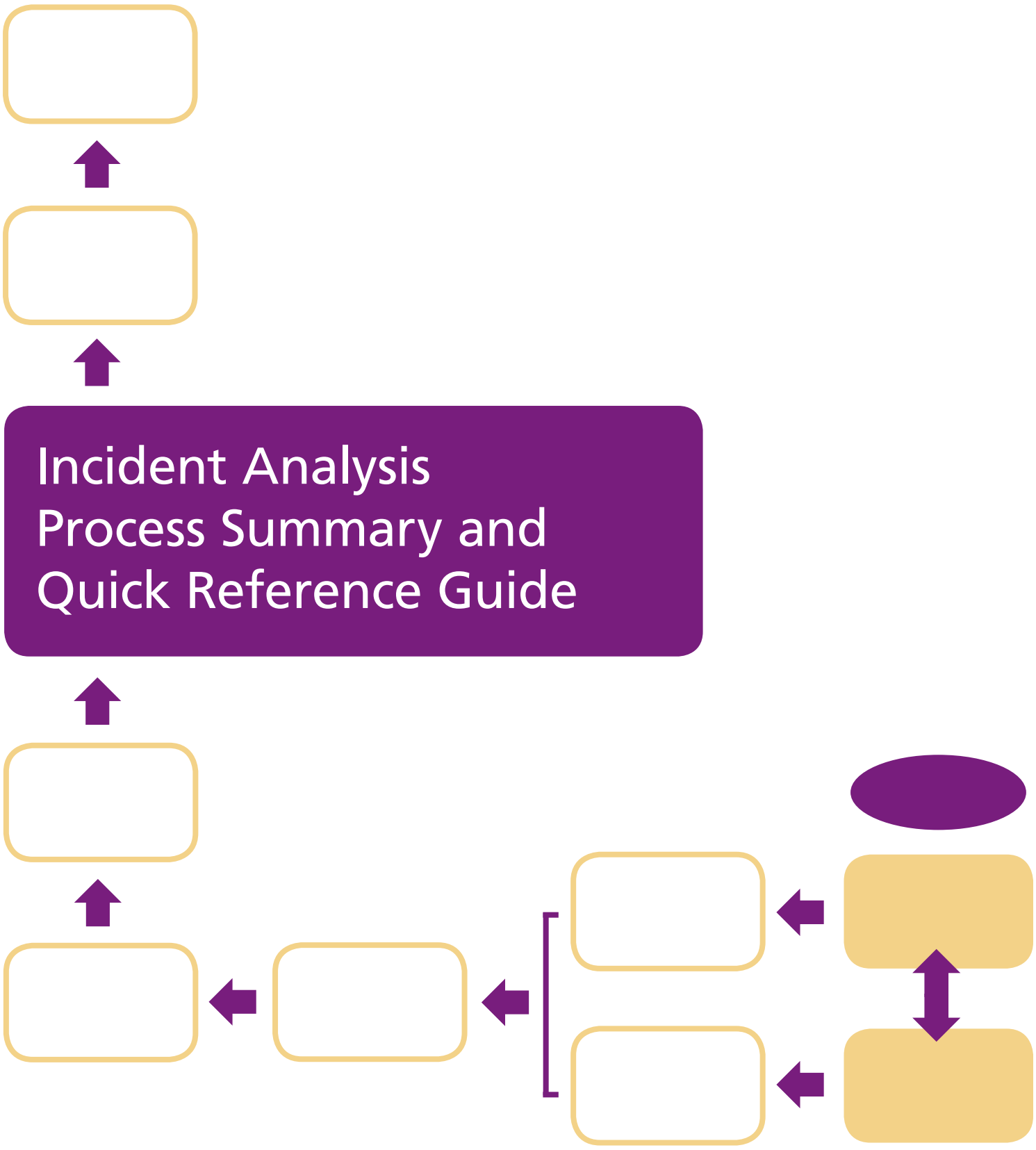
Incident Analysis Process Summary and Quick Reference Guide



Alberta College of Pharmacy

ISMP CANADA

Incident analysis process summary

Step 1: 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 2: Gather information/ initial understanding

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

Step 3: Develop 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 4: 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 5: Develop problem statements

- Draft a problem statement to help articulate the underlying issues and form the basis for action

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 6: Develop action plan

- Specifically address underlying problems with objective and measurable actions that encourage system-level changes. 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 7: Implement actions

- Assign actions to specific individuals and specify timelines
- Plan carefully; consider barriers to implementation and 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

Incident analysis process - detailed version

Step 1: 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 2: Gather information/initial understanding

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

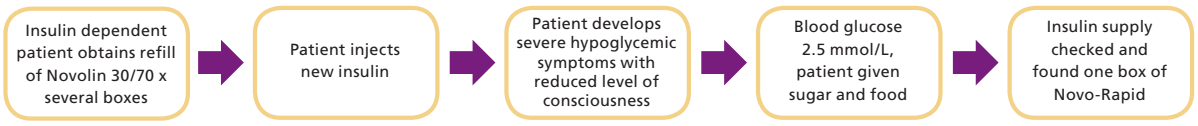


Figure 1: Sample initial understanding

Step 3: Develop 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

Table 1: Partial example of final understanding/timeline

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

Step 4: Identify contributing factors and underlying problems

- Use diagramming (below) 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?

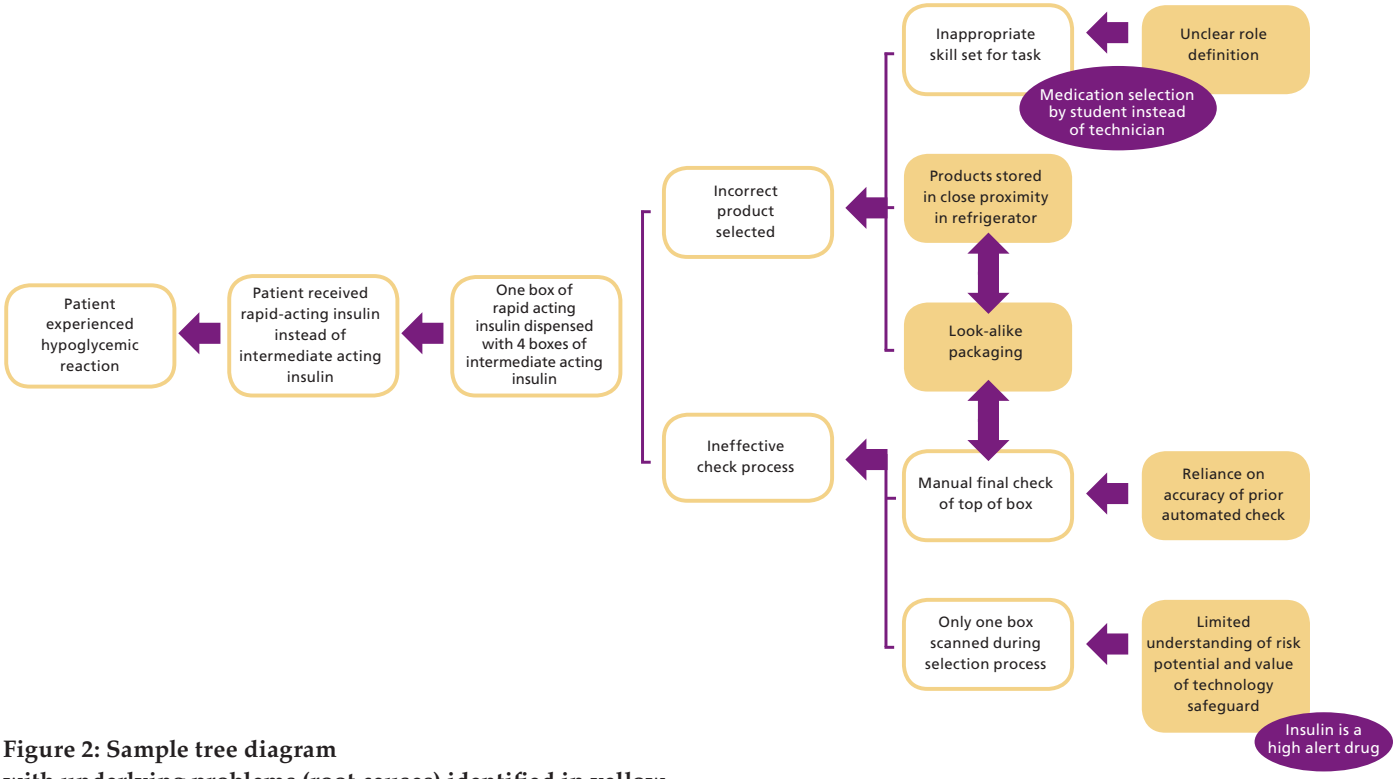


Figure 2: Sample tree diagram with underlying problems (root causes) identified in yellow

- Use the Minimum Scope Checklist (below) and the Triage and Triggering Questions (page 5) to help identify system and process issues and broaden the scope of the analysis.

✓	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[1] for the root cause analysis of a medication error.[2]

1 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.

2 "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

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.

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?

Table 2: Sample excerpt from drug incident report identifying contributing factors

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:

Step 5: Develop problem statements

- Draft a problem statement to help articulate the underlying issues and form the basis for action

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.**
- e.g., **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.**

Step 6: Develop action plan

- Specifically address underlying problems with objective and measurable actions that encourage system-level changes. 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*.

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

Table 3: Sample action and measurement plan with causal statements

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
***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

Step 7: Implement actions

- Assign actions to specific individuals and specify timelines
- Plan carefully; consider barriers to implementation and 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

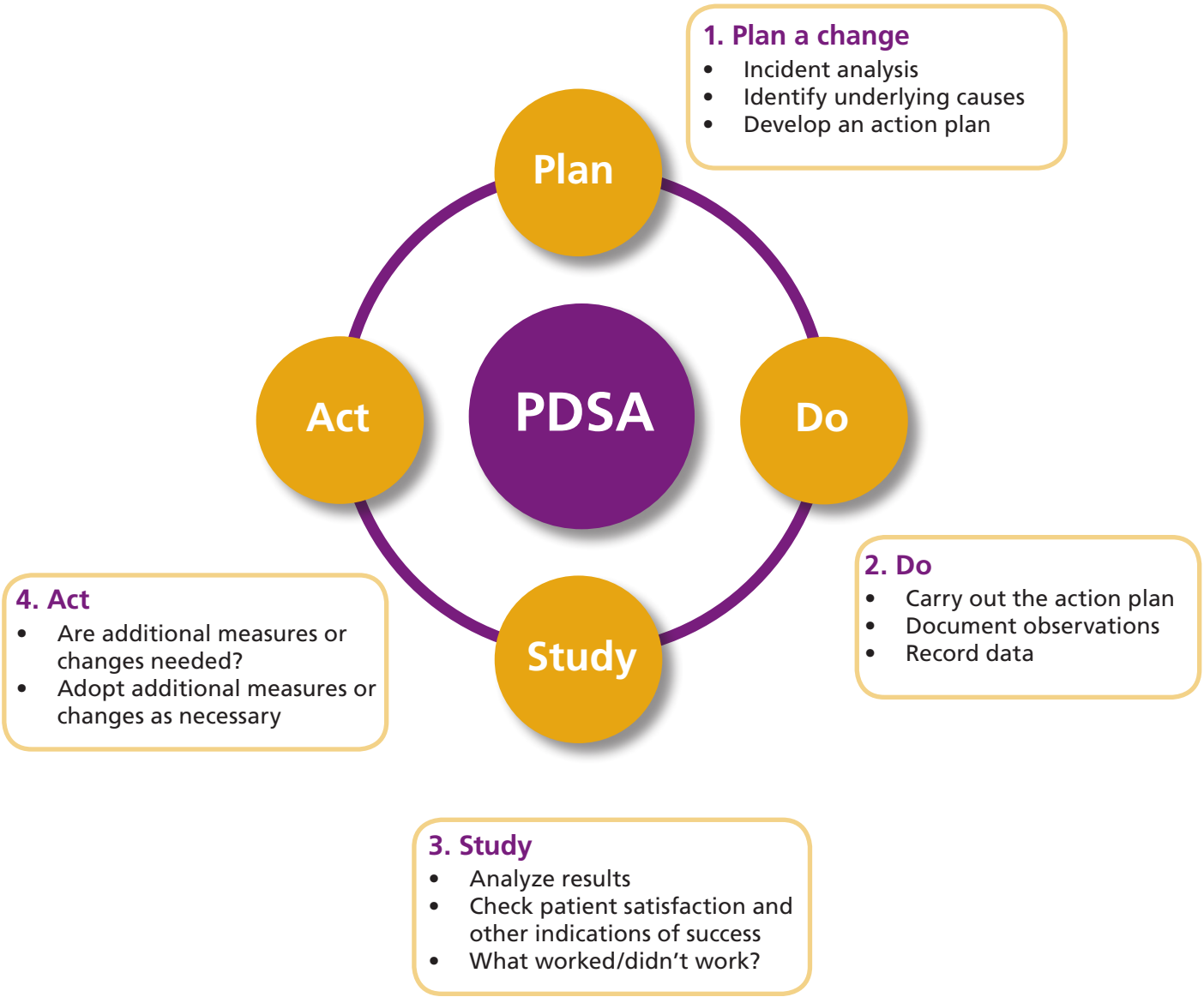


Figure 4: PDSA model

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

- prescribing;
- order communications;
- product labeling, packaging, nomenclature;
- compounding;
- dispensing;
- distribution;
- administration;
- education;
- monitoring; and
- 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

Other relevant demographic data: weight = 75 kg

Rx #: 123456

New or (**repeat**) Rx (circle)

Incident date & discovery date

Incident date: 1900 (hour) 05/05/2011 (day / month / year)

Discovery date: 1000 (hour) 06/05/2011 (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 FlexPen 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 in correct 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)
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_____	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)

Patient:	1000 (hour)	06 / 03 / 2011 (day / month / year)
Prescriber:	1050 (hour)	06 / 03 / 2011 (day / month / year)
Licensee:	1500 (hour)	06 / 03 / 2011 (day / month / year)
Others:		
specify	hour	day / month / year
specify	hour	day / month / year

Staff involved notified

name	position	signature
Pharm Tech	R.Ph.T.	[illegible]
Stu Dent	Pharm. Tech Student	Stu Dent
Joe Druggist	R.Ph.	Joe Druggist

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 the 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 refrigeration, 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 [illegible] check, increased likelihood of [illegible] check of [illegible] leading to the dispensing and administration of the incorrect insulin and the resulting acute hypoglycemia.
4. Limited understanding of the potential and value of technology [illegible] increased the likelihood that only [illegible] 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. Placement of "[illegible]" through [illegible] 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: Specific, Measurable, Attainable, Relevant and Time-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.*

continued on next page

Actions to be implemented (continued)

Simplification/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 registered 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 (hour) 06/05/2011 (day / month / year)

Signature: Jon Druggist

Name: Jon Druggist (please print)

Position title: R.Ph.

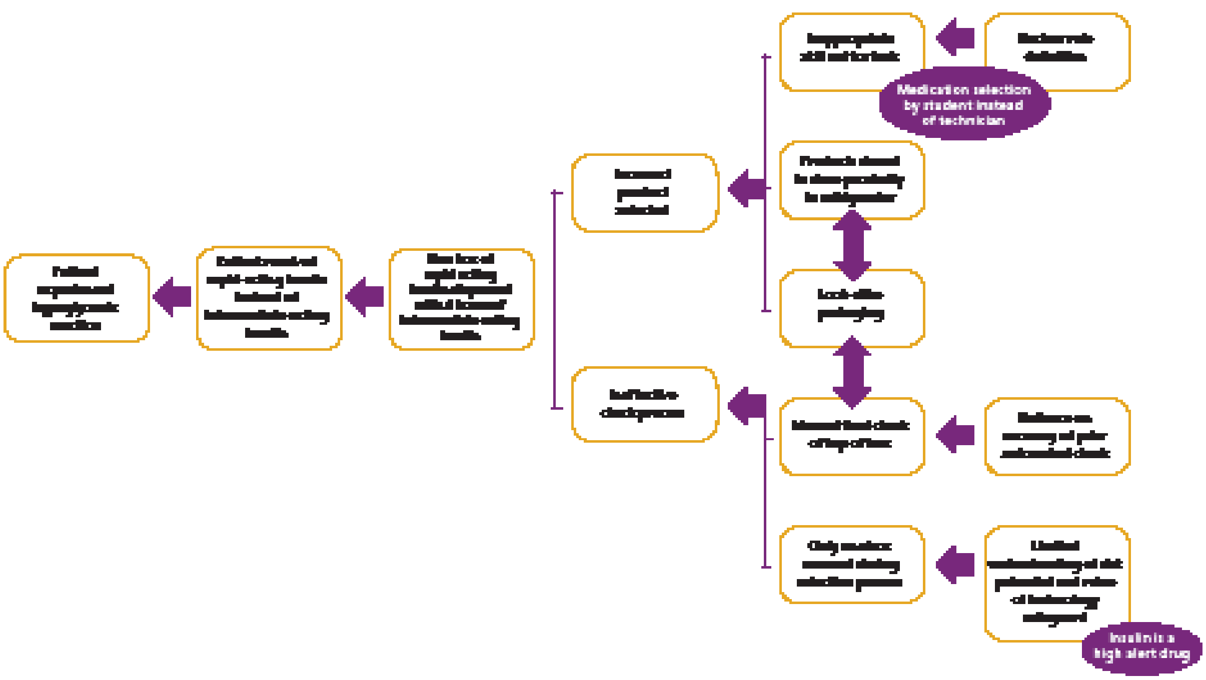
Drug Incident - patient safety report - addendum

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

Final understanding & timeline (partial)

Time	Information item	Information source
4:35 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

- prescribing;
- order communications;
- product labeling, packaging, nomenclature;
- compounding;
- dispensing;
- distribution;
- administration;
- education;
- monitoring; and
- 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

Pharmacy use only - retain for **10** years from discovery date.

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

_____ 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)

_____ 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)

_____ 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)

_____ 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)

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: Specific, Measurable, Attainable, Relevant and Time-based.

Forcing functions/constraints:

Automation/computerization:

Reminders, checklists, double checks:

continued on next page

Actions to be implemented (continued)

Simplification/standardisation:

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: _____ **Signature:** _____
day / month / year

Name: _____ **Position title:** _____
please print

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.

Sample 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

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?); and
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 123458 – incorrect insulin dispensed 2. Rx 105456 – incorrect strength dispensed 3. Rx 156457 – incorrect drug dispensed. Of note, in all three 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 package 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 removed 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

Licensee name: ______________________
please print

Review date: ______________________
day / month / year

Licensee signature: ______________________

Third quarter review - July to September

Licensee name: ______________________
please print

Review date: ______________________
day / month / year

Licensee signature: ______________________

Fourth quarter review - October to December

Licensee name: ______________________
please print

Review date: ______________________
day / month / year

Licensee signature: ______________________

Drug Incident Quarterly Review Report

Alberta College of Pharmacy

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

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Pharmacy information

Pharmacy name: _____

Address: _____

_____

Phone: _____

Email: _____

Licensee name: _____

Reporting year: _____

First quarter review - January to March

Licensee name: _____ please print

Review date: _____ day / month / year

Licensee signature: _____

Second quarter review - April to June

Licensee name: _____ please print

Review date: _____ day / month / year

Licensee signature: _____

Third quarter review - July to September

Licensee name: _____ please print

Review date: _____ day / month / year

Licensee signature: _____

Fourth quarter review - October to December

Licensee name: _____ please print

Review date: _____ day / month / year

Licensee signature: _____

Acknowledgements

This adaptation of the Canadian Root Cause Analysis Framework[3] for the community pharmacy setting has been completed by the Alberta College of Pharmacists 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**.

3 "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**.

Notes