that my employer reserves the right to conduct audits subject to the *Health Information Act* and other relevant provincial and federal privacy legislation to ensure information is protected against unauthorized access, use, disclosure, copying, modification, and disposal.
    g. I will immediately report any violations of the above rules to which I become aware to my supervisor or manager, without threat of penalty for doing so.

3. I have read this confidentiality agreement and understand that the conditions as described in this agreement will remain in force even if I cease to have an association with this organization.

Signature: _____

Date: _____

---

16 Adapted, with permission, from ISMP Canada Confidentiality Agreement.

Incident analysis meeting checklist

Analysis meeting to be held: _____

day / month / year

Location: _____

Incident review team:

	Pharmacy Staff	Name	Name
	Staff Pharmacist(s)		
	Pharmacy Technician(s)		
	Pharmacy Assistant(s)		
	Pharmacy sales clerk(s)		
	Pharmacy student(s)		
	Pharmacy Manager		
	Owner/Regional Manager		
	Other potential participants		
	Patient representative		
	Physician		
	Community nurse		
	Other (e.g., person not directly involved)		

Information available for review by the team:

__ Incident report (de-identified)

__ Copy of original prescription (de-identified) and dispensing record(s)

__ Medication labels as printed, dispensed medication (if available), stock bottles or other containers as applicable

__ Incident timeline based on interviews with practitioners, patient and family members

__ Relevant policies and procedures

__ Relevant standards of practice, best practice guidelines

__ Confidentiality forms

Sample Drug Incident Report Form

Alberta College of Pharmacy

Drug incident - patient safety report

1. As per Standard 1.9 of the Standards of Practice for Pharmacists and Pharmacy Technicians, **each pharmacist and pharmacy technician must participate in the quality assurance processes** required by the Standards for the Operation of Licensed Pharmacies.

2. Use this form for all related drug incidents.

3. As per Standard 6.4(b), the regulated member involved in the drug error must document an account of the error as soon as possible after the discovery. If the regulated member involved is not on duty at the time of discovery, the regulated member or employee who discovers the drug error must initiate the documentation.

4. Notify all regulated health professionals and caregivers whose care for the patient may be affected by the drug error.

5. Attach **Rx & transaction record** – photocopies or originals are acceptable.

6. Retain this report for **10** years from discovery date.

7. This form is for drug incidents, drug errors and adverse drug events only; not adverse drug reaction reporting (ADRs).

8. All reports must be reviewed at least **quarterly** to evaluate success of changes implemented (Standard 6.6).

What is a drug incident? (Standard 6)

a. **Drug incident** means any preventable event that may cause or lead to inappropriate drug use or patient harm. Drug incidents may be related to the practice of pharmacists or the practice of pharmacy technicians, drugs, health care products, aids and devices, procedures or systems, and include:

   i. prescribing;
   ii. order communications;
   iii. product labeling, packaging, nomenclature;
   iv. compounding;
   v. dispensing;
   vi. distribution;
   vii. administration;
   viii. education;
   ix. monitoring; and
   x. use.

b. **Adverse drug event** means an unexpected and undesired incident related to drug therapy that results in patient injury or death or an adverse outcome for a patient, including injury or complication.

c. **Drug error** means an adverse drug event or a drug incident where the drug has been released to the patient.

Patient Information

Name: Sam Anyone

Address: 123 Anystreet Rd.

Anytown, AB T0T 0T0

Phone: 780-123-4567

Email: sam.anyone@yahoo.ca

Sex: (M) or F (circle)

D.O.B.: 01 / 02 / 42
day / month / year

weight = 75 kg

Other relevant demographic data:

Rx #: 123456

New or (repeat) Rx (circle)

Incident date & discovery date

Incident date: 1900   05 / 03 / 2011
hour   _day / month / year_

Discovery date: 1000   06 / 03 / 2011
hour   _day / month / year_

Name of reporter & incident discoverer

Discovered by: _Joe Druggist_   _R. Ph._
name / position title

Report completed by: _Joe Druggist_   _R. Ph._
name / position title

Drug ordered

State: drug/dose/form/route/directions for use. Remember to attach Rx & transaction record!

Novolin® ge 30/70 Penfill SC bid (25 units am, 12 units pm) via insulin pen

Incident description

State only the facts as known at the time of discovery of the incident. Additional detail about the incident may be appended to this form as it becomes available (e.g., final understanding/time line and incident analysis findings).

Patient's wife called to say that patient experienced a severe low blood sugar reaction requiring treatment in the Emergency Department (ED) and the doctor discovered that the wrong insulin had been dispensed. When insulin supply was checked, found 4 boxes of Novolin® ge 30/70 (intermediate + short-acting insulin) and one box of NovoRapid® insulin (rapid-acting insulin). Patient injected incorrect insulin (NovoRapid®) resulting in hypoglycemia and treatment in ED.

Severity

Mark an **X** to the left of the applicable scenario.

_____ **None:** Patient is not symptomatic or no symptoms detected and no treatment required.

___X___ **Mild:** Patient is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g., extra observation, investigation, review or minor treatment) is required.

_____ **Moderate:** Patient is symptomatic, requiring intervention (e.g., additional operative procedure; additional therapeutic treatment), an increased length of stay, or causing permanent or long term harm or loss of function).

_____ **Severe:** Patient is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function.

_____ **Death:** On balance of probabilities, death was caused or brought forward in the short term by the incident.

➡ If no harm occurred in this case, was there significant potential for harm? (**Yes**) **No** (circle)

➡ If the patient received incorrect medication, or did not receive medication that should have been received, **how many doses were involved?** _one_ (1)

Type of incident

Mark an **X** to the left of each applicable item.

__X__ Incorrect drug

_____ Incorrect patient

_____ Incorrect dose/strength

_____ Documented allergy/ADR to drug dispensed

_____ Incorrect/inappropriate packaging (e.g., child-resistant packaging not used, or packaged without regard to nature of drug including light and temperature requirements)

_____ Incorrect label/directions

_____ Incorrect dosage form/incorrect route

_____ Omission (drug not supplied/untreated condition)

_____ Drug interaction not followed up

_____ Therapeutic duplication

_____ Outdated product

_____ Incorrect quantity

_____ Incorrect generic substitution/incorrect brand supplied

_____ Incorrect indication/incorrect or improper administration (e.g., injection provided to a child under 5 years)

_____ Other - please specify:

Contributing factors

To be completed by the staff member(s) with the most knowledge of the incident.
Mark an **X** to the left of each applicable item.

_____ Patient identification process

_____ Transcription/order entry process

_____ Patient assessment process (e.g., questions to gather information on new and refill medications incomplete or lacking)

_____ Counselling process (e.g., hearing/visual impairment, low literacy skills, language barrier, availability/provision of written materials)

_____ Monitoring process (e.g., follow-up not completed, lab values not available/not reviewed)

_____ Drug order interpretation (e.g., misread/misheard/misinterpreted)

_____ Drug unavailable (e.g., supply shortage and no alternative drug obtained on behalf of patient)

__X__ Education/training/skills/experience (e.g., unfamiliarity with drug product, device, or process)

_____ Compounding process (e.g., assignment of incorrect beyond-use-date, complex formula, formula not available, drug stability problem, procedure unhygienic, cross-contamination)

_____ Prescribing problem (e.g., problematic abbreviations, legibility issues)

__X__ Checking process (e.g., pharmacist working alone, ingredient check omitted/failed, final check omitted/failed)

_____ Documentation process (incomplete/unclear)

_____ Drug storage/security (e.g., narcotic safe left unlocked)

__X__ Environmental factors (e.g., pharmacist working alone, fatigue due to extended shift/short-staffing, interruptions, higher than normal Rx volume, look-alike packaging, look-alike/sound-alike drug names, technology)

_____ Other - please specify:

Notifications

Complete the following in accordance with SOLP 6.5(b) and (c)

	hour	day / month / year
Patient:	1000	06 / 03 / 2011
Prescriber:	1030	06 / 03 / 2011
Licensee:	1300	06 / 03 / 2011

Others:

_____   _____   _____
specify   *hour*   *day / month / year*

_____   _____   _____
specify   *hour*   *day / month / year*

Staff involved notified

Pharm Tech	R.Ph.T.	*PharmTech*

name / position / signature

Stu Dent	Pharm. Tech Student	*Stu Dent*

name / position / signature

Joe Druggist	R.Ph.	*Joe Druggist*

name / position / signature

_____
name / position / signature

_____
name / position / signature

_____
name / position / signature

Outcome of investigation

Problems identified: Use the **causal statement format** to describe underlying problems/contributing factors identified through incident analysis.

> **A = Antecedent**   **(A)** This set of circumstances
> **B = Bridging**   **(B)** increased/decreased the likelihood
> **C = Consequences**   **(C)** that this set of consequences would/would not occur.

1. Unclear role definition increased the likelihood that a pharmacy technician student would work outside his skill set, in this case selecting the incorrect form of insulin, leading to the dispensing and administration of the incorrect insulin and the resulting acute hypoglycemia.

2. Products with look-alike packaging were stored in close proximity in refrigerator, increasing the likelihood of selecting the incorrect form of insulin, leading to the dispensing and administration of the incorrect insulin and the resulting acute hypoglycemia.

3. Reliance on accuracy of prior automated check, increased likelihood of manual final check of top box only leading to the dispensing and administration of the incorrect insulin and the resulting acute hypoglycemia.

4. Limited understanding of risk potential and value of technology safeguard increased the likelihood that only one box of insulin would be scanned during the selection process, leading to the dispensing and administration of the incorrect insulin and the resulting acute hypoglycemia.

5. Pharmaceutical "branding" through look-alike packaging increased the likelihood of incorrect product selection and dispensing of the incorrect insulin, leading to administration by the patient, and the resulting acute hypoglycemia.

Actions to be implemented

Favour higher leverage (effectiveness) change options where possible. Note that the actions below are in descending order of leverage. Actions should be **SMART**: **S**pecific, **M**easurable, **A**ttainable, **R**elevant and **T**ime-based.

Forcing functions/constraints:

Contact software vendor by March 10, 2011 to discuss implementation of electronic verification forcing functions that must occur before the prescription can be released (i.e., multiple drug packages dispensed require independent verification/scanning) to ensure selection errors will be detected. Will obtain implementation date from software vendor at time of contact.

Reminders, checklists, double checks:

Pharmacy technician to apply warning labels to all look-alike insulin products in refrigerator by March 7, 2011. Pharmacy manager to audit weekly x 6 weeks then monthly, then quarterly.

Actions to be implemented (continued)

Simplifications/standardization:

Pharmacy technician to segregate short, -intermediate-and long-acting insulins in the refrigerator by March 7, 2011. Pharmacy manager to audit weekly x 6 weeks then monthly, then quarterly.

Pharmacy manager to develop standard job descriptions by May 1, 2011 for all dispensary staff with clearly defined role expectations and review expectations during orientation. Pharmacy manager will perform annual audit to ensure job descriptions for all positions.

Education or training provided/course(s) taken:

Pharmacy manager immediately requires final check of DIN to be performed by pharmacist or regulated pharmacy technician on each item that will be part of the final package. Process to be observed by pharmacy manager weekly x 6 weeks then monthly, then quarterly to reinforce compliance.

Pharmacy technician to train pharmacy technician student by March 14, 2011 to check that DIN on all items to be packaged match that of the label. Pharmacy technician responsible for training to audit weekly x 6 weeks then monthly, then quarterly. All staff to begin scanning each item that will be part of the final package immediately. Process to be observed by pharmacy manager weekly x 6 weeks then monthly, then quarterly to reinforce compliance.

Pharmacy manager to provide a copy of the job description by May 15, 2011, review expectations during orientation of new staff members, and follow-up with individual staff at time of annual performance review.

Other (please specify):

Novo Nordisk (manufacturer of insulin) and ISMP Canada to be contacted by pharmacy manager by March 10, 2011 to advise of nature of error and potential for change in product labeling to make differences more conspicuous.

Evaluation

Please describe whether the actions taken have resolved the issue. Is the patient satisfied with the outcome? Has the potential for recurrence been mitigated?

Advised patient/patient's wife and physician that the above actions have now been taken to minimize chance of recurrence. Will monitor on a quarterly basis to ensure changes implemented continue to be effective.

Date: _1000_____ _06 / 03 / 2011_ Signature: _Joe Druggist_____
      hour   day / month / year

Name: _Joe Druggist_____ Position
                             please print   title: _____R.Ph._____

Drug Incident - patient safety report - addendum

Please attach details of drug incident investigation including initial/final understanding, time lines, and incident analysis findings, including causal chains as applicable.

Insulin dependent patient obtains refill of Novolin 30/70 x several boxes → Patient injects new insulin → Patient develops severe hypoglycemic symptoms with reduced level of consciousness → Blood glucose 2.5 mmol/L, patient given sugar and food → Insulin supply checked and found one box of Novo-Rapid
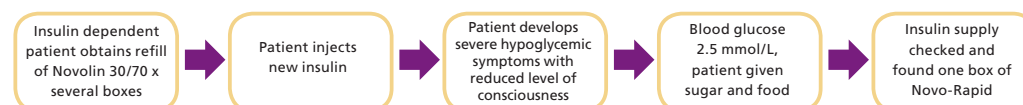
Final understanding & timeline (partial)

Time	Information item	Information source
4:30 p.m., 3 days prior to event	Patient calls for refill of insulin prescription from community pharmacy - will pick up in evening.	Prescription record
5:00 p.m.	Technician processes refill in the computer and leaves the label in a basket for filling by the dispensary student.	Technician interview
5:30 p.m.	Student obtains 5 boxes of insulin from fridge and scans the top box 5 times, labels the top box, and then tapes all 5 boxes together. The prescription is left in the basket for the pharmacist to check.	Technician & student interview
5:50 p.m.	Pharmacist sees that insulin boxes look the same, checks DIN on the top box against prescription hard copy and signs off. Insulin placed in refrigerator for pick-up; bag and receipt in pick-up bin with note, "medication in fridge."	Pharmacist interview
8:40 p.m.	Patient's wife comes in to pick up insulin. Student retrieves from refrigerator, bags and gives to patient's wife.	Student and patient/family interview

Identification of root causes - tree diagram

Drug Incident Report Form

Alberta College of Pharmacy

Drug incident - patient safety report

1. As per Standard 1.9 of the Standards of Practice for Pharmacists and Pharmacy Technicians, **each pharmacist and pharmacy technician must participate in the quality assurance processes** required by the Standards for the Operation of Licensed Pharmacies.

2. Use this form for all related drug incidents.

3. As per Standard 6.4(b), the regulated member involved in the drug error must document an account of the error as soon as possible after the discovery. If the regulated member involved is not on duty at the time of discovery, the regulated member or employee who discovers the drug error must initiate the documentation.

4. Notify all regulated health professionals and caregivers whose care for the patient may be affected by the drug error.

5. Attach **Rx & transaction record** – photocopies or originals are acceptable.

6. Retain this report for **10** years from discovery date.

7. This form is for drug incidents, drug errors and adverse drug events only; not adverse drug reaction reporting (ADRs).

8. All reports must be reviewed at least **quarterly** to evaluate success of changes implemented (Standard 6.6).

What is a drug incident? (Standard 6)

a. **Drug incident** means any preventable event that may cause or lead to inappropriate drug use or patient harm. Drug incidents may be related to the practice of pharmacists or the practice of pharmacy technicians, drugs, health care products, aids and devices, procedures or systems, and include:

   i. prescribing;
   ii. order communications;
   iii. product labeling, packaging, nomenclature;
   iv. compounding;
   v. dispensing;
   vi. distribution;
   vii. administration;
   viii. education;
   ix. monitoring; and
   x. use.

b. **Adverse drug event** means an unexpected and undesired incident related to drug therapy that results in patient injury or death or an adverse outcome for a patient, including injury or complication.

c. **Drug error** means an adverse drug event or a drug incident where the drug has been released to the patient.

Patient information

Name: _____

Address: _____

Phone: _____

Email: _____

Sex: ☐ M ☐ F

D.O.B.: _____
day / month / year

Other relevant demographic data: _____

Rx #: _____

☐ New Rx ☐ Repeat Rx

Incident date & discovery date

Incident date: _____
hour   day / month / year

Discovery date: _____
hour   day / month / year

Name of reporter & incident discoverer

Discovered by: _____
name / position title

Report
completed by: _____
name / position title

Drug ordered

State: drug/dose/form/route/directions for use. Remember to attach Rx & transaction record!

Incident description

State only the facts as known at the time of discovery of the incident. Additional detail about the incident may be appended to this form as it becomes available (e.g., final understanding/time line and incident analysis findings).

Severity

Mark an **X** to the left of the applicable scenario.

_____ **None:** Patient is not symptomatic or no symptoms detected and no treatment required.

_____ **Mild:** Patient is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g., extra observation, investigation, review or minor treatment) is required.

_____ **Moderate:** Patient is symptomatic, requiring intervention (e.g., additional operative procedure; additional therapeutic treatment), an increased length of stay, or causing permanent or long term harm or loss of function).

_____ **Severe:** Patient is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function.

_____ **Death:** On balance of probabilities, death was caused or brought forward in the short term by the incident.

➡ If no harm occurred in this case, was there significant potential for harm?   **Yes   No**   (circle)

➡ If the patient received incorrect medication, or did not receive medication that should have been received, **how many doses were involved?**

Type of incident

Mark an **X** to the left of each applicable item.

_____ Incorrect drug	_____ Omission (drug not supplied/untreated condition)
_____ Incorrect patient	_____ Drug interaction not followed up
_____ Incorrect dose/strength	_____ Therapeutic duplication
_____ Documented allergy/ADR to drug dispensed	_____ Outdated product
_____ Incorrect/inappropriate packaging (e.g., child-resistant packaging not used, or packaged without regard to nature of drug including light and temperature requirements)	_____ Incorrect quantity
	_____ Incorrect generic substitution/incorrect brand supplied
	_____ Incorrect indication/incorrect or improper administration (e.g., injection provided to a child under 5 years)
_____ Incorrect label/directions	
_____ Incorrect dosage form/incorrect route	_____ Other - please specify:

Contributing factors

To be completed by the staff member(s) with the most knowledge of the incident.
Mark an **X** to the left of each applicable item.

_____ Patient identification process	_____ Compounding process (e.g., assignment of incorrect beyond-use-date, complex formula, formula not available, drug stability problem, procedure unhygienic, cross-contamination)
_____ Transcription/order entry process	
_____ Patient assessment process (e.g., questions to gather information on new and refill medications incomplete or lacking)	_____ Prescribing problem (e.g., problematic abbreviations, legibility issues)
_____ Counselling process (e.g., hearing/visual impairment, low literacy skills, language barrier, availability/provision of written materials)	_____ Checking process (e.g., pharmacist working alone, ingredient check omitted/failed, final check omitted/failed)
	_____ Documentation process (incomplete/unclear)
_____ Monitoring process (e.g., follow-up not completed, lab values not available/not reviewed)	_____ Drug storage/security (e.g., narcotic safe left unlocked)
_____ Drug order interpretation (e.g., misread/misheard/misinterpreted)	_____ Environmental factors (e.g., pharmacist working alone, fatigue due to extended shift/short-staffing, interruptions, higher than normal Rx volume, look-alike packaging, look-alike/sound-alike drug names, technology)
_____ Drug unavailable (e.g., supply shortage and no alternative drug obtained on behalf of patient)	
_____ Education/training/skills/experience (e.g., unfamiliarity with drug product, device, or process)	_____ Other - please specify:

Notifications

Complete the following in accordance with SOLP 6.5(b) and (c)

Patient: _____
          hour   day / month / year

Prescriber: _____
             hour   day / month / year

Licensee: _____
           hour   day / month / year

Others:

_____ _____
specify   hour   day / month / year

_____ _____
specify   hour   day / month / year

Staff involved notified

_____
name / position / signature

_____
name / position / signature

_____
name / position / signature

_____
name / position / signature

_____
name / position / signature

_____
name / position / signature

Outcome of investigation

Problems identified: Use the **causal statement format** to describe underlying problems/contributing factors identified through incident analysis.

A = Antecedent	**(A)** This set of circumstances
B = Bridging	**(B)** increased/decreased the likelihood
C = Consequences	**(C)** that this set of consequences would/would not occur.

Actions to be implemented

Favour higher leverage (effectiveness) change options where possible. Note that the actions below are in descending order of leverage. Actions should be **SMART**: **S**pecific, **M**easurable, **A**ttainable, **R**elevant and **T**ime-based.

Forcing functions/constraints:

Automation/computerization:

Reminders, checklists, double checks:

Actions to be implemented (continued)

Simplifications/standardization:

Policy/procedure change:

Education or training provided/course(s) taken:

Other (please specify):

Evaluation

Please describe whether the actions taken have resolved the issue. Is the patient satisfied with the outcome?
Has the potential for recurrence been mitigated?

Date: _____
hour   *day / month / year*

Signature: _____

Name: _____
please print

Position
title: _____

Drug incident - patient safety report - addendum

Please attach details of drug incident investigation including initial/final understanding, time lines, and incident analysis
findings, including causal chains as applicable.

Narrative timeline template

Date and Time	Information Item	Information Source

Minimum scope of incident analysis for a medication incident

✓	Item	Applicable to Incident	Not Applicable
	Physical assessment process		
	Individual identification process		
	Continuum of care		
	Staffing levels		
	Orientation and training of staff		
	Competency assessment/credentialing		
	Supervision of staff (includes supervision of physicians in training)		
	Communication with individual/family		
	Communication among staff members		
	Availability of information		
	Adequacy of technical support		
	Equipment maintenance/management		
	Physical environment (includes furnishings, hardware, lighting, distractions)		
	Medication management (includes selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration and monitoring)		

This checklist has been adapted from the assessment criteria developed by the US Joint Commission[17] for the root cause analysis of a medication error.[18]

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17 The Joint Commission is the primary accrediting body for healthcare organizations and programs in the United States. Organizations accredited by the Joint Commission are expected to conduct a root cause analysis of any sentinel events and provide a report to the Commission within 45 days of the event or becoming aware of the event.

18 "Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events in Sentinel Event Guidelines for Ambulatory Care, January 2011." *Adapted from the Joint Commission.* 23 Feb. 2011. <**www.jointcommission.org/assets/1/6/2011_CAMAC_SE.pdf**>

Triage and triggering questions for incident analysis[19]

The United States Veterans Affairs National Center for Patient Safety, a world leader in patient safety and root cause analysis, has developed a list of triage and triggering questions to assist analysis teams in conducting incident analyses. These questions are not the only questions to be asked during an incident analysis, but are designed to help identify contributing factors and underlying problems that may not otherwise be considered. These questions have been adapted to focus on issues relevant to medication incidents in community pharmacy.

Starting point

Was this event thought to be the result of a criminal act, a purposefully unsafe act related to alcohol or substance abuse (impaired provider/staff), or events involving alleged or suspected patient abuse of any kind (i.e., those situations which are outside the scope of the patient safety program)? If YES, request that the incident analysis process be stopped and that an administrative process be started.

I. Human factors: Communication

Questions in this section are intended to help assess issues related to communication, flow of information and availability of information as needed.

1. Was the patient correctly identified?
2. Was information from various patient assessments shared and used by members of the treatment team on a timely basis?
3. Did existing documentation provide a clear picture of the work-up, the treatment plan and the patient's response to treatment? (Including, for example, assessments, consultations, orders, treatment team notes, medication administration records, lab reports, etc.)
4. Was communication between management/supervisors and front line staff adequate?
5. Was communication between front line team members adequate?
6. Were policies and procedures communicated adequately?
7. Were there methods for monitoring adequacy of staff communication? Were there methods for read-back, confirmation of messages, debriefs, etc?
8. Was there a manufacturer's recall/alert/bulletin on file for medication or equipment at the time of the event or close call? Were relevant staff members aware of the recall/alert/bulletin?
9. If relevant, were the patient and their family/significant others actively included in the assessment and treatment planning?
10. Did management establish adequate methods to provide information to employees who needed it in a manner that was easy to access/use and timely?
11. Did the overall culture of the facility encourage or welcome observations, suggestions or early warnings from staff about risky situations and risk reduction? (Also, has this happened before and was anything done to prevent it from happening again?)

II. Human factors: Training

These questions are related to routine job training, special training and continuing education, including the timing of that training. Training issues may concern application of approved procedures, correct use of equipment or appropriate manipulation of protective barriers. These questions also focus on the interfaces between people, workspace and equipment.

1. Was there a program to identify what is actually needed for training of staff?
2. Was training provided prior to the start of the work process?
3. Were the results of training monitored over time?
4. Was the training adequate? (If not, consider supervisory responsibility, procedure omission, flawed training, flawed policies or procedures.)
5. Were training programs for staff designed up-front with the intent of helping staff perform their tasks without errors?
6. Had procedures and equipment been reviewed to ensure that there was a good match between people and the tasks they did, or people and the equipment they used (i.e., application of human factors engineering principles)?
7. If equipment was involved, did it work smoothly in the context of staff needs and experience, existing procedures, requirements and workload, physical space and location?

III. Human factors: Fatigue/scheduling

Questions in this section weigh the influence of stress and fatigue that may result from scheduling and staffing issues, sleep deprivation or environmental distractions such as noise. These questions also evaluate relationships to training issues, equipment use, and management concern and involvement.

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19 "Triage and Triggering Questions." *Adapted from the United States Department of Veterans Affairs National Center for Patient Safety.* 14 Feb. 2011.
<**www.patientsafety.gov/CogAids/Triage/index.html#page=page-1**>

1. Were the levels of vibration, noise or other environmental conditions appropriate?
2. If applicable, were environmental stressors properly anticipated (e.g., distractions)?
3. Did scheduling allow personnel adequate sleep?
4. Was fatigue (e.g., due to workload or scheduling) properly anticipated?
5. Was there sufficient staff with the appropriate skills on hand for the workload at the time?
6. Was the level of automation appropriate for the tasks to be accomplished?

IV. Environment: Equipment

These questions are intended to help evaluate factors related to use and location of equipment, fire protection and disaster drills, codes, specifications and regulations, the general suitability of the environment, and the possibility of recovery after an error has occurred. These questions show that what appears to be equipment failure may relate to human factors issues, policy and procedure questions, and training needs.

1. Was the work area/environment designed to support the function it was being used for?
2. Were the work environment stress levels (either physical or psychological) appropriate (e.g., temperature, space, noise)?
3. Did the work area/environment meet current codes, specifications and regulations?
4. Was there adequate equipment to perform the work processes?
5. Was there a documented safety review/maintenance program performed on the equipment involved? If relevant, was recommended service/recall/maintenance, etc., completed in a timely manner?
6. Were emergency provisions and back-up systems available in case of equipment failure?

7. Was the equipment designed such that usage mistakes would be unlikely to happen?
8. Had this type of equipment worked correctly and been used appropriately in the past?
9. Were personnel trained appropriately to operate the equipment involved in the adverse event/close call?
10. Did the design of the equipment enable detection of problems and make them obvious to the operator in a timely manner?
11. Were equipment displays and controls working properly and interpreted correctly?
12. Was the medical equipment or device intended to be reused (i.e., not a single use device)?

V. Rules: Policies/procedure

Questions in this section are focused on the existence and ready accessibility of policies and procedures, including technical information for assessing risk, mechanisms for feedback on key processes, effective interventions developed after previous events, compliance with national and provincial regulations, and the usefulness of and incentives for compliance with codes, standards and regulations. This section also considers the qualifications of the facility and employees for the level of care provided, orientation, and training for compliance with safety and security measures including handling of hazardous material and emergency preparedness, and the availability of information to all part-time, temporary or voluntary workers and students.

1. Was there an overall management plan for addressing risk and assigning responsibility for risk management?
2. Did management have an audit or quality control system to inform them how key processes related to the adverse event are functioning?
3. Had a previous audit been done for a similar event, were the causes

identified and were effective interventions developed and implemented on a timely basis? Would this problem have gone unidentified or uncorrected after an audit/review?
4. Was required care for the patient within the scope of the organization's mission, staff expertise and availability, technical and support service resources?
5. Were the staff involved in the adverse event or close call properly qualified and trained to perform their functions?
6. Were all involved staff oriented to the job, facility and unit policies regarding: safety, security, hazardous material management, emergency preparedness, medical equipment management?
7. Were there written up-to-date policies and procedures that addressed the work processes related to the adverse event or close call?
8. Were these policies/procedures consistent with relevant provincial and national standards and regulations?
9. Were relevant policies/procedures clear, understandable and readily available to all staff?
10. Were the relevant policies and procedures actually used on a day-to-day basis?
11. If the policies and procedures were not used, what got in the way of their usefulness to the staff?

VI. Barriers

1. What barriers and controls were involved in this adverse event or close call?
2. Were these barriers designed to protect patients, staff, equipment, or environment?
3. Was patient risk considered when designing these barriers and controls?
4. Were these barriers and controls in place before the event happened?
5. Had these barriers and controls been evaluated for reliability?

6. Were the relevant barriers and controls maintained and routinely checked by designated staff?
7. Would the adverse event have been prevented if the existing barriers and controls had functioned correctly?

Incident analysis diagram template

Root Cause

Actions and Conditions

Incident

Outcome

1. Consider factors that led to the outcome, not just the incident.

2. Consider inter-relationships between actions and conditions – relationships are often not linear.

Sample Drug Incident Quarterly Review Report

Alberta College of Pharmacists

Follow-up process: Standards for the Operation of Licensed Pharmacies

6.6 The licensee must, at least quarterly:

    a. review the drug-error reports for the licensed pharmacy to evaluate whether practice changes or preventative measures are required to prevent future drug errors, and

    b. assess whether any changes implemented as a result of a drug error were successful in advancing patient safety.

6.7 Nothing in Standard 6.6 relieves a licensee from the duty to make changes or take preventative measures promptly in response to a drug error if the protection of the public requires it.

6.8 The licensee must communicate the results of the licensee's drug error review to all employees who work in the prescription department, along with any other information required to assist in ensuring that the risk of a drug error is reduced.

Retain this report for 10 years.

How to complete this report

For each quarter, please document the following:

1. Drug incidents and required actions reviewed - consider a review of ISMP Canada drug error reports for insight on similar errors

2. Any significant findings (e.g., repeated incidents of similar errors - are there any patterns?)

3. Further actions implemented and whether those actions resolved the issue

Pharmacy information

Pharmacy name: **PPC Drugstore**

Address: **456 Anyroad Ave**

Anytown, AB T2T 2T2

Phone: **780-456-7890**

Email: **ph1@ppcdrugs.ca**

Licensee name: **Sam Pharmer**

Reporting year: **2011**

First quarter review - January to March

Three drug incidents this quarter: 1. Rx 123456 – incorrect insulin dispensed. 2. Rx 135456 – incorrect strength dispensed 3. Rx 158457 – incorrect drug dispensed. Of note, in all 3 cases product labels were very similar in appearance, increasing the likelihood that the incorrect drug product/dose would be selected and dispensed to the respective patient. Reviewed findings with pharmacy staff. Some staff members were forgetting to scan all items to be included in final drug packaged and still multiple products with similar labeling stored next to each other on shelving. Assigned a staff member to arrange medications in a manner that minimizes risk of drug error and reviewed importance of verifying the DIN for all items during final check and of scanning all items during final check. Additionally, consulted with pharmacy software vendor to implement mandatory scanning such that drug product cannot be scanned out of pharmacy (i.e. picked up by patient) until proper scanning of product occurs. Will continue to monitor and follow-up in 2nd quarter to determine if these actions have resolved the issue.

Review date: 01 / 04 / 2011
day / month / year

Licensee name: Sam Pharmer
please print

Licensee signature: *Sam Pharmer*

Second quarter review - April to June

Review date: _____
day / month / year

Licensee name: _____
please print

Licensee signature: _____

Third quarter review - July to September

Review date: _____
day / month / year

Licensee name: _____
please print

Licensee signature: _____

Fourth quarter review - October to December

Review date: _____
day / month / year

Licensee name: _____
please print

Licensee signature: _____

Drug Incident Quarterly Review Report

Alberta College of Pharmacy

Follow-up process: Standards for the Operation of Licensed Pharmacies

6.6 The licensee must, at least quarterly:

a.   review the drug-error reports for the licensed pharmacy to evaluate whether practice changes or preventative measures are required to prevent future drug errors, and

b.   assess whether any changes implemented as a result of a drug error were successful in advancing patient safety.

6.7   Nothing in Standard 6.6 relieves a licensee from the duty to make changes or take preventative measures promptly in response to a drug error if the protection of the public requires it.

6.8   The licensee must communicate the results of the licensee's drug error review to all employees who work in the prescription department, along with any other information required to assist in ensuring that the risk of a drug error is reduced.

Retain this report for 10 years.

How to complete this report

For each quarter, please document the following:

1.   Drug incidents and required actions reviewed - consider a review of ISMP Canada drug error reports for insight on similar errors

2.   Any significant findings (e.g., repeated incidents of similar errors - are there any patterns?)

3.   Further actions implemented and whether those actions resolved the issue

Pharmacy information

Pharmacy name: _____

Address: _____

_____

Phone: _____

Email: _____

Licensee name: _____

Reporting year: _____

First quarter review - January to March

Review date: _____
day / month / year

Licensee name: _____
please print

Licensee signature: _____

Second quarter review - April to June

Review date: _____
day / month / year

Licensee name: _____
please print

Licensee signature: _____

Third quarter review - July to September

Review date: _____
day / month / year

Licensee name: _____
please print

Licensee signature: _____

Fourth quarter review - October to December

Review date: _____
day / month / year

Licensee name: _____
please print

Licensee signature: _____

Incident analysis action and measurement plan template

*Use the causal statement format to describe underlying problems/contributing factors identified through incident analysis

A = Antecedent
B = Bridging or behavioural language
C = Consequences

e.g., (A) This set of circumstances (B) increased/decreased the likelihood (C) that this set of consequences would/would not occur.

Action #	Recommended action	Strength of action	Time frame for implementation	Individual(s) responsible	Measurement plan
*Root cause #					
A					
B					
C					
*Root cause #					
A					
B					
C					

Sample completed incident analysis action and measurement plan template

Action #	Recommended action	Strength of action	Time frame for implementation	Individual(s) responsible	Measurement plan
*Root cause # 1					
Unclear role definition increased the likelihood that a student would work outside his/her skill set, in this case selecting the incorrect form of insulin, leading to the dispensing and administration of the incorrect insulin and the resulting acute hypoglycemia.					
A	Develop standard job descriptions for all dispensary staff with clearly defined role expectations and review expectations during orientation.	Medium - standardization and simplification	Intermediate (3-6 months)	Dispensary manager	Annual audit to ensure job descriptions for all positions
B	Provide a copy of the job description and review expectations during orientation of new staff members.	Low - education and information	Intermediate (3-6 months)	Dispensary manager	Follow up with individual new staff
*Root cause # 2					
Storage of both intermediate and rapid-acting insulins in close proximity in the refrigerator increased the likelihood of incorrect product selection and dispensing of the incorrect insulin, leading to administration by the patient and the resulting acute hypoglycemia.					
A	Segregate short-, -intermediate-and long-acting insulins in the refrigerator.	Medium - standardization and simplification	Immediate	Dispensary manager	Audit weekly x 6 weeks, then monthly, then quarterly
B					

Continued

Action #	Recommended action	Strength of action	Time frame for implementation	Individual(s) responsible	Measurement plan
*Root cause # 3					
Pharmaceutical "branding" through look-alike packaging increased the likelihood of incorrect product selection and dispensing of the incorrect insulin, leading to administration by the patient and the resulting acute hypoglycemia.					
A	Apply warning labels to all look-alike insulin products in refrigerator.	Medium - reminders, checklists, double checks	Immediate	Dispensary manager	Audit weekly x 6 weeks, then monthly, then quarterly
B	Report look-alike labeling to manufacturer, Health Canada and ISMP Canada.	Low - education and information (but potential for higher level change)	Immediate	Dispensary manager	N/A - no internal measurement plan
*Root cause # 4					
Reliance on the accuracy of an automated check in the drug selection process, combined with look-alike packaging, decreased the likelihood that an incorrect drug selection would be detected during the final manual check process, leading to dispensing of the incorrect insulin, followed by administration by the patient and the resulting acute hypoglycemia.					
A	Require that each item be scanned during the dispensing process to maximize the value of the automated check process and reduce reliance on the final manual check.	Low - education and information	Immediate	Dispensary manager	Process observation by manager; peer audit and feedback
B	Work with computer system vendor to implement forcing functions and electronic verification forcing functions that must occur before the prescription can be released (e.g., multiple containers dispensed require independent verification) to ensure selection errors will be detected.	High - forcing function	Intermediate to long-term	Owner/vendor	Forcing function in place
*Root cause # 5					
Limited understanding of the risk potential related to insulin and the value of bar coding as a safeguard increased the likelihood that the bar coding system would be used in a way that did not maximize its effectiveness, in turn decreasing the likelihood that the selection error would be detected and corrected prior to the medication being dispensed to the patient, followed by administration by the patient and the resulting acute hypoglycemia.					
A	Provide education for all dispensary staff about high alert medications (i.e., those that are more likely to cause harm if used in error) and the need for additional attention with these medications.	Low - education and information	Immediate	Dispensary manager	Provide initial training for all staff, repeat on an annual basis and when orienting new staff.
B	Provide education for all dispensary staff about the optimal use of the bar coding technology and the risks associated with workarounds and shortcuts in the scanning process.	Low - education and information	Immediate	Dispensary manager	Provide initial training for all staff, repeat on an annual basis and when orienting new staff.

Incident analysis process summary and quick reference guide

Step 1: Ensure eligibility

- Was this event thought to be the result of a criminal act or other purposefully unsafe act, alcohol or substance abuse (impaired provider/staff), or events involving alleged or suspected patient abuse of any kind? Answers to all these questions should be NO. **If the answer to any of these questions is YES, the event is not appropriate for this type of quality improvement analysis.**

Step 2: Form an incident analysis team

- Ensure all appropriate disciplines are represented
- Include front-line staff who understand related care processes
- Determine team member roles and responsibilities

Step 3: Gather information/ initial understanding

- Review original prescription and other relevant documents
- Develop initial understanding of event and identify additional information needed

Step 4: Final understanding and timeline

- Review physical environment, packaging and labelling, and conduct interviews
- Conduct literature review to determine relevant standards of practice, evidence based guidelines, preventive strategies and interventions
- Develop narrative timeline and final understanding of sequence of events leading to incident

Step 5: Analysis - Identify contributing factors and underlying problems

- Use diagramming to move away from the sharp end to the underlying problems that contributed to the incident

Tips:
- To help identify root causes, remember the bottom line: If this factor were eliminated or corrected, would there be a real chance to prevent a similar event from occurring?
- Use the Minimum Scope Checklist and the Triage and Triggering Questions to help identify system and process issues and broaden the scope of the analysis

Step 6: Develop problem statements

- Problem statements help to articulate the underlying issues and form the basis for action development

Tip:
- Use the A B C format: **A = antecedent B = behaviour/bridge C = consequences**
- **(A) This set of circumstances (B) increased/decreased the likelihood (C) that this set of consequences would/would not occur.**

Step 7: Develop action plan

- Specifically address underlying problems with objective and measurable actions that encourage system level changes, i.e., action plans should be **SMART** (**S**pecific, **M**easurable, **A**ttainable, **R**elevant, and **T**ime-based)

Tip:
- Consider human factors engineering principles and the *hierarchy of effectiveness*

Step 8: Implement actions

- Assign actions to specific individuals and specify timelines
- Plan carefully; consider barriers to implementation, pilot test changes
- Use small cycles of change model: Plan, Do, Study, Act (PDSA)
- Consider whether additional measures or changes are needed and implement as necessary

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Notes

Notes

Notes