Quality Assurance for Community Pharmacies – The Systems Approach

A Patient Safety Primer

Healthy Albertans through excellence in pharmacy practice
Rationale

The ultimate purpose of a critical incident investigation is always to prevent similar occurrences and thus improve safety.

Matches objective of SOLP 6.6:
(a) Review drug error reports to determine if any changes necessary to prevent future drug errors;
(b) Assess if changes implemented improved patient safety.

Case example

- Rx for Novolin® ge 30/70 Penfill twice daily via insulin pen
Case example (continued)

- Patient obtained insulin Rx refill
- Next morning, inserted new cartridge into pen
- A short time later, patient found:
  - Diaphoretic (perspiring profusely)
  - Pupils dilated
  - Decreased level of consciousness
  - Glucometer 2.5 mmol/L (normal 4-7 mmol/L)
Step 1: Form an incident analysis team

Purpose

• Detailed examination by team often discovers new information not previously known by individual team members

• Participation creates greater acceptance of recommendations & implementation of action plans

Tips:

• Blame & threat of discipline leads to secrecy and unresolved drug errors

• Focus on system-based issues to encourage openness which ultimately leads to improving patient safety!
Step 1 – Analysis team participation

Who must participate in QA?

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.

Health Professions Act: Standards of Practice for Pharmacists and Pharmacy Technicians 1.9
Step 1 – Additional participants

Who else should participate in QA?

• Multidisciplinary
  – Ensure all appropriate disciplines are represented
• Invaluable to include front-line staff who understand related care processes
• Determine team member roles and responsibilities
• Include those with direct knowledge of the event processes
• Include those responsible for change

SOLP 6.5 (c) – duty to advise regulated health professionals and caregivers whose care of patient may be affected by drug error
Steps 2-3: What happened?

- Information gathering
- Analysis of information
- Identification of root causes
- Development of action plan
- Initial understanding
- Final understanding / timeline
- Interviews
- Additional information
- Literature search
- Policies and procedures
- Formulate causal statements
- Incidental findings

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Determining “what happened?” is a team approach

Quality assurance process

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.**

*Pharmacy and Drug Act: SOLP 6.4(b)*

Why is this important?

- The more timely the documentation the more details can be remembered, resulting in better action plans and less chance of recurrence!
Step 2: Gather information/initial understanding

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

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

Figure 1: Sample initial understanding using insulin case example
Step 3: Final understanding/timeline

What information do we need to review?

- Prescription
- Drug labelling and packaging  
  - Understand how error was made  
  - e.g. look-alike packaging
- Pharmacy physical environment  
  - Dispensary workflow and design can affect patient safety!
- ISMP Canada drug error reports  
  - Learn from others  
  - What preventive strategies and interventions were implemented  
  - Practitioner Reporting: [www.ismp-canada.org/err_ipr.htm](http://www.ismp-canada.org/err_ipr.htm)

SOLP 6.5(e) – take reasonable steps to ensure incorrect drug returned to pharmacy
Step 3: Interviews & timeline

Who should we talk to in order to get more information?
• Individuals directly and indirectly involved
• Others familiar with the usual work processes

Develop a narrative timeline and final understanding of sequence of events leading to incident
• To obtain more detailed information than previously aware of during initial understanding
## Step 3: Final understanding

### Table 1: Final understanding/ timeline (partial)

<table>
<thead>
<tr>
<th>Time</th>
<th>Information Item</th>
<th>Information Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>4:30 pm, 3 days prior to event</td>
<td>Patient calls for refill of insulin prescription from community pharmacy – will pick up in evening.</td>
<td>Prescription record</td>
</tr>
<tr>
<td>5:00 pm</td>
<td>Technician processes refill in the computer and leaves the label in a basket for filling by the dispensary student</td>
<td>Technician interview</td>
</tr>
<tr>
<td>5:30 pm</td>
<td><strong>Student obtains 5 boxes of insulin from fridge and scans the top box 5 times</strong>, labels the top box, and then tapes all 5 boxes together. The prescription is left in the basket for the pharmacist to check.</td>
<td>Technician and student interview</td>
</tr>
<tr>
<td>5:50 pm</td>
<td><strong>Pharmacist sees that insulin boxes look the same, checks DIN on top box</strong> 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”</td>
<td>Pharmacist interview</td>
</tr>
<tr>
<td>8:40 pm</td>
<td>Patient’s wife comes in to pick up insulin. Student retrieves from refrigerator, bags and gives to patient’s wife.</td>
<td>Student and patient/family interview</td>
</tr>
</tbody>
</table>
Case example - what happened?

- 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)
Steps 4-5: Why did it happen?

- Information gathering
- Analysis of information
  - Identification of root causes
    - Incidental findings
  - Development of action plan
- Initial understanding
- Final understanding / timeline
  - Diagramming
    - Formulate causal statements
  - Identification of root causes
- Additional information
  - Literature search
  - Policies and procedures
  - Interviews

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Step 4: Identify contributing factors & underlying problems

- Reasons for incidents are multi-factorial
- Need to consider
  - System/process design
  - Workflow
  - Individual accountability
    - e.g. workarounds: natural tendency to take shortcuts to make work easier without realizing safety implications
Step 4: Diagramming

Documentation tool
- “What led to what”
- Easier to see complex or overlapping relationships

Prompting tool
- Visualization aids understanding
- Moves team “deeper” i.e. away from the patient—health care provider interface or “sharp end” to the underlying system-based problems or “blunt end” that contributed to the incident.
- Supports assessment of system performance rather than individual performance
Step 4: Diagramming

**Tip:** How do I know if it’s a root cause?
- **Use the 5 “Whys”**
- **Ask:** If this factor were eliminated or corrected, would there be a real chance to prevent a similar event from occurring?

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**Outcome**

**Incident**

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

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Step 4: Minimum scope

Tip:

- Use the Minimum Scope Checklist to help identify system and process issues and broaden the scope of the analysis
### Step 4: Minimum scope checklist

#### Table 2: Minimum Scope Checklist

<table>
<thead>
<tr>
<th>Item</th>
<th>Applicable to incident</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical assessment process</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual identification process</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuum of care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staffing levels</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orientation and training of staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Competency assessment/credentialling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supervision of staff (includes supervision of physicians in training)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communication with individual/family</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communication amongst staff members</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Availability of information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequacy of technical support</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment maintenance/management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical environment (includes furnishings, hardware (e.g. bars, hooks, rods), lighting, distractions)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication management (includes selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration and monitoring)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Step 4: Triggering questions

Tip: Use the Triage and Triggering Questions

• Help identify contributing factors and underlying problems that may not otherwise be considered.

• Questions cover the following topics:
  – Communication
  – Training
  – Fatigue / scheduling
  – Environment / equipment
  – Rules / policies / procedures
  – Barriers and controls used to protect patients, staff, equipment or the environment

• Document contributing factors in the drug incident report as per SOLP 6.4(d)
# Step 4 – Report Contributing Factors

Table 3: Sample excerpt from drug incident report identifying contributing factors

<table>
<thead>
<tr>
<th>Contributing Factors</th>
<th>Description</th>
<th>Marked</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient identification process</td>
<td>Drug order interpretation (e.g. misread/misheard/misinterpreted)</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Checking process (e.g. pharmacist working alone, ingredient check omitted/failed, final check omitted/failed)</td>
<td></td>
</tr>
<tr>
<td>Transcription/order entry process</td>
<td>Drug unavailable (e.g. supply shortage and no alternative drug obtained on behalf of patient)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Documentation process (incomplete/unclear)</td>
<td></td>
</tr>
<tr>
<td>Patient assessment process (e.g. questions to gather information on new and refill medications incomplete or lacking)</td>
<td>Education/training/skills/experience (e.g. unfamiliarity with drug product/device/process)</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Drug storage/security (e.g. narcotic safe left unlocked)</td>
<td></td>
</tr>
<tr>
<td>Counselling process (e.g. hearing/visual impairment, low literacy skills, language barrier, availability/provision of written materials)</td>
<td>Compounding process (e.g. assignment of incorrect beyond-use-date, complex formula, formula not available, drug stability problem, procedure unhygienic, cross-contamination)</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td>Monitoring process (e.g. follow-up not completed, lab values not available/not reviewed)</td>
<td>Prescribing problem (e.g. problematic abbreviation(s), legibility issues)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other – please specify (e.g. patient factors such as age, pregnancy or lactation status; organ function; cognitive, mental and physical challenges; lifestyle; cultural beliefs):</td>
<td></td>
</tr>
</tbody>
</table>
Step 5 – Develop Problem Statements

Purpose

- Clearly articulates the underlying issues
- Avoids blame game
  - focuses on system issues, not individuals
- Basis for action development

Where to begin?

- Look at each contributing factor
- Ask: “If this factor were eliminated or corrected, would it have prevented the outcome or mitigated the harm?”
- If the answer is “Yes”, begin developing a causal statement around this factor
Step 5: ABC Format

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.

Example:

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.
Steps 6-7: Preventing recurrence

Information gathering

Analysis of information

Identification of root causes

Development of action plan

Initial understanding

Final understanding / timeline

Formulate causal statements

Diagramming

Incidental findings

Interviews

Additional information

Policies and procedures

Literature search
Step 6: Develop action plan

• These are “actions” (not recommendations or suggestions)
• Clear and concise
• Specifically address identified problems
• Offer long term solutions vs. temporary “work-arounds”
• Objective and measurable (SMART goals)
Step 6: Options for change

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

Tip: While rules, policies and procedures and educational measures are important, these have typically been the focus of most pharmacy teams, and yet they are the least effective strategies to reduce drug incident recurrence. 
Try to use higher leverage strategies where possible!
Step 6: Higher leverage options - forcing functions

“A design feature that makes it impossible to perform a specific erroneous act”.


Example:
• Bar-code scanning system for drug product verification
Step 6: Higher leverage options - differentiation strategies

To decrease selection error, focus on drugs with look-alike packaging.

- Purchase different strengths of medications in different pack sizes or from different manufacturers.
- Consider using auxiliary warning labels for high-alert drugs such as warfarin.
Case example: How can we reduce the likelihood of a recurrence?

Higher leverage strategies:

• Use technology
  – Implement barcode scanning of every item dispensed

• Enhance differentiation:
  – Review storage options – segregate short, intermediate and long-acting insulins in fridge
  – Consider warning labels
Case example: How can we reduce the likelihood of a recurrence?

Lower leverage:

- Educate staff about high-alert medications and the need for additional safeguards with these items
Step 6: Action / measurement plan

Table 4: Sample Action Plan with Measurement Strategies

<table>
<thead>
<tr>
<th>Action #</th>
<th>Recommended Action</th>
<th>Strength of Action</th>
<th>Timeframe for Implementation</th>
<th>Individual Responsible</th>
<th>Measurement Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>Develop standard job descriptions for all dispensary staff with clearly defined role expectations and review expectations during orientation.</td>
<td>Medium – standardization and simplification</td>
<td>Intermediate (3-6 months)</td>
<td>Dispensary Manager</td>
<td>Annual audit to ensure job descriptions for all positions.</td>
</tr>
<tr>
<td>1B</td>
<td>Provide a copy of the job description and review expectations during orientation of new staff members.</td>
<td>Low – education and information</td>
<td>Intermediate (3-6 months)</td>
<td>Dispensary Manager</td>
<td>Follow up with individual new staff members.</td>
</tr>
<tr>
<td>2A</td>
<td>Segregate short, intermediate and long-acting insulins in the refrigerator.</td>
<td>Medium – simplification and standardization</td>
<td>Immediate</td>
<td>Dispensary Manager</td>
<td>Audit weekly x 6 weeks then monthly, then quarterly</td>
</tr>
<tr>
<td>3A</td>
<td>Apply warning labels to all look-alike insulin products in refrigerator.</td>
<td>Medium - reminders, checklists, double checks</td>
<td>Immediate</td>
<td>Dispensary Manager</td>
<td>Audit weekly x 6 weeks then monthly, then quarterly</td>
</tr>
<tr>
<td>3B</td>
<td>Report look-alike labelling to manufacturer, Health Canada and ISMP Canada.</td>
<td>Low – education and information (but potential for higher level change)</td>
<td>Immediate</td>
<td>Dispensary Manager</td>
<td>N/A – no internal measurement plan</td>
</tr>
</tbody>
</table>
Step 7: Implement actions and follow up

• 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
Step 7: Plan, Do, Study, Act

1. Plan a change
   - Incident analysis
   - Identify underlying causes
   - Develop an action plan

2. Do
   - Carry out the action plan
   - Document observations
   - Record data

3. Study
   - Analyze results
   - Check patient satisfaction and other indicators of success
   - What worked / didn’t work?

4. Act
   - Are additional measures or changes needed?
   - Adopt additional measures or changes as necessary.

Figure 4: PDSA model
Step 7: Follow up process

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.

Pharmacy and Drug Act: Standards for the Operation of Licensed Pharmacies 6.8

Share results of drug error review with all staff!

- Those who participate in an Incident Analysis will be the “change agents” and will support the implementation of recommended actions.
Step 7: Follow up process

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.

_Photocopy and Drug Act: Standards for the Operation of Licensed Pharmacies 6.6_
Step 7: Drug incident quarterly review report

- Use the template provided by ACP to document your quarterly review of drug incidents including:
  1. Drug incidents and required actions reviewed
  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
Summary of key messages

1. Determine “what happened?”
   - Review Rx, packaging/labelling, pharmacy physical environment
   - Conduct interviews
   - Review ISMP Canada drug error reports
   - Develop a final understanding / timeline

2. Determine “why it happened?”
   - Use the minimum scope checklist to broaden the scope of the analysis
   - Use the triage and triggering questions to identify contributing factors and underlying problems that may not otherwise be considered
   - Use tree diagrams to aid understanding and assist in the identification of root causes
   - Form causal statements to clearly articulate the issues and to form the basis for action plan development

3. Determine “what can be done to reduce likelihood of recurrence?”
   - Form an action plan using higher leverage strategies where possible
   - Set SMART goals
   - Evaluate the success of changes implemented by incorporating PDSA and conducting quarterly reviews
Incident analysis beyond drug incidents

- Incident Analysis can be used as a tool to assist in the analysis of much more than just drug incidents. Examples include:
  - Robbery Prevention
  - Workflow
  - You name it...
Robbery prevention tips & strategies

1. Protect the premises
   • Ask the experts: consult an independent contractor and local police re: available safety and security measures
   • Install surveillance equipment: a noticeable camera system can be an effective deterrent
   • Install a centrally monitored alarm system
Protect the premises (continued)

- Display deterrent signage: alarm company signage on doors and entrances, “minimum narcotics on hand” signage
- Take physical measures: time-lock vaults, 2º locations for narcs and min. narc inventories, dead-bolt locks/security gates, keep narc safe locked and restrict access, install interior and exterior security lighting.
Robbery prevention tips & strategies
(continued)

2. Protect patients and staff

• Develop policies and procedures for staff
  - Conduct background checks on all new hires
  - Staff should not discuss security systems, pharmacy layouts, procedures with outsiders
  - Staff should not discuss inventory control measures (e.g. where N are stored) in a manner that can be overheard by clients.
Policies & procedures to protect patients & staff (continued)

- Keep minimal cash on hand and make frequent deposits
- Staff should be alert and observant for suspicious activity, regularly engaging all clients
- Train staff on what to do in the event of a robbery
Incident analysis & robbery prevention – case example

- JS is a pharmacy manager, working alone at High Street Drugs.
Robbery prevention case example (continued)

- His pharmacy has been robbed at gunpoint on 3 occasions: May 1\textsuperscript{st}, May 8\textsuperscript{th}, and May 21\textsuperscript{st}.
- He has tried implementing several prevention strategies, all to no avail: security cameras, alarm system signage, minimum on-hand narcotic signage.
- He is now at wit’s end and has called ACP to see if it is permissible to bring a guard dog into the pharmacy.
Initial understanding

High Street Drugs robbed May 1st

JS, pharmacy manager, hangs security signage

High Street Drugs robbed again May 8th

JS installs security cameras

High Street Drugs robbed May 21st – JS at wit’s end
<table>
<thead>
<tr>
<th>Time</th>
<th>Information Item</th>
<th>Info Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 1&lt;sup&gt;st&lt;/sup&gt;, ~ 10:00 a.m.</td>
<td>An man wearing a balaclava enters High Street Drugs. It appears as though he has a gun in his pocket and demands all available Dilaudid tablets. JS calmly walks to the narcotic safe, unlocks it, grabs all Dilaudid bottles on hand and hands them to the man in a paper bag. The man is seen leaving the store on foot, after which JS locks the doors and calls police.</td>
<td>JS – pharmacy manager</td>
</tr>
<tr>
<td>May 3&lt;sup&gt;rd&lt;/sup&gt;, ~9:00 a.m.</td>
<td><strong>JS hangs alarm company signage and minimum on-hand narcotic signage</strong> after a colleague informs him that these can be an effective deterrent. <strong>He does not reduce his narcotic stock however as he fears this will hurt his business.</strong></td>
<td>JS – pharmacy manager</td>
</tr>
</tbody>
</table>
### Final Understanding/Timeline (partial)

<table>
<thead>
<tr>
<th>Time</th>
<th>Information Item</th>
<th>Info Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 8(^{th}), 1:00 p.m.</td>
<td>A man wearing a balaclava enters the pharmacy, with what appears to be a gun in his pocket demanding all available stock of Oxycontin, Dilaudid, MS Contin and Lectopam. JS hands the items to the man in a paper bag and sees the man leave the store in a Chevy Cavalier. He locks the door and calls police.</td>
<td>JS – pharmacy manager</td>
</tr>
<tr>
<td>May 12(^{th}), 11:00 a.m.</td>
<td>JS has a local security company come in to install security cameras, but decides to hold off on a central alarm system, as this is fairly costly and JS feels that the cameras should do the job.</td>
<td>JS – pharmacy manager</td>
</tr>
</tbody>
</table>
Identify root causes

- Repeated armed robberies
- Inadequate deterrents
- Lack of physical security measures
- Underutilization of 2nd storage locations and minimum inventory
- Police & security experts not consulted
- Unaware of ACP’s Robbery Prevention Tips & Strategies
- Lack of robbery prevention policies
- Regular vs. Time-delayed security vault

Outcome

Incident
# Action development – robbery case (partial)

<table>
<thead>
<tr>
<th>Action #</th>
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<th>Measurement Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>Create formal written robbery prevention strategies specific to the pharmacy.</td>
<td>Low – policies &amp; procedures</td>
<td>Immediate – within 30 days</td>
<td>Pharmacy Manager</td>
<td>F/u with individual new staff</td>
</tr>
</tbody>
</table>

1. Lack of specific pharmacy policies & procedures relating to robbery prevention strategies increased the likelihood that the pharmacy would be subject to repeated armed robberies.

2A Install new time-delayed security vault | High – constraint | Immediate – within 30 days | Pharmacy manager | Monthly, quarterly, then annually for # and frequency of robberies |

2. Lack of a time-delayed security vault increased the likelihood that the pharmacy would be subject to repeated armed robberies.