Alberta College of Pharmacy

Drug incident report form

Drug incident - patient safety report

1. As per Standard 1.10 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

D.O.B: 01 / 02 / 42 (Day / Month / Year)

Address: 123 Anystreet Rd.
Anytown, AB T0T 0T0

Other relevent demographic data: weight = 75 kg

Phone: 780-123-4567

Email: sam.anyone@yahoo.ca

Rx#: 123456

Sex: (M) F

New Rx (Repeat Rx)

Incident date & discovery date

Incident date 1900 (Hour) 05 / 03 / 2011 (Day / Month / Year)

Discovery date 1000 (Hour) 06 / 03 / 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 and transaction record!

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

Incident description

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

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

Severity

Mark an X to the left of the applicable scenario.

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

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

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

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

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

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

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

Type of incident

Mark an X to the left of each applicable item.

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

Contributing factors

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

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

Notifications

Patient	1000	06 / 03 / 2011
	Hour	Day / Month / Year
Prescriber	1030	06 / 03 / 2011
	Hour	Day / Month / Year
Licensee	1300	
	Hour	Day / Month / Year
Others		
	Hour	Day / Month / Year
	Hour	Day / Month / Year

Staff involved notified

Pharm Tech	R.Ph.T.	*Pharm Tech*
		Name / position / signature
Stu Dent	Pharm. Tech Student	*Stu Dent*
		Name / position / signature
Joe Druggist	R.Ph.	*Joe Druggist*
		Name / position / signature
		Name / position / signature
		Name / position / signature

Outcome of investigation

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

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

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

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

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

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

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

Actions to be implemented

Favour higher leverage (effectiveness) change options where possible. The following seven actions are in descending order of leverage and should be **SMART**: Specific, Measurable, Attainable, Relevant and Time-based.

Actions: Forcing functions/constraints, automation/computerization, reminders/checklists/double checks, simplifications/standardization, policy/procedure change, education or training provided/course(s) taken, and other (please specify).

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.

Simplifications/standardization:

Pharmacy technician to segregate short, -intermediate-and long-acting insulins in the refrigerator by March 7, 2011.

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Actions to be implemented (continued)

Pharmacy manager to audit weekly x 6 weeks then monthly, then quarterly.

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

Education or training provided/course(s) taken:

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

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

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

Other (please specify):

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

Evaluation

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

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

Date 1000 (Hour) 06 / 03 / 2011 (Day / Month / Year)

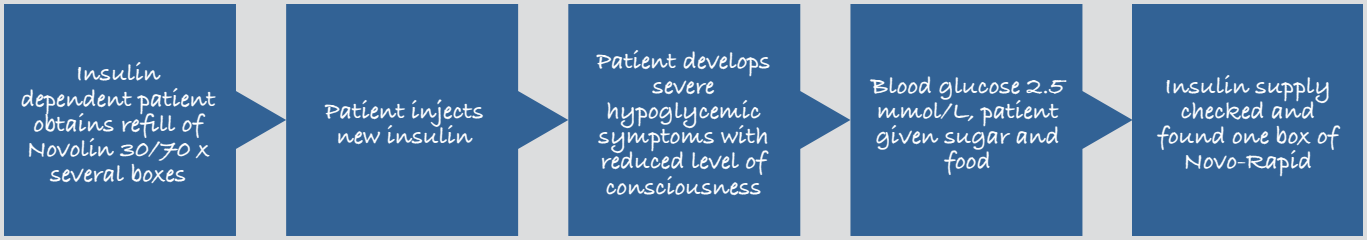
Signature Joe Druggist

Name Joe 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.



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Drug incident - patient safety report - addendum (contined)

Final understanding & timeline (partial)

Time	Information item	Information source
4:30 p.m. 3 days prior to event	Patient calls for refill of insulin prescription from community pharmacy - will pick up in evening.	Prescription record
5:00 p.m.	Technician processes refill in the computer and leaves the label in a basket for filling by the dispensary student .	Technician interview
5:30 p.m.	Student obtains 5 boxes of insulin from fridge and scans the top box 5 times, labels the top box, and then tapes all 5 boxes together. The prescription is left in the basket for the pharmacist to check.	Technician and 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