The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national nonprofit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

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Shared Learning — Reported Incidents Involving Hydromorphone

A previous issue of the *ISMP Canada Safety Bulletin* described an incident in which inadvertent intramuscular administration of 10 mg of hydromorphone, instead of 10 mg of morphine, resulted in a patient's death.[1] A subsequent Bulletin reported that hydromorphone was third on the list of drugs most frequently reported as causing harm as a result of medication error.[2] Analysis of the ISMP Canada database of voluntarily reported medication incidents has identified relatively high numbers of harmful medication incidents involving hydromorphone. The purpose of this bulletin is to provide feedback to reporting health care professionals, to inform stakeholders and to heighten general awareness of safeguards needed in the use of hydromorphone.

ISMP Canada's voluntary reporting program has been in place since 2001. A total of 17,320 incident reports (including reports of near misses) have been collected since the program's inception. Of these, 804 (4.6%) were reported to have resulted in harm to patients, including death. Hydromorphone accounted for 783 of all reported incidents and 75 (9.3%) of the harmful or fatal incidents. It is recognized that it is impossible to infer or project the absolute occurrence rate of specific incidents on the basis of voluntary reports.

Table 1 summarizes data on the stages of the medication use system reported to be involved in hydromorphone incidents. Table 2 delineates the types of incidents that have been encountered with this drug.

Table 1. Reported incidents involving hydromorphone, categorized by stage of the medication use system

		No. of hydromorphone incidents with adverse outcomes	
Stage of medication use system	**No. of reported incidents involving hydromorphone (*n* = 783)***	**Harm† (*n* = 66)***	**Death (*n* = 9)**
Prescriber ordering	45	7	1
Order entry and transcription	125	15	0
Dispensing and delivery	70	13	0
Administration	522	44	6
Monitoring	40	4	2
Other	60	8	0

* The sum of the values in this column exceeds the total n value because some incidents involved more than one stage.

† Temporary or permanent harm, excluding death.[3]

Table 2. Reported incidents involving hydromorphone, categorized by type of incident

		No. of hydromorphone incidents with adverse outcomes	
Type of incident	**All (*n* = 783)**	**Harm† (*n* = 66)**	**Death (*n* = 9)**
Dose omission	131	15	0
Incorrect dose	198	21	1
Incorrect strength or concentration	73	5	0
Incorrect drug	216	16	4
Incorrect dosage form	38	1	0
Incorrect route of administration	33	2	0
Incorrect rate	11	2	2
Incorrect time	14	1	0
Incorrect patient	13	1	0
Monitoring problem	7	0	2
Other	49	2	0

† Temporary or permanent harm, excluding death.

Key Findings of Analysis of Hydromorphone-Related Incidents

1. Substitution errors between hydromorphone and morphine represented 75% of reported harmful "incorrect drug" incidents involving hydromorphone. Of particular concern are incidents in which vials of higher-concentration hydromorphone (e.g., hydromorphone 10 mg/mL) are readily available and inadvertently used instead of morphine. Substitution errors have also occurred with oral dosage forms (e.g., long-acting hydromorphone given instead of long-acting morphine).
2. Harmful "incorrect dose" incidents involving hydromorphone were reported to be associated with the following problems:
   - lack of familiarity with appropriate dosages of hydromorphone;
   - lack of a "leading 0" (e.g., dose written as ".4 mg" was interpreted as 4 mg);
   - misunderstanding of the order (e.g., telephone, verbal or written);
   - cognitive lapse leading to misinterpretation of an order as conveying a dose more commonly associated with morphine.
3. Errors in programming an infusion pump were frequently identified in the harmful incidents reported to involve the "administration" stage of the medication use system.

4. Routine monitoring protocols may be insufficient with higher risk patients or when incidents occur. Signs of opioid toxicity may be overlooked and opportunities for early reversal and mitigation of harm can therefore be missed.

Recommendations

The recommendations listed here have been derived from a cluster analysis of the reported incidents and a review of the reported contributing factors, learning from provincial opioid safety collaborative projects[4], as well as a review of the relevant literature.

1. **Remove high-concentration hydromorphone from patient care areas whenever possible**
   Perform risk assessments for maintaining hydromorphone supplies in patient care areas. The objectives of such assessments would include the following:
   - Eliminate high-concentration items (e.g., hydromorphone injectable products with concentration over 2 mg/mL) from patient care area stock.
   - In circumstances where high-concentration hydromorphone cannot be eliminated (e.g., in palliative care), ensure that it is segregated.
   - Prohibit the transfer of high-concentration hydromorphone products from one patient care area to another ("borrowing").
2. **Reduce "look-alike" potential**
   Add labels to reduce confusion, consider including the brand name equivalent (e.g., hydromorphone [for DILAUDID]).
3. **Require redundancies**
   - Require an independent double check before administration of opioid infusions (continuous or intermittent). See also a previous Bulletin entitled: Lowering the risk of medication errors: Independent double checks.[5]
   - Where automated dispensing cabinets are used, consider the use of safeguards such as requiring a witness when the override feature is used to access hydromorphone. Reminders can be programmed to appear on the screen.
4. **Standardize prescribing and terminology**
   - Standardize the selection and infusion concentrations of parenteral opioid medications used for pain.
   - Use standard protocols (e.g., pre-printed orders, electronic order sets) whenever possible.
   - Avoid verbal or telephone orders whenever possible. If required, ensure such orders are documented in the patient's chart and read back to the prescriber for verification prior to administration of the drug.
   - Ensure that orders are reviewed by a pharmacist prior to administration, whenever possible.
   - Eliminate the use of dangerous abbreviations, symbols, and dose designations.[6] For instance, always use a zero before a decimal point (i.e., use "0.X mg").
   - Standardize terminology to ensure consistency between the order, the medication administration record (MAR), the narcotic sheet, the pharmacy-generated label, and the infusion pump where applicable.
5. **Assess, monitor, and document**
   Implement guidelines and practices for assessment, monitoring and documentation (e.g., vital signs, pain and sedation scales[7]) of opioid therapy. Consider the use of standardized forms (order sets, protocols and flow sheets). Include clear criteria for the identification and treatment of toxicity. Include criteria for when to hold opioid therapy and when to use naloxone so that it can be given quickly when needed, even before calling the physician.
   When developing protocols for assessment and monitoring, the following circumstances should be considered:[8]
   - The initial period of opioid therapy (e.g., 24 hours or longer) and especially at night when nocturnal hypoxia can occur;
   - The use of concomitant medications that may further depress respiration (e.g., sedatives);
   - The patient's underlying disease process (e.g., sleep apnea).

   In addition, consider the manner in which patients are assessed. Patients experiencing opioid-induced respiratory depression or over-sedation can easily be temporarily stimulated to an increased level of consciousness and respiratory rate. This observed momentary level of consciousness and respiratory rate may mask symptoms of toxicity and once the stimulus is removed patients quickly fall back into an over-sedated state. The respiratory rate needs to be assessed without disturbing the patient. Monitoring a patient's level of consciousness accurately appears to be an extremely important assessment component as it has been noted to be the only predictor of an impending opioid-related adverse event.[7]
6. **Educate and inform staff**
   - Make analgesic equivalency charts readily available to all staff involved in the medication-use process, whether prescribing, dispensing or administering medications. Consider including examples of typical starting doses for opioid naïve patients.
   - Educate staff about the differences between hydromorphone and morphine.
   - Share this bulletin broadly, to highlight the lessons learned from reported hydromorphone incidents.
7. **Engage patients and their families as partners in medication safety**
   Patients and families can augment the patient safety activities of medical, nursing, and pharmacy staff. In effect, they can serve as an additional line of defence in preventing medication incidents. This best practice requires that, where appropriate, patients or their relatives or caregivers are:
   - informed about the treatment plan;
   - informed about the drug that has been prescribed;
   - advised about indication, dosage and usual administration time(s);
   - advised about the expected therapeutic effects and advised to be vigilant for possible side effects of the drug, as well as what to do if serious side effects occur;
   - instructed on the use of infusion pumps (e.g., patient-controlled analgesia), if applicable.
8. **Employ technology**
   Although the benefits may only be seen over the longer term, technological solutions such as computerized physician order entry, bar coding and automated dispensing technology requiring pharmacy order review before retrieval of a narcotic

dose, may help to reduce the risk of errors reaching the patient and should be considered in strategic planning.

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ALERT: Generic Fentanyl Patches

A recent report to ISMP Canada raised awareness that drug name and strength are not printed on generic fentanyl patches manufactured by ratiopharm (Figure 1); this information is printed only on the outer packaging, which is removed before placement of the patch. The reporter cited concerns that had been raised by several emergency departments, where health care professionals were unaware of patients' fentanyl patches.

As a result of this report, ISMP Canada contacted the manufacturer and Health Canada. The company has made a commitment to start printing the medication name and strength on these patches. Health Canada is expediting the NOC (Notice of Compliance) approval for this enhancement to product labelling. We thank Health Canada and ratiopharm for their quick response in making this product enhancement (imminent at the time of publication).

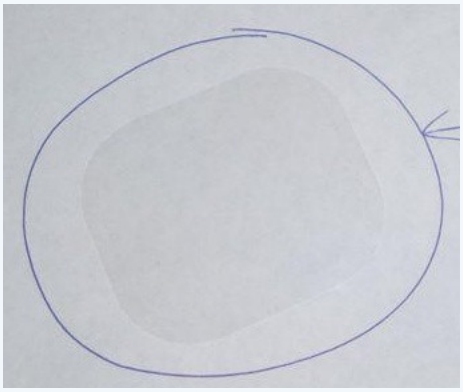

Figure 1. Generic fentanyl patch manufactured by ratiopharm (inside circle). The patch has no printed information about the drug or strength. Changes are imminent to ensure this information is printed on patches. ISMP Canada gratefully acknowledges the reporter for providing this photograph.

ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

Medication Incidents (including near misses) can be reported to ISMP Canada:

(i) through the website http://www.ismp-canada.org/err_report.htm or

(ii) by phone: 416-733-3131 or toll free: 1-866-544-7672.

ISMP Canada can also be contacted by e-mail: cmirps@ismp-canada.org. ISMP Canada guarantees confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications.

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