Quality Assurance for Community Pharmacies – The Systems Approach



A Patient Safety Primer



Rationale

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



Woloshynowych, M. Rogers, S., Taylor-Adams, S., and Vincent, C. The investigation and analysis of critical incidents and adverse events in healthcare. Health Technology Assessment 2005. Vol 9:19.



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

SOLP 6.5 (c) – duty to advise regulated health professionals and caregivers whose care of patient may be affected by drug error

- 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



Steps 2-3: What happened?





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



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: <u>www.ismp-canada.org/err_ipr.htm</u>



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)

Time	Information Item	Information Source
4:30 pm, 3 days prior to event	Patient calls for refill of insulin prescription from community pharmacy – will pick up in evening.	Prescription record
5:00 pm	Technician processes refill in the computer and leaves the label in a basket for filling by the dispensary student	Technician interview
5:30 pm	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 and student interview
5:50 pm	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 pm	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



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?





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?



Inappropriate

skill set for

task

Medication selection by student instead of

Unclear role

definition



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

Physical assessment process		
Individual identification process		
Continuum of care		
Staffing levels		
Orientation and training of staff		
Competency assessment/credentialling		
Supervision of staff (includes supervision of physicians in training)		
Communication with individual/family		
Communication amongst staff members		
Availability of information		
Adequacy of technical support		
Equipment maintenance/management		
Physical environment (includes furnishings, hardware (e.g. bars, hooks, rods), lighting, distractions		
Medication management (includes selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration and monitoring)		
	Individual identification process Continuum of care Staffing levels Orientation and training of staff Competency assessment/credentialling Supervision of staff (includes supervision of physicians in training) Communication with individual/family Communication amongst staff members Availability of information Adequacy of technical support Equipment maintenance/management Physical environment (includes furnishings, hardware (e.g. bars, hooks, rods), lighting, distractions Medication management (includes selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration and monitoring)	Individual identification processIndividual identification processContinuum of careStaffing levelsOrientation and training of staffCompetency assessment/credentiallingSupervision of staff (includes supervision of physicians in training)Communication with individual/familyCommunication with individual/familyCommunication amongst staff membersAvailability of informationAdequacy of technical supportEquipment maintenance/managementPhysical environment (includes furnishings, hardware (e.g. bars, hooks, rods), lighting, distractionsMedication management (includes selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration and monitoring)



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

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

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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





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



Least Effective

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".

Cohen MR (1999). *Medication Errors.* Washington, DC American Pharmaceutical Association.

Example:

Bar-code scanning system for drug product verification

Step 6: Higher leverage options - differentiation strategies



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29

- To decrease selection error, focus on drugs with lookalike 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

Action #	Recommended Action	Strength of Action	Timeframe for Implementation	Individual Responsible	Measurement Plan		
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 ar	nd the resulting acut	e hypoglycemia.			
1A	Develop standard job descriptions for all	Medium –	Intermediate	Dispensary	Annual audit to ensure		
	dispensary staff with clearly defined role	standardization	(3-6 months)	Manager	job descriptions for all		
	expectations and review expectations during	and			positions.		
	orientation.	simplification					
1B	Provide a copy of the job description and review	Low – education	Intermediate	Dispensary	Follow up with		
	expectations during orientation of new staff	and information	(3-6 months)	Manager	individual new staff		
	members.						
2. Storage	2. Storage of both intermediate and rapid-acting insulins in close proximity in the refrigerator increased the likelihood of incorrect product						
selection a	nd dispensing of the incorrect insulin, leading to adm	inistration by the p	atient and the result	ing acute hypogly	rcemia.		
2A	Segregate short, intermediate and long-acting	Medium –	Immediate	Dispensary	Audit weekly x 6		
	insulins in the refrigerator	simplification		Manager	weeks then monthly,		
		and			then quarterly		
		standardization					
3. Pharmaceutical "branding" through look-alike packaging increased the likelihood of incorrect product selection and dispensing of the							
incorrect in	nsulin, leading to administration by the patient and	the resulting acute	hypoglycemia.				
3A	Apply warning labels to all look-alike insulin	Medium -	Immediate	Dispensary	Audit weekly x 6		
	products in refrigerator.	reminders,		Manager	weeks then monthly,		
		checklists,			then quarterly		
		double checks					
3B	Report look-alike labelling to manufacturer, Health	Low – education	Immediate	Dispensary	N/A – no internal		
	Canada and ISMP Canada.	and information		Manager	measurement plan		
		(but potential for					
		higher level					
		change)					



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: 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.

Pharmacy 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 a implemented and whether those actions resolved the issue

Alberta College of Pharmacists Summary of key messages





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, 2° locations for narcs and min. narc inventories, deadbolt 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 > reg 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 1st, May 8th, and May 21st.
- 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





Final understanding/timeline (partial)

Time	Information Item	Info Source
May 1 st , ~ 10:00 a.m.	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.	JS – pharmacy manager
May 3 rd , ~9:00 a.m.	JS hangs alarm company signage and minimum on-hand narcotic signage after a colleague informs him that these can be an effective deterrent. He does not reduce his narcotic stock however as he fears this will hurt his business.	JS – pharmacy manager



Final Understanding/Timeline (partial)

Time	Information Item	Info Source
May 8 th , 1:00 p.m.	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.	JS – pharmacy manager
May 12 th , 11:00 a.m.	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.	JS – pharmacy manager



Identify root causes





Action development – robbery case (partial)

Action #	Recommended Action	Strength of Action	Timeframe for Implementation	Individual Responsible	Measurement Plan	
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.						
1A	Create formal written robbery prevention strategies specific to the pharmacy.	Low – policies & procedures	Immediate – within 30 days	Pharmacy Manager	F/u with individual new staff	
2. Lack of a time-delayed security vault 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	